

Intricon and Over-The-Counter Hearing Aids

By Douglas L. Beck, AuD, F-AAA, CCC-A

Delain Wright has dedicated his life to the field of hearing care. Growing up in a retail hearing care practice, he later worked with multinational companies at an executive level, gaining a deep understanding of the U.S. market as well as the global hearing aid market. Over the past 15 years, Wright has focused extensively on value-based hearing care, with a particular emphasis on over-the-counter hearing care in the U.S. market. Mr. Wright currently works with Intricon, a hearing aid manufacturer, and with TUNED, an AI-based self-fitting hearing aid software developer.

Dr. Beck: Hi, Delain. Good to see you again.

Mr. Wright: Thanks, Doug. Happy to be here.

Dr. Beck: Delain, as I recall, your dad started with Beltone?

Mr. Wright: Yes, he did, and so naturally I grew up in the hearing industry. He originally sold Beltone products, but he wanted to do his own thing and he went multi-line! He was also an early adopter of custom products. But as for me, I decided to work for the manufacturing side, so I started with Rexton as a field representative. After I was there 2 or 3 months, they were sold to Siemens, which was probably in 1987 or so. Prior to the sale to Siemens, Rexton was the largest hearing aid company in the world. Nonetheless, Siemens had a multi-brand strategy, which was a new idea back then, and so acquiring Rexton was a huge step. So long story short, I was suddenly working for Siemens. Siemens sent me to the UK to develop the NHS business and I stayed there for 7 or 8 years, and then came back to the US and stayed with Siemens a few more years. I managed the networks, buying groups, and South America. Bottom line, I came away from those experiences with a new and more insightful perspective. Overall, it was a great learning experience.

Dr. Beck: And after that, you had a few experiences with other startups and entrants into the hearing aid business?



Dr. Douglas L. Beck is among the most prolific authors in audiology with 221+ publications, interviews, and op-eds published by the American Academy of Audiology, *Hearing Review*, *Audiology Online*, and others. His work has addressed a wide variety of audiology and professional topics, including op-eds, audiology, language, pediatrics, cognition, hearing aids, amplification, psychology, neuroscience, anatomy and physiology, counseling, and more. Dr. Beck has delivered more than 1,000 lectures, keynote addresses, webinars, and other professional presentations. He continues to consult for multiple clinical, scientific, and other organizations.



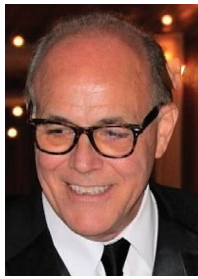
Mr. Wright: Yes, one was with a small group called America Hears, but they never got much traction and ended up part of Lucid Hearing. Then I went to Panasonic for several years and worked with them in the US and in Japan. Although they made fantastic-looking products, they were missing competitive software and hearing aid manufacturing understanding, and they had a very different perspective regarding how business is done. The U.S. regulatory rules and licensed professionals were difficult for them to get their arms around, and after four years they exited the hearing business. One of the companies I was working with at Panasonic was Intricon, and so when Panasonic exited the U.S. hearing aid market in 2013, I joined the executive team at Intricon.

Dr. Beck: Delain, I only know Intricon from their hearing aid involvement. What else do they do?

Mr. Wright: They started in 1977 as a parts supplier named Resistance Technology Incorporated (RTI) and they were involved as a supplier and manufacturer of micro-electronic parts. As time went on and digital technology took over, they got into complete hearing aids and for a number of years they were the exclusive provider of hearing aids to United Health Care (UHC) and that's when they focused on the "Value Hearing" (lower cost) products. When UHC bought EPIC from Sonova, the supply chain changed.

Dr. Beck: And then wasn't there a relationship between Intricon and ADA called EarVenture?

Mr. Wright: Yes, and that was controversial in some circles as some people weren't in favor of a professional organization



Delain Wright

selling products to their members, and Value Hearing was in its early days in the U.S. market. Then about seven years ago (or so), Intricon bought PC Worth in the UK, we got on the NHS contract, and that was an interesting venture! The NHS distributes over 1.7 million hearing aids a year and is a good example of Value Hearing. And then about two years ago, Intricon was sold to private equity. Prior to

that, they were on the NASDAQ.

Dr. Beck: Intricon has a fascinating history, and they were often way ahead of the curve. What is their status in 2024?

Mr. Wright: Intricon is a dynamic group and serves multiple major medical device companies. We have some 800 employees, many are in Minnesota as well as Singapore and Indonesia. Most recently, Intricon opened nearshore manufacturing in Costa Rica.

Dr. Beck: OK. Let's talk about the over-the-counter (OTC) initiative and the status quo. Did the OTC ruling from the FDA go as you predicted it would?

Mr. Wright: Yes. I was very outspoken and very involved. Of course, there was pushback and a lot of controversy, but I was one who thought the legislation would pass from the beginning because of the need for more efficient solutions and the end users' demand for better technology in the user experience at a more affordable price.

