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Top Senator 'Disappointed' With Missing MDUFA Package

by [Ferdous Al-Faruque](#)

Sen. Patty Murray said she doesn't want more uncertainty about user fees during the COVID-19 pandemic and will move to get all the user fees renewed before they expire in September.

The chair of the Senate Health, Energy, Labor and Pensions (HELP) Committee tells *Medtech Insight* she's disappointed that the Medical Device User Fee Amendments (MDUFA V) was not included in the package of user fees submitted to the US Congress for approval.

"I'm disappointed we haven't received the proposed medical device user fee agreements yet," Sen. Patty Murray, D-WA, said. "The medical device user fee amendments provide the agency the resources it needs to continue its important work protecting patients and ensuring the devices people entrust their health to are safe and effective."

"The last thing we need during this pandemic is more uncertainty, so I plan to move quickly to reauthorize all of the user fee programs that expire this year," she added.

The US Food and Drug Administration and the medical device industry have been struggling to come to terms on a new device user fee deal, and failed to submit an agreement to lawmakers on the HELP committee by the 15 January deadline. (Also see "[FDA, Industry To Miss MDUFA V Congressional Deadline; Insiders At Odds Over Future Of Deal](#)" - Medtech Insight, 14 Jan, 2022.)

Sources are at odds over how close the two sides are on coming to an agreement, but as of the last meeting minutes provided to the public, industry and the FDA had serious disagreements about a proposed total product lifecycle advisory program (TAP) that would seek engagement from outside stakeholders such as health care insurance providers, use of carryover funds from MDUFA IV, and the agency's ability to continue to meet MDUFA deadlines with current resources. (Also see "[MDUFA V: Industry, FDA Tangle Over TAP Program, Agency Finances, Reinstatement Of Fifth-Year Offset Funds](#)" - Medtech Insight, 8 Jul, 2021.)

Medtech Insight reached out to the FDA for comments on the status of the MDUFA negotiations, but the agency said it did not have any update to share at this time.

“When our negotiations have been finalized, we will be communicating with the public about the status of the agreements reached through the MDUFA negotiation process,” FDA spokesperson Lauren-Jei McCarthy said.

Medtech Insight also reached out to industry representatives who also declined to comment on the status of the negotiations at this time.