

# **Exhibit B**

Declaration of  
Jessica Nouhavandi, Pharm.D.

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF HAWAII

HEIDI PURCELL, M.D., FACOG, *et al.*

Plaintiffs,

v.

DORIS FINK, J.D., *in her  
official capacity as* ACTING  
SECRETARY,  
U.S. D.H.H.S., *et al.*,

Defendants.

CIVIL ACTION

Case No. 1:17-cv-  
00493-JAO-RT

**DECLARATION  
OF JESSICA  
NOUHAVANDI,  
PHARM.D**

Jessica Nouhavandi, Pharm.D, declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am the owner, co-founder, and Pharmacist-in-Charge at Honeybee Health (“Honeybee”), a mail-order pharmacy serving patients across the country. I am also a member of the Society of Family Planning.

3. I submit this declaration in support of Plaintiffs’ motion for summary judgment and in opposition to Defendants’ motion for summary judgment in Plaintiffs’ challenge to the U.S. Food and Drug Administration’s (“FDA”) mifepristone Risk Evaluation and Mitigation Strategy (“REMS”).

### **Background on Honeybee**

4. After earning my bachelor's degree in Bioethics and a Doctorate in Pharmacy, I began working as the Pharmacist-in-Charge of a small, independent pharmacy in California. We knew our patients well—their names, their birthdays, their kids, their pets. Yet too often, we saw our patients leave the counter unable to afford their medications because of high co-pays, or purchase their medications but at the cost of other essentials for their families. That is what prompted me and my co-founder to create Honeybee in 2017 with the mission of bringing lower prices, transparency, and top-notch service to patients nationwide.

5. Honeybee is a licensed pharmacy in all 50 states and D.C. We provide pharmacy services for a broad range of health conditions, such as epilepsy, diabetes, high blood pressure, erectile dysfunction, depression, and menopause. In addition to filling prescriptions, my team of board-certified pharmacists provides other services to improve patient care and make patients' lives easier. For instance, we provide information about the medications we dispense both on our website and through our complementary pharmacist consultation service; send patients automated reminders when it's time for a refill of their prescription; and recommend over-the-counter medications and other supplies relating to their prescription (e.g., ibuprofen, anti-nausea medications, single-use heating pads, pregnancy tests, custom vitamins) so that we can be a one-stop shop for our patients' pharmacy needs.

6. Honeybee has been recognized for the excellent care we provide, including by CNBC (“Upstart 100,” 2019), Los Angeles Business Journal (“Innovator Award Honoree,” 2021), Fast Company (“10 Most Innovative Health Companies,” 2021), TIME Magazine (“100 Most Influential Companies,” 2023), Everyday Health (“Best Online Pharmacies,” 2023), and Health.com (“Best Online Pharmacy for Customer Support,” 2024).

### **Honeybee’s Provision of Medication Abortion Before January 2023**

7. It is also part of Honeybee’s mission to ensure that women and other patients seeking reproductive health care can access the safe, essential medications they need, including medication abortion.

8. In the summer of 2020, a court order in *ACOG v. FDA* enjoined FDA’s in-person dispensing requirement for mifepristone during the COVID-19 Public Health Emergency and for the first time permitted mail-order pharmacies to dispense mifepristone. Shortly thereafter, Honeybee began dispensing mifepristone and misoprostol for medication abortion. When the U.S. Supreme Court stayed that preliminary injunction in January 2021, Honeybee paused this aspect of our operations. After the FDA announced in April 2021 that it would exercise enforcement discretion with respect to its in-person dispensing requirement for the duration of the COVID-19 Public Health Emergency, Honeybee again began to dispense the medications used for medication abortion, and we have continued ever

since. For years, we have safely dispensed thousands of mifepristone prescriptions by mail each month.

9. Complying with the mifepristone REMS was challenging and costly from the start. As an initial matter, while we maintain licensing status information for all prescribers, there is no other medication Honeybee dispenses for which we are required to confirm that a licensed prescriber is specially “certified” before filling their prescription. Before January 2023, when FDA added a new pharmacy certification Element to Assure Safe Use (“ETASU”) to the mifepristone REMS program, Honeybee was not required to keep prescriber certifications forms on file. Instead, our staff verified prescriber certifications by communicating with GenBioPro, the drug sponsor for the generic version of mifepristone. Even so, this requirement was a strain on my and my staff’s time, necessitating outreach outside our normal workflow and our automated systems.

10. Additionally, because FDA required mifepristone prescribers to certify that they would record the serial number of each package of mifepristone in the patient’s medical record, Honeybee had to record that number for each mifepristone package we dispensed and relay it back to the prescriber. This, too, was outside our standard workflow and automated systems. It is not part of the normal practice of pharmacy for pharmacists to have to share information with prescribers about the medication package, and we had to develop entirely new protocols for this process.

11. As Honeybee's volume of medication abortion patients increased, it became increasingly inefficient and costly for our staff to manually record the mifepristone serial number and relay it back to each prescriber. We therefore decided to make a substantial financial investment in developing a special, HIPAA-compliant "dashboard" that would enable us to streamline the process of relaying the serial number to mifepristone prescribers, as the REMS requires.

12. Honeybee offers FedEx and USPS as options for our mail-order deliveries. Pre-2023, mifepristone patients could choose the carrier and shipping option (e.g., overnight, next-day, ground) that made the most sense for them. And on average, it took only 36 hours for patients to receive their medication from the time Honeybee received their prescription. We reported that average shipping time to GenBioPro, which I understand shared our data with FDA. I am not aware of a single instance of a mifepristone patient experiencing a serious adverse event relating to a shipping delay or any other aspect of Honeybee's provision of medication abortion.

