EXHIBIT 1

#WeCount Report April 2022 to June 2025 (Dec. 9, 2025)

#WeCount report, April 2022 to June 2025
Released: December 9, 2025

#WeCount is a reporting effort that aims to capture national shifts in abortion volume, by state and month, following the *Dobbs v Jackson Women's Health Organization* Supreme Court decision to overturn Roe v Wade. This report includes data from April 2022 to June 2025.

For media inquiries, please contact SFP@ConwayStrategic.com.

For questions about #WeCount and information on how to enroll your practice, please contact WeCount@SocietyFP.org.

Please use the citation below to cite this #WeCount report.

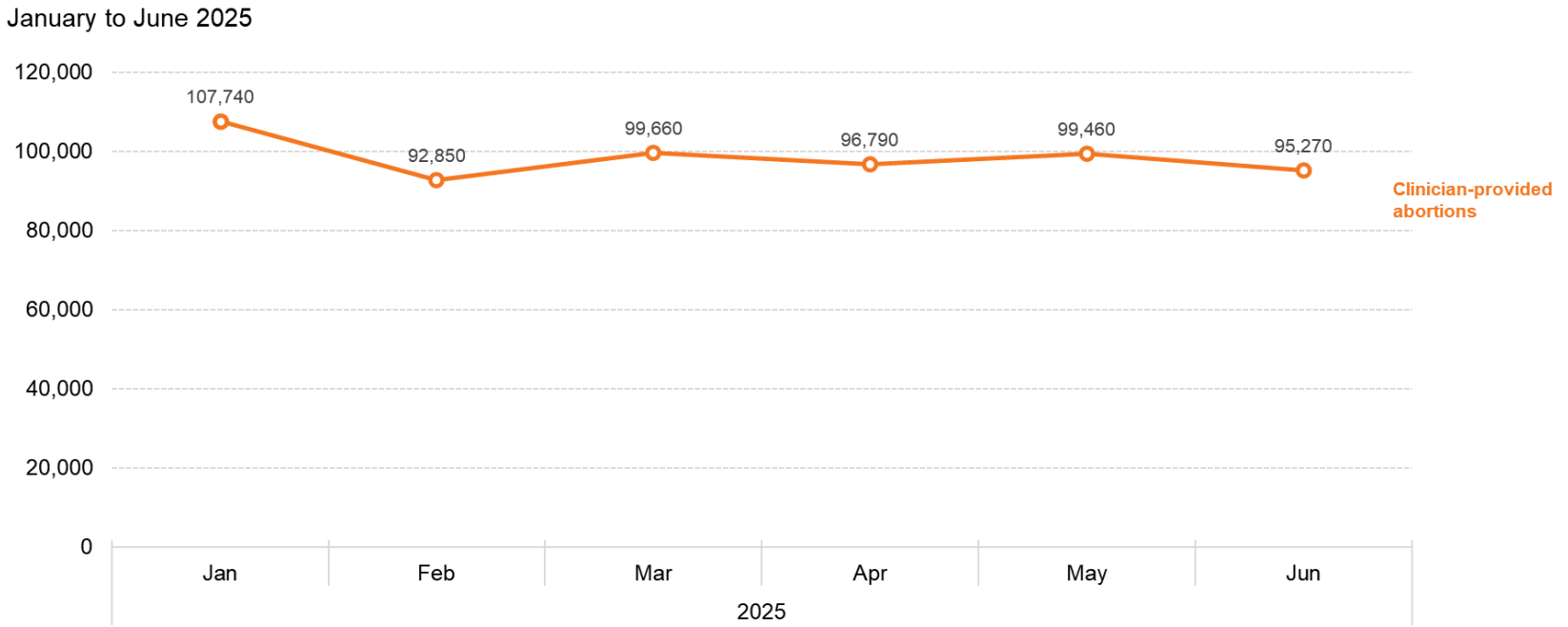
> *Society of Family Planning. #WeCount Report April 2022 through June 2025. 9 Dec. 2025, https://societyfp.org/wecount-report-10-june-2025-data/, https://doi.org/10.46621/750591yxmcwh.*

Key findings

- The number of abortions in the US healthcare system **continued to increase**, but with a smaller increase than in previous years.
- The monthly average number of abortions was **slightly higher in the first half of 2025** than the monthly average was in 2024.
- Nationally, the majority of abortions still occurred **in-person**.
- The number of abortions delivered via **telehealth has continued to increase**.
- In the first half of 2025, **27%** of all abortions within the US healthcare system were provided via telehealth.
- **Shield laws** continue to facilitate abortion access, with nearly 15,000 abortions per month provided under shield laws by June 2025.

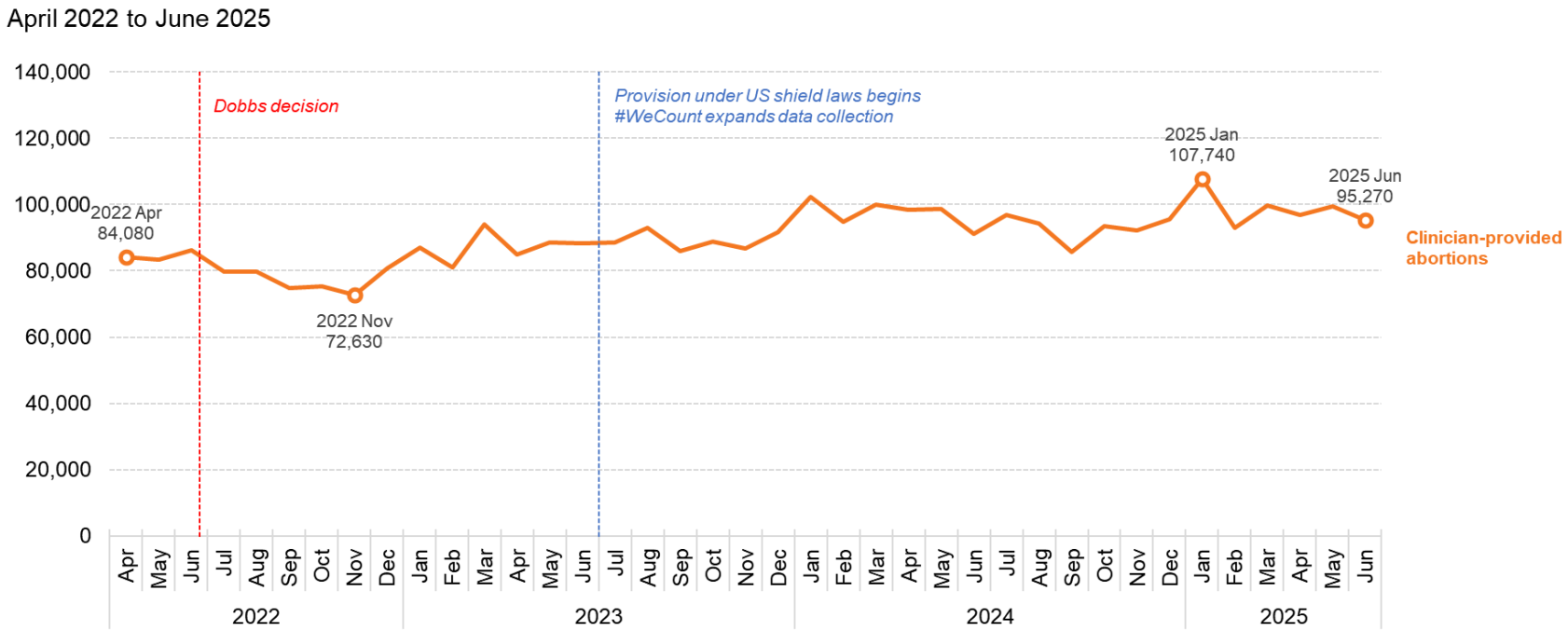
National findings

US abortions totaled 591,770 in the first six months of 2025



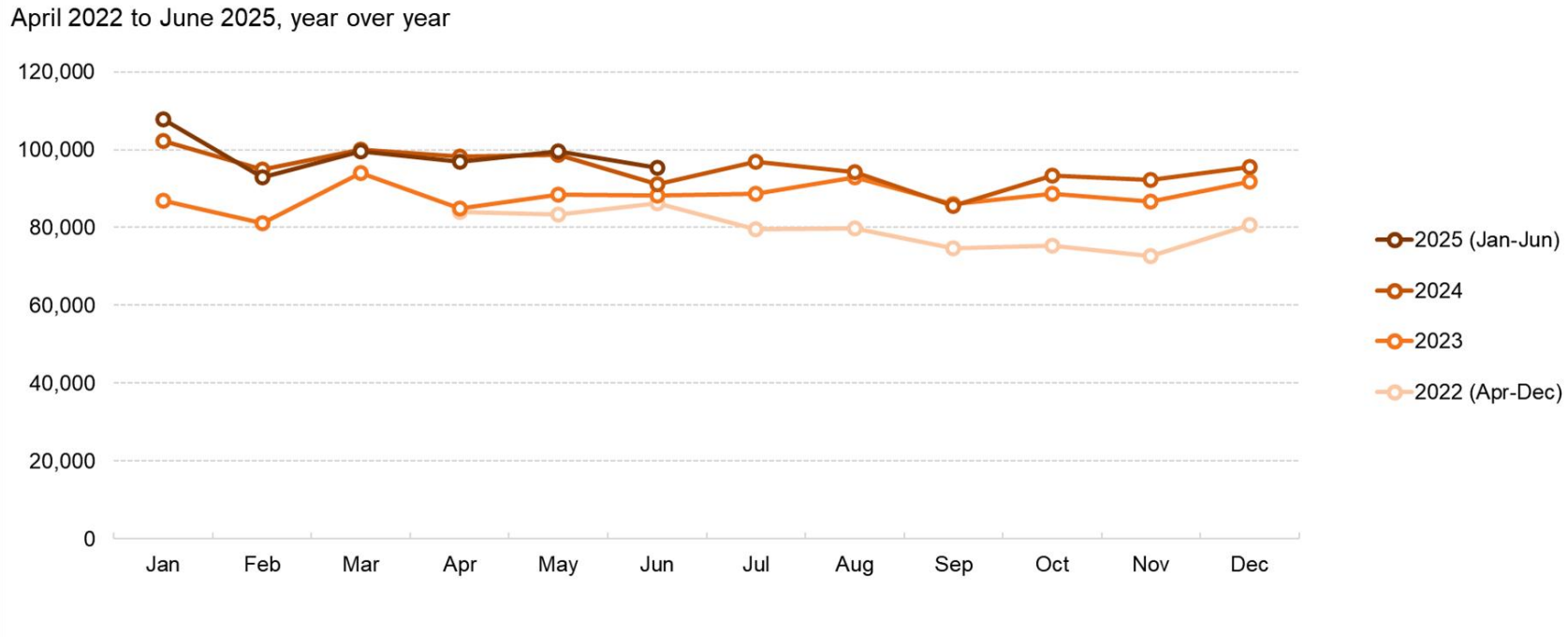
This #WeCount report includes new data for the first 6 months of 2025, when a total of 591,770 abortions were provided in the US healthcare system.

Abortions in the US have increased since *Dobbs*



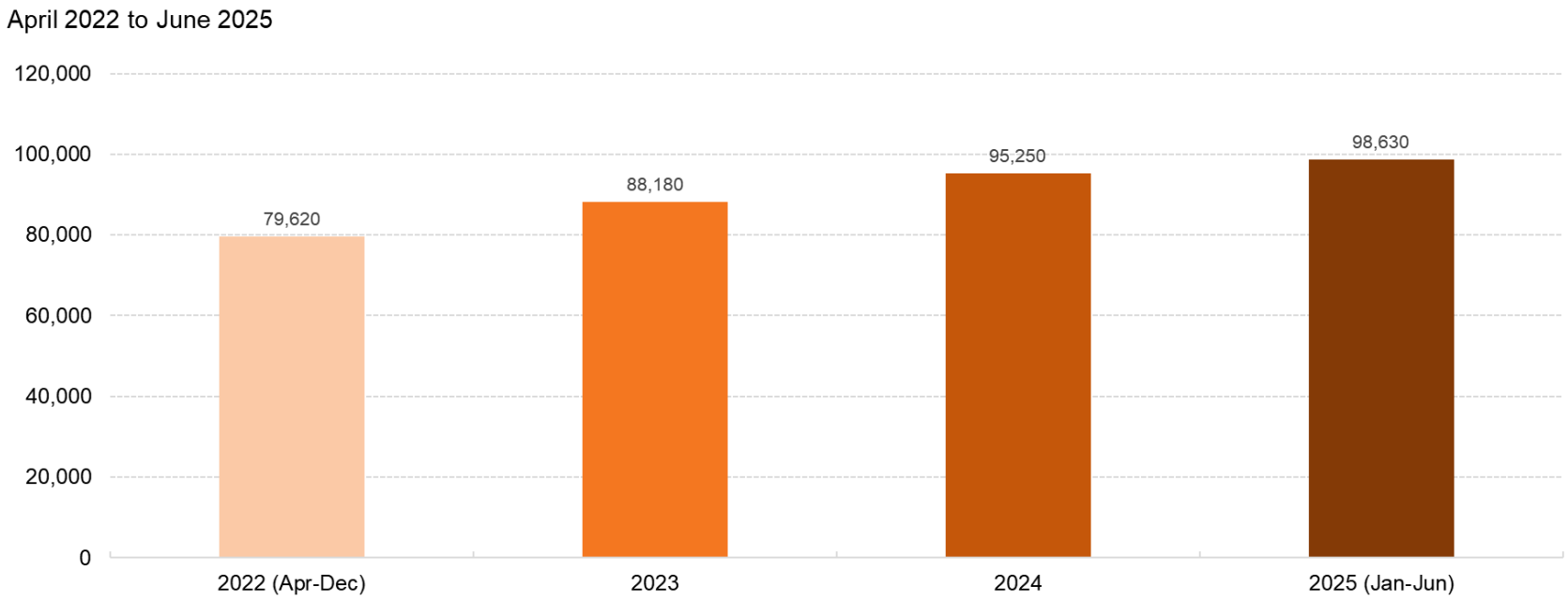
The monthly number of abortions increased gradually over time in the US since 2022. The monthly total peaked in January 2025 for the entire duration of #WeCount, reaching 107,740 abortions in a single month.

Abortion volume fluctuates from month to month, and has increased year-over-year



In addition to some monthly fluctuation, abortion volume is also increasing year-over-year, with 2025 monthly numbers only slightly higher than 2024.

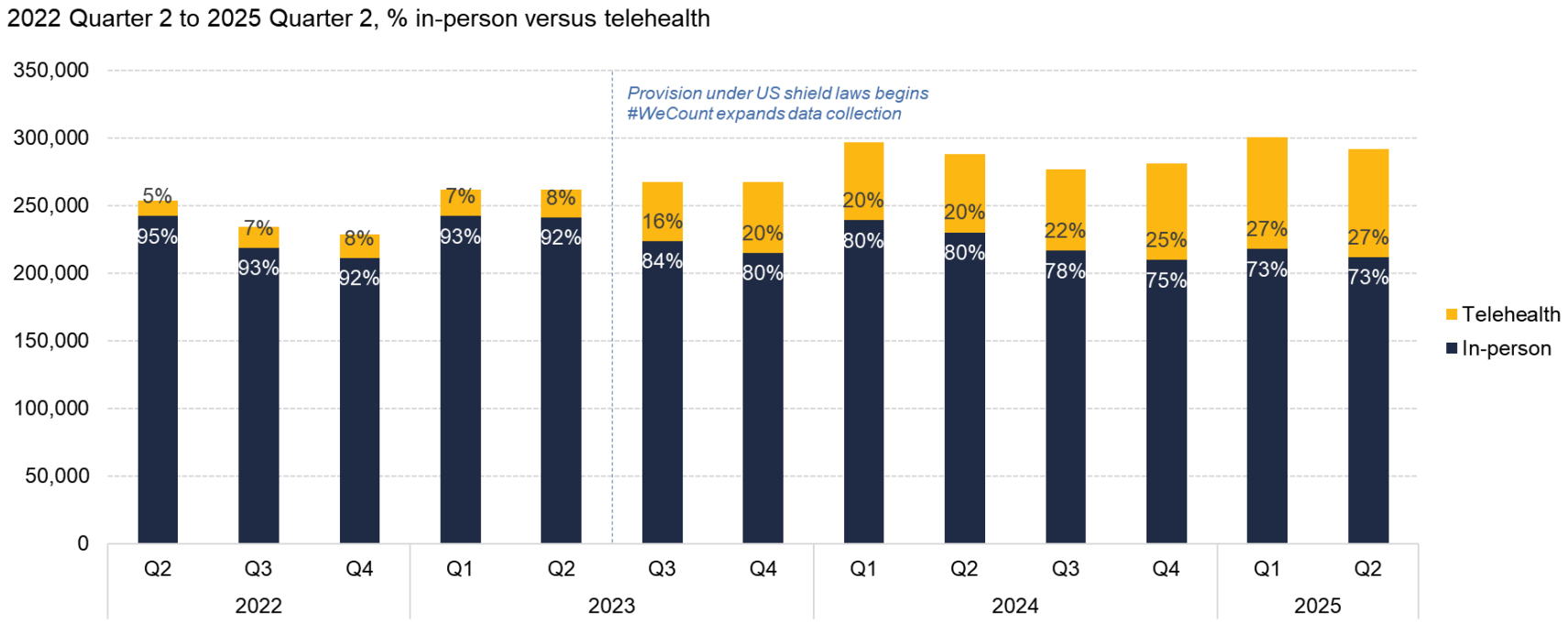
Monthly average numbers of abortions increased each year



The monthly average number of abortions climbed from 79,600 in 2022, to 88,200 in 2023, to 95,300 in 2024, to 98,800 in 2025. Note that the 2022 and 2025 monthly averages reflect partial years of data.

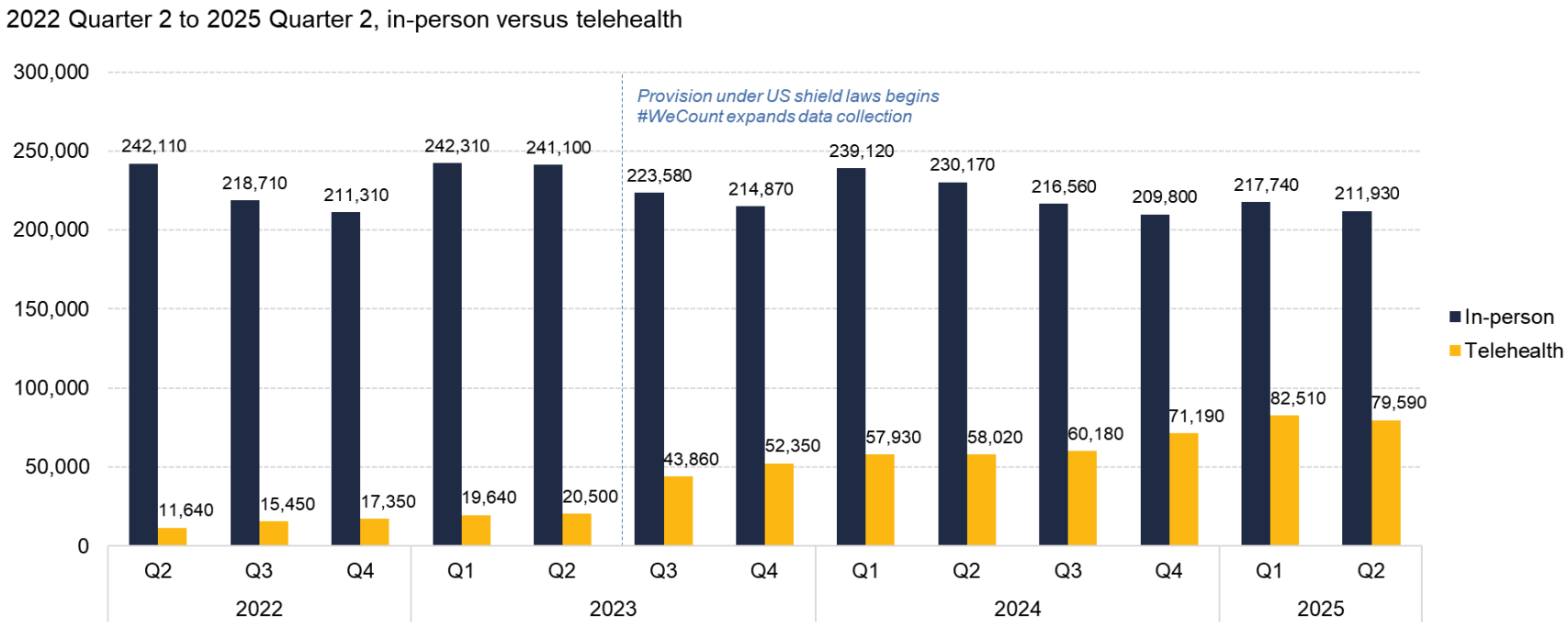
Telehealth findings

In the first six months of 2025, 27% of abortions were provided via telehealth



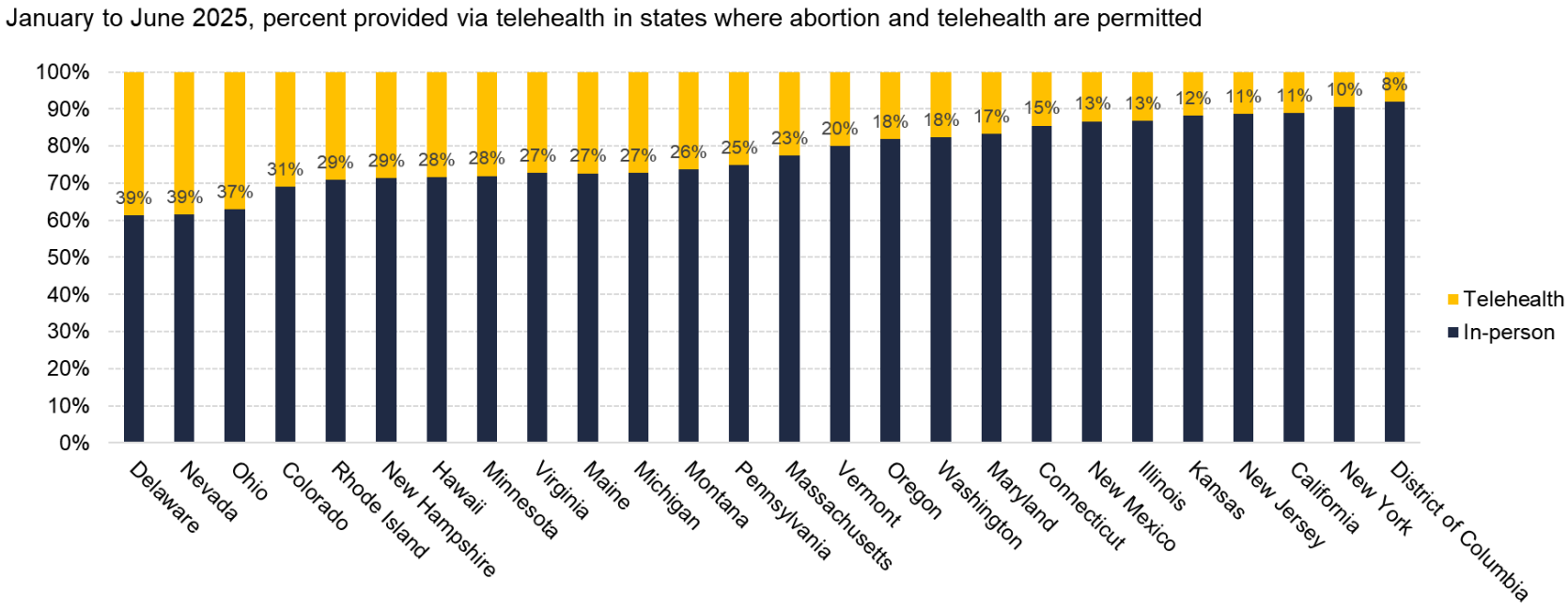
The proportion of abortions that were provided via telehealth increased over time from 5% in Quarter 2 of 2022 to 27% by Quarter 2 of 2025.

In-person abortion care declined slightly, while telehealth grew



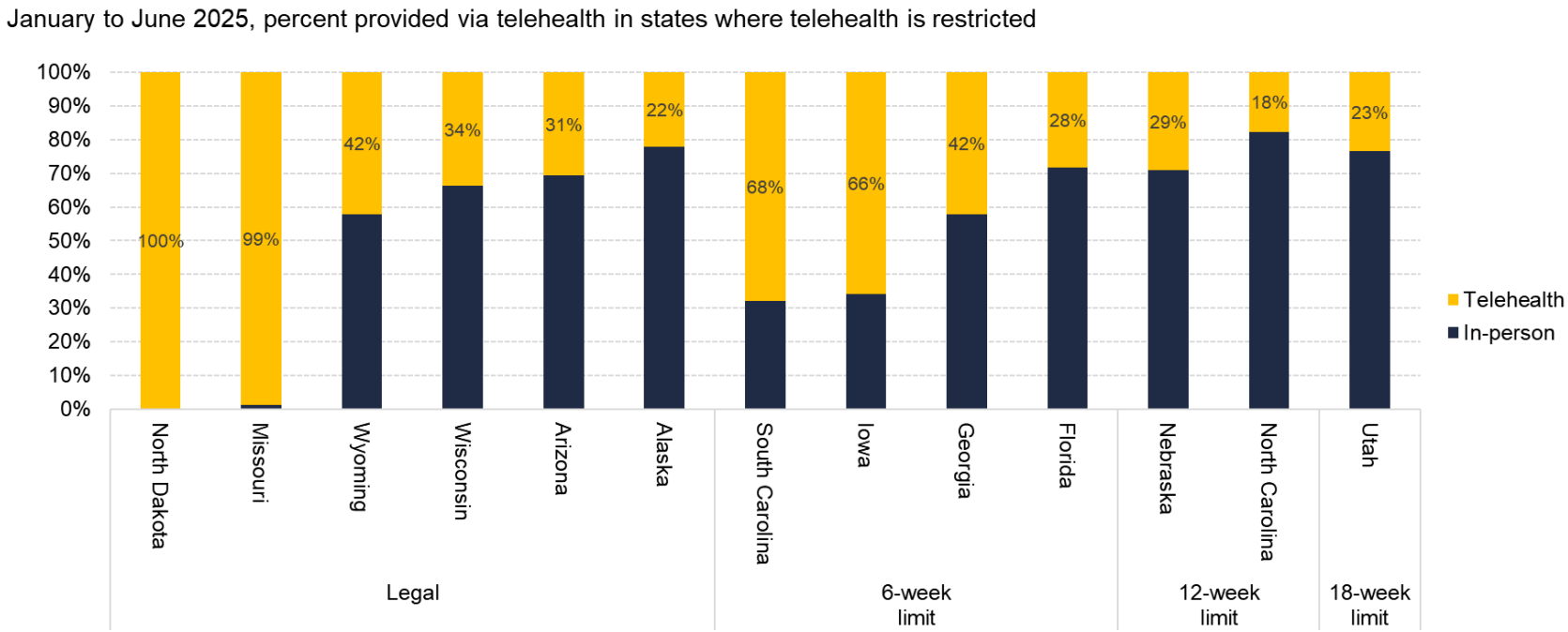
Telehealth abortion care (which involves mailing medication abortion pills) increased both in proportion and in absolute numbers over the study period. In-person abortion care (which includes both procedural abortions and medication abortion pills dispensed in person), was much more common than telehealth abortion. As telehealth has grown, the number of in-person abortions has not declined commensurately. The number of in-person abortions was lower in the second half of each year compared to the first half.

Where abortion and telehealth are permitted, the share of abortions provided via telehealth varied widely



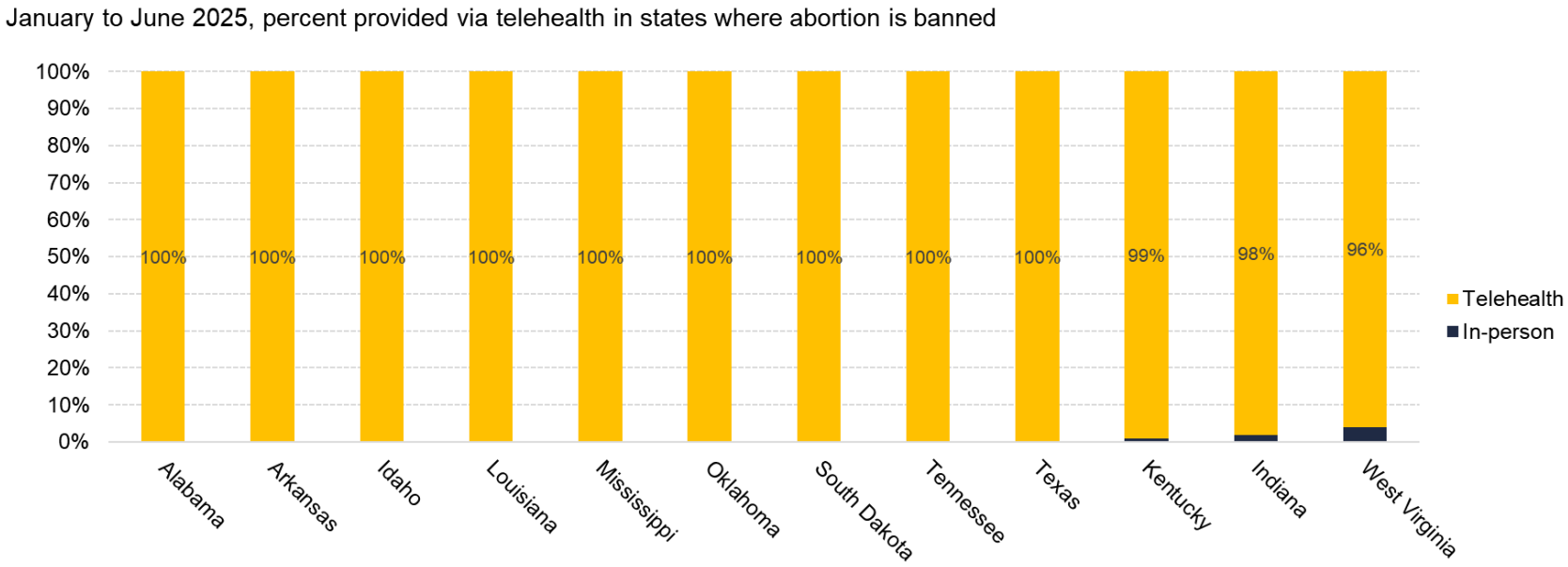
Across the US, in states that permit abortion and telehealth provision of abortion, there was substantial variation in the proportion of abortions provided via telehealth, ranging from 8% to 39%. In several larger states (eg, California, New Jersey, and New York), telehealth represents a smaller share of abortions, at about 9-13% of all abortions.

