

Biogen's \$26 Billion (and Counting)

Pricing Question

- Pricing Strategy
- Pricing Research



The Question

In less than 6 months, \$22+ billion was made, then \$26+ billion lost, in Biogen's (BIIB) market value (dramatic % swings against its previous ~\$40 billion market cap). Was the "confident pricing" of its new Alzheimer's drug, Aduhelm, a gigantic overreach (or even bet-the-firm bluff) that will cost Biogen and the rest of us long into the future?



Starting with (Priceless?) Hope

On June 7, the FDA approved Aduhelm on its using the <u>Accelerated Approval</u> pathway typically reserved for niche cancer drugs. It was the first FDA approval of a new Alzheimer's drug in nearly 20 years. Like millions around the world with loved ones in unwinnable struggles with this terrifying disease, I initially cheered the approval. Aduhelm's historic FDA clearance could only mean the clinical value claims of this drug were compelling. Relief for Alzehimer's patients seemed finally within reach.

A Confident Price Tag

Then came the price tag: \$56,000 **per year** (not including costs of procedures for injections, scans, etc). The markets cheered, adding over \$22 billion (more than 50%) to Biogen's market cap. Markets like "confident price signaling" and, in general, so do most pricing experts they may employ.

Biogen's CEO characterized the price (which for most patients is likely to be billed to Medicare / the taxpayers) in "value-based" terms: a "fair price" and an "investment" in fighting the cost of Alzheimer's, which he pegged at \$600 Billion / year. Huge problem, patent-protected monopoly on the solution, and voila, \$22 billion of extra market cap. What's not to like?

Collapsing Value Claims

A lot is not to like, it turns out. Less than 6 months later, all the \$22 billion and then some has been erased from Biogen's market cap, as high-profile setbacks spiraled. The media and political backlash was fierce. The catastrophic projections of economic cost to taxpayers / Medicare from that confident price tag put a huge target on Biogen's back. Perhaps worst of all, the "value claims" about the drug's benefits were discredited or challenged by experts until it seemed the emperor had no clothes. The drug was never going to provide anything close to a cure. Rather, it claimed to "slow" the progression of the disease, a claim that turned out to be heatedly disputed. Eminent FDA panel experts who had recommended against approval based on dubious clinical results (including outright failed trials) resigned and published op-eds excoriating the FDA's decision. Aduhelm's side effects (brain swelling) are deemed by such experts as unacceptably high-incidence and high-risk. Also, according to these experts, the FDA had issued an impermissibly broad "label" for use across categories of patients that should clearly have been excluded.

The Smoke Was There Early

When, immediately after the Biogen CEO interview, I curiously googled cost of Alzheimer's to see where he got that \$600 Billion / year cost figure, the result I landed on was a <u>study Biogen</u> <u>itself paid for</u>. With some of the experts resigning and publishing editorials, I had seen enough to turn deeply skeptical ... Just 4 days after the approval, on my <u>Impact Pricing Podcast chat</u> with <u>Mark Stiving, Ph.D.</u> I referred to this situation as an example of ... the opposite of mission-driven pricing. Shortly after, I wrote a generic piece inspired by this situation, named <u>"When Value-Based Pricing Means ... Nothing"</u> ... which in retrospect looks pretty accurate.

Confident Pricing, or Pricing Overreach?

The well-respected ICER (Institute for Clinical and Economic Review), an independent institute that analyzes economic benefits of drugs, had recommended a price for Aduhelm, under a best-scenario of patients best suited to it, of \$3-8,400. Biogen had confidently swept aside this independent evaluation (made publicly available and widely cited by press and politicians alike), going instead with its \$56,000 amount, 7 times higher than ICER's highest conceivable end of range price point. There was no counter analysis to support why Biogen saw a value that was not just higher, but indeed utterly disconnected from that seen by ICER's independent experts. Subliminally, it felt like Biogen was signaling its drug was on the same plane as a Warhol or a Picasso ... no explanation or economic value claim justification for the price tag necessary, as long as someone to pay for it can be found.