#### **Honeybee's Provision of Medication Abortion under the January 2023 REMS**

13. Given Honeybee's strong track record of patient safety and satisfaction with respect to mifepristone in 2020 and 2021, I was surprised to learn in December 2021 that FDA intended to add a new pharmacy certification ETASU to the mifepristone REMS, making the process of dispensing mifepristone even more

burdensome. I was even more dismayed to see the details of that ETASU in January 2023 when FDA released the updated REMS.

14. Because Honeybee had already spent multiple years and a significant amount of money developing the infrastructure to comply with the mifepristone REMS, we were able to quickly submit a pharmacy certification form in January 2023. But this ETASU continues to impose extensive, expensive burdens on Honeybee. It also imposes needless costs on our patients.

15. First, Honeybee bears even greater burdens relating to prescriber certification since January 2023. Whenever a new prescriber sends us a mifepristone prescription—which happens on a regular basis—we must now collect, verify, and store their certification form. If a new prescriber has not sent a certification form along with the mifepristone prescription, we must try to get in touch with them to explain the certification process and obtain the form. And we must continually maintain all certification forms on file, including developing confidentiality protocols specific to this unique REMS requirement and training staff accordingly. There is no other medication Honeybee dispenses for which we must collect, verify, and store a signed agreement from the prescriber.

16. Second, Honeybee bears heavy costs and burdens from the requirement that pharmacies must certify they will “[d]ispense mifepristone such that it is delivered to the patient within 4 calendar days of the date the pharmacy receives the

prescription,” or else “[c]onfirm with the prescriber the appropriateness of dispensing mifepristone for patients who will receive the drug more than 4 calendar days after the date the pharmacy receives the prescription and document the prescriber’s decision.” Although patients were already receiving their mifepristone on average within 36 hours of Honeybee’s receipt of the prescription before FDA added the pharmacy certification ETASU, we must now default to using more expensive shipping services in order to *guarantee* that the medication arrives within four days—regardless of whether the patient would otherwise choose that shipping option. We must also track every delivery and communicate directly with the prescriber (not just the patient) in the event of unexpected shipping delays that might push delivery past four days.

17. Because Honeybee is committed to keeping mifepristone affordable for our patients, we absorb the overwhelming majority of these additional shipping fees—costing our pharmacy thousands of dollars every month.<sup>1</sup> While we ensure that no mifepristone patient has to pay more than \$10-15 extra in shipping, I know firsthand from my conversations with patients (and with prescribers on behalf of their patients) that even an increase of \$10 can be very difficult for low-income patients to cover. And the extra shipping costs that Honeybee bears because of this

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<sup>1</sup> The price range depends on which carrier is used; for patients who use P.O. boxes (for instance, because they live in a remote area without mailbox service), only USPS—not FedEx—is available.



ETASU often far exceed that per-patient amount. For instance, for patients living in remote locales, the increased shipping costs are especially high; and standard two-day shipping options are not available for Saturday deliveries, so depending on what day and time the prescription comes in, we may have to pay for next-day delivery.

18. Third, FDA still requires pharmacies to record and transmit back to the prescriber a specific number corresponding with the mifepristone prescription—now, the lot number rather than the serial number. As I mentioned, it is extremely unusual for a pharmacy to have to transmit information about a medication package back to a prescriber; there is no other drug Honeybee dispenses for which such communications are routine. We now utilize the special dashboard we created for this purpose, but we still face ongoing costs to do so, for instance for ongoing tech support, platform maintenance, and updates.

19. Fourth, we have to undergo annual audits for compliance with the REMS, which poses ongoing burdens on Honeybee in time and resources for staff training and compliance paperwork.

20. Because of the REMS, we have a specific employee at Honeybee whose principal job it is to onboard mifepristone prescribers, including confirming their prescriber certification forms and helping them securely gain access to our dashboard so they can obtain the mifepristone package lot numbers for their patients. This employee also gathers the data necessary for REMS audits. The money that

Honeybee expends on this employee's salary and benefits is another ongoing burden directly attributable to the REMS.

21. Because Honeybee is public about our provision of medication abortion care, and because I have experience with both mail-order and retail (i.e., brick-and-mortar) pharmacies, I am frequently contacted by pharmacists seeking to understand what would be required of them to dispense mifepristone. In those conversations, it quickly becomes clear that the very significant costs and burdens of complying with the REMS are a major deterrent for pharmacies, particularly independent (i.e., non-chain) retail pharmacies who are, as a general rule, operating with extremely slim margins and struggling to keep their doors open. Indeed, multiple pharmacists have told me directly that they will not dispense mifepristone because the burdens of the pharmacy certification ETASU are too great.

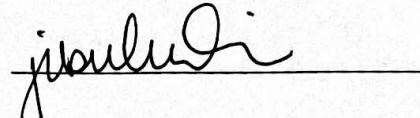
### **Conclusion**

22. I am familiar with mifepristone's safety record given my role as Honeybee's owner and Pharmacist-in-Charge in overseeing our provision of mifepristone and mifepristone-related counseling consultations. Mifepristone's safety record is comparable to or better than the safety record of many other medications that Honeybee dispenses, such as Viagra and ibuprofen. There is simply no medical basis for subjecting pharmacies, prescribers, and patients to the burdens of the REMS. And it is beyond question that the pharmacy certification ETASU is

reducing where patients can access this medication and increasing burdens on the health care system.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on January 30, 2025, in Los Angeles, California.

A handwritten signature in black ink, appearing to read "Jessica Nouhavandi", is written over a horizontal line.

Jessica Nouhavandi, Pharm.D.