EMAA EXPANDING MEDICATION ABORTION ACCESS

Brief of Former FDA Commissioners as *Amici Curiae* In Support of Petitioners

“FDA is the expert agency that Congress has tasked with reviewing and approving drugs according to established scientific principles, made up of doctors, pharmacologists, chemists, biologists, and statisticians. Through FDA’s consideration of each NDA, its reviewers make hundreds of scientific judgments that lead the Agency to an ultimate decision whether to approve or deny the application. Further, once an NDA is approved, the Agency continues to monitor the drug’s safety and efficacy.” (Page: 5)

“Mifepristone’s approval was carried out using the process Congress created and FDA has been implementing since its enactment more than 60 years ago. In 2008, the U.S. Government Accountability Office (GAO) confirmed that FDA’s review and approval of mifepristone was consistent with the processes for other Subpart H drugs.” (Page: 11)

“Similar with other drugs, FDA did not approve mifepristone after the sponsor’s initial submission; FDA denied approval twice to require and evaluate additional data and information from the drug sponsor.” (Page 13)

“In 2021, during the COVID-19 pandemic, FDA exercised its enforcement discretion, determining that the available data and information supported modification of the REMS to reduce the burden on the health care delivery system and to ensure that the benefits of the product outweigh its risks.” (Page: 14-15)

“In reviewing FDA’s approval of mifepristone, the courts below did not review FDA’s interpretation of a law. Instead, they reviewed FDA’s scientific evaluation of the studies and other data supporting the Agency’s modifications of mifepristone’s conditions of use in 2016 and 2021. In finding that Respondents were likely to prevail on the merits of their APA claims, the Fifth Circuit misapplied the well-established arbitrary and capricious standard and failed to give FDA the requisite deference.” (Page: 15)

“No court has ever restricted access to an FDA-approved drug by invalidating FDA’s modification of a drug approval, as the Fifth Circuit did here. The only two district courts to overturn FDA drug approvals were each reversed by the D.C. Circuit and Fifth Circuit.” (Page: 17)

“Adopting the Fifth Circuit’s approach would open the door to the re-litigation of drug approvals by many interested parties. This new paradigm would take a significant toll on public health, as successful litigation challenging drug approvals could threaten patient access to necessary drugs and vaccines. Further, it would chill crucial investment in pharmaceutical research and the development of new medications, discouraging companies from investing in new life-saving remedies.” (Page 23)

Brief of Pharmaceutical Companies as *Amici Curiae* In Support of Petitioners

"[The Fifth Circuit] decision casts a shadow of lasting uncertainty over every FDA approval and invites spurious lawsuits challenging FDA's settled safety and effectiveness determinations after the fact. Under the Fifth Circuit's logic, *any* physician can ask a judge to undermine patient access to *any* drug nationwide— even if the physician does not treat patients using that drug— based on mere disagreement with FDA's scientific judgment. The destabilizing effects of that outcome cannot be overstated. It could chill crucial research and drug development." (Page: 3)

"If a court can overturn those judgments many years later through a process devoid of scientific rigor, the resulting uncertainty will create intolerable risks and undermine the incentives for investment regardless of the drug at issue. This, in turn, will ultimately hurt patients." (Page: 9)

"Because all drugs have the potential for adverse effects, demonstrating a drug's safety does not require the sponsor to show that the drug has *no* potential adverse effects, but rather that the drug's benefits outweigh any risks it poses. This balancing of benefits and risks is the core of FDA's drug-approval standard, whether FDA is considering a new original application or an sNDA. Congress entrusted this determination to FDA as the expert agency, not to the courts." (Page: 6)

"Instead of relying on FDA's scientific expertise, and in lieu of following the approval standards established by Congress and implemented by FDA, the court invented its own novel standards for drug development and approval— standards that are wholly unworkable and would deprive industry of the critical stability that comes with FDA approval, including the FDA process for approval of labeling changes." (Page: 9)

"The court's reasoning thus calls into question whether FDA can *ever* rely on the FAERS system, creating doubt about FDA decisions beyond those at issue here and casting a pall of uncertainty over drug development and post-approval changes more generally. And by calling into question all safety data generated after the 2016 REMS modification, the Fifth Circuit could effectively prevent the agency from ever loosening additional reporting requirements imposed under a REMS - regardless of how unnecessary and burdensome such requirements may be." (Page: 17-18)

Brief of Patient and Provider Advocacy Organizations as *Amici Curiae* in Support of Petitioners

“For many patients, their lives depend on the reliability of FDA’s approvals. The Fifth Circuit’s opinion partially affirming the district court’s preliminary injunction jeopardizes patients’ and providers’ ability to rely on FDA’s expert process to deem drugs and their conditions of use safe and effective, and therefore available for treatment.” (Page: 1)

“Amici are particularly concerned that the decision improperly dismissed, and fundamentally misunderstood, the significant reliance interests that patients and providers have on the agency’s decisions to approve updates to a drug’s labeling and other conditions of use.” (Page: 3)

“If approved drugs or modifications to conditions of use can be so readily enjoined despite FDA’s scientific assessments, the resulting uncertainty would jeopardize patient access to drugs, particularly in cases where FDA has expanded the approved uses of a drug to cover new diseases or conditions.” (Page: 3-4)

“The Fifth Circuit’s decision would impair the development of new treatments, as uncertainty disincentivizes pharmaceutical manufacturers, clinicians, and patients from undertaking time- and resource-intensive clinical trials to study new drugs and new indications for approved drugs.” (Page: 4)

“Study of the safety and effectiveness of drugs, both investigational and approved, is the cornerstone of FDA’s oversight at each stage of a drug’s life cycle.” (Page: 5)

“FDA has approved another form of mifepristone, the drug at issue here, to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing’s syndrome who have type 2 diabetes mellitus or glucose intolerance. FDA’s ability to expand labeling indications is thus critical to the treatment of rare diseases and disabilities….These kinds of labeling changes result from FDA’s determination that a drug continues to offer a positive benefit-risk profile but requires new or additional safeguards.” (Page: 13)

“Patients and their providers have a critical interest in being able to rely not only on FDA’s initial approval of a drug, but also on the agency’s decision to apply updates to the conditions of that drug’s use.” (Page: 22)

“If the Fifth Circuit’s approach is upheld, courts would be invited to upend FDA’s approval process, without consideration of impact on patients, the availability of alternative treatments, and other factors that comprise the statutorily based risk-benefit determination.” (Page: 22)

“The [FDA’s] ability to update REMS, whether adding or removing restrictions, helps expand patient access to life-saving drugs while maintaining safe use. But the Fifth Circuit’s approach threatens access to medications that could provide crucial health benefits when new information has demonstrated they can be safely administered.” (Page: 25)

“The serious harm to patients from the loss of access to medications is self-evident. Studies conducted in the context of drug shortages have found that sudden lack of availability of drugs causes serious harms, including significant rates of delayed and canceled treatment and surgical intervention, increased medication errors, and serious adverse patient outcomes—including death. Uncertainty regarding access to medication also causes serious psychological harm.” (Page: 27-28)