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Former FDA commissioner Scott Gottlieb (Photo by Mark Wilson/Getty Images)

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Pharma

Scott Gottlieb criticizes CMS in feud over Aduhelm coverage, calls out their lack of expertise

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Former FDA commissioner and current Pfizer board member Scott Gottlieb went on the offensive against CMS this morning — citing the agency's "flawed decision making" and how the agency's decision on Aduhelm is putting not just Alzheimer's drug research in limbo but potentially setting a negative precedent for accelerated approvals.

Gottlieb, who was in charge of the federal agency from 2017-2019, talked with *BioCentury's* Steve Usdin on how the precedent that CMS is setting could impact accelerated approvals outside of Alzheimer's — and even further, blurring the lines of authority between the FDA and CMS.

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Gottlieb, who spent some time in the early 2000s as a CMS senior advisor, said that the center's decision would create a lot of obstacles for patients.

The former FDA commissioner added:

> *I think a lot of critics on the outside sort of applauded Medicare's muscular response in their coverage decision without really questioning the precedent that was getting set in the context of that decision. First of all, Medicare largely rejected the analysis of the FDA — didn't really condition its coverage decision on the FDA analysis — went out and sought a separate analysis from the NIH. They took the unprecedented position that because the drug was approved under accelerated approval, that it didn't necessarily prove an advantage and didn't necessarily need to be covered.*

Gottlieb further drove the point on accelerated approvals, and that CMS' decision put pretty much the entire field of Alzheimer's drug research in limbo. He said that CMS is "now using the issue of whether or not a drug is approved under regular approval versus accelerated approval as a basis potentially going forward for denying coverage to drugs."

Mark McClellan

And this led to Gottlieb's next point — since CMS pretty much said that the impact on cognition in the clinical trial isn't enough to merit approval, what impact would merit such approval? And since nobody knows where that line is, it leaves the entire field of Alzheimer's drug development in a state of limbo, in Gottlieb's view.

The comments from Gottlieb echo those released by Duke's Margolis Center for Health Policy, run by another former FDA commissioner Mark McClellan, from earlier this week on the draft NCD. The center asked CMS bluntly: "Can CMS clarify what evidence is needed for broader coverage of a particular mAb?"

Industry group PhRMA also argued the ethics of some receiving a placebo (and paying to receive a placebo) in the CMS-mandated trials, rather than an FDA-approved drug.

"Nobody knows what the objective measure is that CMS is going to base its coverage decision around when it comes to improving cognition," Gottlieb said. "Presumably because CMS doesn't know they sort of denied this — said it wasn't a robust enough effect on cognition, but didn't say what they would judge to be a robust enough effect."

Gottlieb continued in his critique of CMS' decision, calling it "problematic to have a single agency inside Washington staffed by eight physicians who don't have expertise in the areas that they're adjudicating, making coverage decisions that are effectively binding across the entire market. Because every single private payer is going to ultimately peg its own decisions to the decision made by CMS."

But many others have called the draft NCD a solid move by CMS, explaining that Biogen still hasn't confirmed clinical benefit in a trial and therefore doesn't merit widespread coverage yet.

Lon Schneider, who directs the University of Southern California's State of California Alzheimer's Disease Center, previously told Endpoints that the draft NCD was "a smackdown" as CMS "also told Lilly that FDA might give you AA [accelerated approval] or BTD [breakthrough designation] but we'll wait to see positive trials results."

The Aduhelm approval, which originally failed an 11-member adcomm back in 2020 before being approved last June, led to heated criticism that then led Medicare to decide to only limit reimbursement to patients in a clinical trial.

At the same time, Biogen is attempting to coordinate a backlash that would persuade Medicare to change course before it finalizes its coverage decision in April.

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