Where telehealth abortion is restricted, the share of abortions provided via telehealth under shield laws varied widely



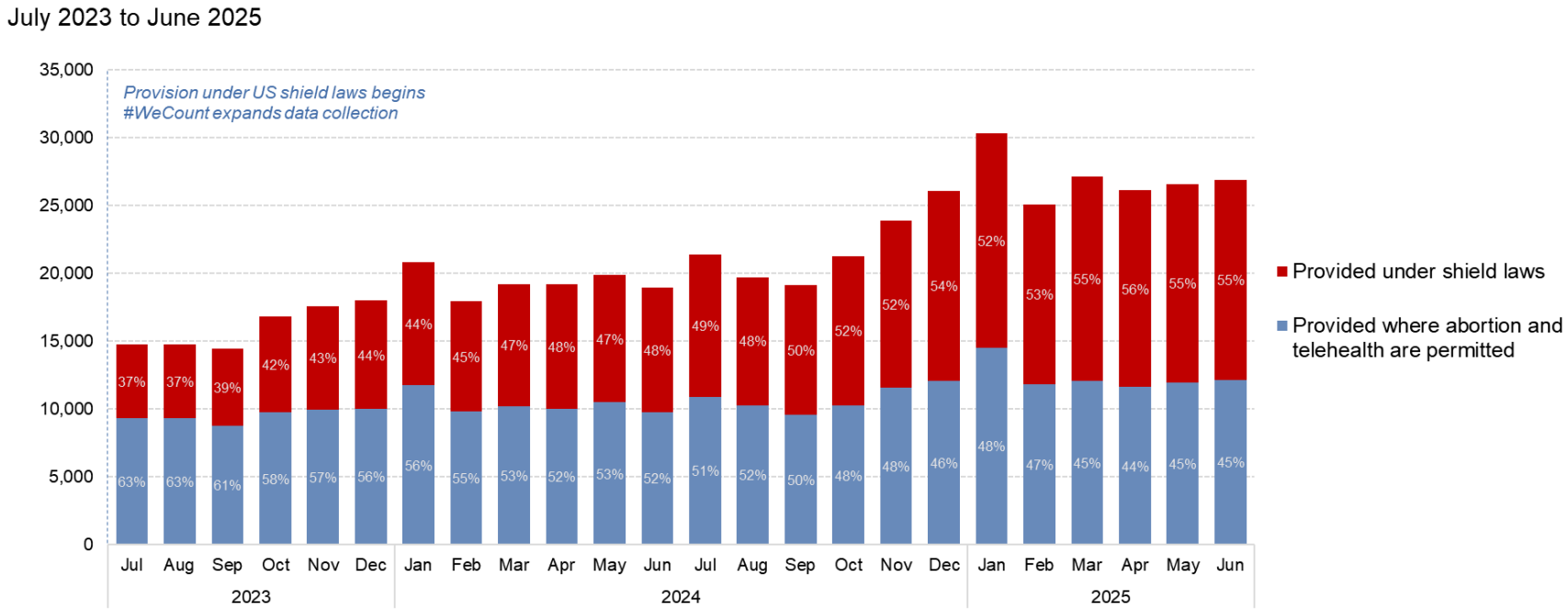
In states where abortion is permitted but telehealth is restricted, including states with 6, 12, and 18-week bans, the proportion of abortions provided by telehealth varies widely. In North Dakota, no abortion facilities were providing in-person care from January to June 2025.

Where abortion is banned, nearly all abortions were provided via telehealth under shield laws



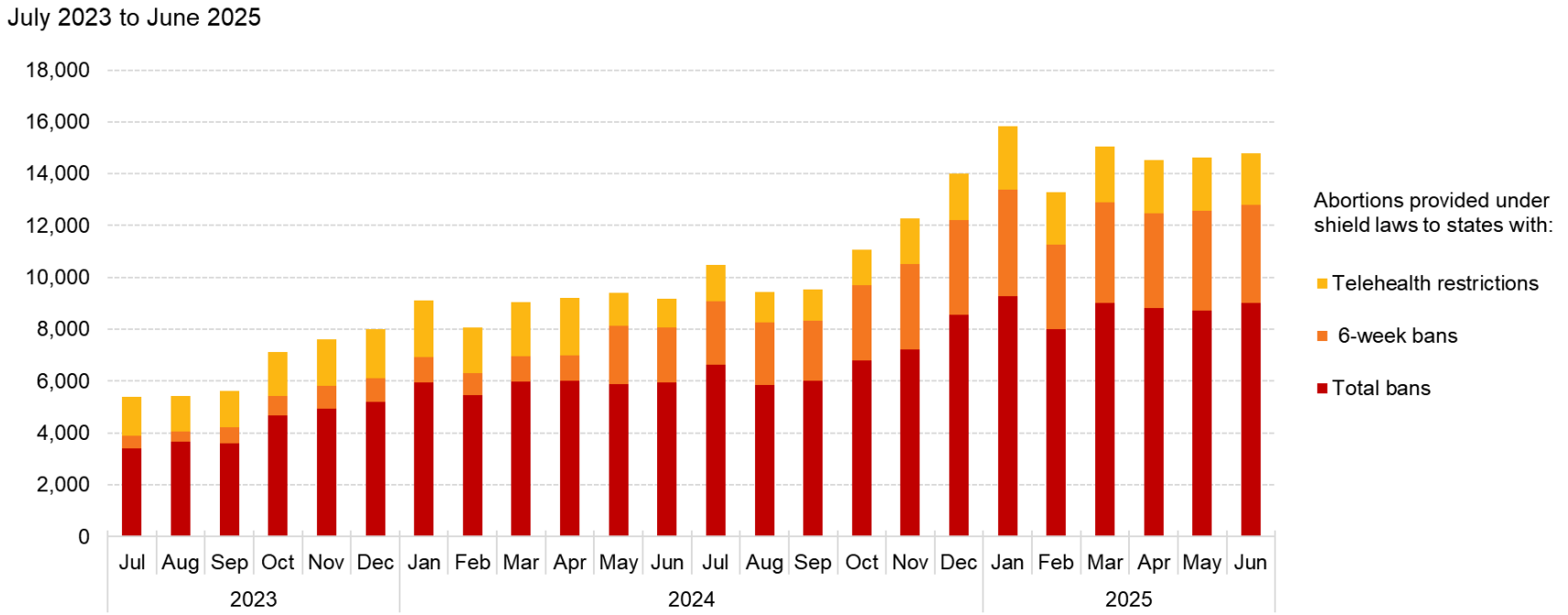
In states with total abortion bans, telehealth abortions provided under shield laws make up nearly all abortions occurring within those states. Residents may travel to other states to obtain care. Abortion provided in person under exceptions are represented in dark blue, making up 2% of abortions in Indiana and 4% of abortions in West Virginia.

A growing share of telehealth abortions are provided under shield laws



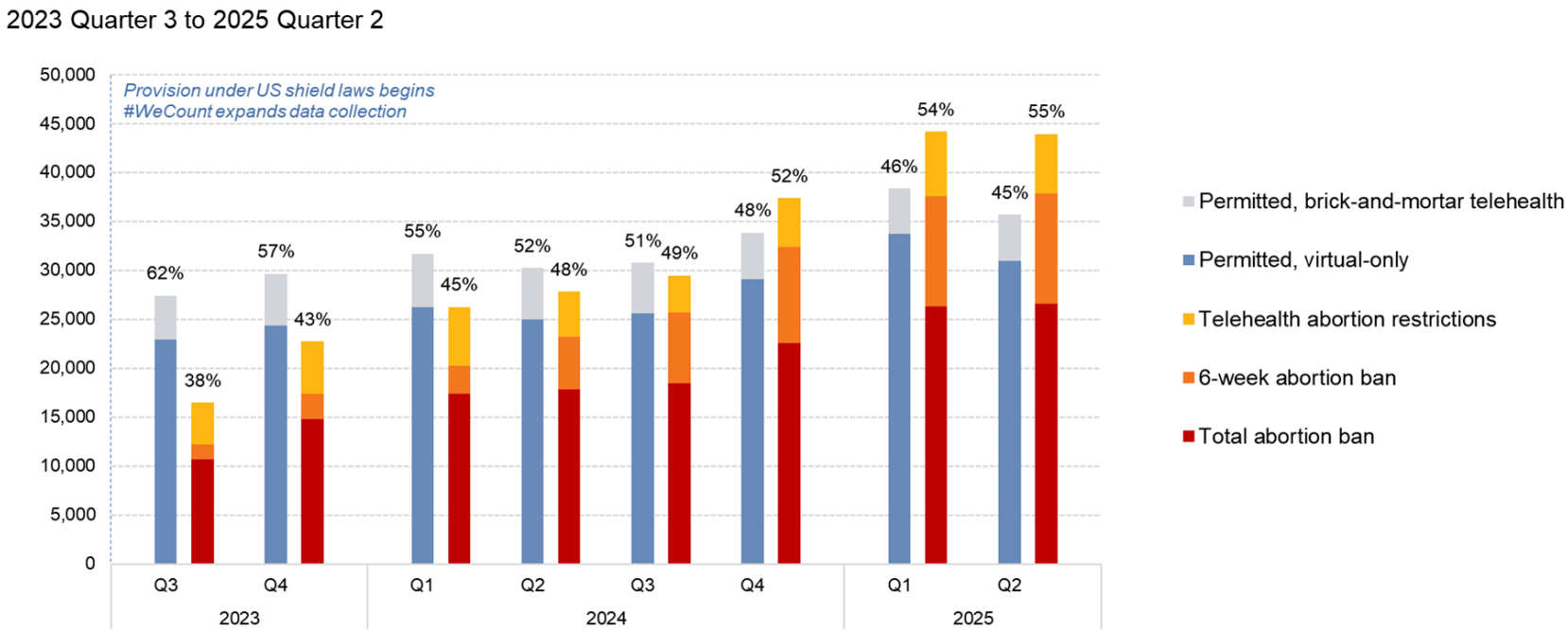
The number and proportion of telehealth abortions provided under shield laws has increased over time. As of June 2025, more than half (55%) of telehealth abortions are provided under shield laws.

Number of abortions provided via shield laws is increasing



By June 2025, abortions provided under shield laws totaled 14,770 per month. Shield laws provide protections for providers to mail medication abortion pills to people in states with telehealth restrictions, 6-week bans, and total abortion bans. The number of abortions provided under shield laws into states with these restrictions has increased since providers began to offer abortion under shield laws in July 2023, with notable increases in provision to states after enactment of 6-week bans and total abortion bans. Some of the increase in states with 6-week bans is due to changes in restrictions at the state-level, such as states that transitioned from having telehealth restrictions to having 6-week bans during this time period and thus switched categories.

Abortions provided under shield laws account for a growing share of all telehealth abortions



Telehealth abortions provided by virtual clinics (those that that are online only and have no brick-and-mortar clinic) to states that permit abortion and telehealth abortion have increased since 2023. Telehealth abortions provided by brick-and-mortar clinics have remained steady. Telehealth abortions provided to people in states with telehealth restrictions also remained relatively steady. Telehealth abortions provided to people in states with 6-week bans increased. Telehealth abortions provided to people living in states with total bans increased substantially in the first six months of 2025.

Background

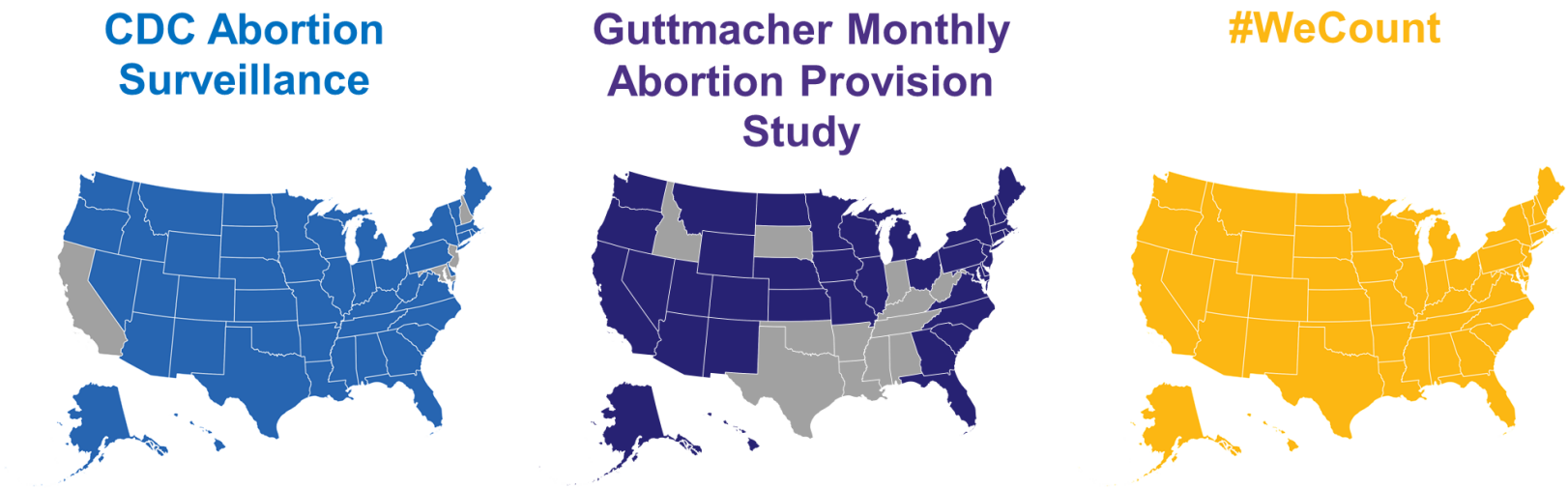
#WeCount is a national effort that aims to report the monthly number of abortions in the US, by state and month starting in April 2022. #WeCount data include clinician-provided abortions, defined in this report as medication or procedural abortions completed by a licensed clinician within the US in a clinic, private medical office, hospital, or virtual-only clinic. This report does not reflect any self-managed abortions, defined as ending a pregnancy outside the formal healthcare system, such as medications provided by community networks or websites that sell pills outside of the US healthcare system. These data reflect the status of abortion provision in the US and can be used by healthcare systems, public health practitioners, and policymakers so that their decisions can be informed by evidence.

#WeCount in context: the landscape of research efforts to count abortions

#WeCount is one of several efforts to capture changes in abortion volume in the US. Below, we outline the features of three of these initiatives, including their geographic reach, timing, the types of abortions included, and additional variables collected.

		#WeCount	Guttmacher Monthly Abortion Provision Study	CDC Abortion Surveillance
Timing	Reporting cadence every…	6 months	1 month	1 year (last 2022)
	Data interval	Monthly	Monthly	Annual
Type	Telehealth abortions to states where permitted	**Yes**	**Yes**	**Some**
	Abortions provided under shield laws to states with any legal abortion	**Yes**	**Yes**	No
	Abortions provided under shield laws to states with bans	**Yes**	No	No
	Abortions provided outside the formal healthcare system	No	No	No
Additional variables	Reports telehealth breakdown	**Yes**	No	No
	Abortion characteristics beyond counts	No	**Yes**	**Yes**

States reflected across efforts to count abortions



Terminology

Delivery settings

- **Brick and mortar clinic:** A physical clinic where a patient can go to receive care
- **Virtual-only clinic:** An online-only provider

Delivery methods

- **Brick-and-mortar telehealth:** Telehealth abortions offered by a brick-and-mortar clinic
- **In-person care:** Abortions in which a clinician meets with the patient face-to-face; can be procedural or medication abortions
- **Self-managed abortion:** Abortion using medications, herbs, or something else, or obtaining pills from friends or online without clinician assistance
- **Telehealth abortion:** Medication abortion offered by a clinician through remote consultation with the patient, resulting in remote dispensing of medications by mail

Types of care

- **Medication abortion:** Abortion performed with medications, including mifepristone, misoprostol, and misoprostol alone
- **Procedural abortion:** Abortion performed with instrumentation, including uterine aspiration (manual or electric), dilation and curettage, dilation and evacuation, or dilation and extraction

Legal context

- **Shield laws:** Legal protections put in place by some states to reduce legal risk for clinicians who offer abortions to patients in states where abortion is prohibited or severely restricted

Methods

In early 2022, #WeCount developed a database of all clinics, private medical offices, hospitals, and virtual clinic providers in the US known to offer abortion care. We started with the Abortion Facility Database from Advancing New Standards in Reproductive Health (ANSIRH) at University of California, San Francisco. Throughout the study period, we added new providers to our database as we became aware of them, using AbortionFinder.org and INeedanA.com to conduct regular searches in all 50 states and the District of Columbia. This report also includes abortions provided under shield laws by US-based licensed providers who are following their own state law. The Society provided compensation to participating facilities for each monthly submission.

The data in this report includes the monthly counts reported by providers for April 2022 through June 2025. From April 2022 to December 2024, 19% of abortions were imputed. From January to June 2025, 28% of abortions were imputed. The magnitude of imputation in each state is noted with symbols in the data tables. For providers that reported some months of data, we created a provider-level imputation for missing months. For these imputations, we calculated the average percent change in abortion volume in the state to impute values for the missing months. For providers that never reported to #WeCount, we imputed all months of data. To develop our imputations, we used information from news articles, contacts known to the non-reporting clinics, knowledge of the abortion volumes by state, or the median #WeCount number to determine the provider type. To compute medians, we categorized reporters to #WeCount into five types of facilities and calculated the median for April and May 2022 for each category: 1) small abortion clinics, 2) large abortion clinics, 3) primary care clinics, 4) low volume hospitals, and 5) high volume hospitals. In ten states we also used publicly available state administrative data to supplement our estimates. We developed separate imputations for virtual clinics that did not submit data to us, using the median number of abortions that were provided by other virtual clinics in the state. For virtual clinics with missing months of data, we calculated the average month-to-month change in virtual clinic abortion volume in the state and imputed values.

We reported the number of abortions by state and by restrictiveness level using three categories: states that banned abortion, states that restricted abortion to before detection of embryonic cardiac activity, also referred to as a “6-week bans” because detection of such activity usually occurs around that point, and states that permitted abortion. These categories were based on the abortion policy in each state on the 15th of each month as reported by the New York Times. For a legal analysis of restrictions that prevent explicitly ban telehealth or implicitly preclude telehealth abortion, we rely on the RHITES map. Monthly state totals were rounded to the nearest 10.

#WeCount was deemed exempt by Advarra IRB. This research was sponsored by the Society of Family Planning.

Limitations

Counts are likely an underrepresentation of all abortions in the US. #WeCount has a comprehensive count of abortions provided by licensed clinicians, with more than 81% of all abortions reported and about 19% imputed. Abortions provided by individual hospitals and private practice clinicians may be underreported. These counts also do not include abortions that take place in the US outside of the formal healthcare system.

#WeCount reports abortion service type by distinguishing telehealth from in-person abortion care. #WeCount does not report medication abortions separately from procedural abortions. Thus, the in-person abortion counts include both medication and procedural abortions that were provided in clinics, while all telehealth abortions are medication abortions.

We do not have estimates of the proportion of people who did not take the medications sent to them. These data show telehealth abortions as the providers documented mailing them. Some people may not have taken the pills, and we do not have an estimate of that. Use of shield laws to provide abortion via telehealth into states with total or 6-week abortion bans or with telehealth abortion restrictions started in July 2023, and #WeCount began to count abortions provided under shield laws at that time. Because of this transition in abortion provision, #WeCount does not have a comparator for previous months.

#WeCount cannot estimate unmet needs for abortion. Research has yet to accurately capture the underlying need for abortion. We don't have any counts of the number of people who needed an abortion and didn't get it.
#WeCount is designed to describe changes in abortion access and provision, rather than to explain why these changes are taking place.

Contributors

#WeCount is made possible by the many abortion providers who generously reported their data in support of this effort. This report was prepared by the #WeCount Co-Chairs and Society of Family Planning staff, as well as many members of the Society of Family Planning community.

#WeCount Co-Chairs

- Alison Norris, MD, PhD; Ohio State University
- Ushma Upadhyay, PhD, MPH; University of California, San Francisco

#WeCount Society of Family Planning staff

- Leah Koenig, PhD, MSPH; #WeCount Director
- Jenny O'Donnell, ScD, MS; Vice President of Research and Evaluation
- Claire Yuan, MPP; #WeCount Data Manager

EXHIBIT 2

#WeCount Report Summary Slides with National and 51 State-Level Findings April 2022 to June 2025 (Dec. 9, 2025)

#WeCount in context: the landscape of research efforts to count abortions

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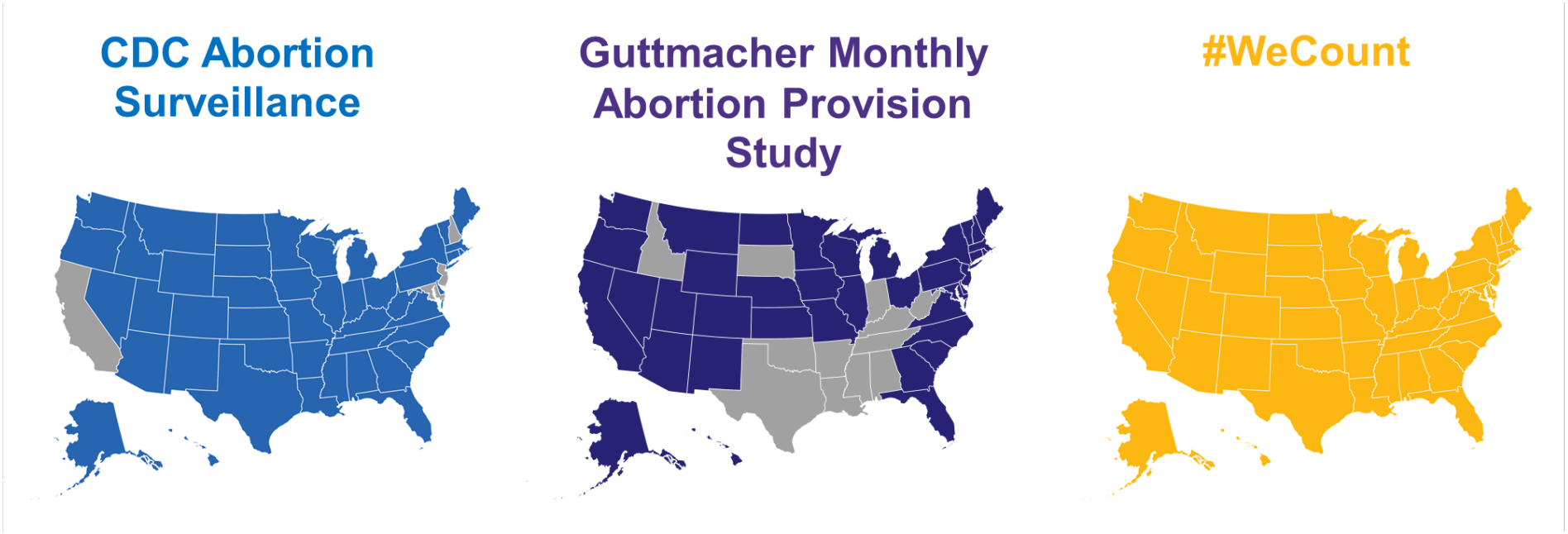
Source: Society of Family Planning, December 2025

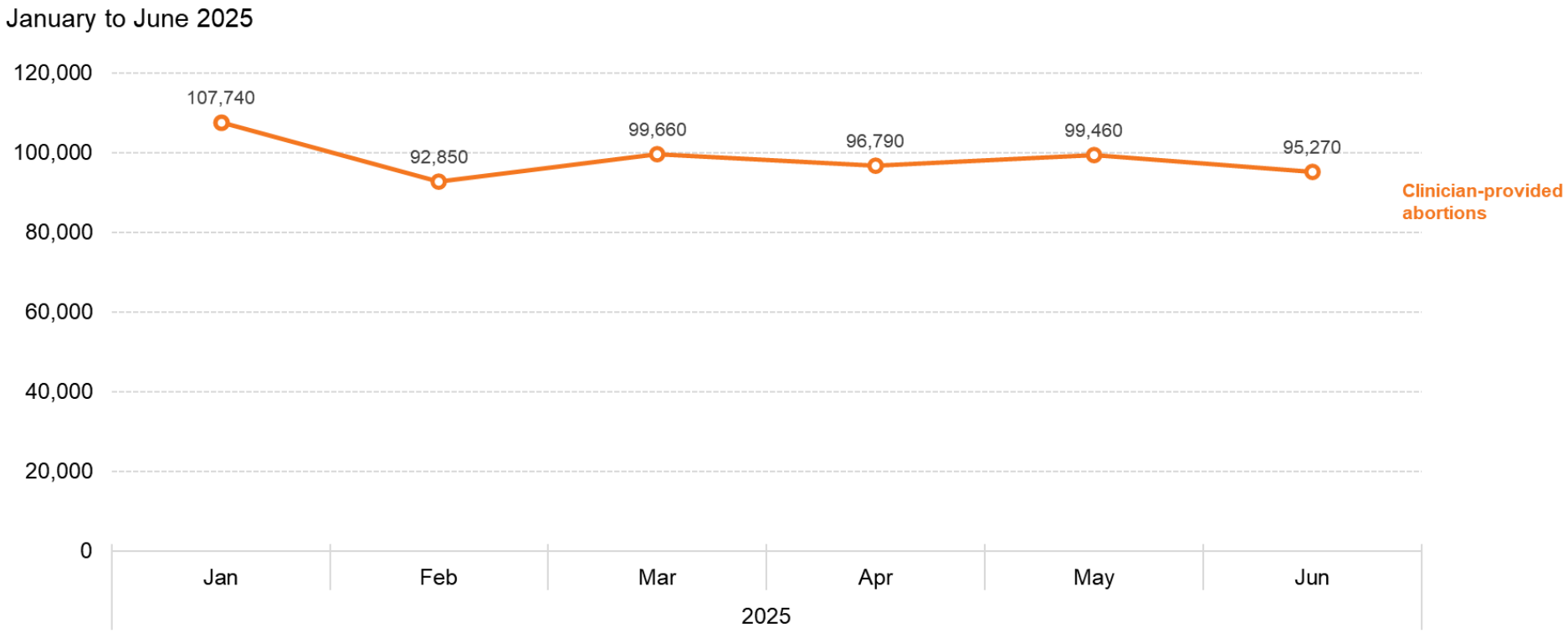
States reflected across efforts to count abortions



Source: Society of Family Planning, December 2025

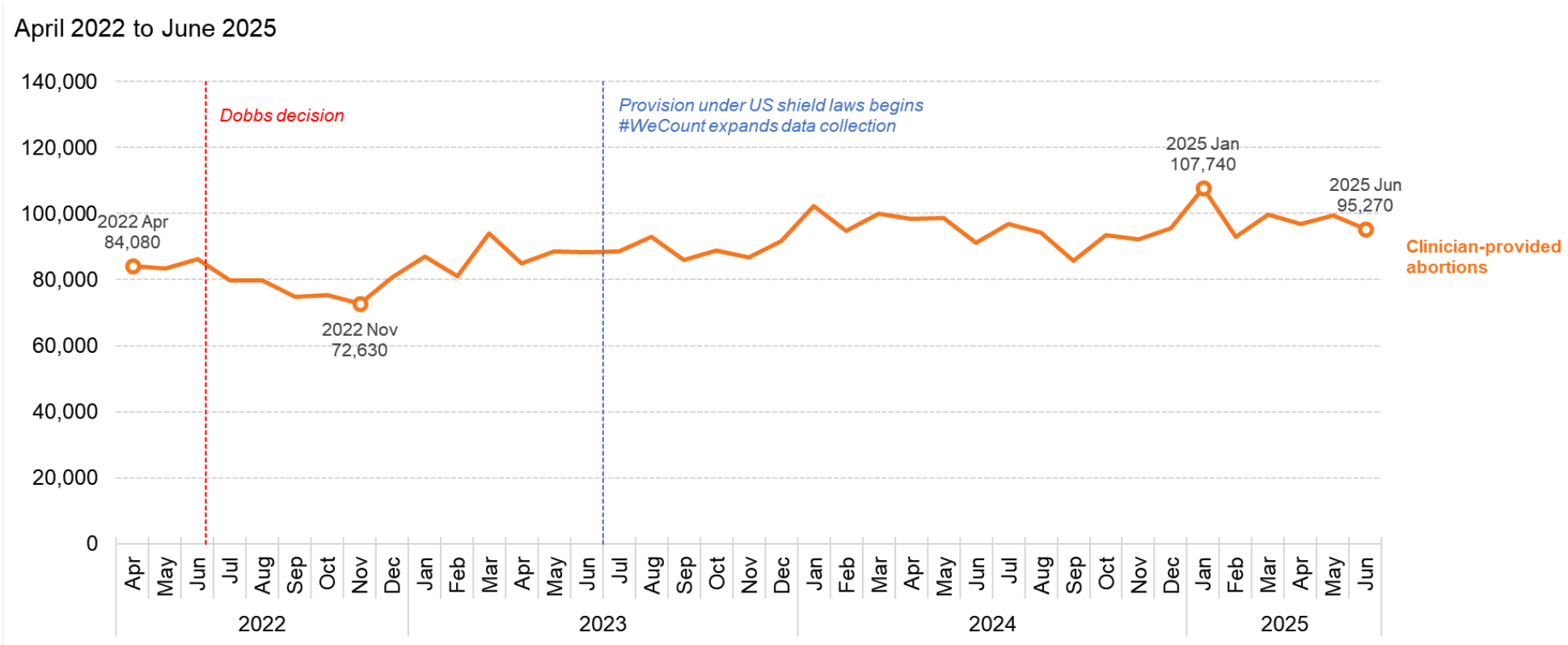
National findings

US abortions totaled 591,770 in the first six months of 2025



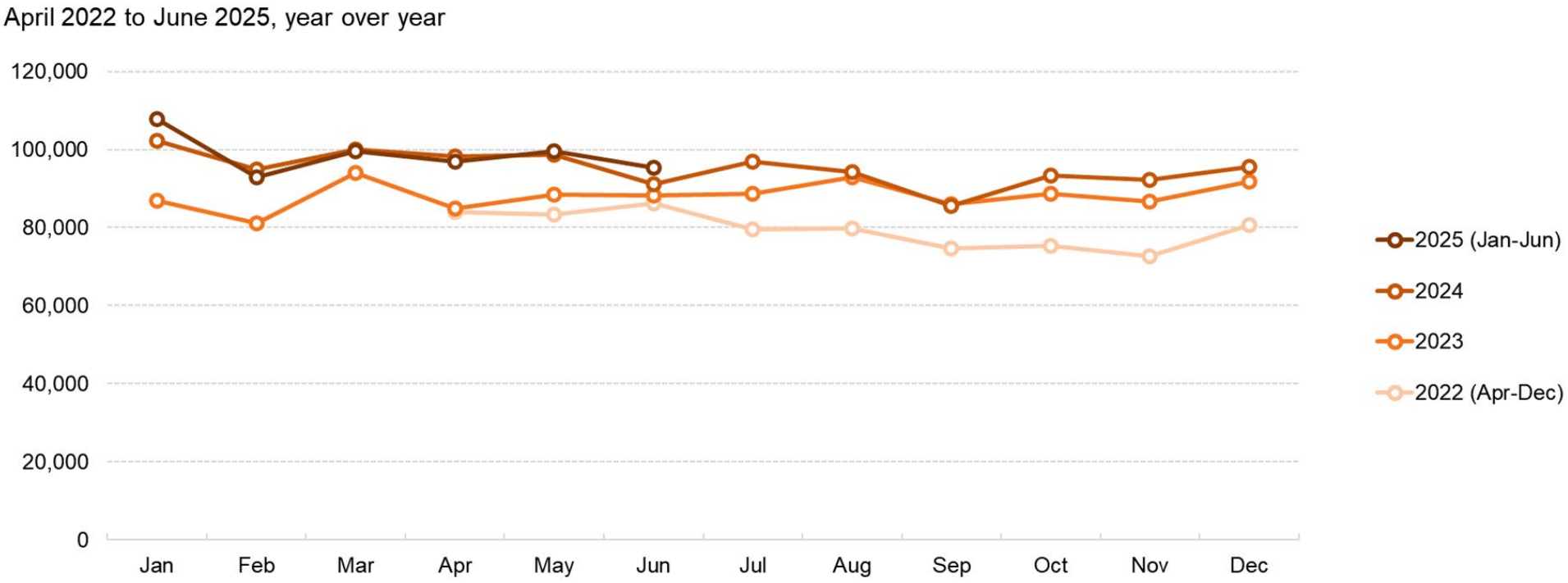
Source: Society of Family Planning, December 2025

