

**23-236 DANCO LABORATORIES, LLC V. ALLIANCE FOR HIPPOCRATIC MEDICINE**

DECISION BELOW: 78 F.4th 210

LOWER COURT CASE NUMBER: 23-10362

QUESTION PRESENTED:

In 2000, the Food and Drug Administration (FDA) approved Danco's drug Mifeprex for termination of early pregnancy based on the agency's expert judgment that clinical data showed the drug to be safe and effective. The agency later modified certain conditions of use for mifepristone in 2016 and 2021, again relying on clinical data and the agency's expert judgment that the drug would remain safe and effective under the modified conditions of use. In 2022, associations of doctors who have never prescribed Mifeprex sued FDA, arguing that FDA's actions modifying the drug's conditions of use in 2016 and 2021 violated the Administrative Procedure Act. The questions presented are:

1. Whether an association can demonstrate Article III standing to enjoin a government action by arguing that some unspecified member may be injured at some future time by the challenged action; and

2. Whether the Fifth Circuit erred in upholding the preliminary injunction of FDA's 2016 and 2021 actions based on the court's review of an incomplete administrative record.

Consolidated with 23-235 and a total of one hour is allotted for oral argument

CERT. GRANTED 12/13/2023