

# U.S. Sen. Baldwin: Joins 240 members of congress in urging appeals court to prevent dangerous ruling threatening access to mifepristone from taking effect

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WASHINGTON, D.C. – Senator Tammy Baldwin (D-WI) joined 240 Members of Congress in submitting an [amicus brief](#) to the U.S. Court of Appeals for the Fifth Circuit in the case of *Alliance for Hippocratic Medicine v. FDA*, in support of the Biden administration’s appeal of federal district court judge Matthew J. Kacsmaryk’s ruling that suspends the Food and Drug Administration’s (FDA) more than 20-year-old approval of mifepristone—threatening access to mifepristone for patients nationwide, as well as FDA’s Congressionally-mandated authority and drug approval process. The amicus brief comes as the Biden administration asked the Supreme Court to intervene to stop restrictions set by Kacsmaryk’s decision.

In the new amicus brief, the Members of Congress underscore that the district court ruling has no basis in law, risks denying patients in every part of the country access to mifepristone, a safe and effective medication widely used in abortion care and miscarriage management for years, and jeopardizes patients’ access to a wide array of other medications by threatening FDA’s drug approval process, which was designed and mandated by Congress. Accordingly, they ask the court to stay the district court’s order.

“The district court appears to have second-guessed FDA’s scientific determinations with cherry-picked anecdotes and studies, and on that basis, imposed a remedy that could significantly upend the status quo,” **write the lawmakers in their**

## **brief.**

If the district court ruling were left to stand and were to go into effect, the Members stress that not only could patients in every state be denied access to the most common form of abortion care—and a key drug used in miscarriage management—but FDA’s authority to determine the safety and efficacy of other drugs would be put at risk, threatening patients’ access to all manner of other medications.

“[T]he district court’s misguided stay under Section 705 of the Administrative Procedure Act will reduce access to abortion, exacerbating an already significant reproductive health crisis,” **write the lawmakers, adding:** “The consequences of the district court’s remedy could extend far beyond mifepristone, for it undermines the science-based, expert-driven process that Congress designed for determining whether drugs are safe and effective.”

“Its perilous consequences reach far beyond mifepristone. Providers and patients rely on the availability of thousands of FDA-approved drugs to treat or manage a range of medical conditions, including asthma, HIV, infertility, heart disease, diabetes, and more,” **the lawmakers state.**

The Members also explain that Congress specifically designed FDA’s expert-driven drug approval process to ensure that the medications relied on by Americans every day are safe and effective. FDA followed that careful review process before it approved mifepristone for use in 2000, and its approval has been repeatedly affirmed in the more than 20 years since.

“For the last century, a statutory scheme designed by Congress has assured the safety and effectiveness of the drugs available in the United States. At its core resides the application of scientific standards by agency experts,” **the lawmakers write.** “Here, FDA’s determination that mifepristone is safe and effective is based on a thorough and comprehensive review process prescribed and overseen by the legislative branch. Since mifepristone’s initial approval in 2000, FDA has repeatedly and consistently reaffirmed that the medication is safe and effective for its approved conditions of use. FDA’s process and conclusions have been validated by both Congress and the Government Accountability Office—and by the lived experience of over 5 million patients who have used the drug in the United States.”

**The lawmakers conclude by asking the Fifth Circuit to stay the decision,**

**writing:** “emergency relief from the order is necessary to mitigate the imminent harm facing members of the public, many of whom rely on the availability of mifepristone for reproductive care—and many more of whom rely on the integrity of FDA’s drug approval process for continued access to life-improving and lifesaving drugs. Congress intended to—and did—vest authority in FDA to evaluate and ensure the safety and efficacy of drugs in the United States, and *Amici* call on this Court to give due weight to that intent.”

In the Senate, the amicus brief was signed by 50 Senators: Senators Schumer, Murray, Sanders, Durbin, Blumenthal, Baldwin, Bennet, Booker, Brown, Cantwell, Cardin, Carper, Casey Jr., Coons, Cortez Masto, Duckworth, Feinstein, Fetterman, Gillibrand, Hassan, Heinrich, Hickenlooper, Hirono, Kaine, Kelly, King, Klobuchar, Luján, Markey, Menendez, Merkley, Murphy, Ossoff, Padilla, Peters, Reed, Rosen, Schatz, Shaheen, Sinema, Smith, Stabenow, Tester, Van Hollen, Warner, Warnock, Warren, Welch, Whitehouse, Wyden.

In the House, the brief was signed by 190 Representatives: Representatives Jeffries, Clark, Pallone, Nadler, DeGette, Barbara Lee, Adams, Allred, Aguilar, Auchincloss, Balint, Barragán, Beatty, Bera, Beyer, Bishop, Blumenauer, Blunt Rochester, Bonamici, Bowman, Boyle, Brown, Brownley, Budzinski, Bush, Caraveo, Carbajal, Cárdenas, Carter, Cartwright, Casar, Case, Casten, Castor, Castro, Cherfilus-McCormick, Chu, Cicilline, Clarke, Cleaver, Clyburn, Cohen, Connolly, Courtney, Craig, Crockett, Crow, Davids, Davis, Dean, DeLauro, DelBene, Deluzio, DeSaulnier, Dingell, Doggett, Escobar, Eshoo, Espaillat, Evans, Fletcher, Foster, Foushee, Frankel, Frost, Gallego, Garamendi, R. Garcia, C. García, Gluesenkamp Perez, Goldman, Gomez, Gottheimer, Green, Grijalva, Higgins, Himes, Holmes Norton, Horsford, Houlahan, Hoyer, Hoyle, Huffman, Ivey, Jackson Lee, Jacobs, Jayapal, Johnson, Kamlager-Dove, Kaptur, Kelly, Khanna, Kildee, Kilmer, Kim, Krishnamoorthi, Kuster, Landsman, Larson, Susie Lee, Summer Lee, Leger Fernandez, Levin, Lieu, Lofgren, Lynch, Magaziner, Manning, Matsui, McClellan, McCollum, McGovern, Meeks, Menendez, Meng, Moore, Morelle, Moskowitz, Mullin, Napolitano, Neal, Neguse, Nickel, Norcross, Ocasio-Cortez, Omar, Panetta, Pappas, Pascrell, Payne, Pelosi, Peltola, Peters, Pettersen, Phillips, Pingree, Pocan, Porter, Pressley, Quigley, Raskin, Ross, Ruiz, Ruppertsberger, Ryan, Sablan, Salinas, Sánchez, Sarbanes, Scanlon, Schakowsky, Schiff, Scholten, Schrier, Bobby Scott, Sewell, Sherman, Sherrill, Slotkin, Smith, Sorensen, Soto, Spanberger, Stansbury, Stanton, Stevens, Strickland, Swalwell, Sykes, Takano, Thompson, Titus, Tlaib, Tokuda, Tonko, Ritchie Torres, Norma Torres, Trahan, Trone, Underwood, Vasquez, Veasey, Velázquez,

Wasserman Schultz, Waters, Watson Coleman, Wexton, Wild, Williams, Wilson.

The lawmakers' amicus brief can be read in full [here](#).

An online version of this release is available [here](#).