Abortions in the US have increased since *Dobbs*



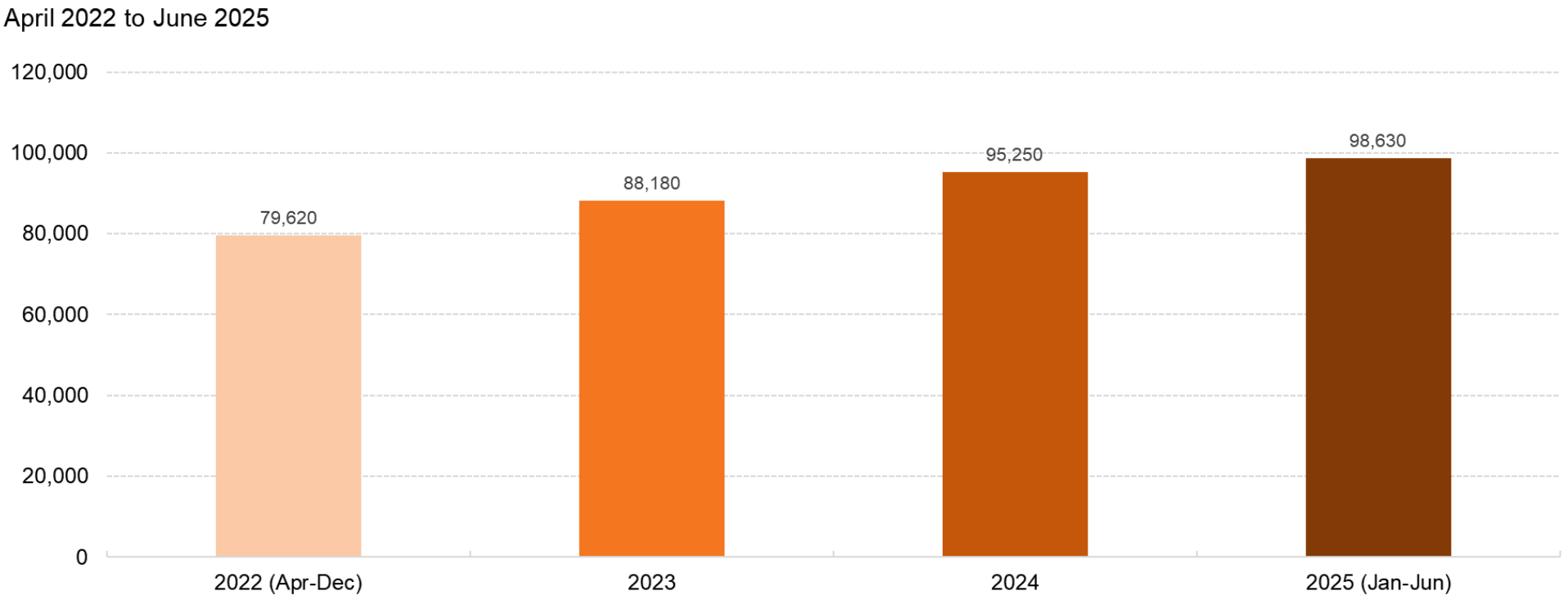
Source: Society of Family Planning, December 2025

Abortion volume fluctuates from month to month, and has increased year-over-year



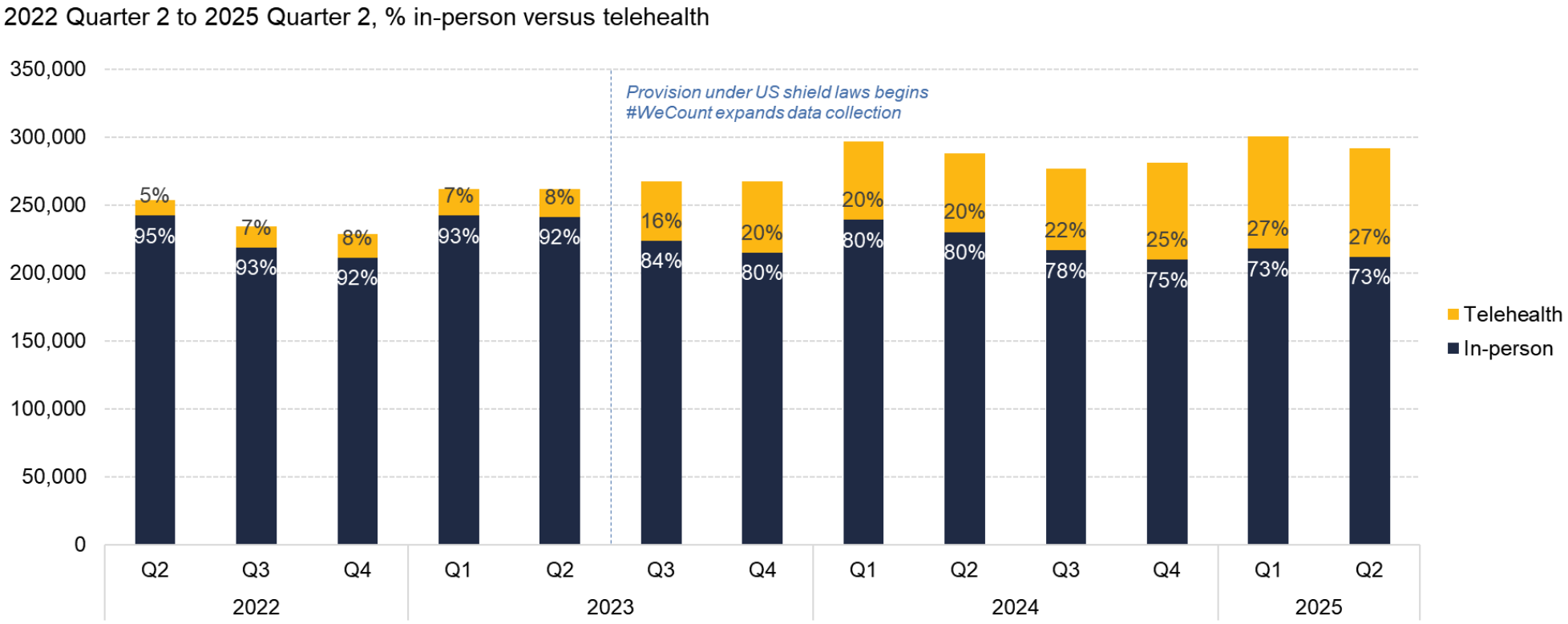
Source: Society of Family Planning, December 2025

Monthly average number of abortions increased each year



Source: Society of Family Planning, December 2025

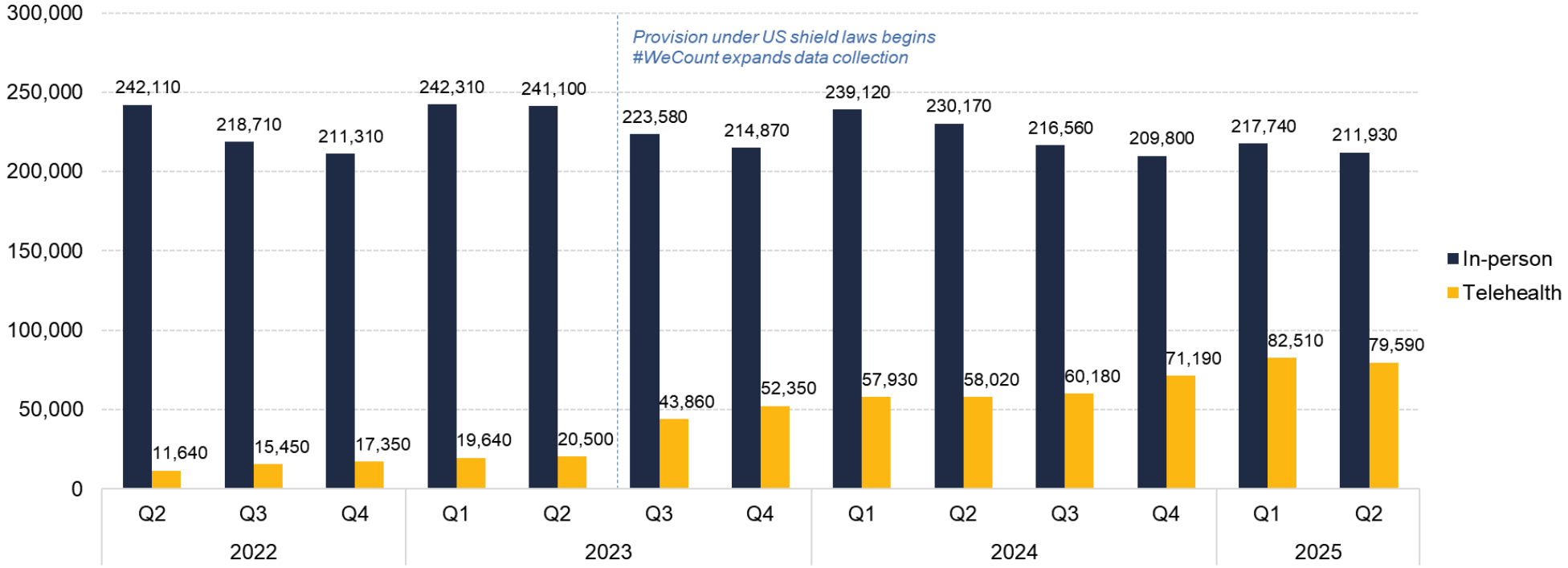
In the first six months of 2025, 27% of abortions were provided via telehealth



Source: Society of Family Planning, December 2025

In-person abortion care declined slightly, while telehealth grew

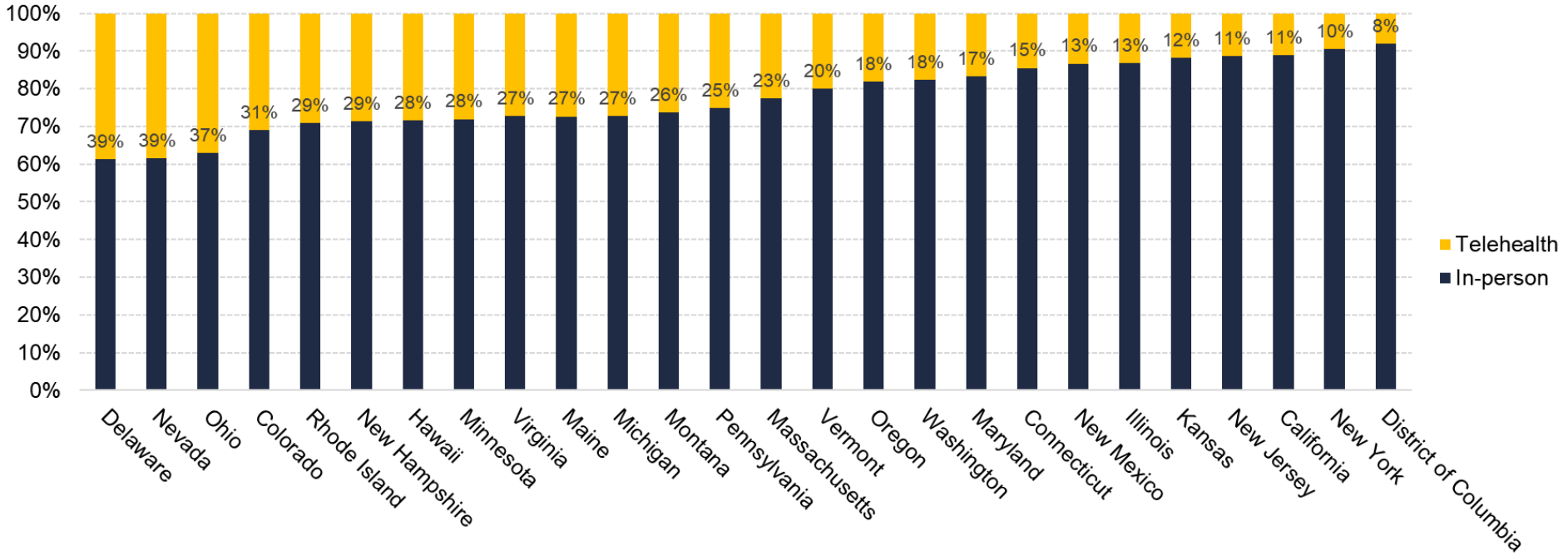
2022 Quarter 2 to 2025 Quarter 2, in-person versus telehealth



Source: Society of Family Planning, December 2025

Where abortion and telehealth are permitted, the share of abortions provided via telehealth varied widely

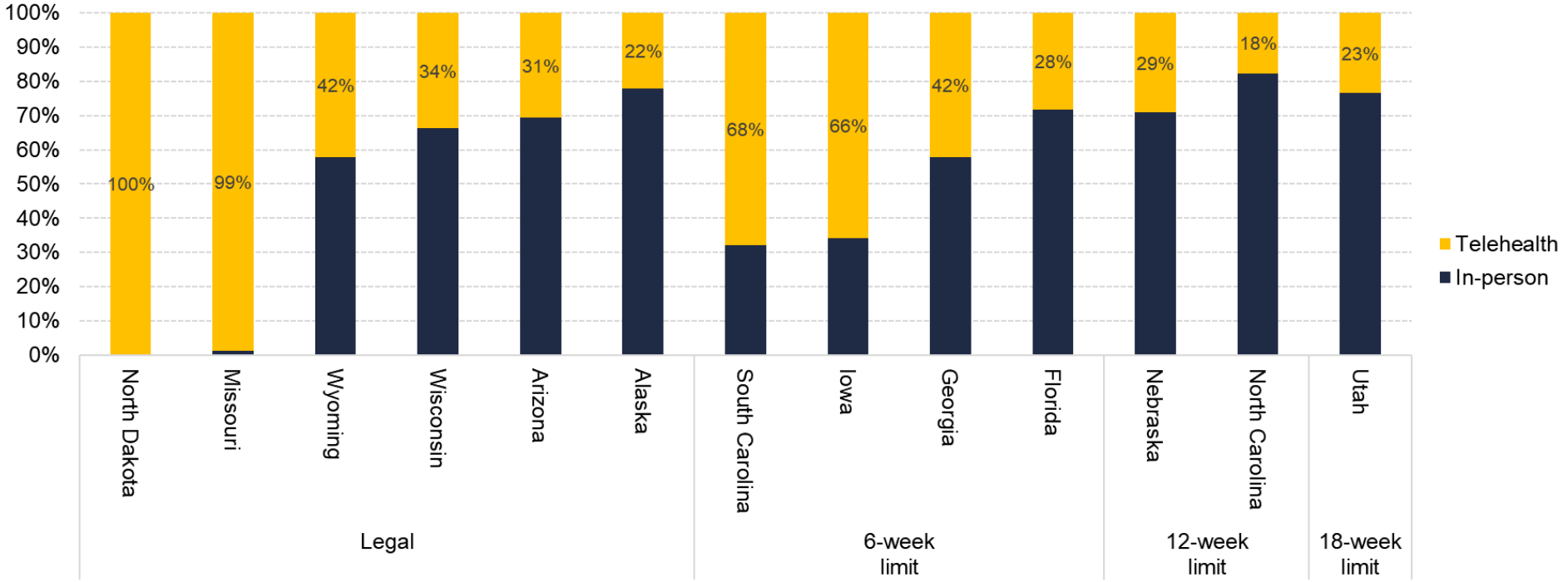
January to June 2025, percent provided via telehealth in states where abortion and telehealth are permitted



Source: Society of Family Planning, December 2025

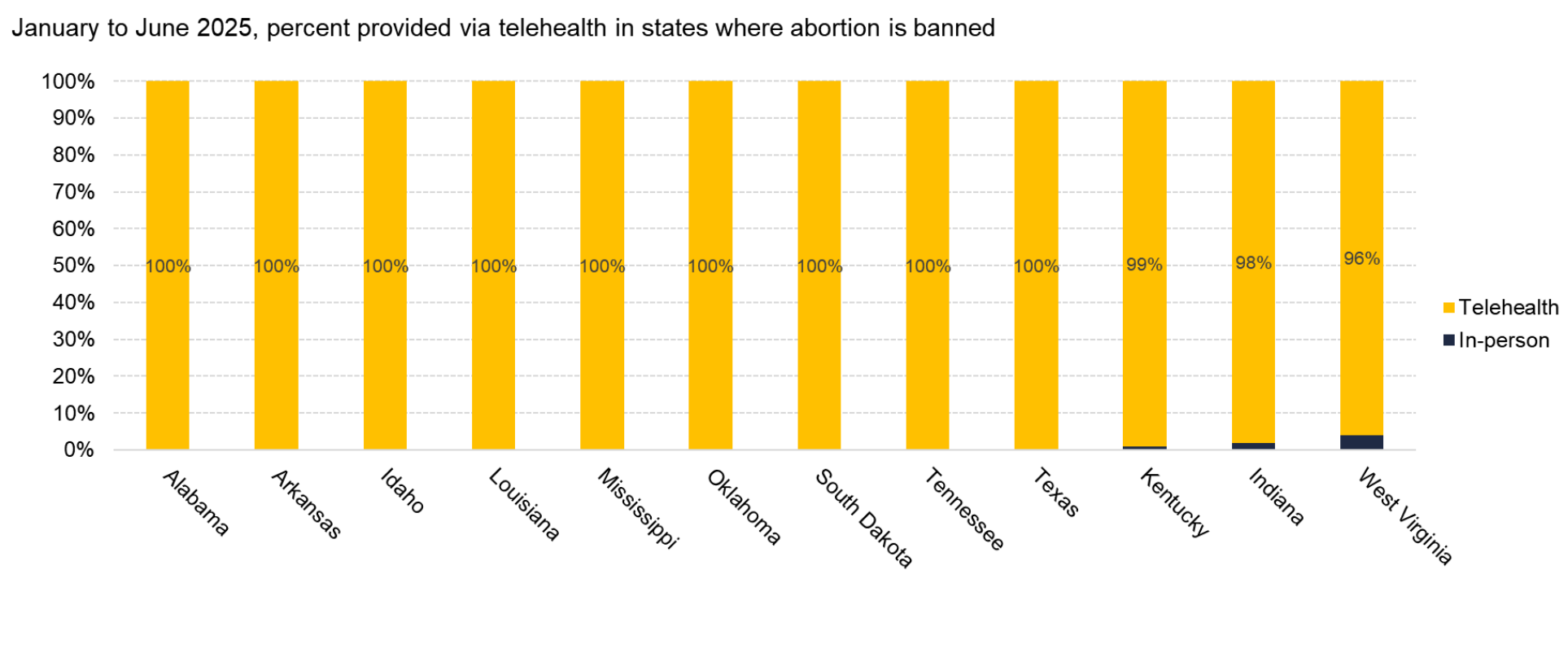
Where telehealth abortion is restricted, the share of abortions provided via telehealth under shield laws varied widely

January to June 2025, percent provided via telehealth in states where telehealth is restricted



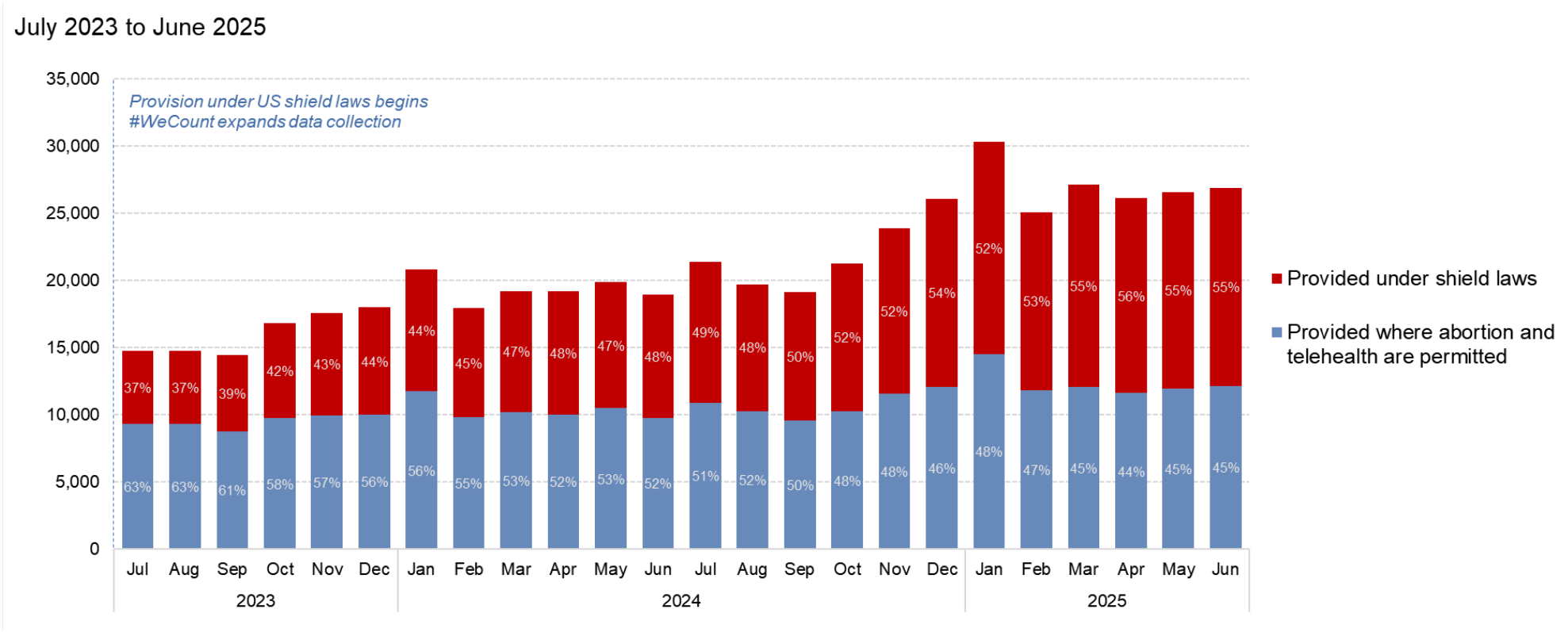
Source: Society of Family Planning, December 2025

Where abortion is banned, nearly all abortions were provided via telehealth under shield laws



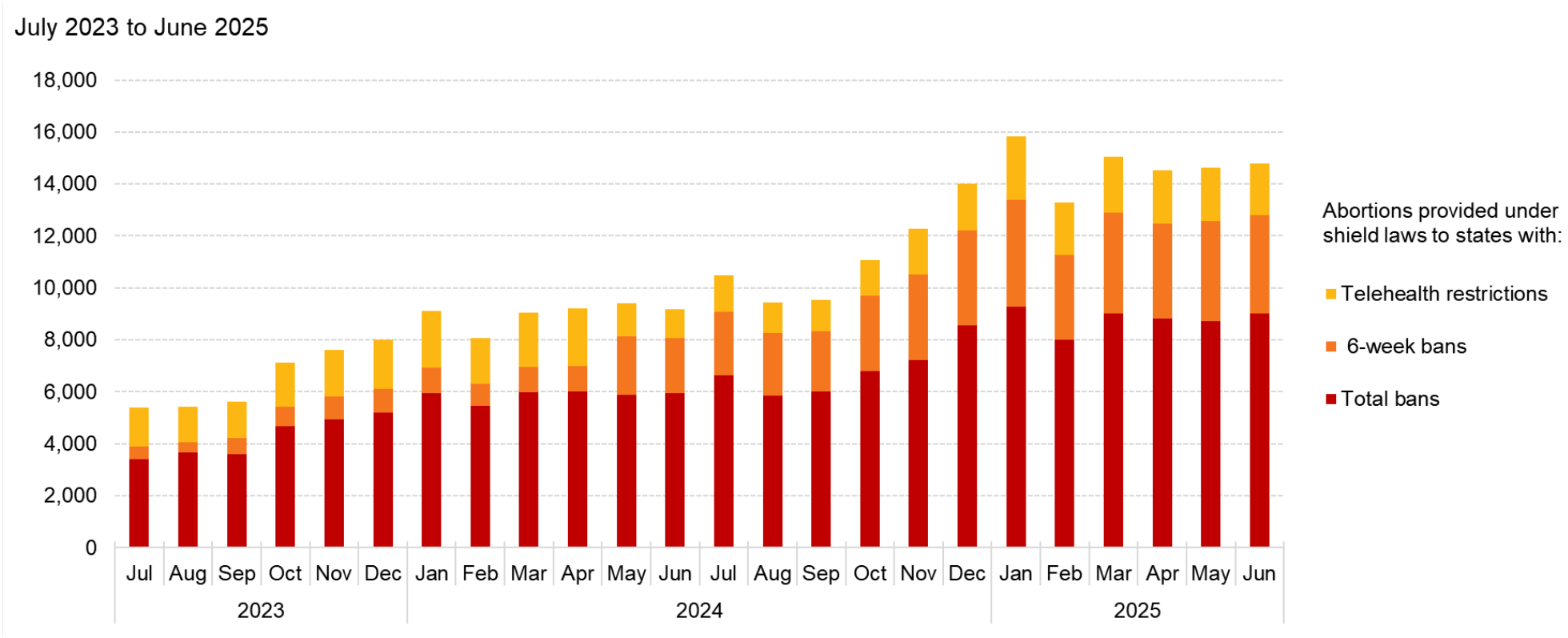
Source: Society of Family Planning, December 2025

A growing share of telehealth abortions are provided under shield laws



Source: Society of Family Planning, December 2025

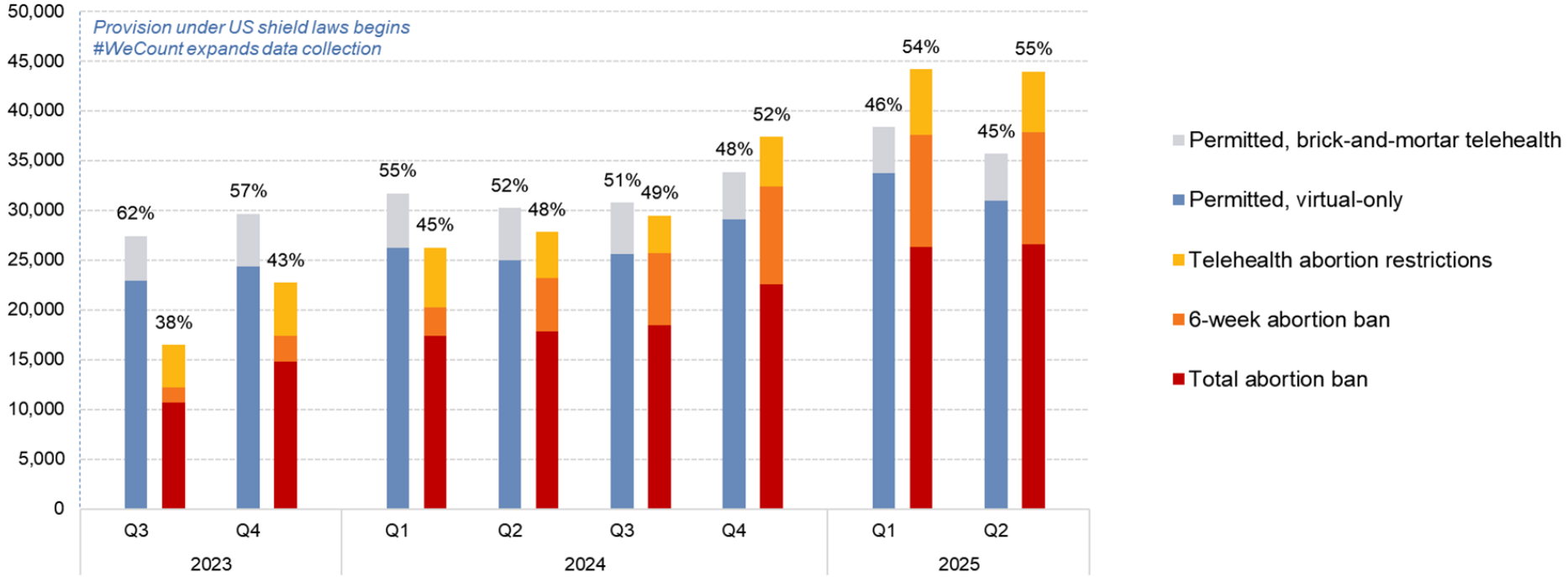
Number of abortions provided via shield laws is increasing



Source: Society of Family Planning, December 2025

Abortions provided under shield laws account for a growing share of all telehealth abortions