Dr. Beck: There was a lot of controversy, but mostly it seemed (to me) to be about safety issues. As I recall, the most important issues were things like making sure the consumer was not at-risk for physical injury, and to make sure OTC products wouldn't cause additional hearing loss. Of course, many of us were disappointed by the still undefined "self-perceived mild-to-moderate hearing loss." There were also discussions about inside the box and outside the box labeling, gain (which didn't make it to the final FDA rule), maximal output with and without compression, and things like that. I don't recall any of the major manufacturers or organizations saying they were opposed to OTC, although they certainly advocated for clarifications, which ultimately led to a better FDA ruling.

Nonetheless, I wonder if you have any idea as to how many OTC products have been sold in 2023. I know the national estimates have been 2-3% or so, but it seems to me the number may be much higher.

Mr. Wright: This is a bit of a concern because the reporting companies are the well-established and well-known members of the hearing aid trade association, but the association has no way to know the quantity of OTCs sold by manufacturers who are not members of the association. For example, if a major OTC supplier from China, Asia, or elsewhere sells direct to

consumers through the U.S. mail or Amazon or any website, how would we know?

Now the good news is the established, traditional hearing aid sales channels are doing well and have continued to grow in 2023. So, in that regard, all is well! Sales are increasing and OTC has not slowed that down.

Yet, it seems probable that in a "parallel universe" OTC sales are growing, too, and OTC sales may not be visible if we're measuring it by, or looking for decreases in, traditional prescription products.

Based on my knowledge of our OTC business and other analysis I've done, I think OTC may have delivered a million units in 2023, or maybe 1.2 million? Importantly, OTC sales did not cannibalize the prescription market as OTC sales were probably mostly to new consumers, perhaps younger consumers, who were not going to see a hearing care professional (HCP) in 2023 but were happy to get OTC products.

Dr. Beck: I've heard this line of reasoning before. I think we can agree that we simply have no way of knowing the true numbers. Then again, as long as the prescription channel remains healthy and growing, maybe it's not as important as it might have been if OTC had "cannibalized" the prescription products.

Mr. Wright: Right. It may not impact HCPs or the prescription products, and so in that regard, maybe it doesn't matter. But I think as time goes on, things will change.

Dr. Beck: Delain, do you think the insurance companies are going to initiate OTC hearing aids as a benefit, rather than prescription hearing aids?

Mr. Wright: Absolutely. I think that would be a huge win for the OTC companies if they can find a way to be directly on the insurance company benefits programs. In that case, the insurers would likely get excellent pricing on the products, and there would be fewer professional appointments for the patients. So if they can make that happen, I suspect they will push for it.

Dr. Beck: And pricing is a very interesting topic as OTCs range from perhaps \$300 to \$1,000, and that's quite a range with a vast and varied product offering across the spectrum. Indeed, some OTCs cost more than entry-level prescription products, and those less expensive prescription products come with a diagnosis, referral as needed, a warranty, as well as loss, theft and damage coverage, licensed professionals to guide the patient, and the licensed professional would program and reprogram the product as needed, but that ship has sailed for many of the OTC consumers.

Mr. Wright: I agree. It may become more clear in the next few years that the OTC consumer is potentially from a different demographic than is the prescription patient. So far in the OTC space, most have taken the easy path; get a product, place the product in an established retail location, and sell the product through the existing retail channel. The long-game and the more profitable channel would be to embed the product in the insurance programs. For the consumer, it becomes potentially

a very easy path to amplification, and for the insurance company, it potentially reduces their overall cost for hearing health care for many of their beneficiaries.

Dr. Beck: And, if it is truly a different demographic, the impact on the HCP might be negligible. My suspicion is that it's not truly a separate demographic, but more likely the two overlap, although it's too early to say how much overlap exists.

Mr. Wright: Yes, and a lot of this will be determined by three things: the form factor, price, and how we can engage with the user through AI more effectively. Many OTC products now are ear-bud-like products which are not necessarily attractive for many people. The other thing is the price point that OTC is delivered at. Originally, back in the early arguments for OTC the two main arguments for OTC were access and affordability. Access is addressed through the retail chains, but affordability

for the better products is just a little lower than the prescription products, and so that's a problem. I think OTC should be delivered at substantially a lower price than the prescription products to meet the affordability criteria, and to really energize the OTC marketplace. Ultimately the OTC product should have top-end software and technology, a brilliant and easy-to-use app, RIC/RITE form factors, a low price, and then OTC will be successful, but so far, most OTC products are not there yet.

Dr. Beck: Delain, it's always great to speak with you. I appreciate your insight and knowledge, and you always make me think!

Mr. Wright: Thank you, too, Doug. I appreciate the opportunity to address these issues and to share my thoughts with your readers. [📄](#)