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OPINION LIFE SCIENCE

President Trump's Marty Makary Problem

Bad decisions and lots of drama make the FDA commissioner a headache for the president.



By Allysia Finley [Follow](#)

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Has any Trump administration official caused more political headaches for the president than Marty Makary? His Food and Drug Administration has turned into a soap opera, with real lives hanging in the balance.

Start with the FDA's arbitrary rejections of rare-disease and cancer drugs, which have spurred an outcry from patient groups and physicians. In each case, the FDA reversed prior guidance and contrived technical pretexts to deny access to a life-saving drug.

After receiving Replimune's melanoma treatment, one-third of patients who hadn't responded to other immunotherapies went into remission. A back-of-the-envelope calculation suggests that it could save 2,500 lives each year. Dr. Makary decided patients shouldn't have the right to try the drug.

Ditto a gene therapy by UniQure for the brutal neurodegenerative Huntington's Disease, which slowed progression by 75% in a clinical trial. The FDA has demanded the company run another trial in which some patients would have to undergo sham brain surgery to serve as a control group. This is unethical.

To add insult to injury, after Huntington's patients blasted Dr. Makary and the FDA, a spokesperson for the agency derided them on social media as "the swamp." In a CNBC interview, Dr. Makary claimed the drug had "no benefit" and that the agency was being "pressured to approve" it by industry.

Dr. Makary is slicker than a pharmaceutical salesman. In public interviews, he boasts about accelerating access to gene therapies and rare-disease drugs, even as he and his deputies block them. When FDA rejections draw criticism, he uses "industry" as a bogeyman. Lawmakers aren't buying his act.

Wisconsin Sen. Ron Johnson in March announced an investigation into the FDA's rejection of rare-disease treatments. "The stories are so outrageous," he said. "It just appears that they're looking for excuses to say no." He said he's heard the agency keeps a "blacklist" of companies that "make too much noise."

Members of Congress are also investigating whistleblower complaints of retaliation by agency leadership against FDA staff who have recommended approvals of drugs with which Dr. Makary and his left-hand man, Vinay Prasad, disagreed. Dr. Prasad is a Bernie Sanders acolyte whom the commissioner tapped to lead the FDA's biologics and gene-therapy division.

As it happens, Dr. Prasad's last day at the agency was Thursday. White House officials gave him the boot last summer after he torpedoed gene therapies, causing a ruckus. He was soon brought back after Dr. Makary pleaded his case. Dr. Prasad then went back to his obstructionist ways, which prompted the White House to give him the boot again.

Dr. Prasad is an example of how Dr. Makary's personnel decisions have created continuous drama and dysfunction. Dr. Prasad pushed out agency

veterans who have been supportive of rare-disease and cancer drugs, which resulted in a brain drain at the agency and delayed drug reviews.

Then there was the fiasco last fall involving George Tidmarsh, whom Dr. Makary tapped to oversee small-molecule drugs. Dr. Tidmarsh stepped down after former business partner Kevin Tang accused him of using his regulatory authority to extort him. Dr. Tidmarsh denied wrongdoing and said he was pushed out because he clashed with Dr. Prasad.

Then Dr. Makary elevated Richard Pazdur, longtime head of the agency's oncology division, to replace Dr. Tidmarsh. Dr. Pazdur backed accelerating approvals for cancer drugs, but he left the agency weeks later after clashing with Dr. Prasad.

If all this drama weren't enough, Dr. Makary has infuriated pro-lifers. Last June, he promised a safety review of the abortion pill mifepristone and a Biden 2023 decision to remove an in-person requirement for dispensing the drug. The Biden team wanted to enable women in states with restrictive laws to obtain the abortifacient via telemedicine providers in other states.

Press reports in December said Dr. Makary ordered the review slow-walked. Missouri Sen. Josh Hawley slammed the commissioner: "This is totally unacceptable." At the same time, Dr. Makary has defended the Biden relaxed dispensing rules in legal challenges by Republican states. On Friday, the Fifth U.S. Circuit Court of Appeals put the Biden changes on ice.

Dr. Makary has even managed to alienate the small conservative vaping community by reneging on the president's campaign promise to ease the Biden ban on flavored products. The Journal last month reported that his office overruled career FDA scientists who recommended authorization. Is the White House paying attention?

His lack of transparency and his doublespeak have further undermined trust in public-health officials, which the Biden team squandered during the

pandemic. My sources say that patience with Dr. Makary is wearing thin among Republicans in Congress and White House officials. It's time for Mr. Trump to pull the plug on the Makary show.



Dr. Marty Makary, Food and Drug Administration commissioner, in the Oval Office of the White House, April 23. MARK SCHIEFELBEIN/ASSOCIATED PRESS

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