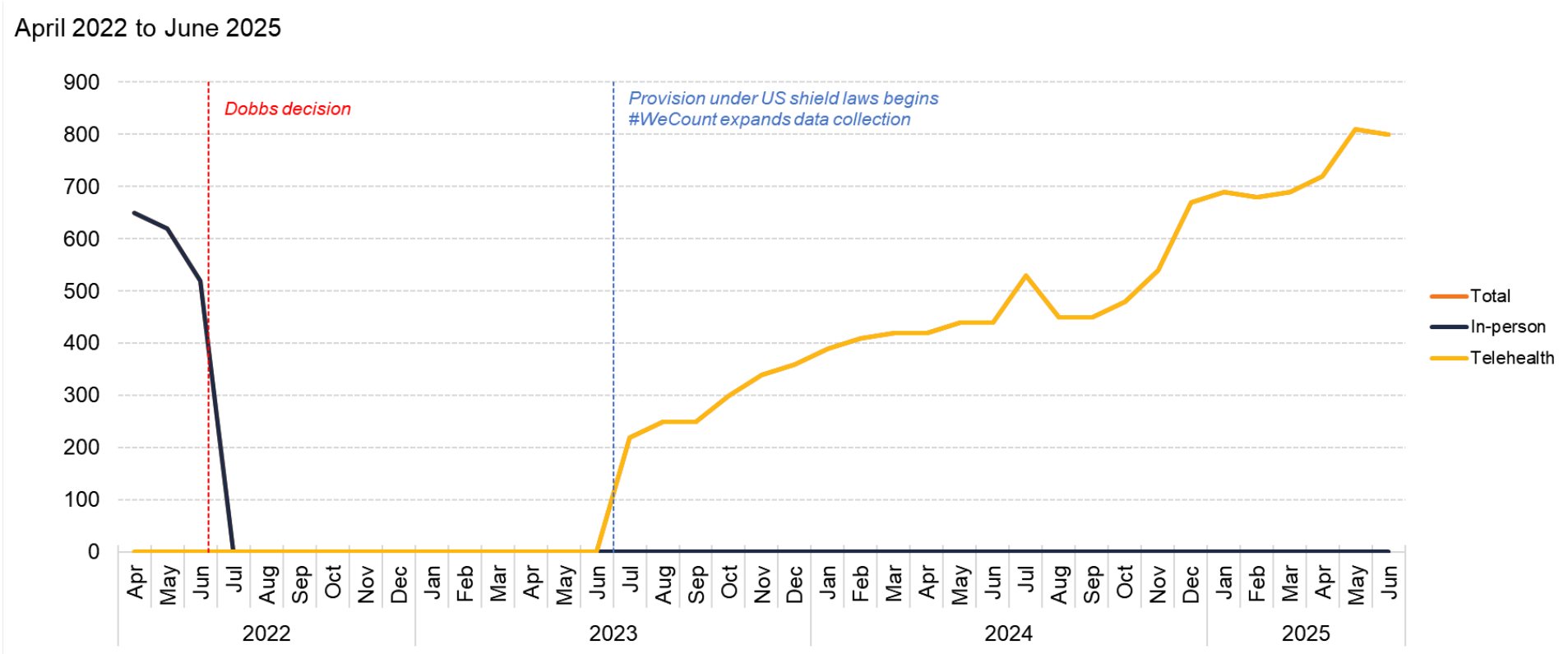
2023 Quarter 3 to 2025 Quarter 2



Source: Society of Family Planning, December 2025

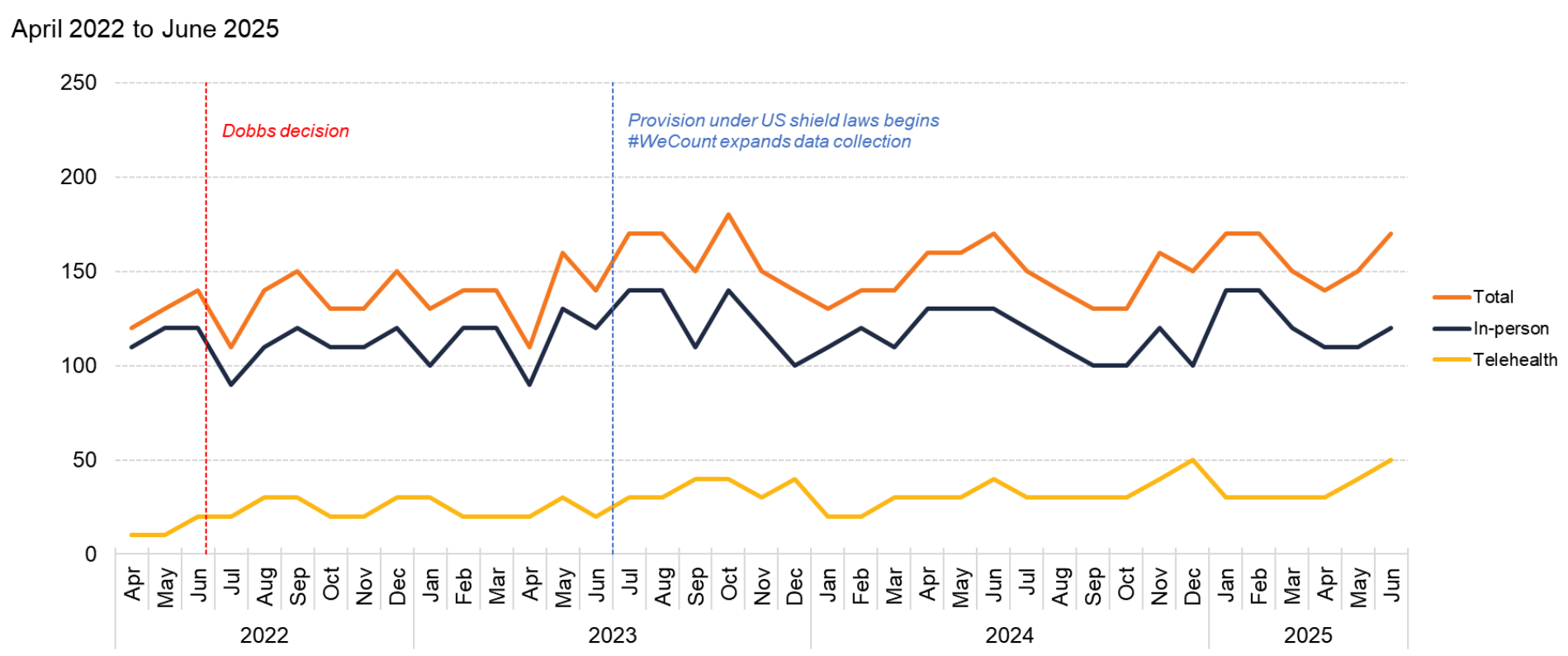
State-level findings

Alabama



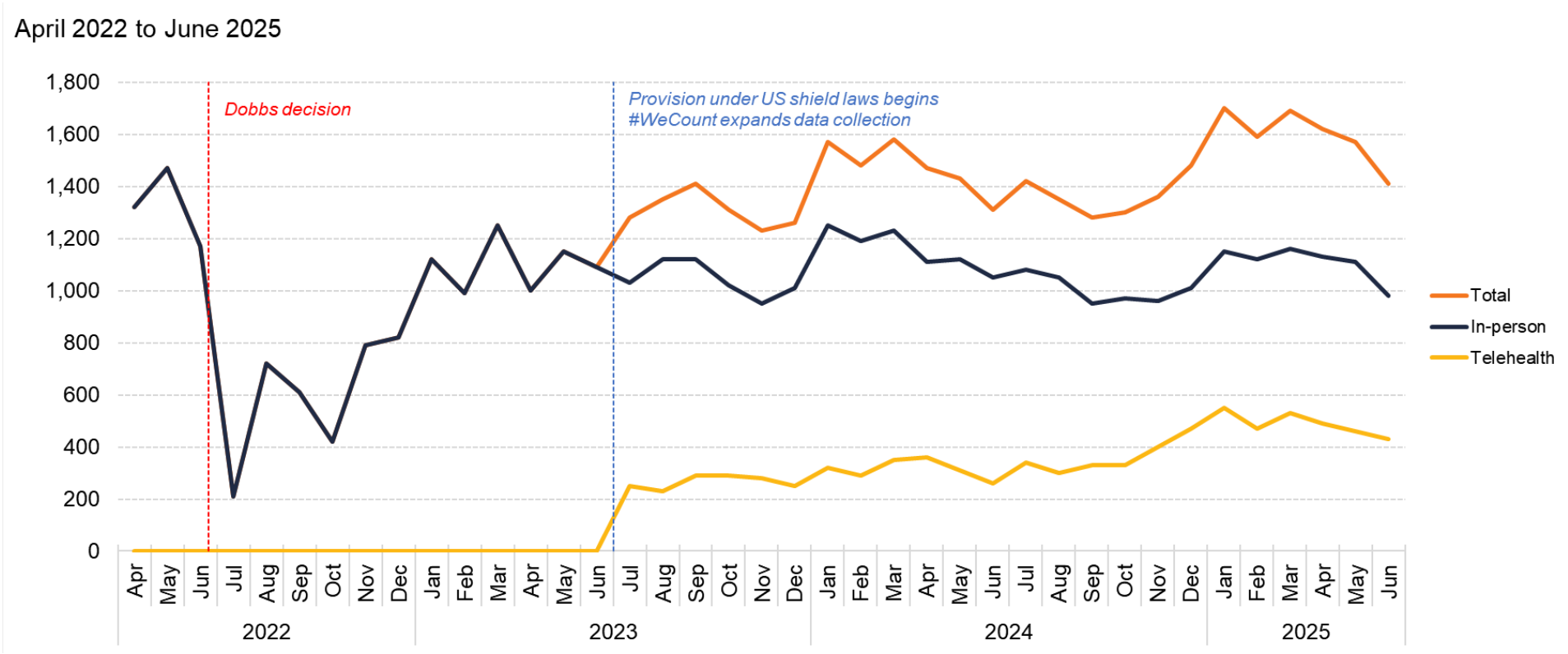
Source: Society of Family Planning, December 2025

Alaska



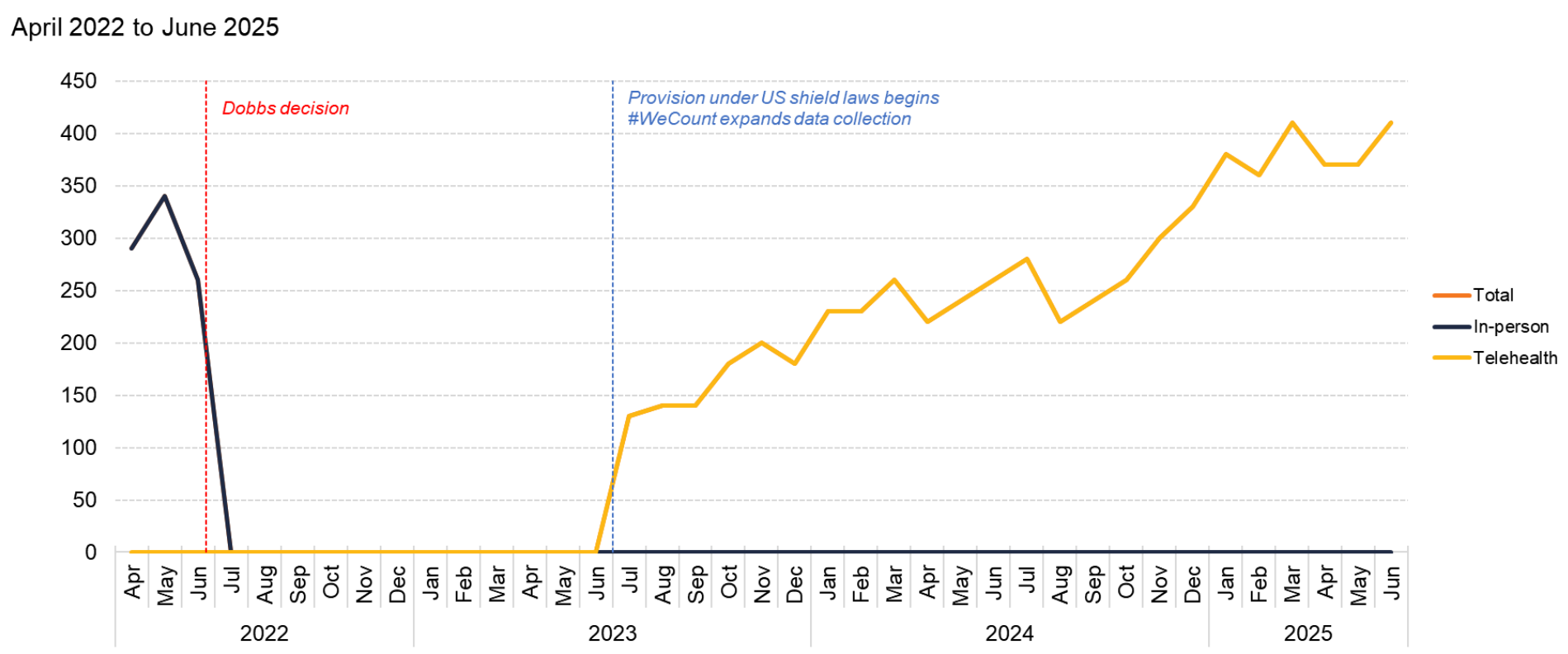
Source: Society of Family Planning, December 2025

Arizona



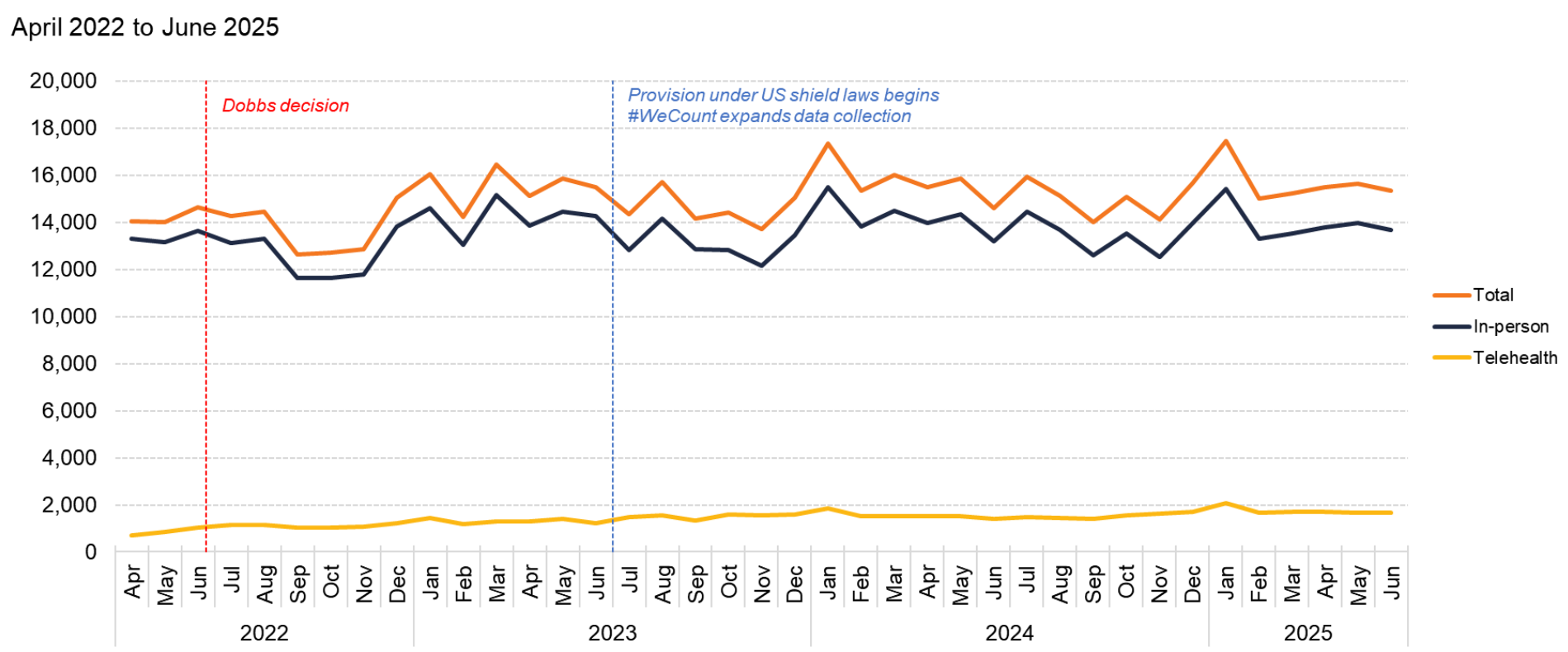
Source: Society of Family Planning, December 2025

Arkansas



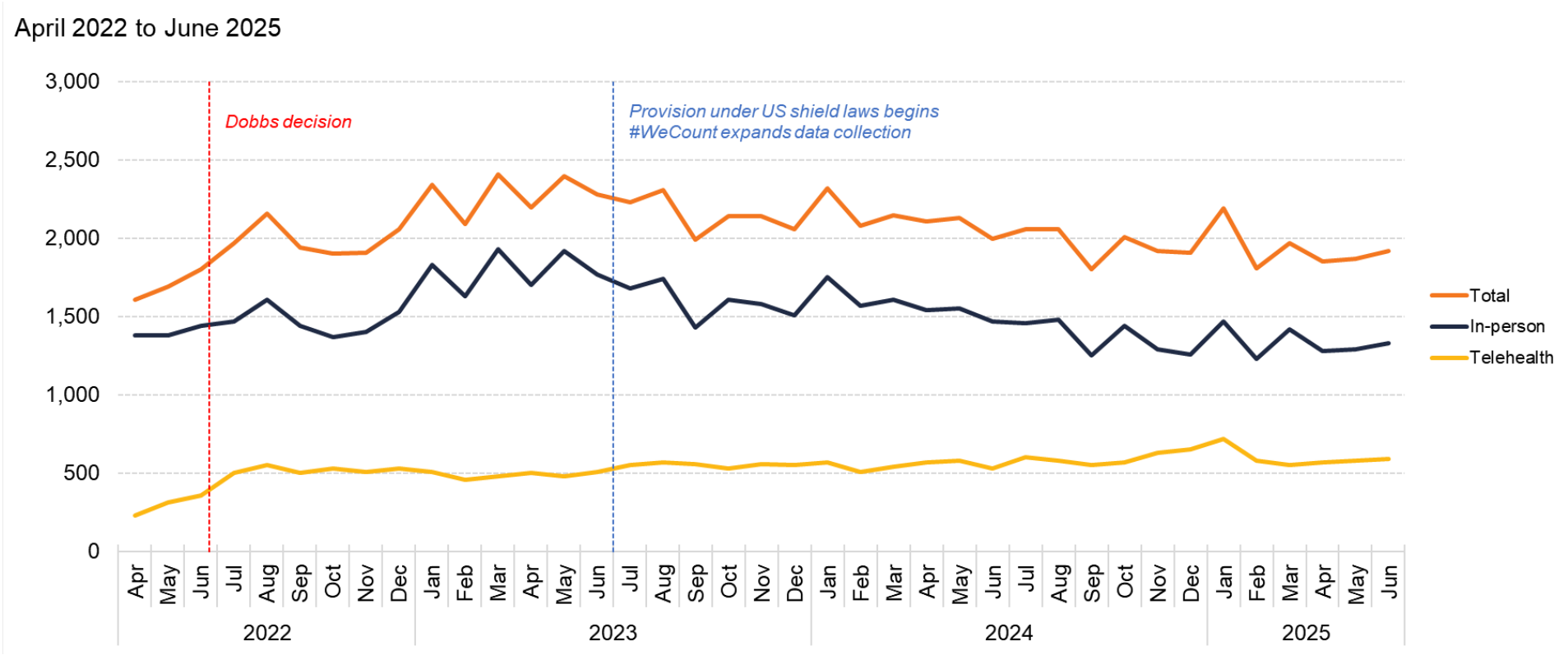
Source: Society of Family Planning, December 2025

California



Source: Society of Family Planning, December 2025

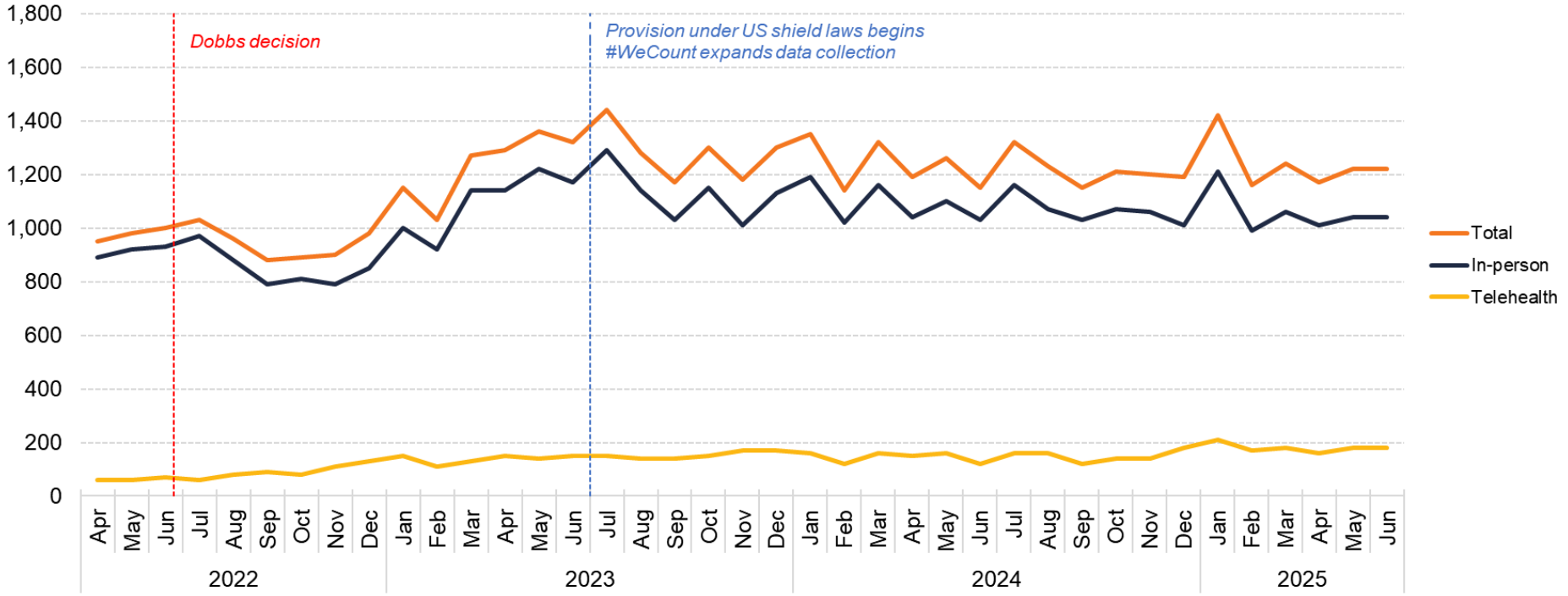
Colorado



Source: Society of Family Planning, December 2025

Connecticut

April 2022 to June 2025



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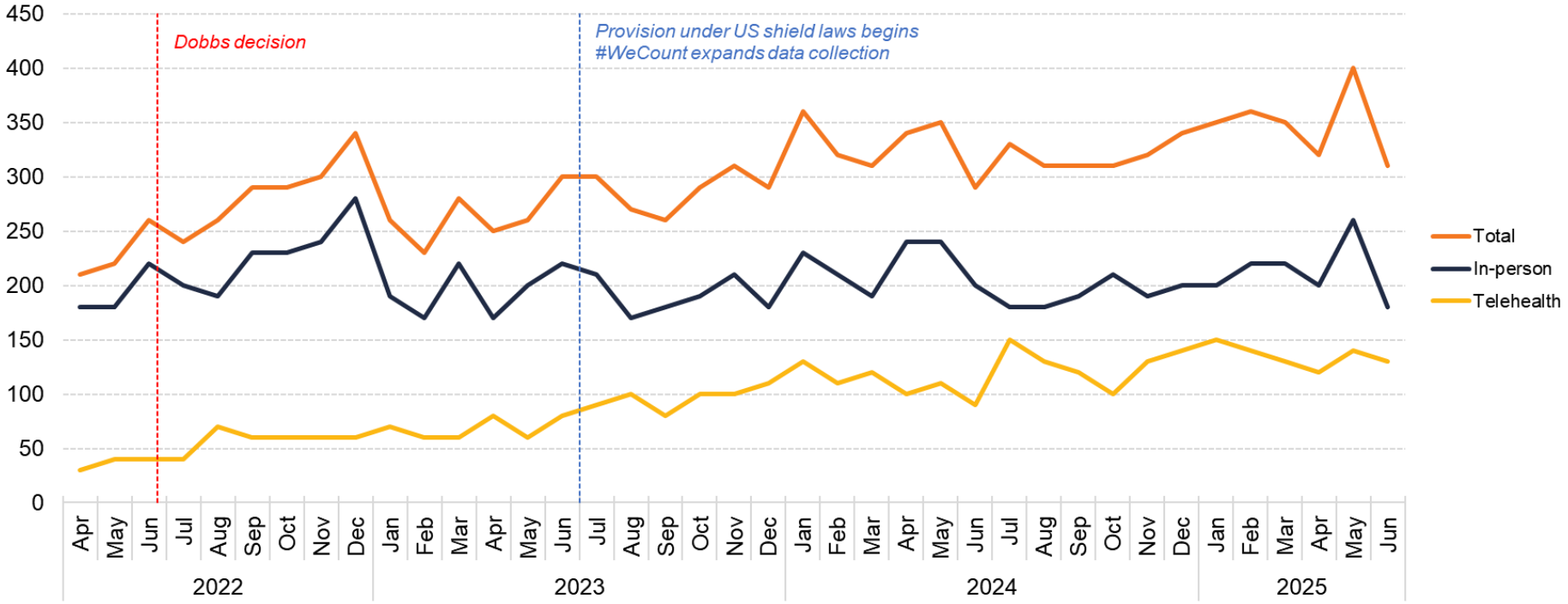

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District of Columbia

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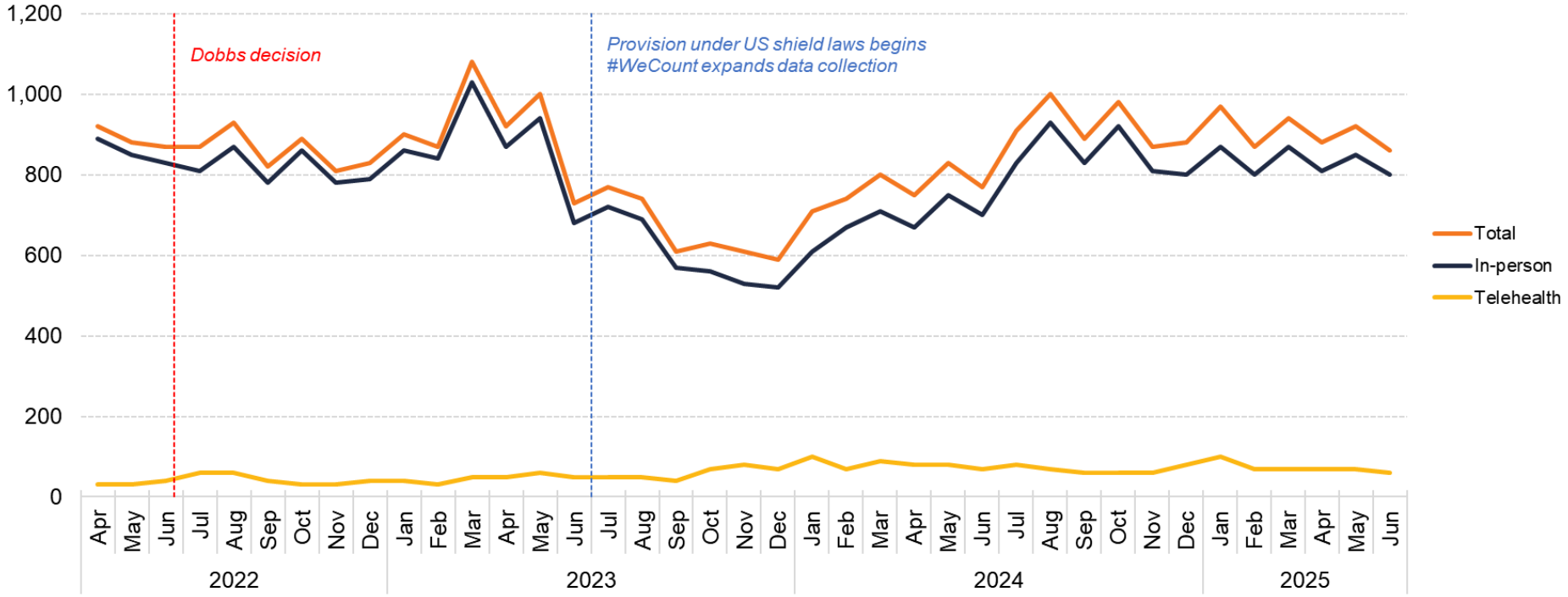

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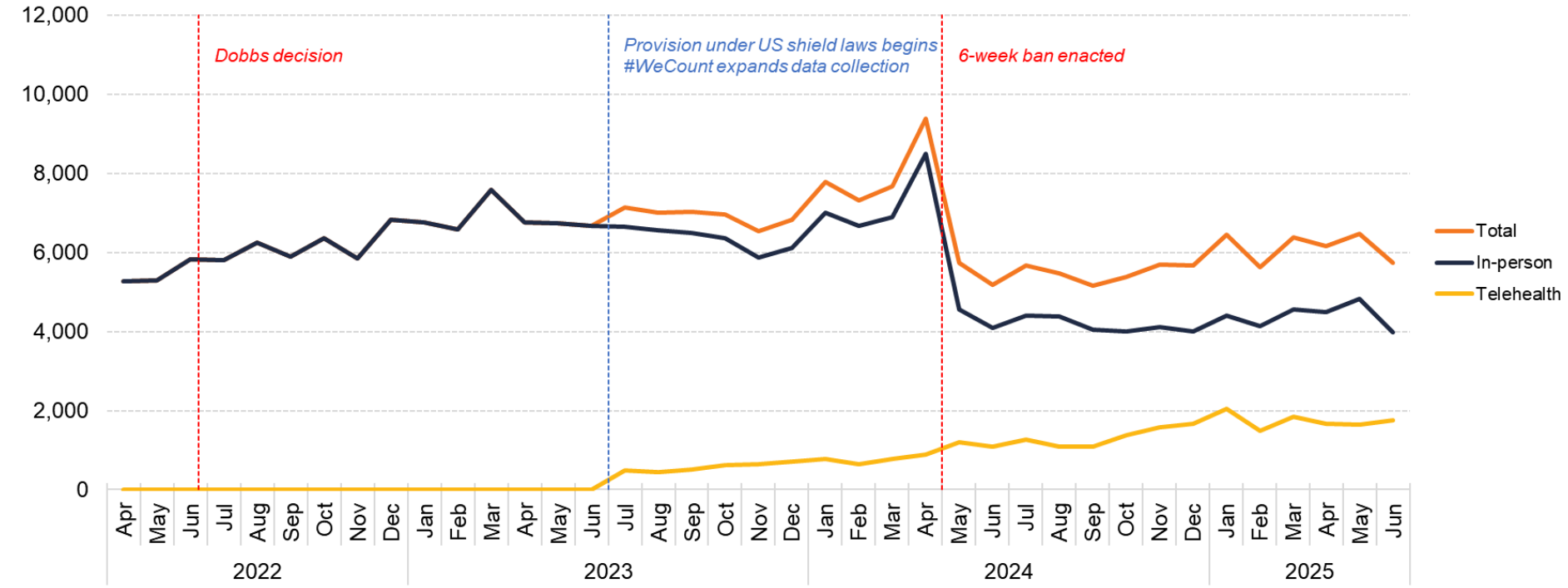