The \$56,000 Target on Biogen's Back

The backlash was swift, and its pricing "confidence" landed Biogen in the minefield of public discourse primed to look for the next drug pricing scandal. Some projections had this one drug bankrupting Medicare, making it an instant poster topic for senators and politicians (seemingly apropos, as AbbVie's CEO had been grilled in Congress just days earlier about giant price increases over time on Humira and other drugs).

Sometimes, faced with pricing a novel good or service without a close alternative, comparisons with what else the same price might buy can serve as useful sanity checks. I picked this one: one year of a patient on Aduhelm (some patients could be on the drug for decades) would cost roughly the same as an entire college education (in-state) at a respected public institution like University of Minnesota. Given that some patients could be on Aduhelm for decades, Biogen's price tag implicitly begged the question: should the taxpayer pay for every patient that takes Aduhelm an amount that could send five, 10 or even 20 kids to an excellent college?

Did this make any sense for **a drug whose only remaining value claim, increasingly, seemed to be that somehow the FDA had approved it** (which was suddenly, seemingly inexplicable even to the FDA itself, as it stunningly called for its own process to be investigated by Congress)? All of a sudden,

we seemed to be in an alternate reality of the "When Value-Based Pricing Means ... Nothing" variety. Some of the nation's most prestigious healthcare providers wanted nothing to do with Aduhelm, and publicly announced they won't prescribe it. The market saw the writing on the wall as Biogen announced near zero sales through the first few months.

Heads Must Roll (Ahem, Retire!) ... Layoffs are Afoot, and the Fallout Continues

On Nov 16, Biogen announced that Dr. Alfred Sandrock, the man most closely associated with its controversial Alzheimer's disease therapy, will retire at the end of the year. <u>Today, StatNews</u> <u>published a comprehensive story detailing the internal quagmire at Biogen</u>, and allegations that Sandrock is being used as the scapegoat for one of the most controversial drug rollouts in recent history. And Biogen is preparing its largest ever layoffs, rumored to exceed 1,000 employees. But is it the scientists / R&D / employees that should take the fall?

What "Should" or "Could" Biogen Have Done Differently?

I am not here to speculate, but the role of price in this story begs the question(s). Were it not for Aduhelm's gigantic price tag galvanizing politicians and clinicians alike into unprecedented scrutiny, could Biogen have met a very different trajectory in reception and sales of this drug? Could it have had a smaller, but more sustainable market cap gain by pricing, say, at \$10,000/year (confidently above, but not 10x above, the ICER recommended range)? Did management truly think that decoupling the price tag from any accountable expert analysis as if Biogen had only itself to persuade was a good idea? Or did it know about the drug's value claims being vulnerable (to put it charitably) and thought only a giant pricing bluff would project enough confidence to overcome the weakness of its hand?

Your thoughts are as good as mine. One thing is for sure: nobody will be able to blame Biogen for "anchoring low" (or lacking chutzpah). Time will tell, but the biggest beneficiaries may be Lilly and other competitors with Alzheimer's drugs in the pipeline for FDA approval. They just acquired, at Biogen's expense, a priceless "precedent" that got approved on very thin clinical claims, and a national audience thoroughly primed to expect very high prices for any Alzheimer's drug our future may yet hold.

The Context in Headlines:

- June 7 (CNBC) <u>Biogen shares surge 38% after FDA approves Alzheimer's drug, the first new</u> therapy for the disease in nearly two decades
- June 7 (Biogen.com) "We have established a price for Aduhelm that reflects the overall value this treatment brings to patients, caregivers and society and one that will enable continuous innovation," wrote Biogen's CEO Michel Vounatsos in <u>a letter announcing the approval</u>.
- June 7 (CNBC) <u>Biogen CEO interview describes price tag as a "fair price" and an "investment"</u>
 (no headline)
- June 8 (Pharma Forum) <u>FDA slammed over Aduhelm OK as Biogen takes heat for \$56k price</u>
- June 8 (CNBC) <u>Cowen upgrades Biogen and doubles price target after Alzheimer's drug</u> <u>approval</u>
- June 8 (FiercePharma) <u>Biogen's high price for Aduhelm—plus the drug's broad label—could</u> trigger drug pricing reform, analysts say
- June 10 (NYT) Three F.D.A. Advisers Resign Over Agency's Approval of Alzheimer's Drug
- June 11 (FOX) <u>Medicare copays for new Alzheimer's drug could soar</u>
- June 14 (FiercePharma) <u>Biogen's \$56K price on Aduhelm 'simply unacceptable,' Alzheimer's</u>
 Association says after vouching for FDA approval
- June 15 (StatNews) 6 ways the FDA's approval of Aduhelm does more harm than good
- June 15 (NYT) The F.D.A. Has Reached a New Low
- June 22 (NYT) New Drug Could Cost the Government as Much as It Spends on NASA
- June 25 (Boston Globe) <u>Biogen says pricey new Alzheimer's drug reflects treatment's overall</u>
 <u>value. Critics vehemently disagree</u>
- June 25 (FOX) <u>Sen. Cassidy, Warren lead Biogen's Alzheimer drug Medicare inquiry</u>
- June 28 (FOX) <u>Costly new Alzheimer's drug could force Medicare to restrict access</u>
- June 29 (StatNews) <u>Inside 'Project Onyx': How Biogen used an FDA back channel to win</u> approval of its polarizing Alzheimer's drug
- June 30 (BioPharmaDive) <u>ICER stands by view on Biogen's Aduhelm, says sharp price cut</u>
- July 8 (NYT) In Reversal, F.D.A. Calls for Limits on Who Gets Alzheimer's Drug
- July 9 (NYT) F.D.A. Seeks Investigation of Its Own Alzheimer's Drug Approval

- July 9 (FiercePharma) <u>Biogen Alzheimer's Drug Will Exceed the \$56,000 List Price for Many,</u>
 <u>Analysis Says</u>
- July 9 (StatNews) <u>With Aduhelm, is history repeating itself with another win for Wall Street and a loss for patients?</u>
- July 13 (Boston Globe) <u>'This is unprecedented': Several private insurers won't cover Biogen's</u>
 <u>Alzheimer's drug</u>
- July 15 (NYT) Cleveland Clinic and Mount Sinai Won't Administer Aduhelm to Patients
- July 15 (CNBC) <u>Biogen shares drop as big clinics announce they won't administer controversial</u>
 <u>Alzheimer's drug</u>
- July 15 (StatNews) Expert panel votes unanimously that Biogen Alzheimer's drug doesn't offer patient benefits
- July 16 (FOX) Panel says Biogen's Aduhelm Alzheimer's drug shows no benefit
- July 19 (FiercePharma) <u>High-profile Biogen ads hype early Alzheimer's detection as hospitals</u>
 reject Aduhelm prescriptions
- July 20 (CNN) <u>The hard math on the new \$56,000 Alzheimer's drug</u>
- July 20 (FiercePharma) <u>Scandal aside</u>, <u>Biogen's Aduhelm sales set to reach \$1B next year and</u>
 \$6B+ by 2025: analysts
- (Lots more adverse headlines July Nov)
- Nov 19 (StatNews) <u>Biogen's reckoning: How the Aduhelm debacle pushed a troubled company</u> and its fractured leadership to the brink.

Disclaimer

This is not a position paper or personal statement on pharma pricing. While I wholly believe pharma pricing can and sometimes does lead to questionable economic outcomes (as it would for Aduhelm), blaming the pharma industry as a whole or the putative "greed" of pharma executives for such outcomes is misplaced, one-sided or simply not a productive conversation. To the extent we see outcomes we don't agree with, I prefer to question the incentives our healthcare system creates and the political logjam that prevents change, rather than individuals and companies functioning under those systems and "maximizing returns".



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