

House lawmaker raises new concerns over FDA's ultra-fast drug review program

BY MATTHEW PERRONE
AP HEALTH WRITER

WASHINGTON — A Democratic lawmaker is raising new concerns about a Food and Drug Administration program designed to drastically shorten the review of certain drugs, including whether senior officials involved in the effort are complying with federal ethics rules.

In a letter sent Tuesday, Rep. Jake Auchincloss of Massachusetts took issue with the agency's handling of the program and questioned its legal underpinnings, noting that Congress did not sign off on the plan.

The new scrutiny comes as the FDA is scheduled to hold an employee town hall

Tuesday afternoon on the Commissioner's National Priority Voucher program, according to three agency staffers who spoke to The Associated Press on condition of anonymity to discuss confidential agency matters.

Under the voucher program, drugmakers are promised expedited reviews of one to two months for new medicines that support "national interests." It's at the center of FDA Commissioner Marty Makary's stated goal of "cutting red tape" and "challenging assumptions" at the agency.

But the effort has become a flashpoint for controversy outside and inside the agency, with several senior staffers declining to sign off on drug approvals going through the program, as previously

reported by the AP.

"The public must have transparency about the 'voucher' program, under which drug approvals have been made almost wholly and in an unprecedented manner by the FDA's political leadership," states Auchincloss, who is a member of a House subcommittee on health.

Auchincloss asserts that the FDA has failed to publish or disclose financial disclosure forms for eight senior FDA officials who vote on which drugs should receive priority

vouchers. Membership of group, which was first reported by Stat News, is mostly comprised of officials closely aligned with Health Secretary Robert F. Kennedy Jr., including Deputy FDA Commissioner Dr. Sara Brenner, Dr. Vinay Prasad, who oversees vaccines, and Dr. Tracy Beth Hoeg, FDA's drug center director.

The forms, which are collected annually by the Office of Government Ethics, list investments, outside income and other financial details for

senior government officials and their spouses. Such disclosures are considered critical to avoiding potential conflicts of interest at the FDA, where staffers are often involved in regulating multibillion-dollar, publicly traded companies.

A Department of Health and Human Services spokesperson didn't immediately respond to AP's questions about the letter.

Elsewhere in his letter, Auchincloss questions whether the FDA had the legal authority to establish the voucher program without action from Congress, which typically legislates such programs into law. His letter states that the FDA's legal office "was not consulted nor provided findings to support the agency's claim," that it could independently establish the program.

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