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Georgia

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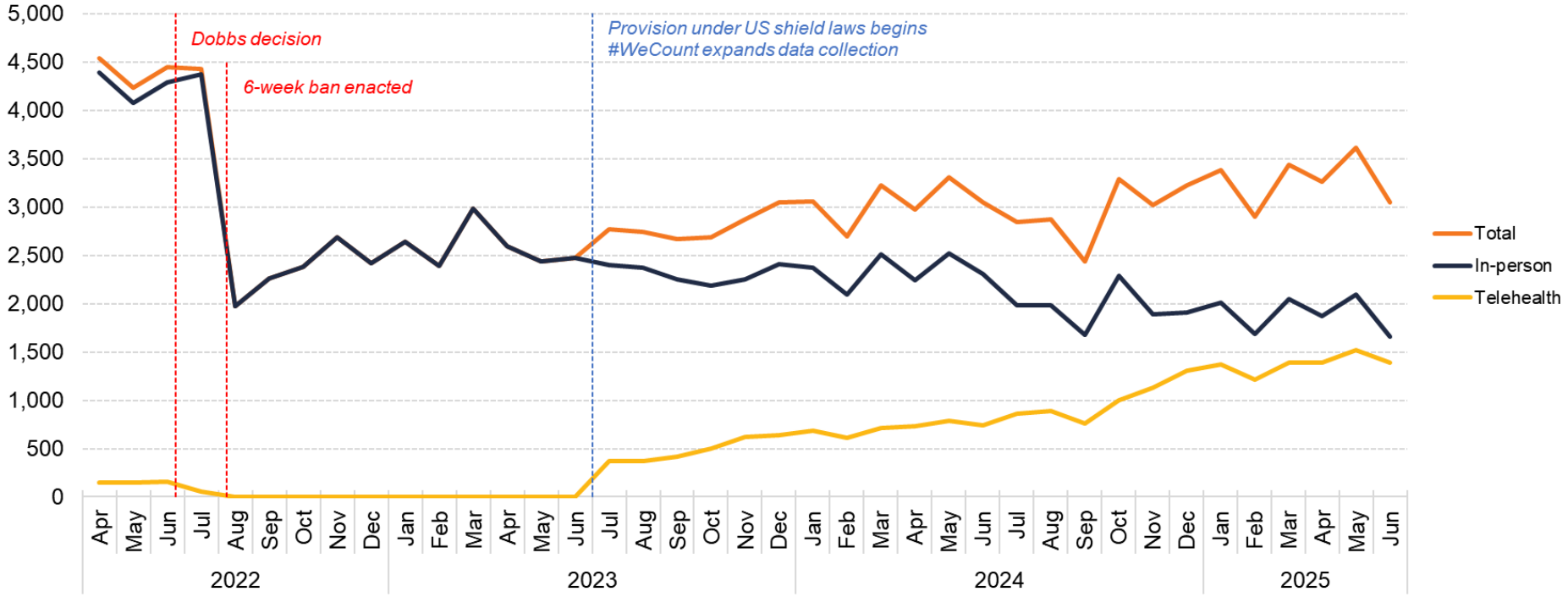

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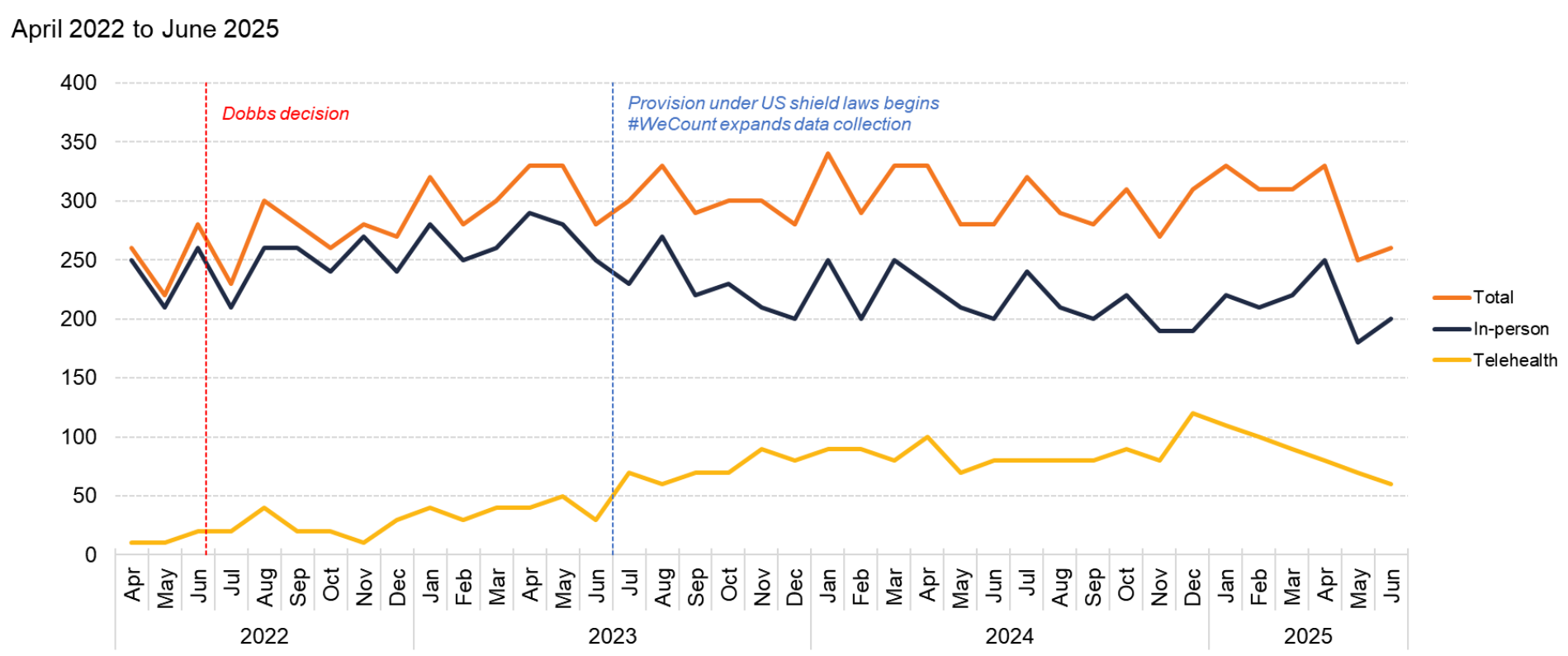
Hawaii



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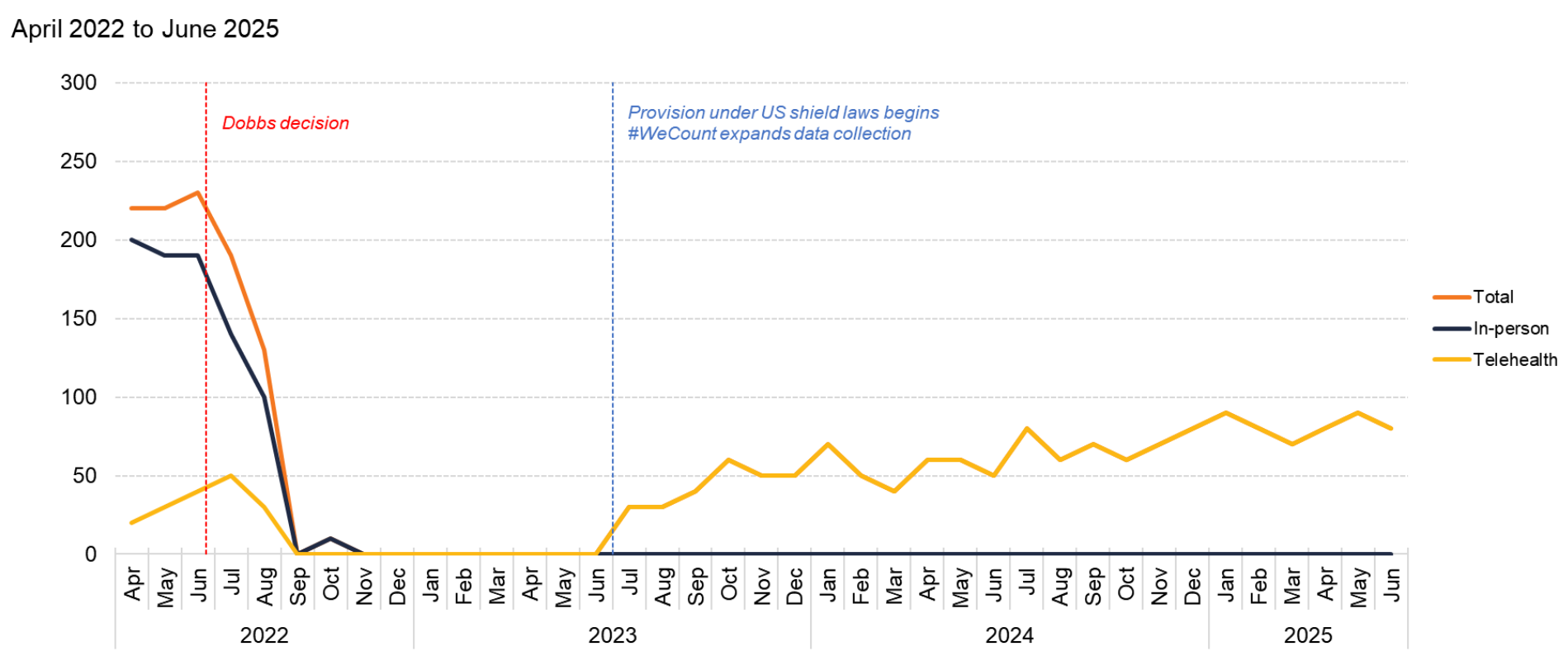

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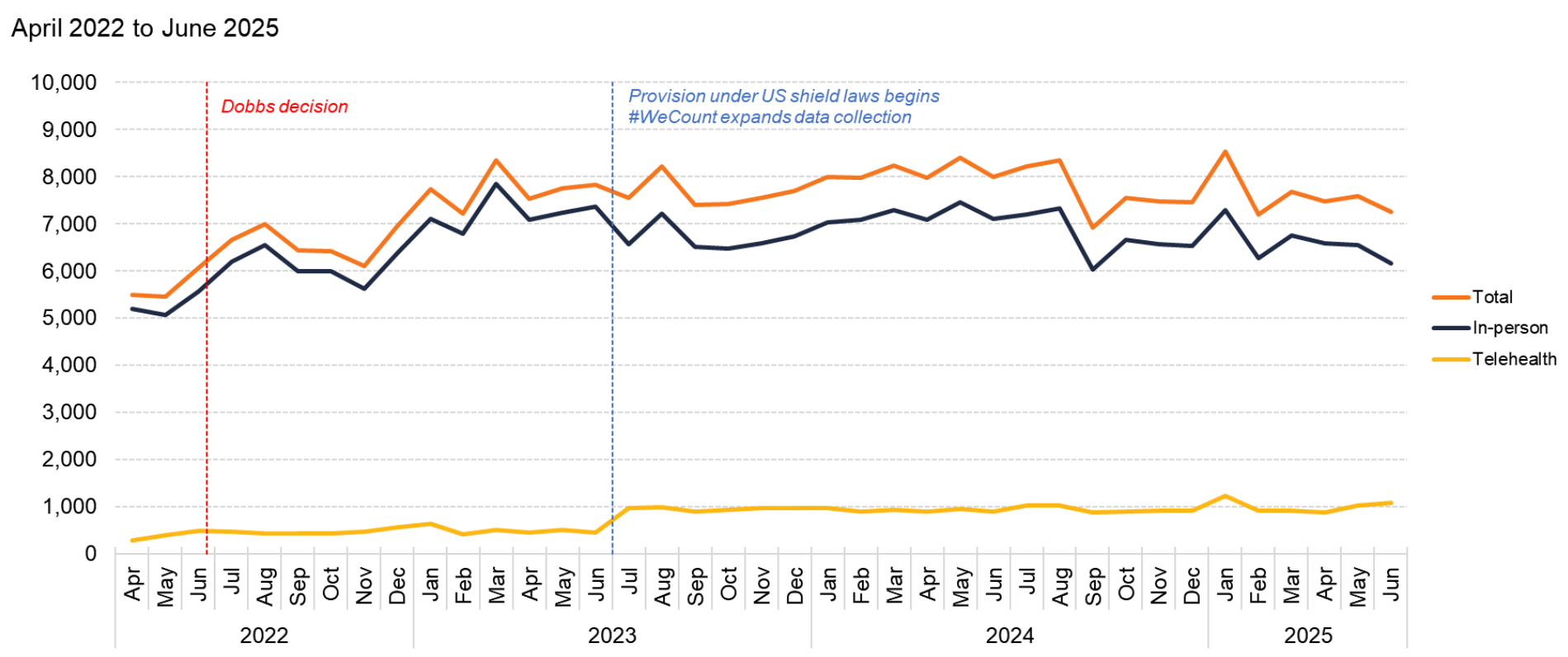

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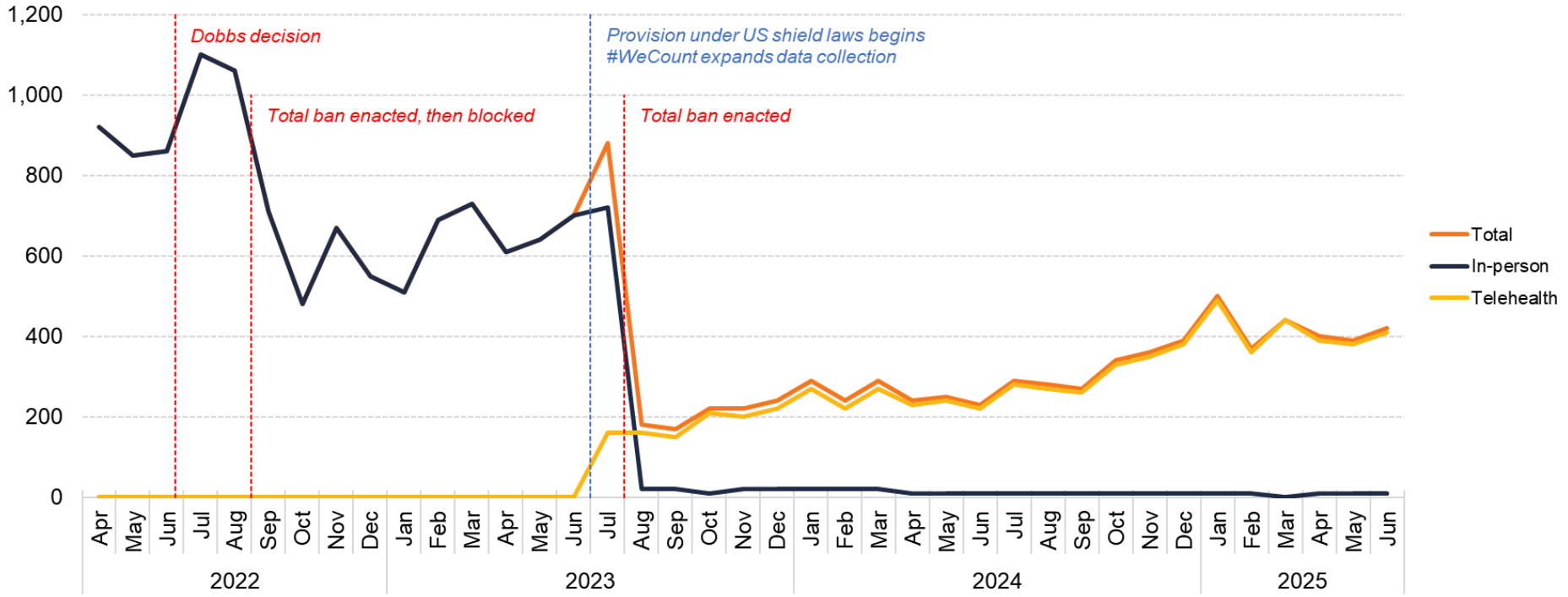
Indiana

April 2022 to June 2025



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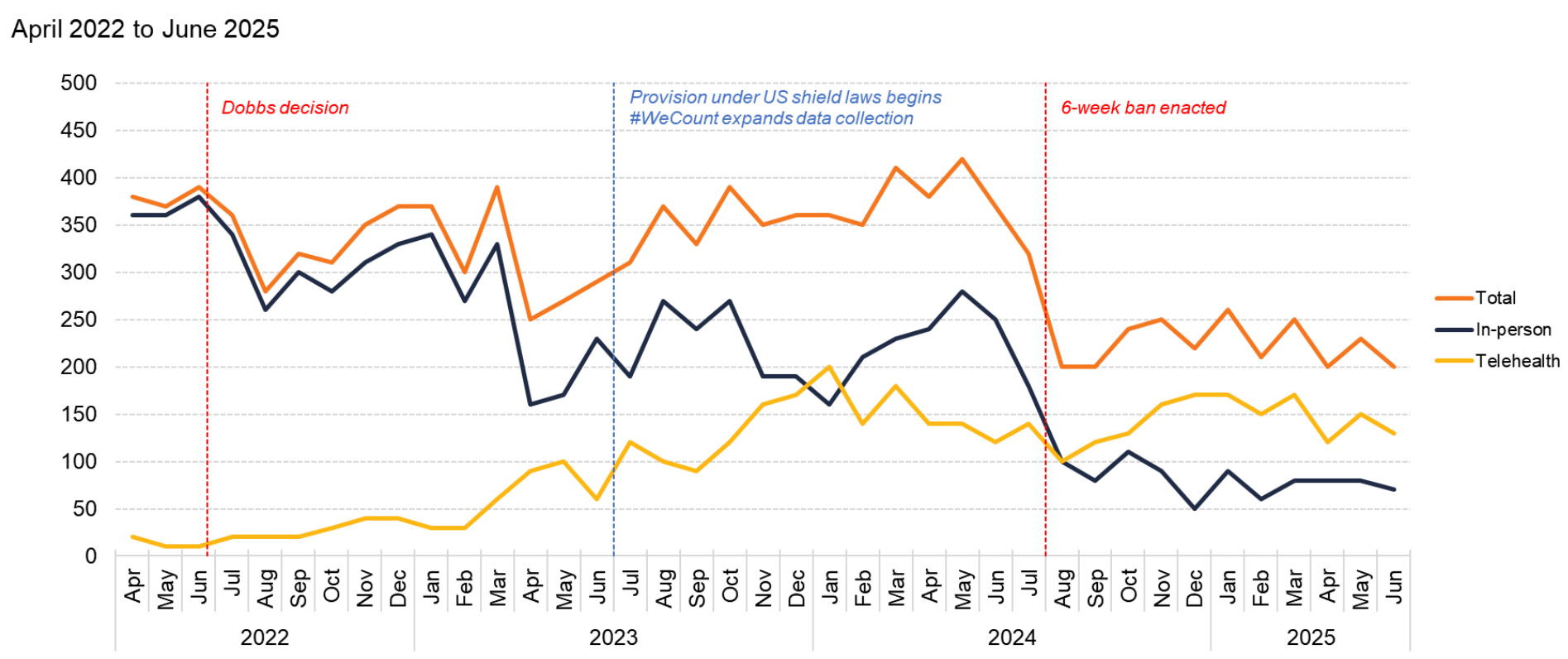
Iowa



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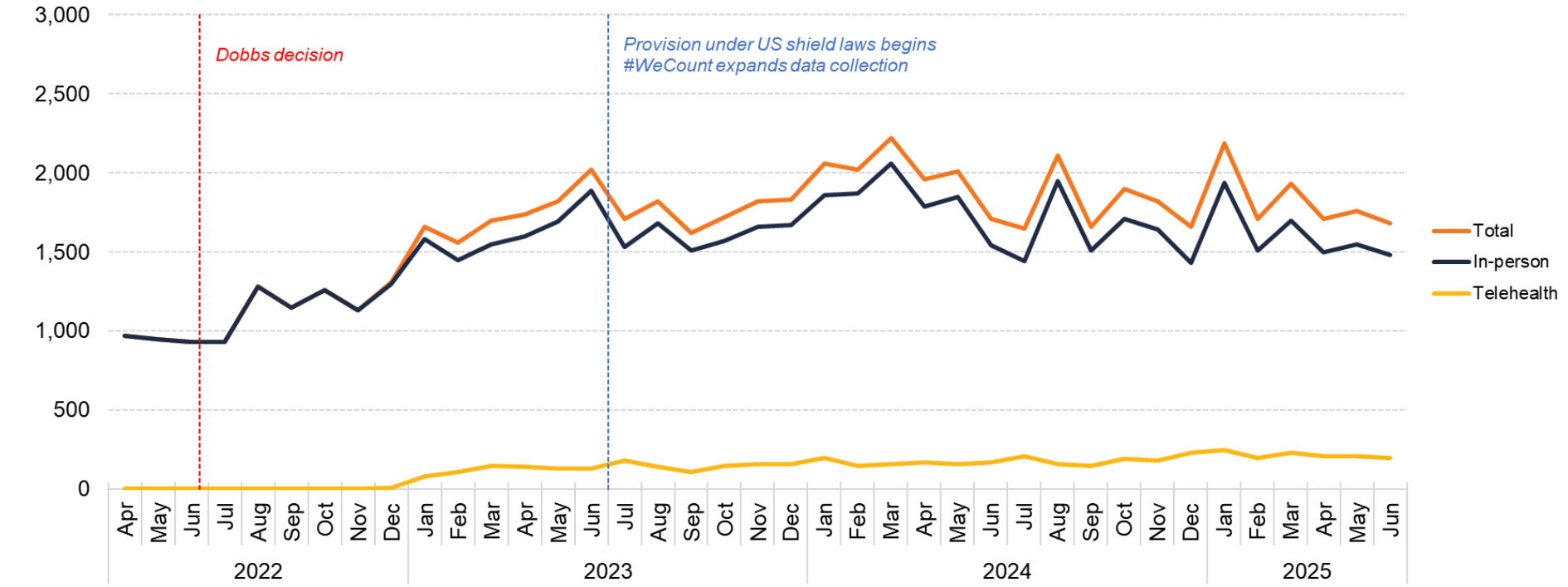
Kansas

April 2022 to June 2025



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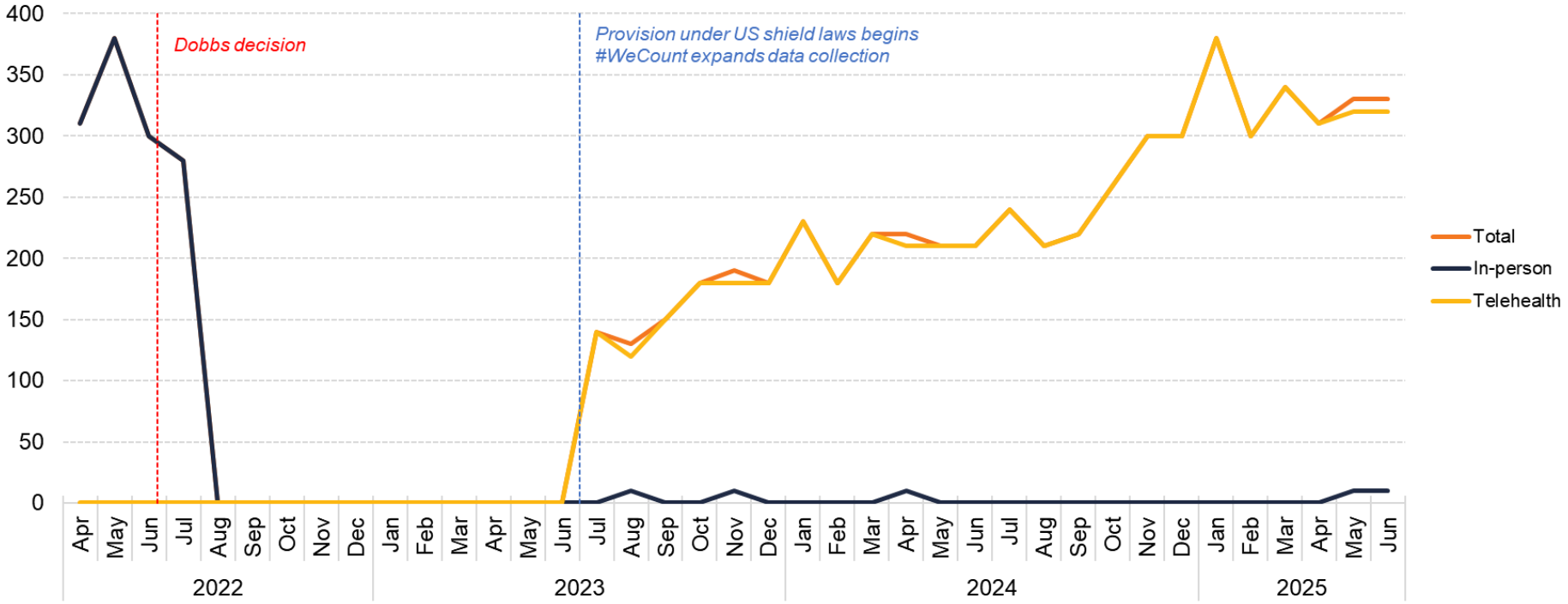
April 2022 to June 2025



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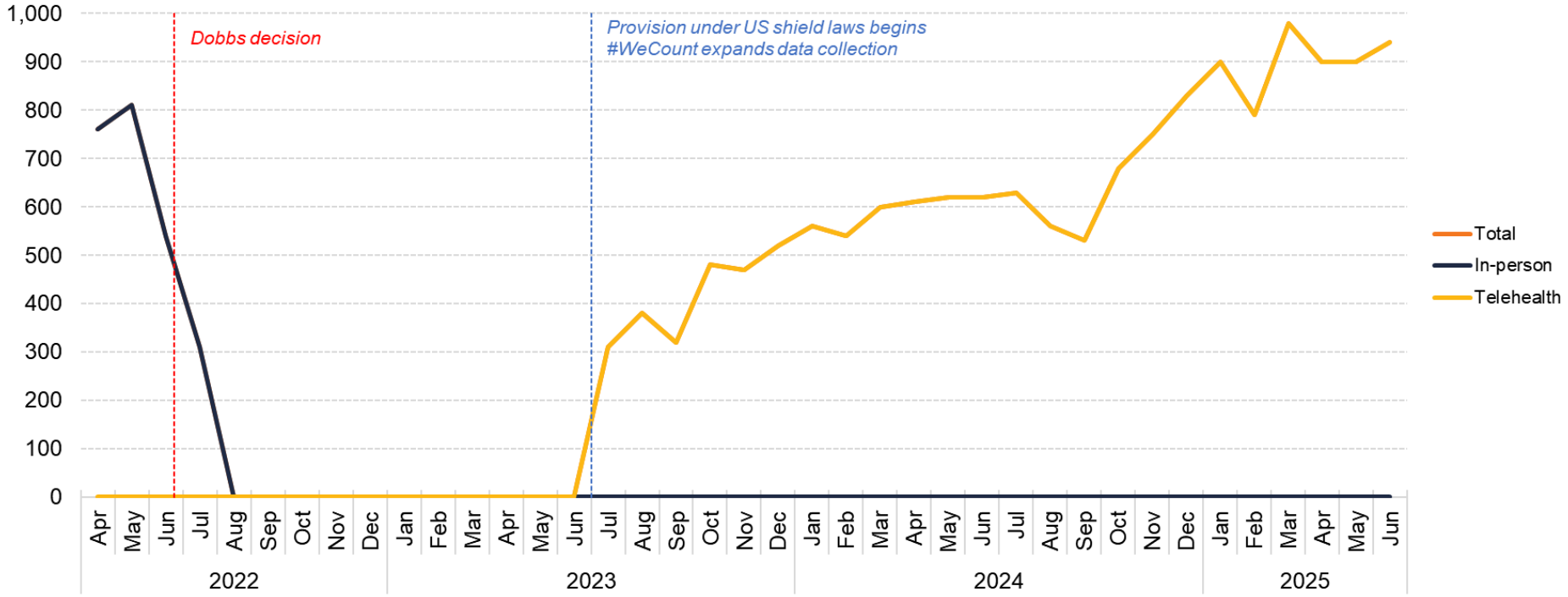

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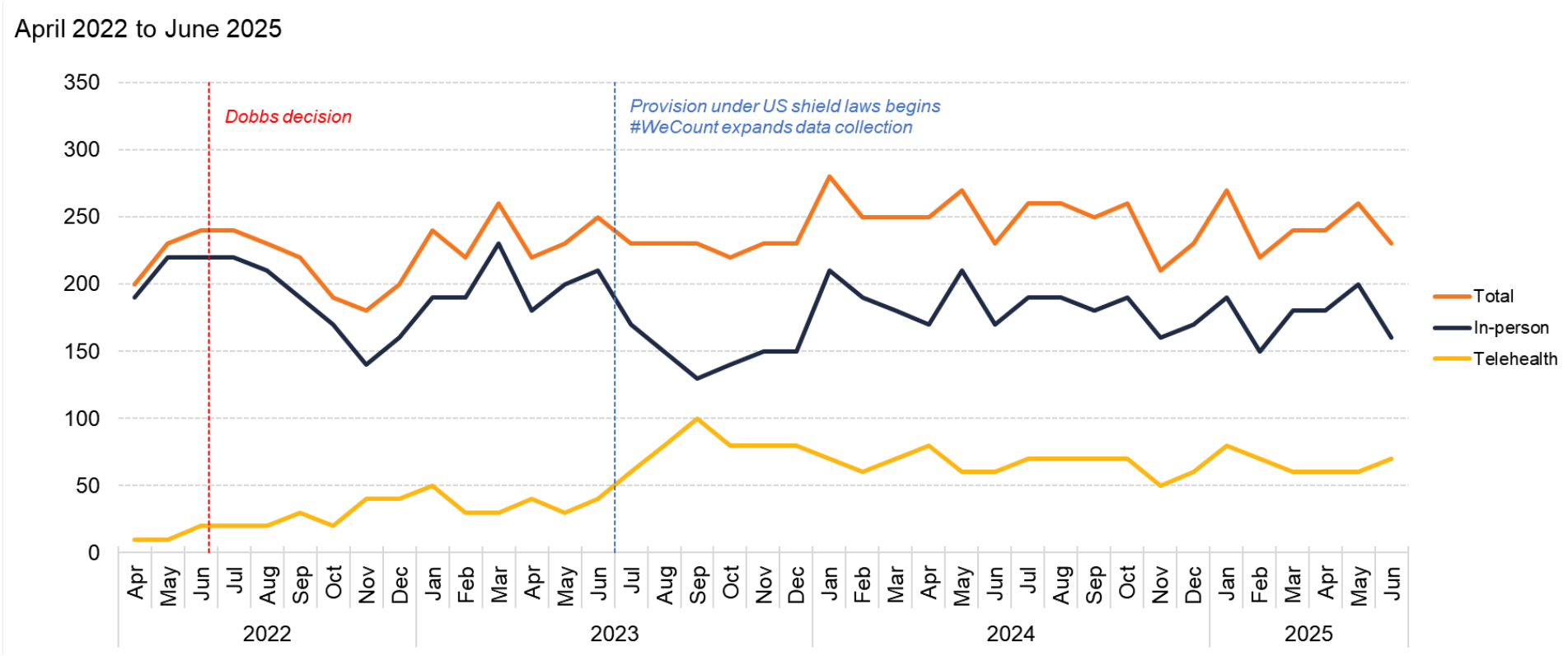
Maine



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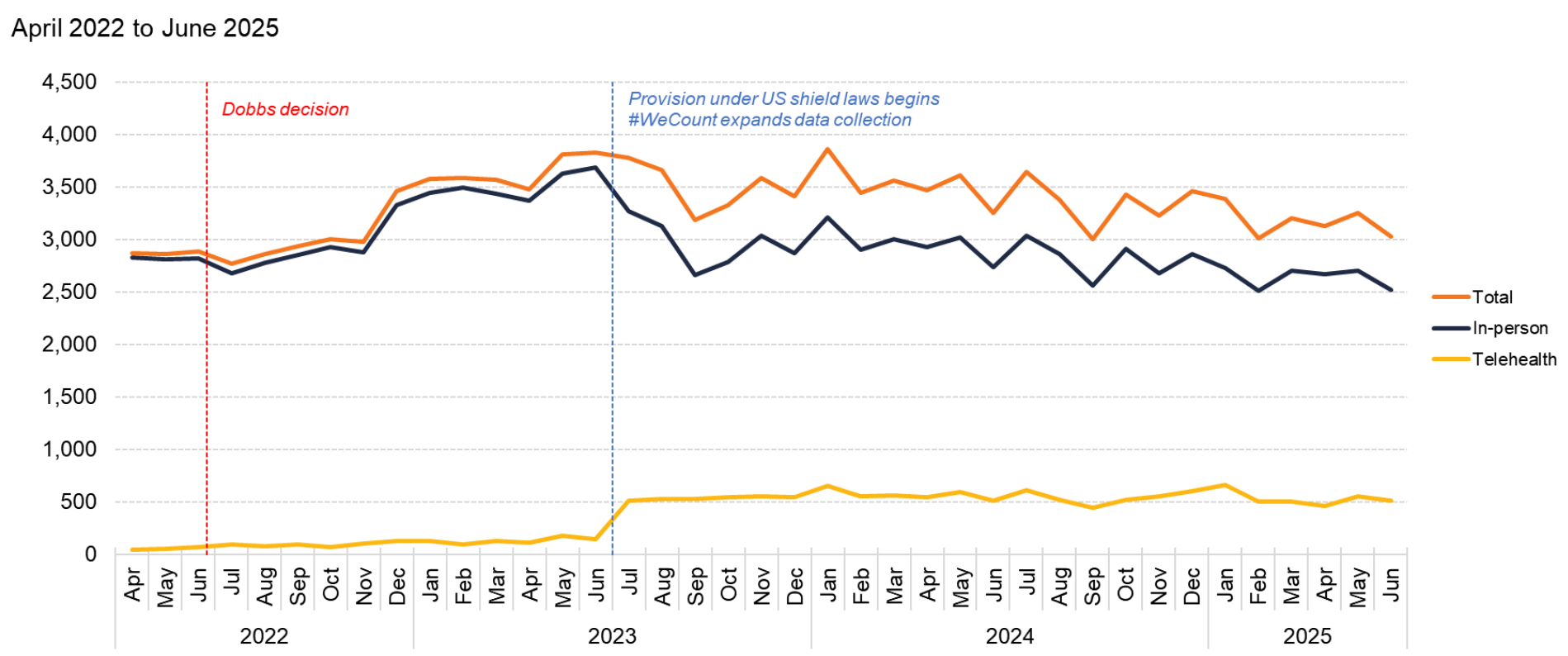
Maryland



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Massachusetts

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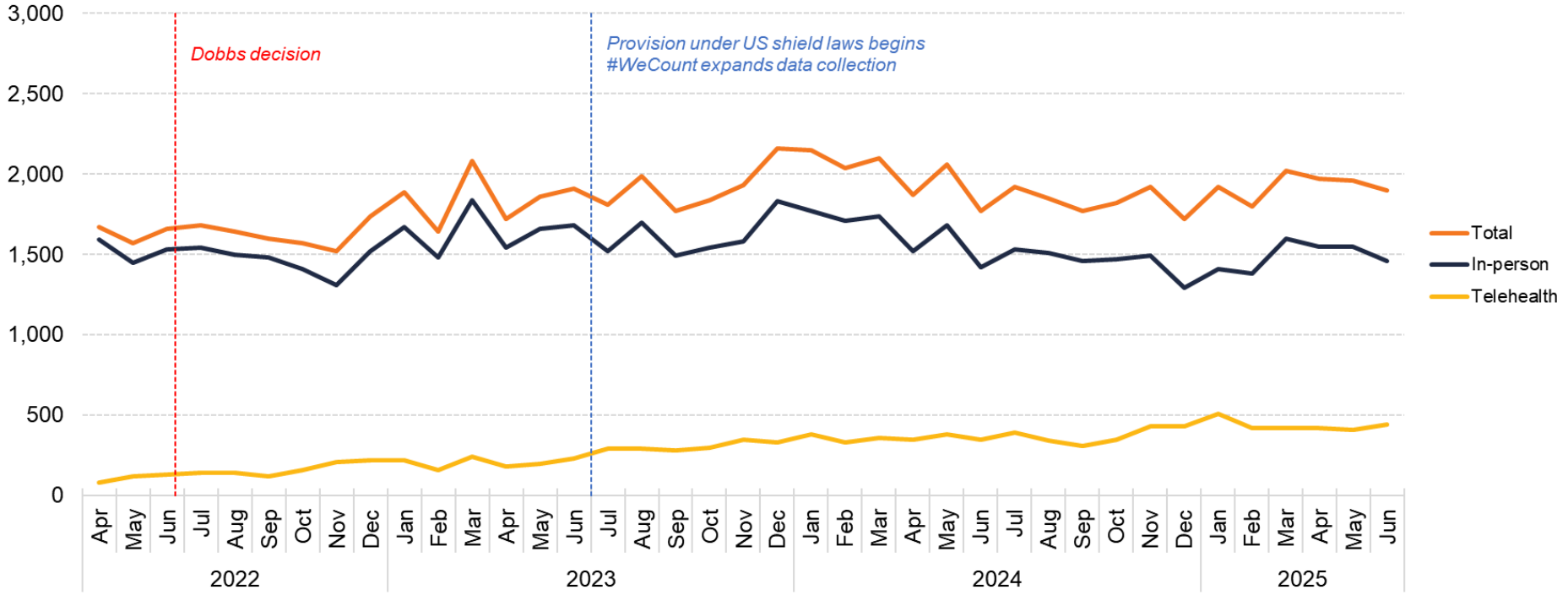

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Michigan

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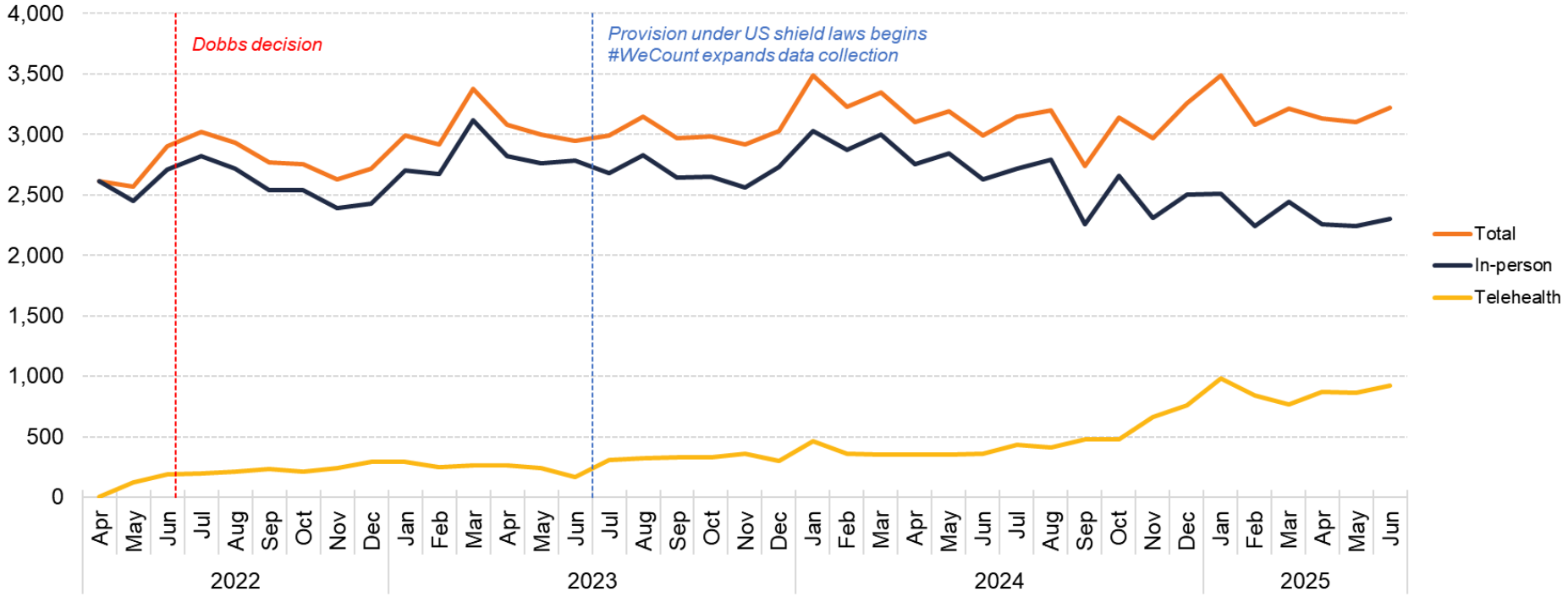

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Minnesota

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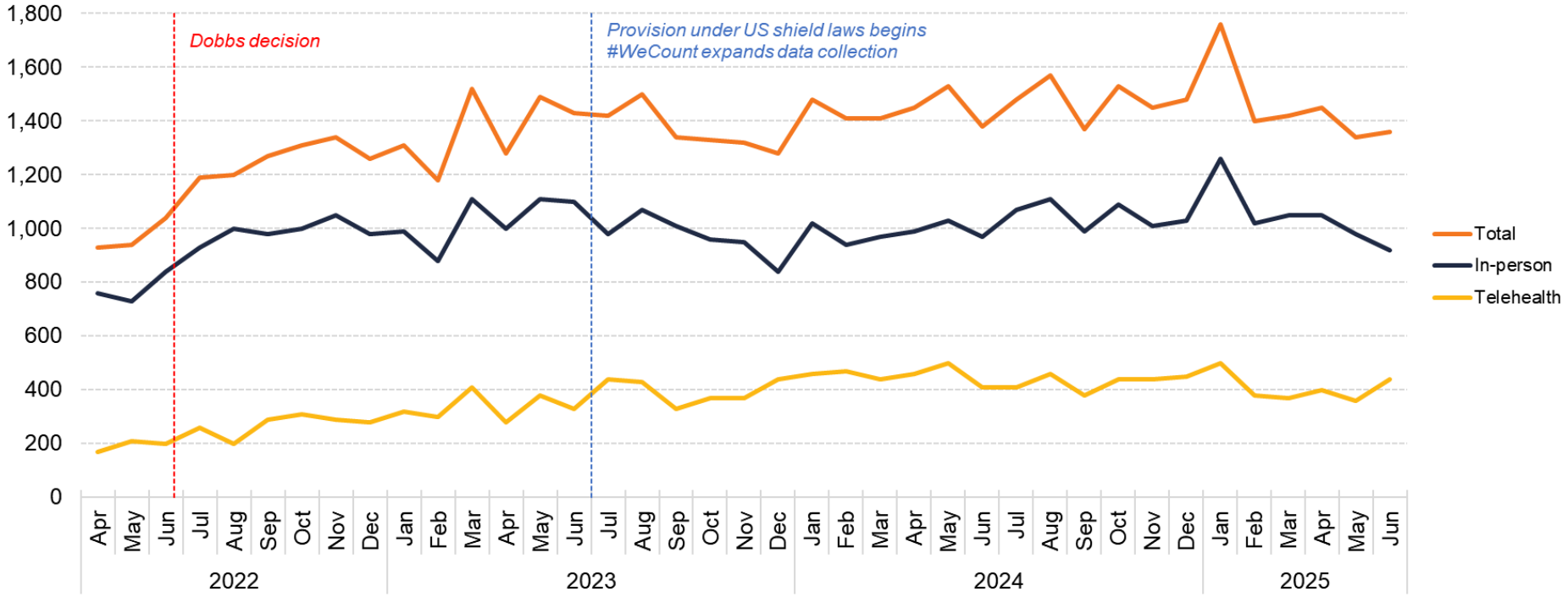

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Mississippi

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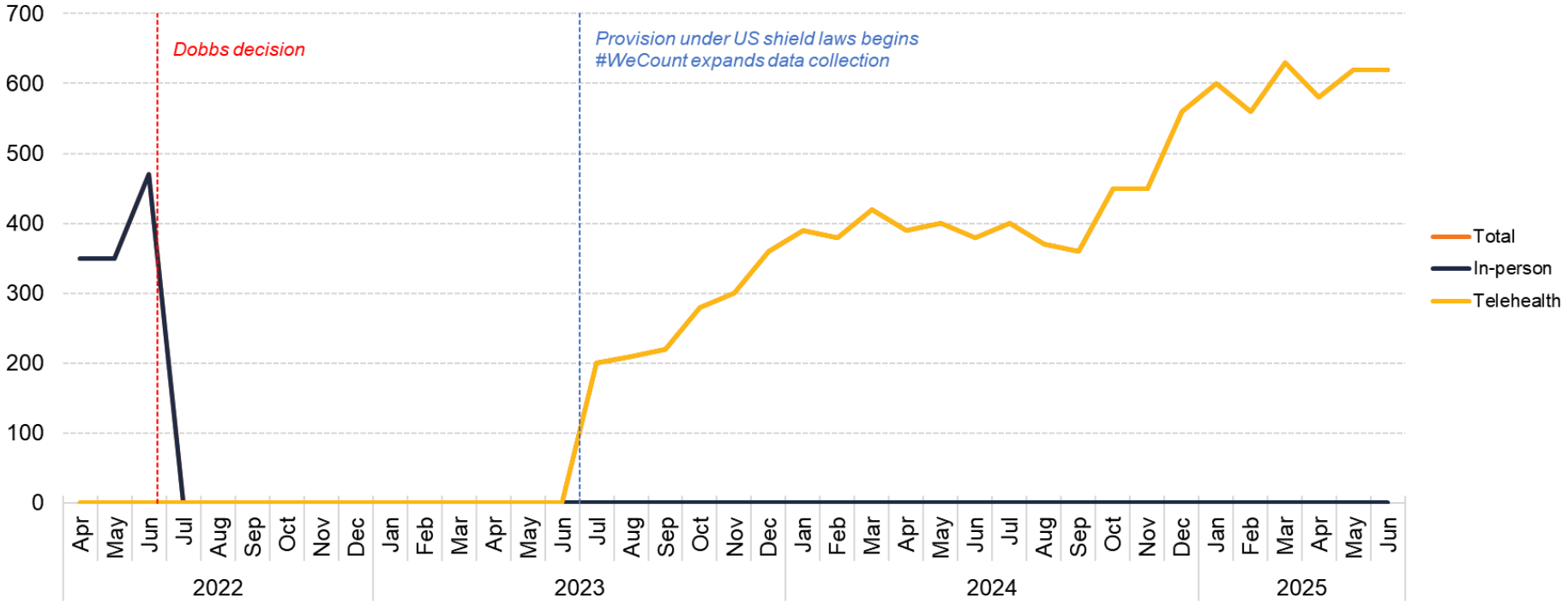

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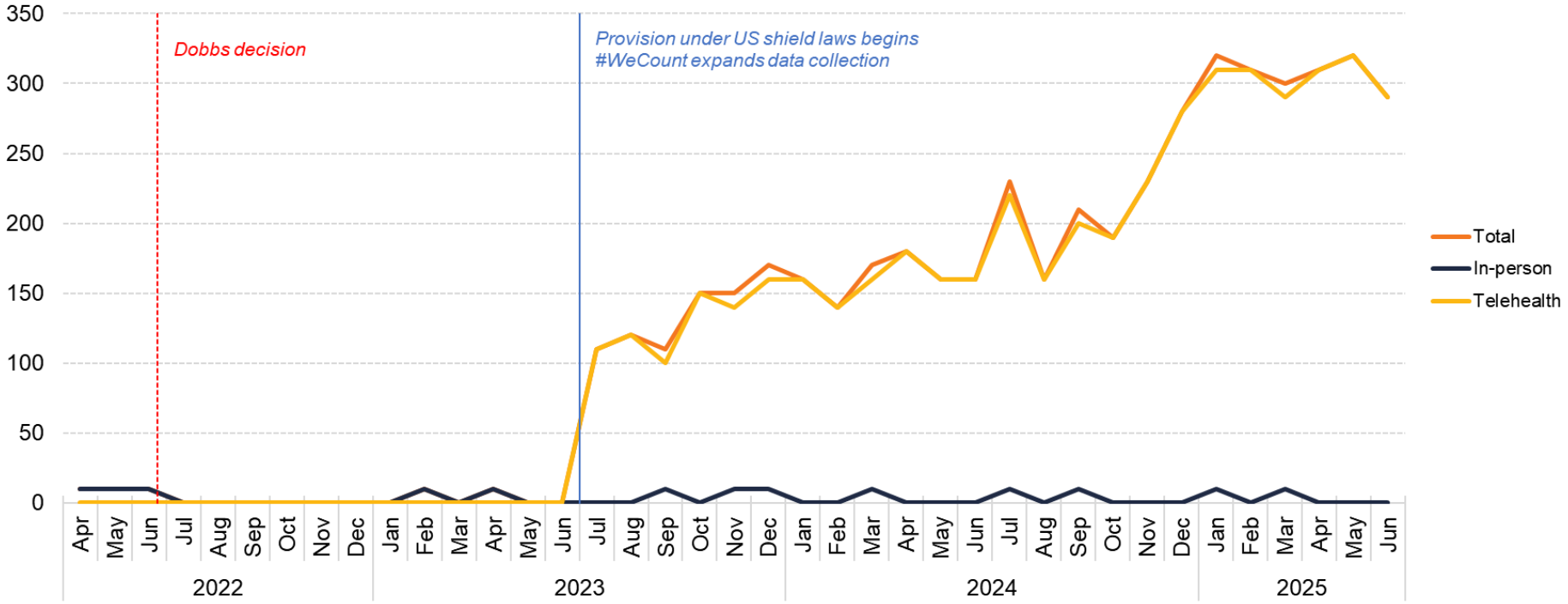

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Montana

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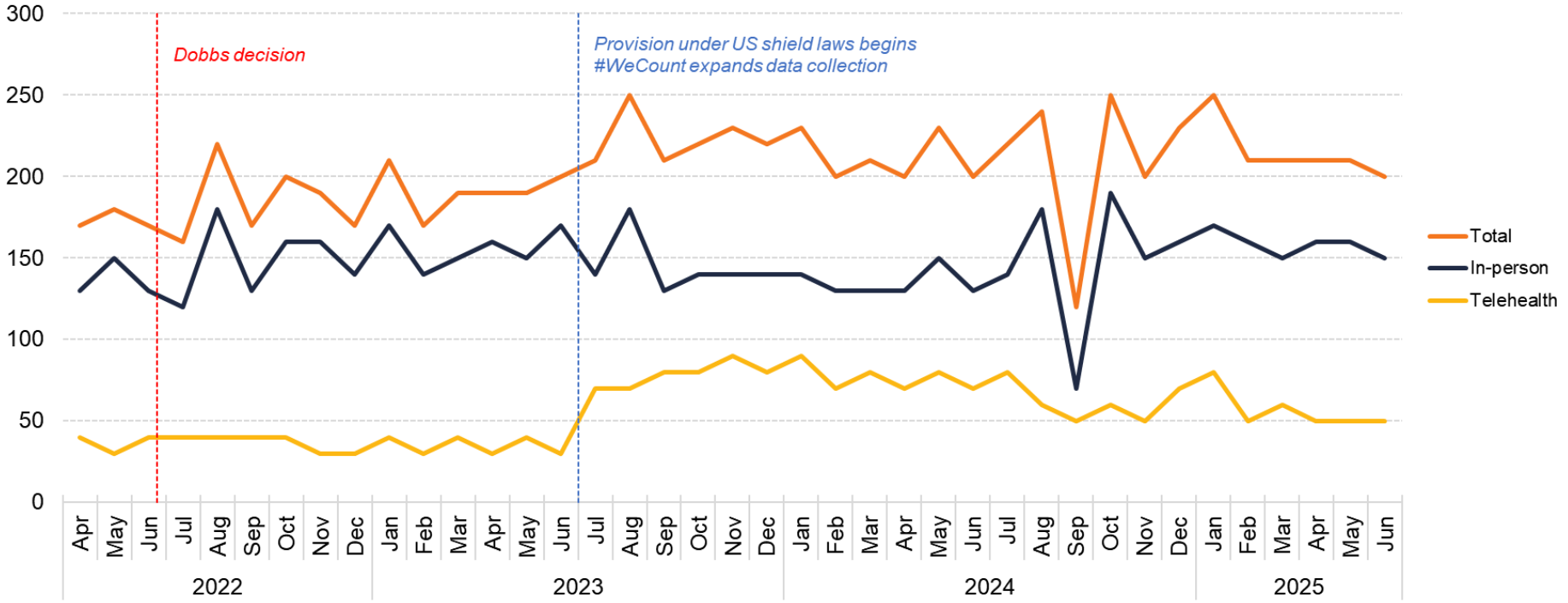

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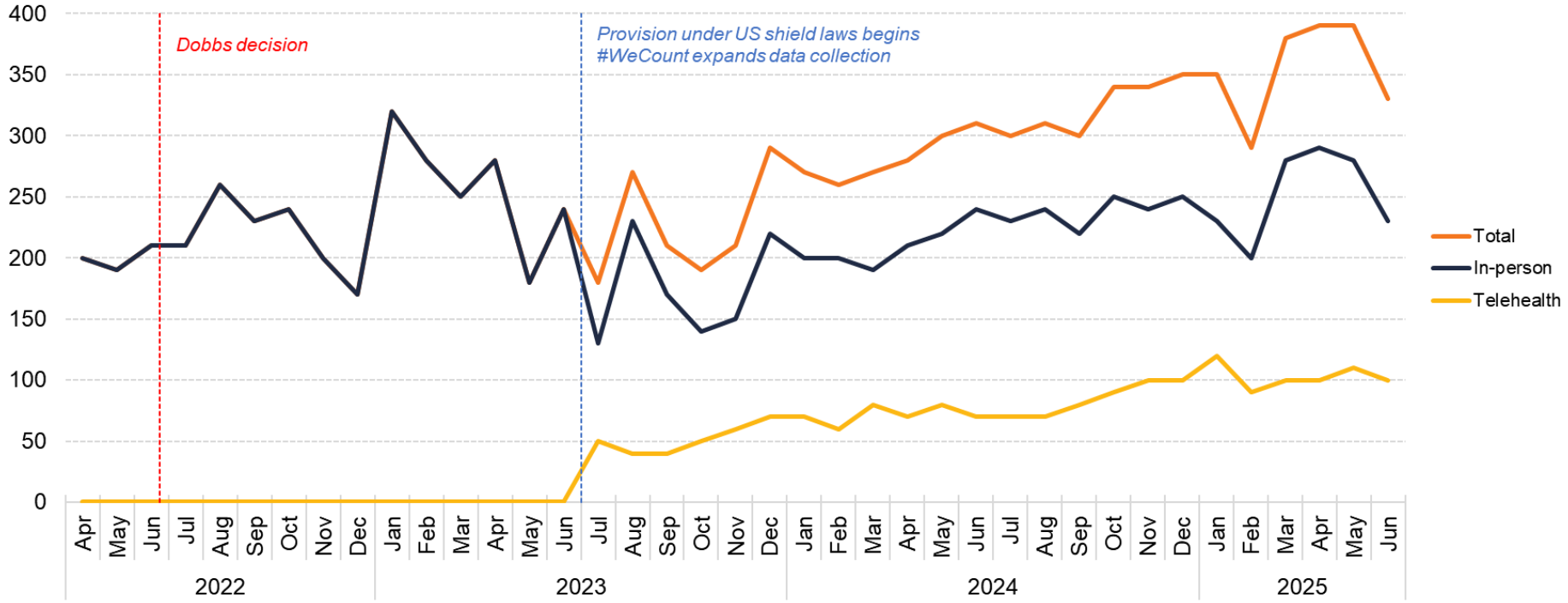

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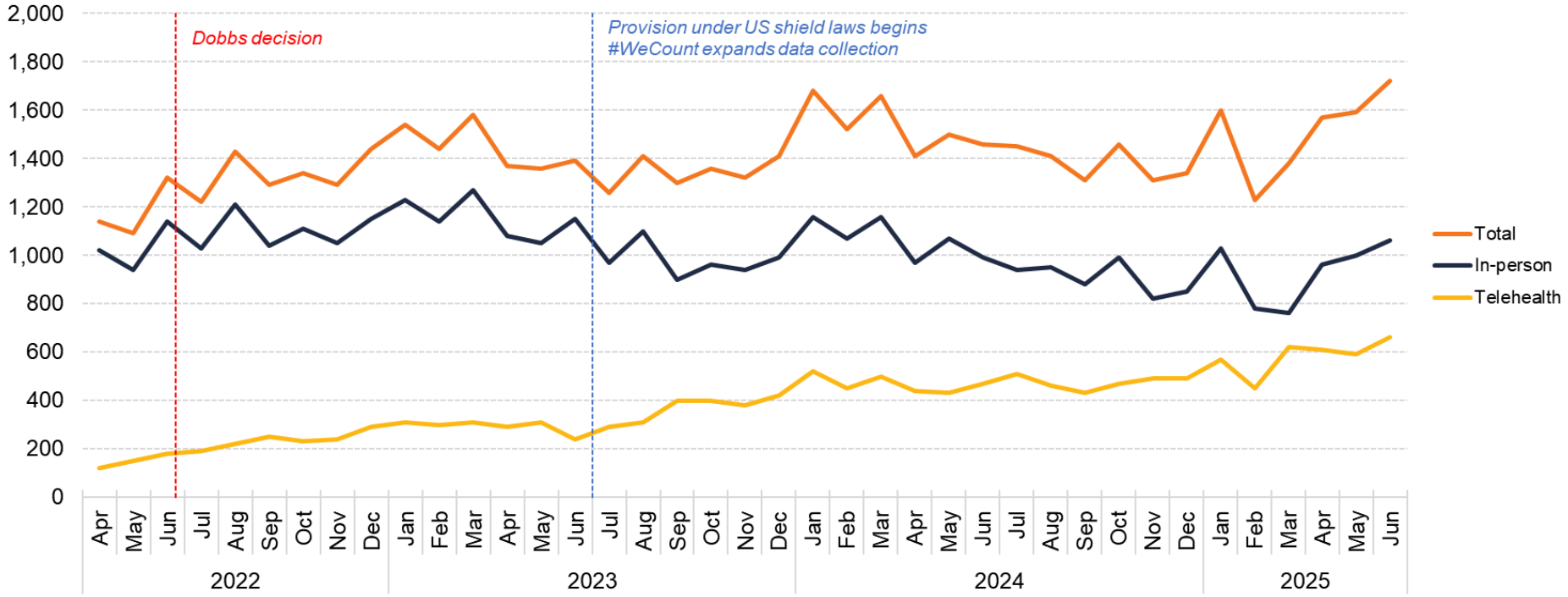
Nevada

April 2022 to June 2025



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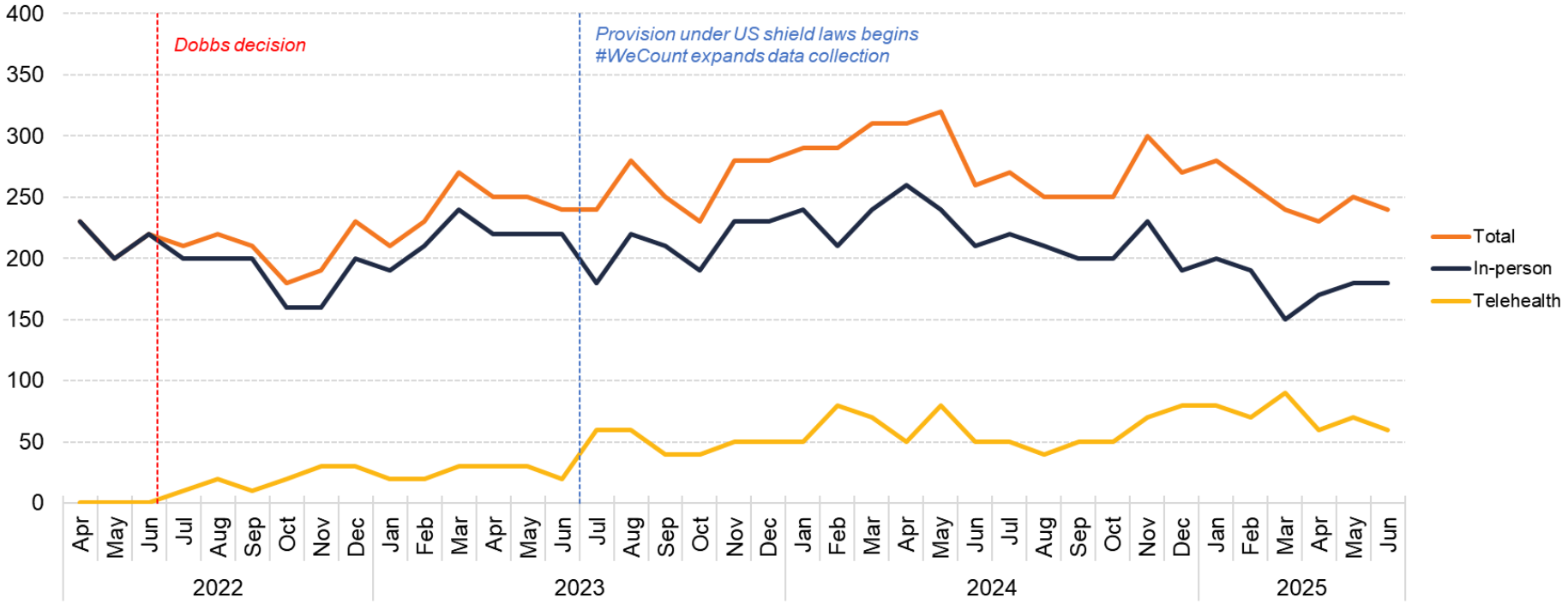
April 2022 to June 2025



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New Jersey

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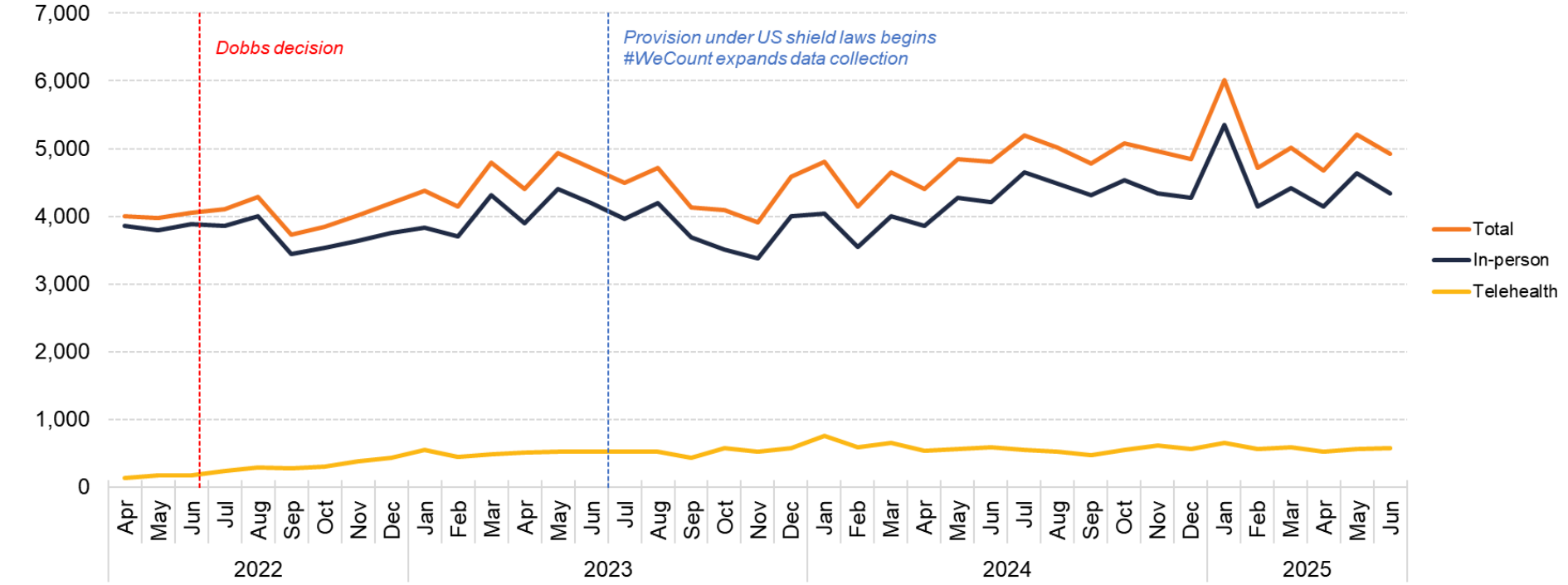

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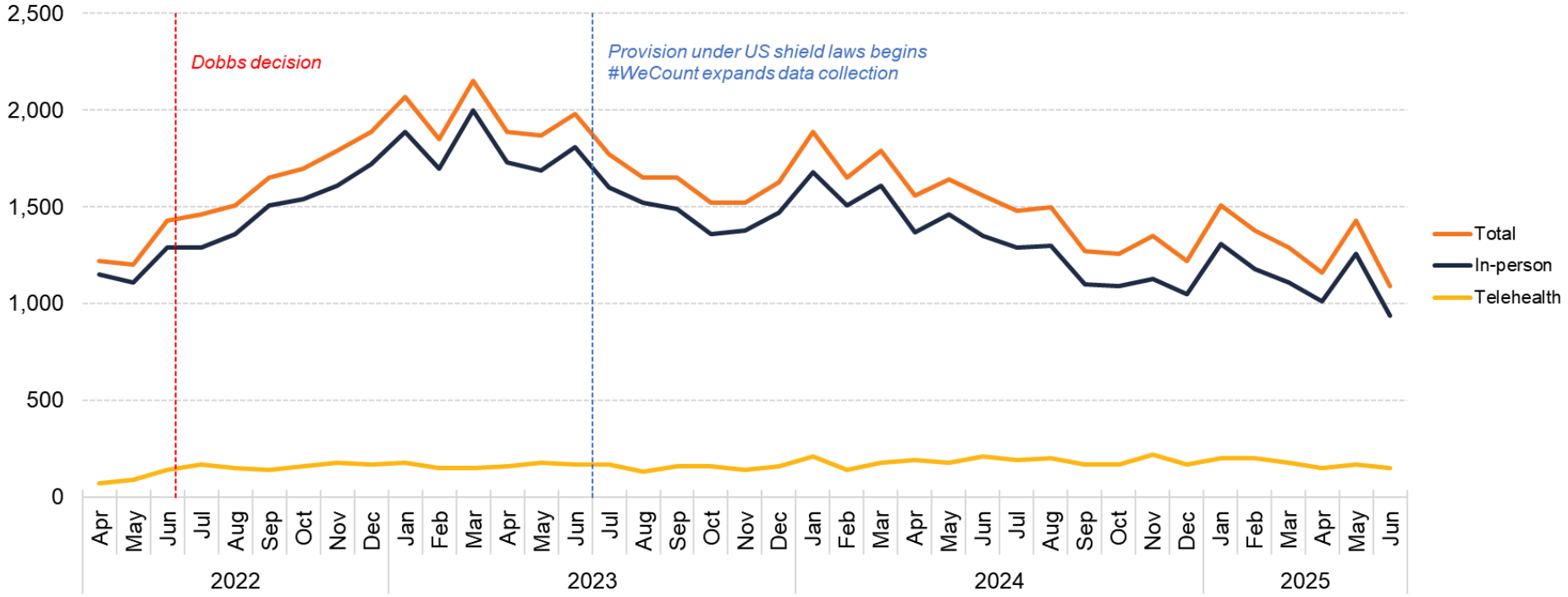

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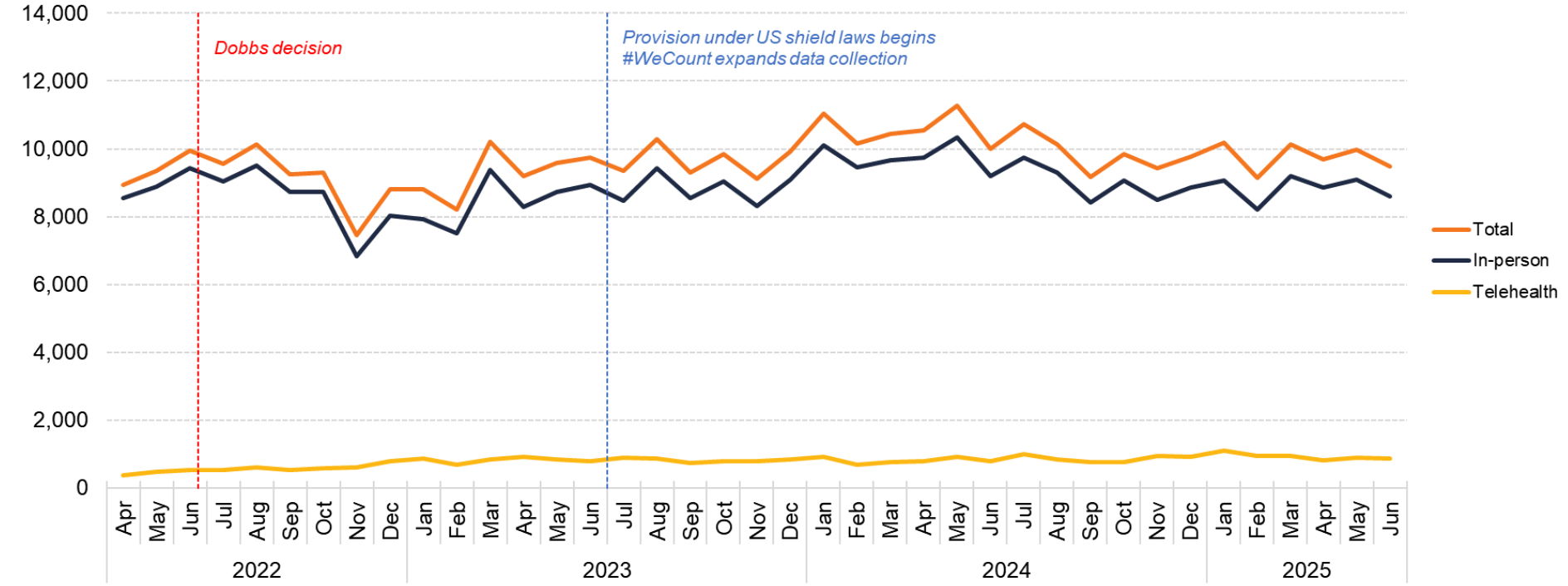

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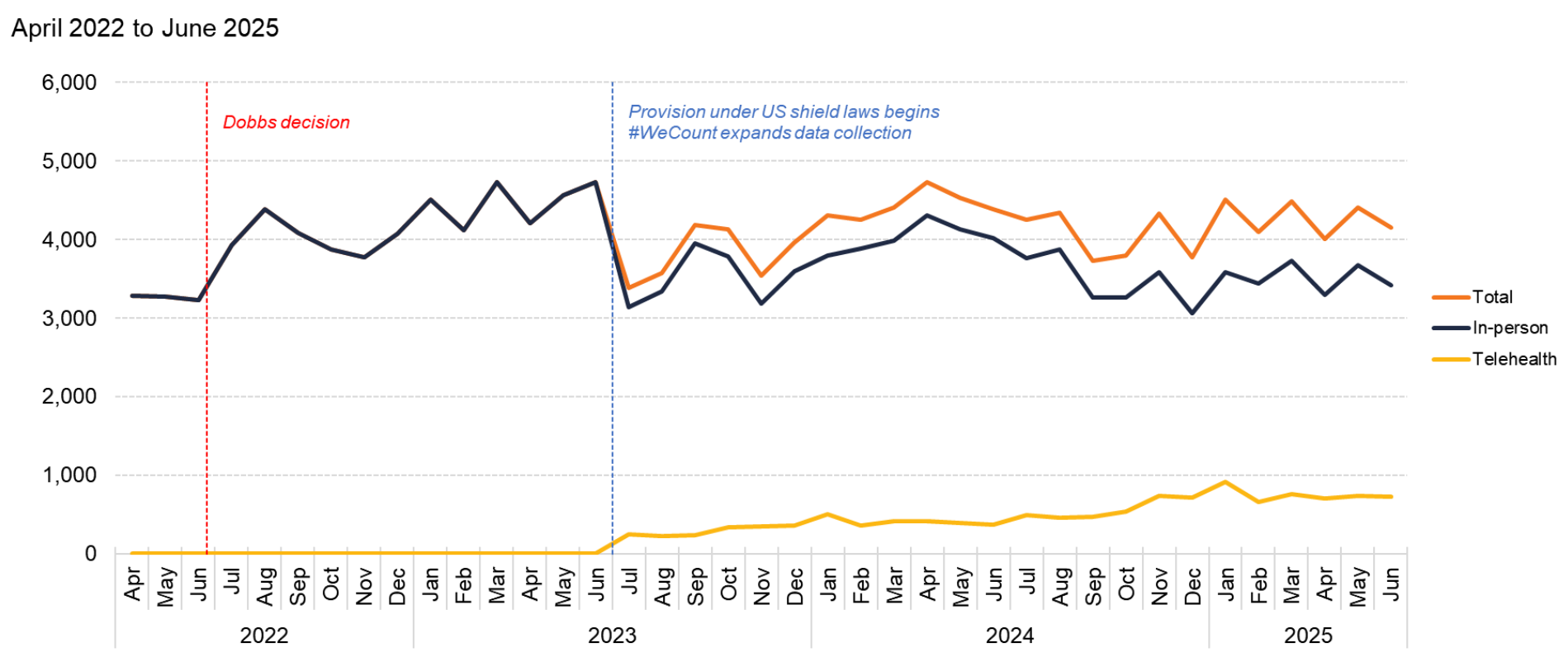
North Carolina



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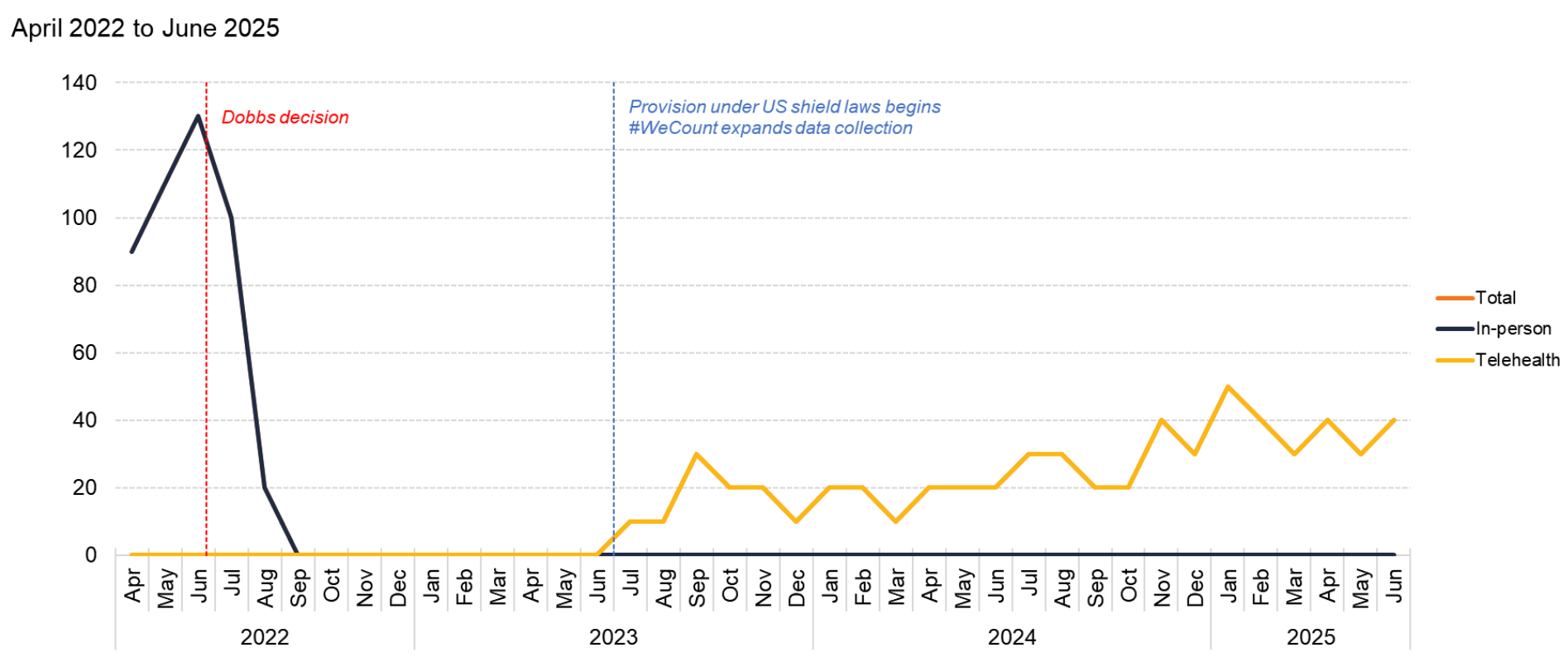

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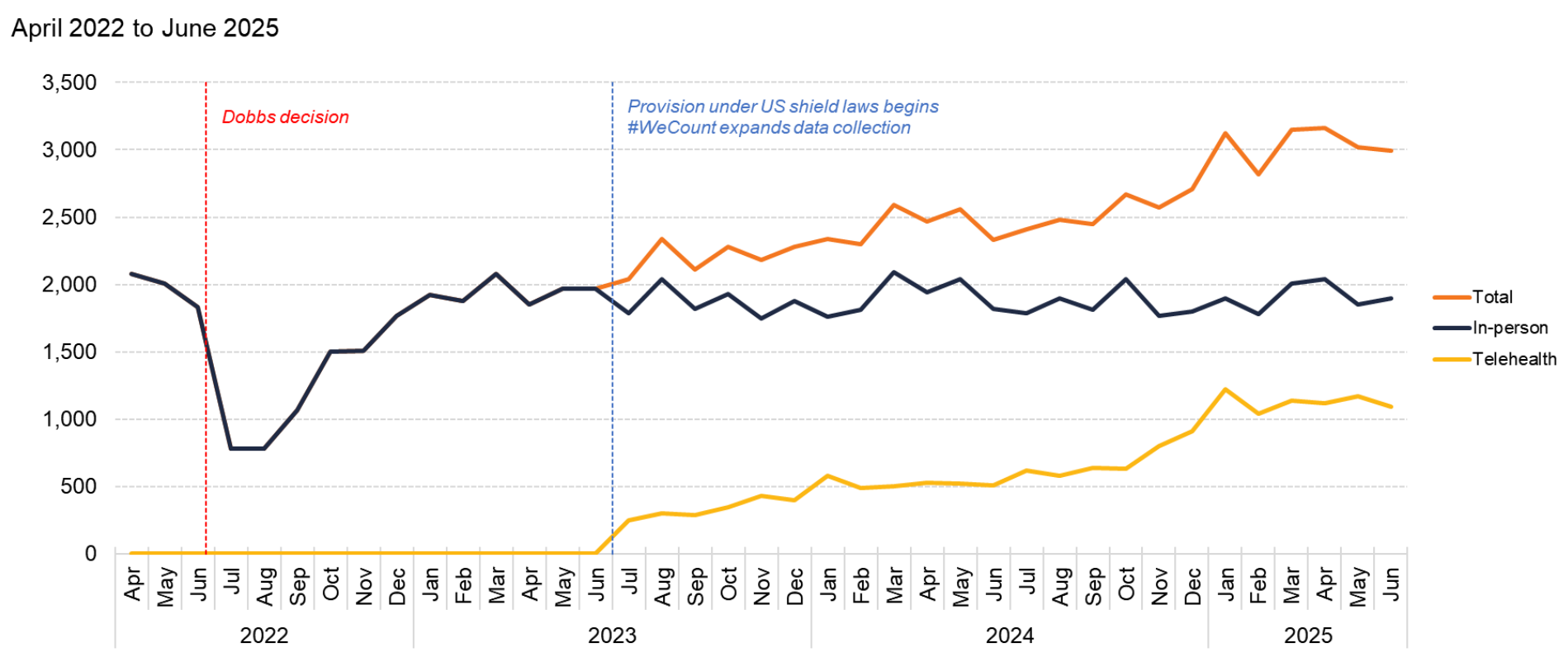

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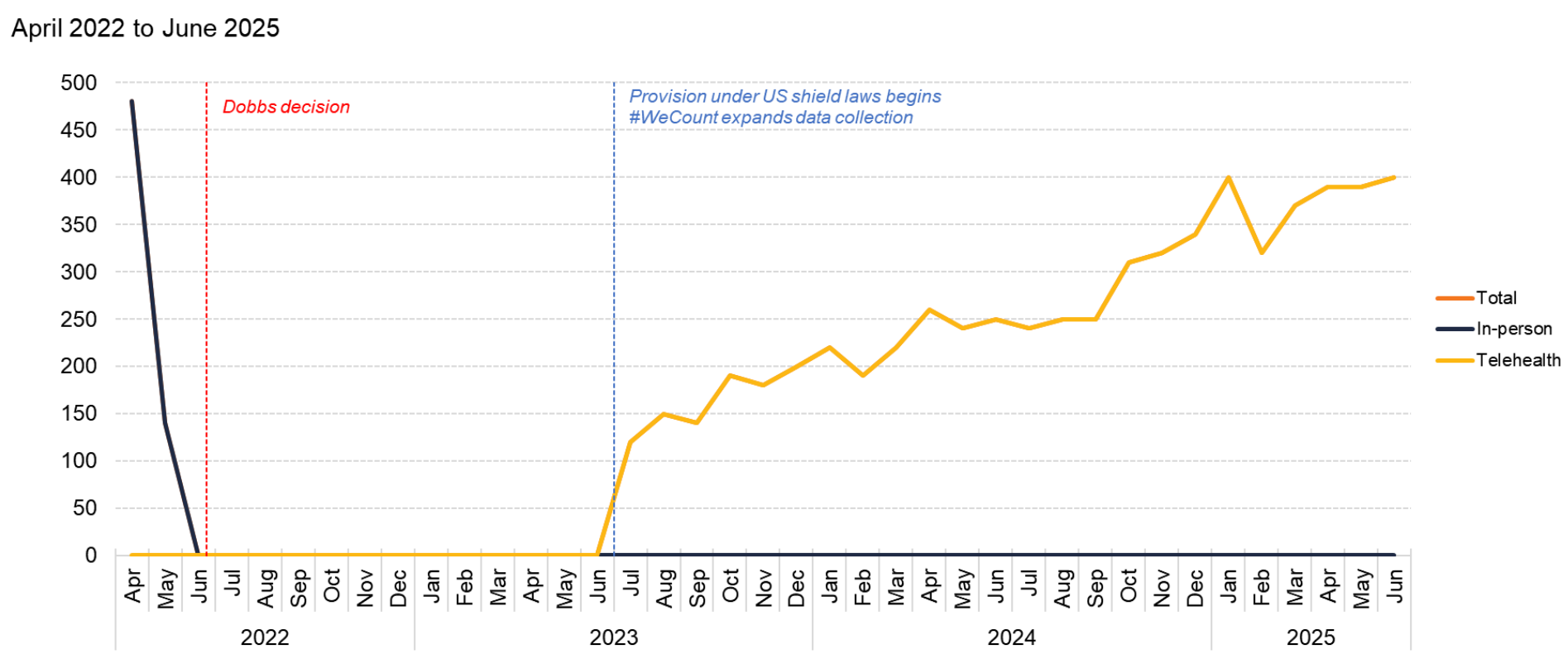
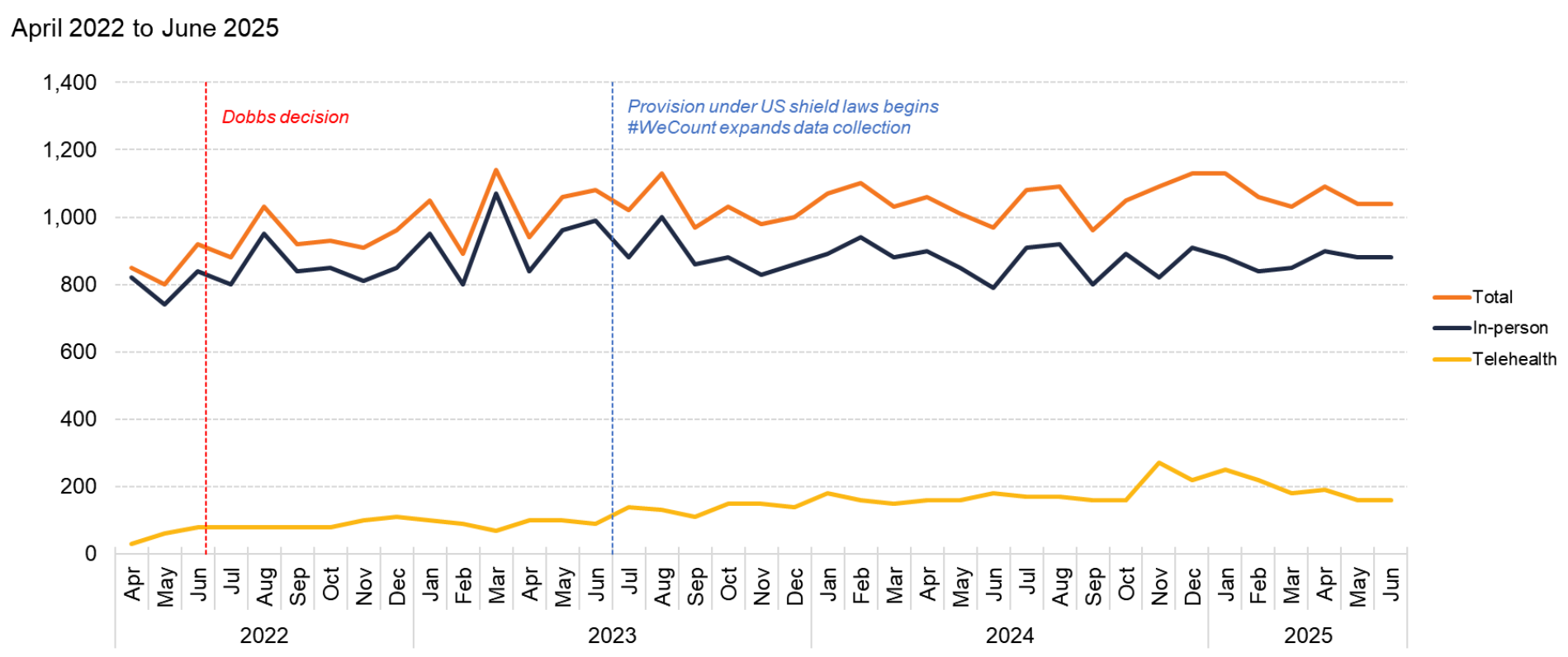
Oklahoma



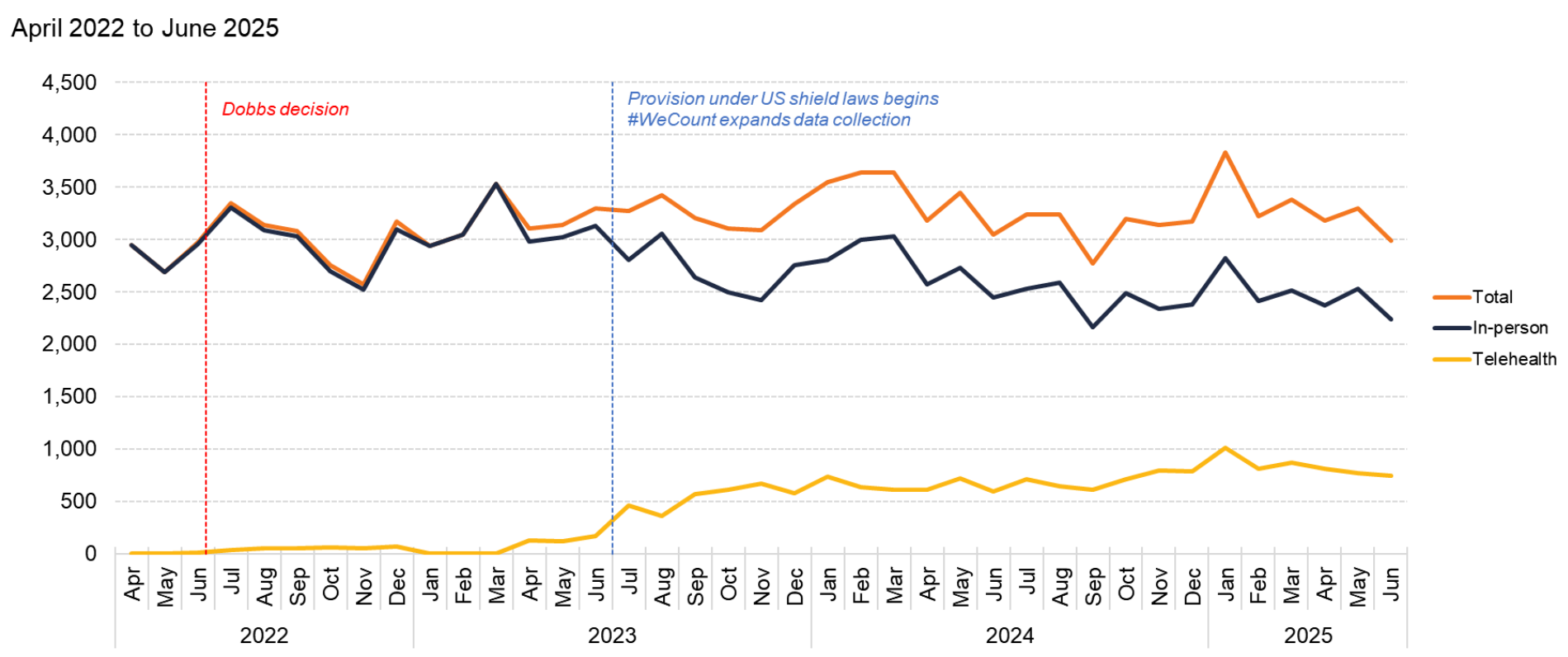
Source: Society of Family Planning, December 2025

Oregon



Source: Society of Family Planning, December 2025

Pennsylvania



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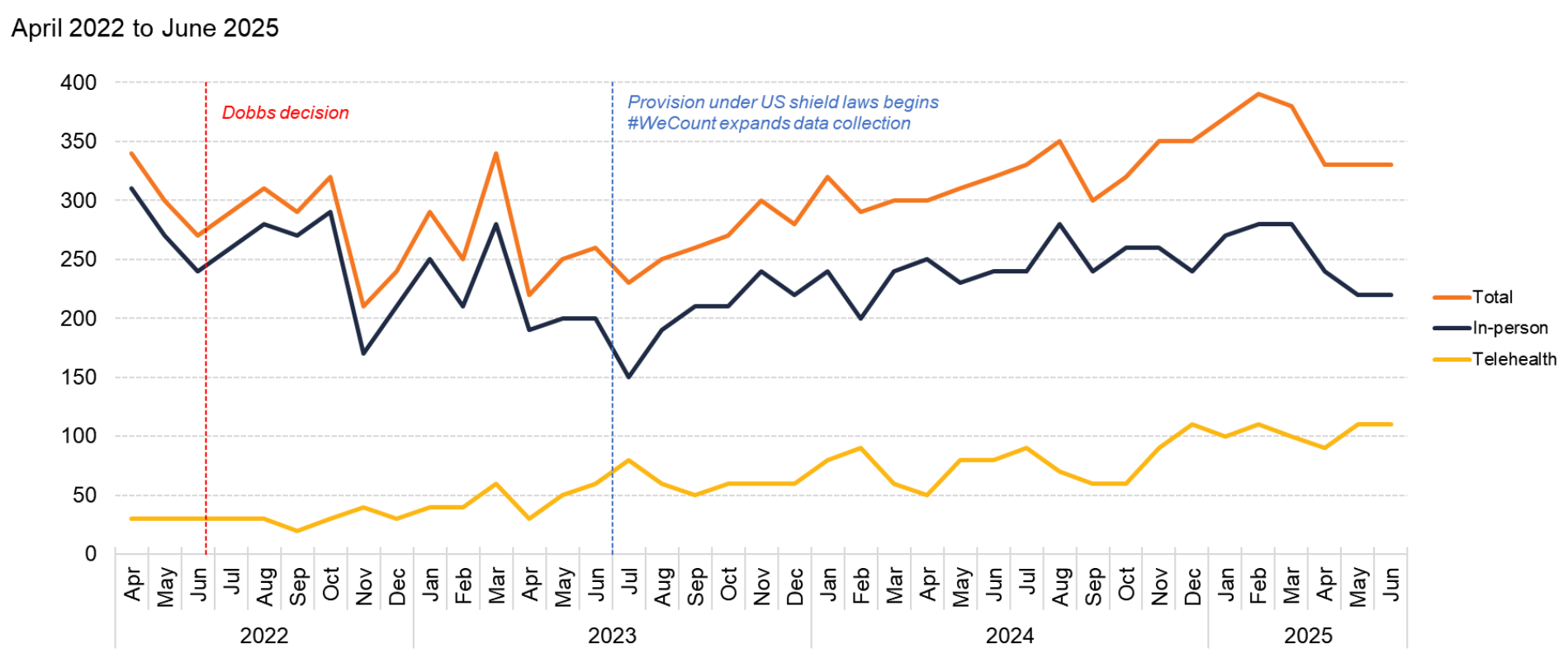
Rhode Island



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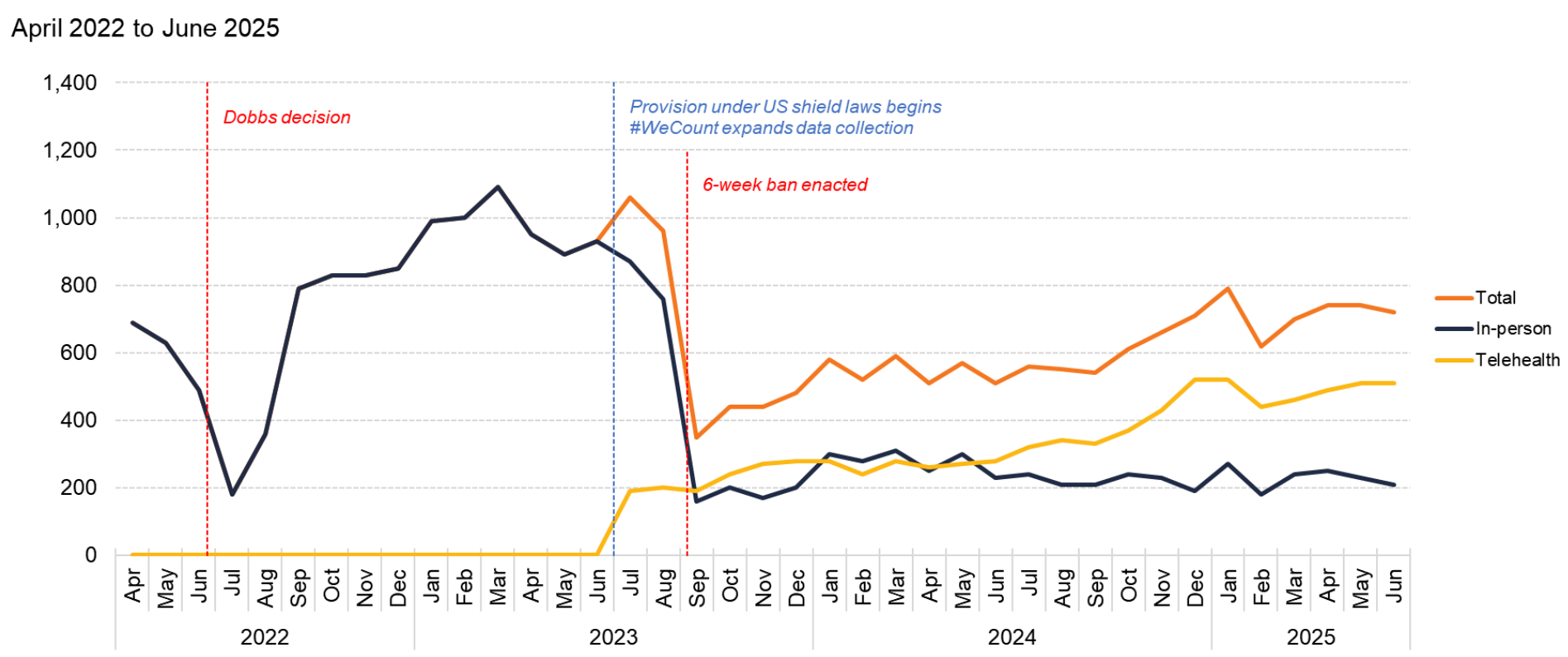
South Carolina



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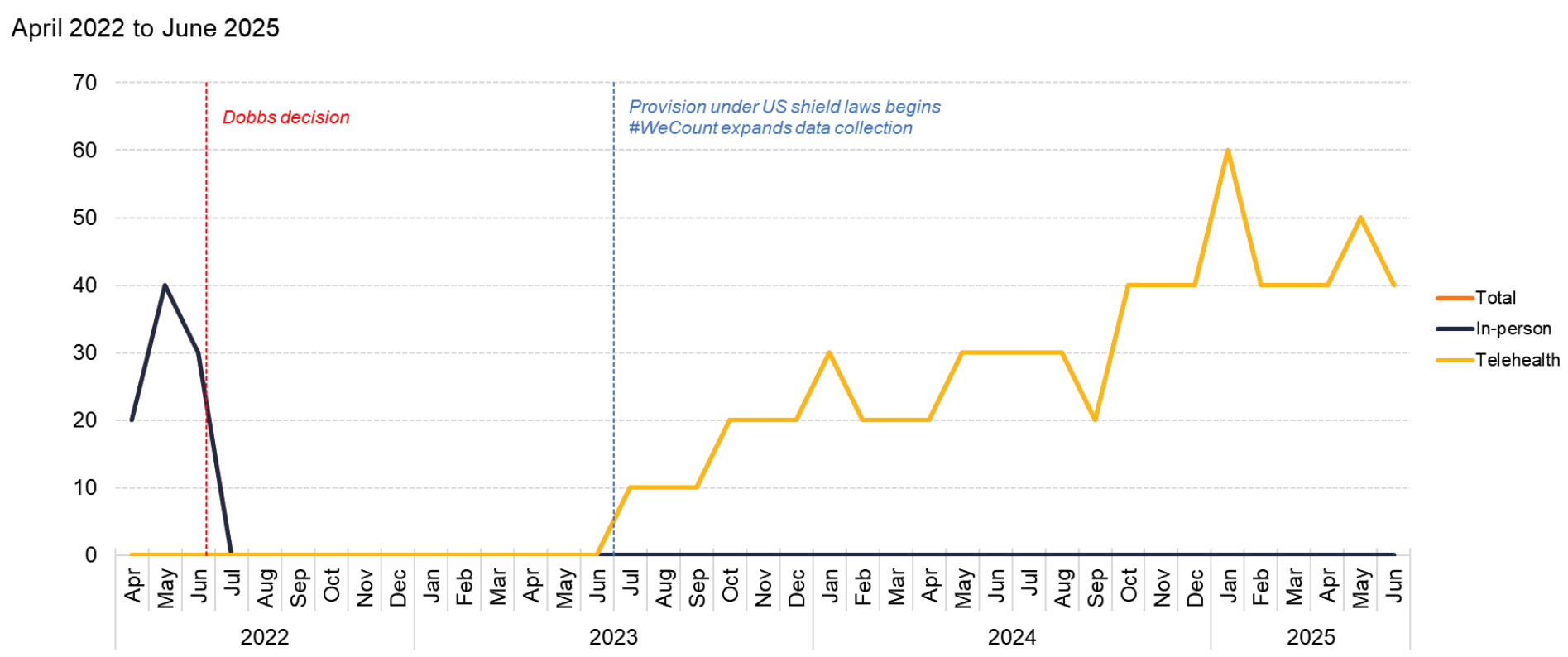
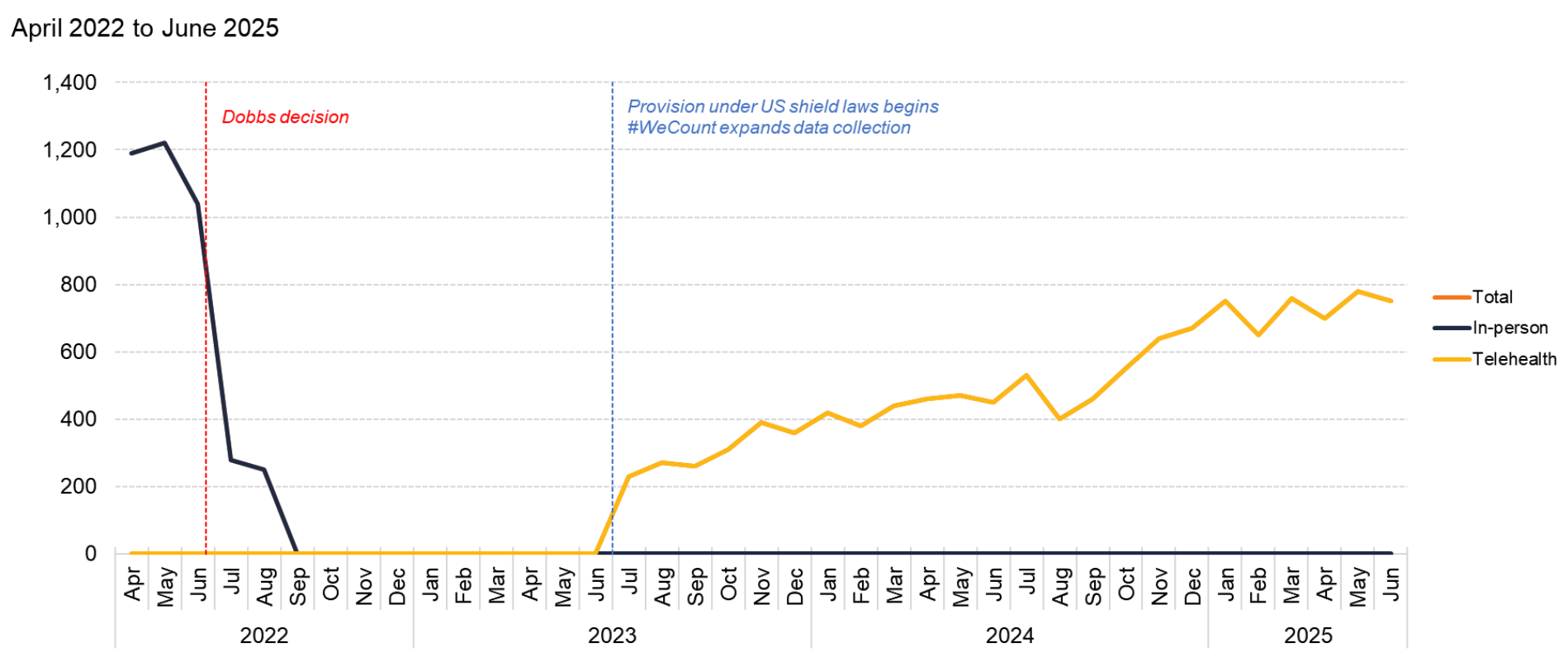
South Dakota



Source: Society of Family Planning, December 2025

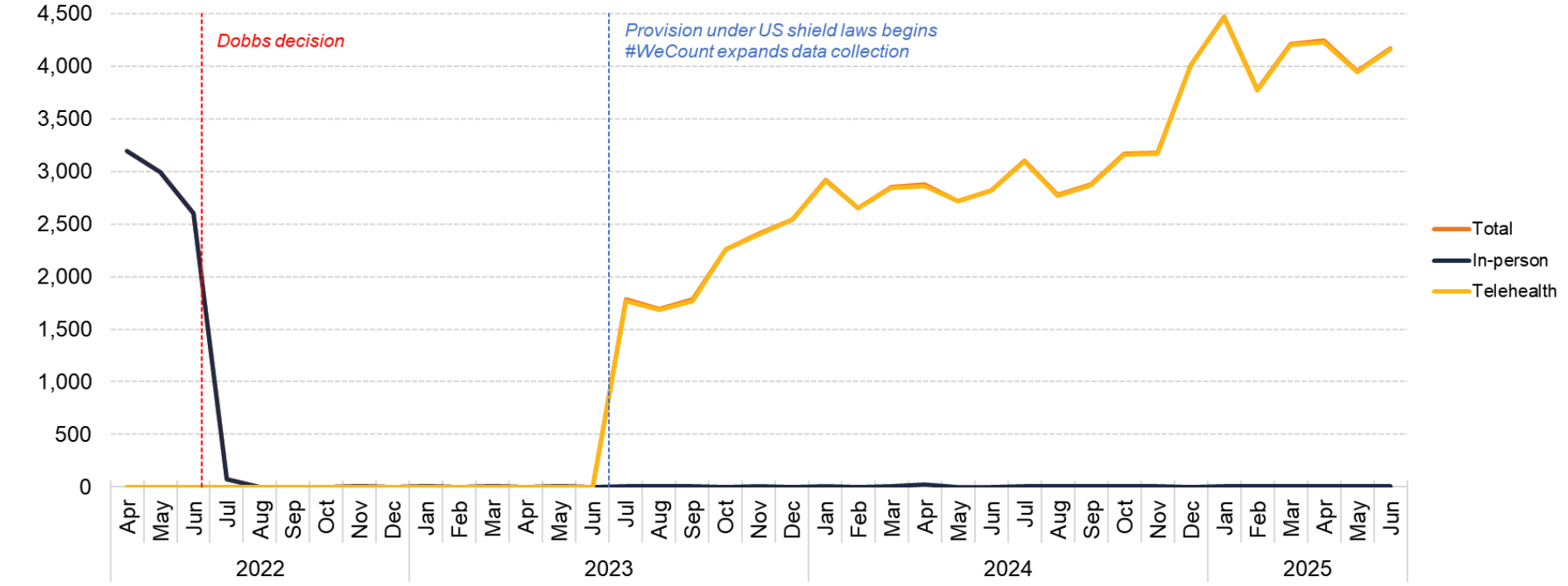
Tennessee



Source: Society of Family Planning, December 2025

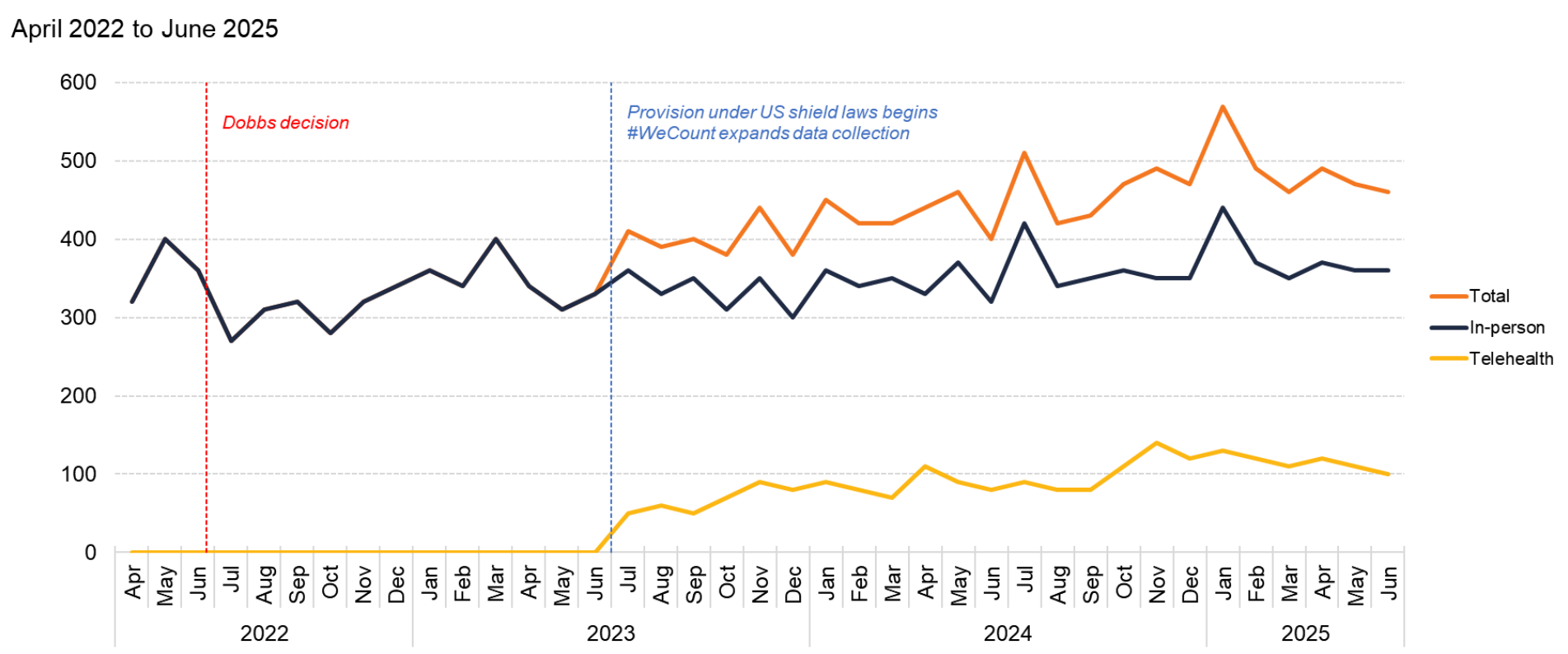
Texas

April 2022 to June 2025



Source: Society of Family Planning, December 2025

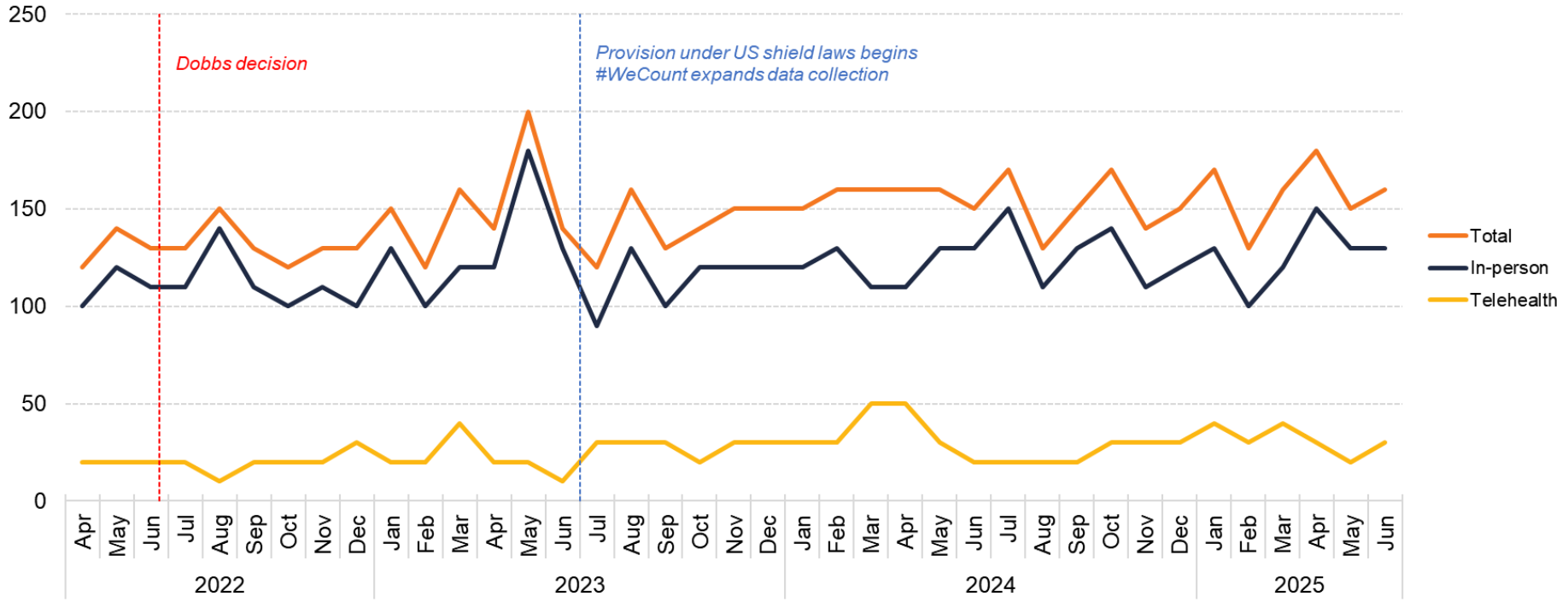
Utah



Source: Society of Family Planning, December 2025

Vermont

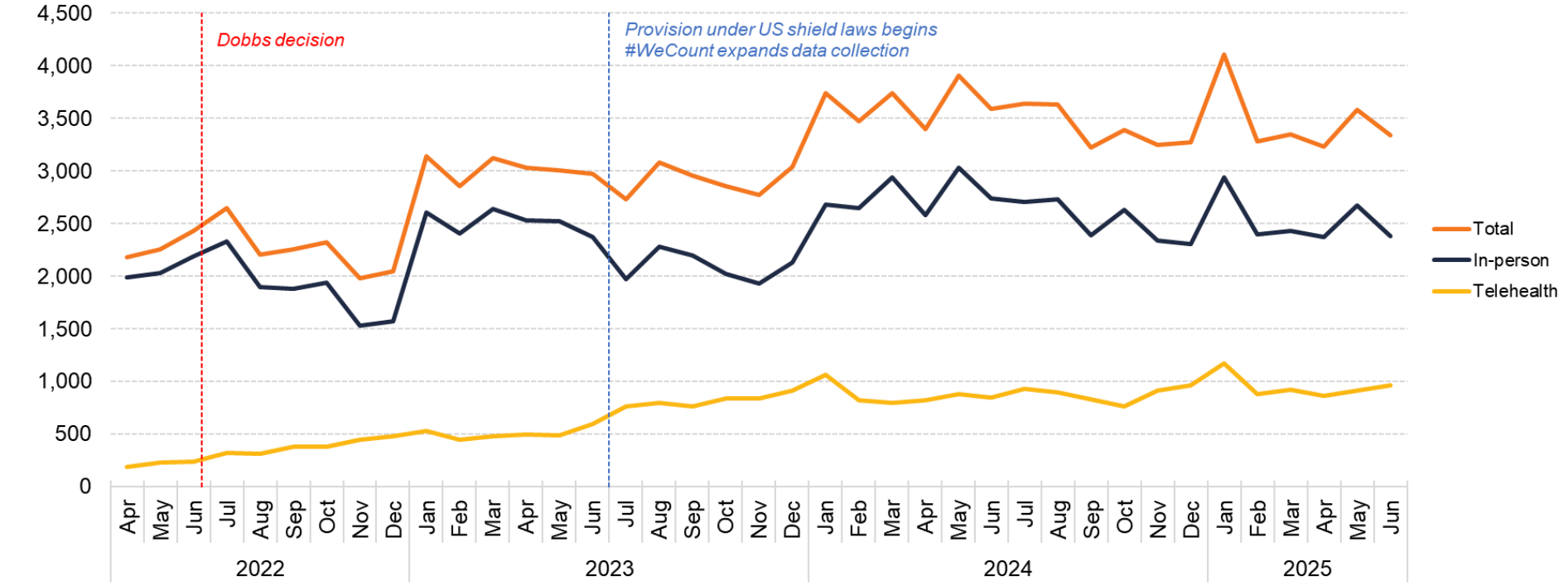
April 2022 to June 2025



Source: Society of Family Planning, December 2025

Virginia

April 2022 to June 2025



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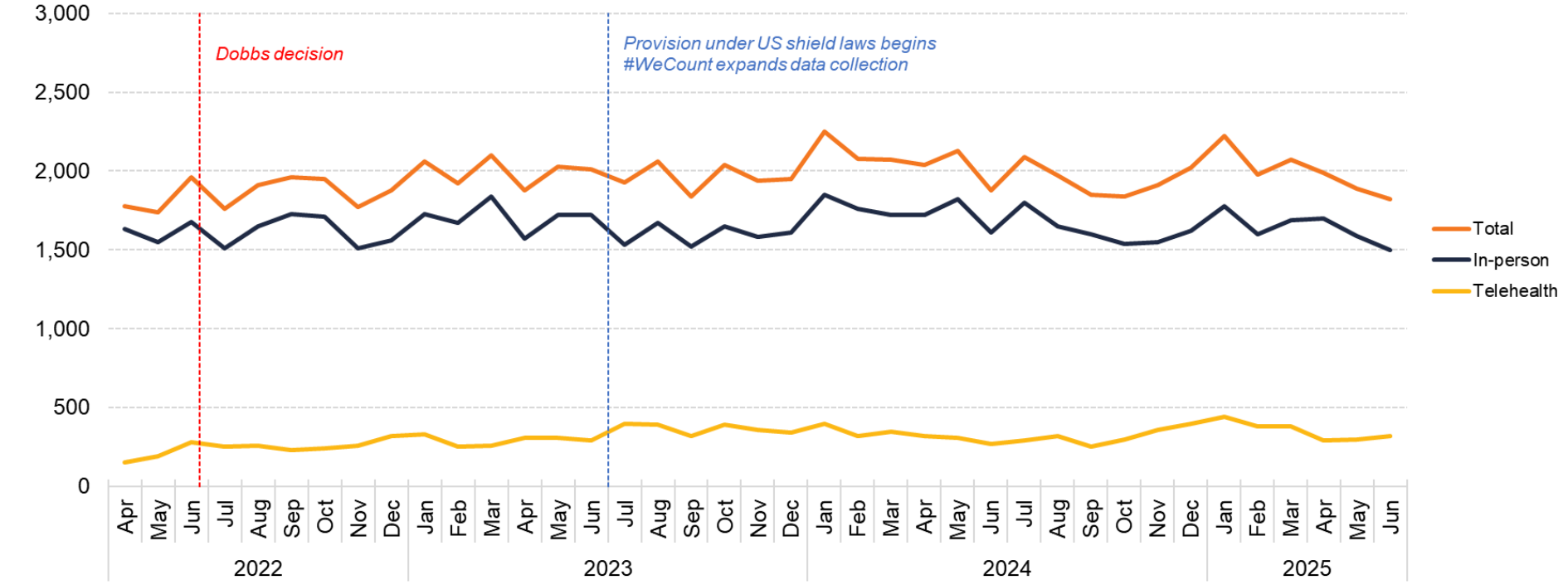
Washington

April 2022 to June 2025



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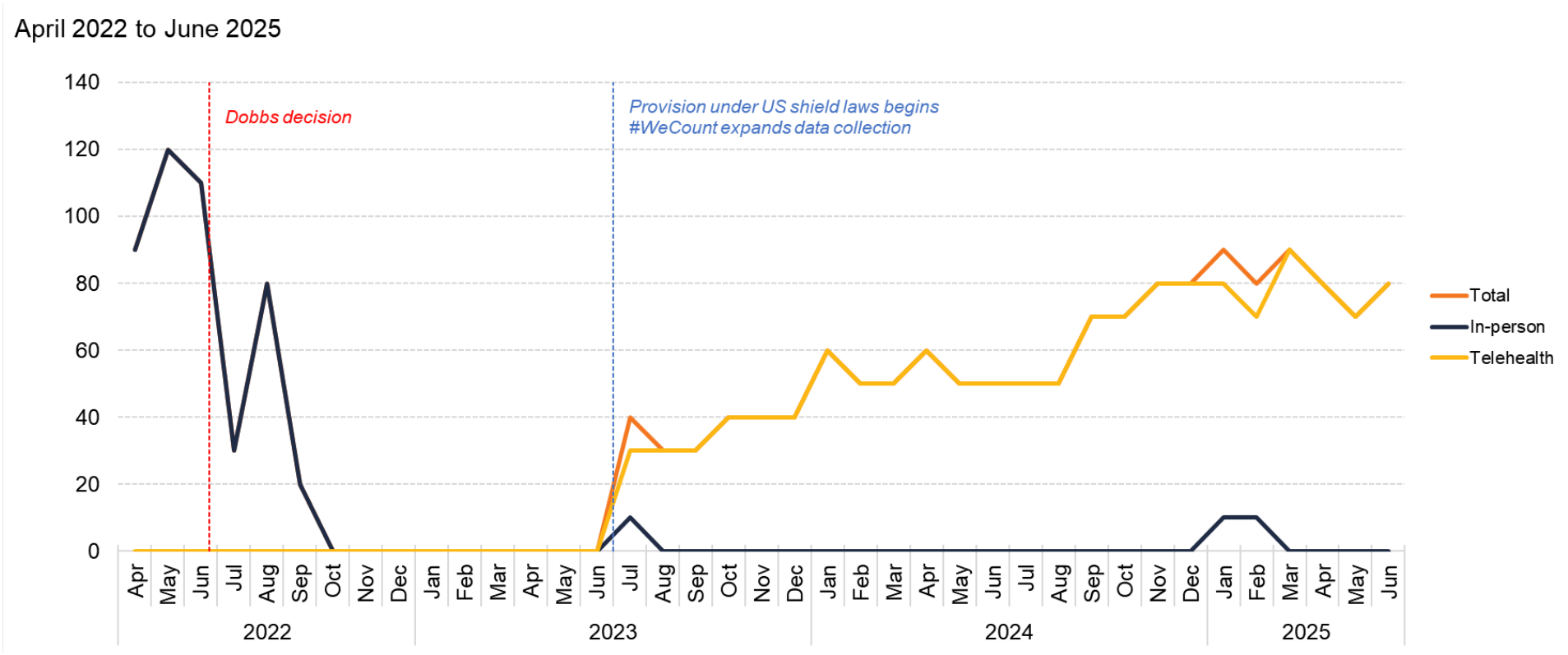
West Virginia



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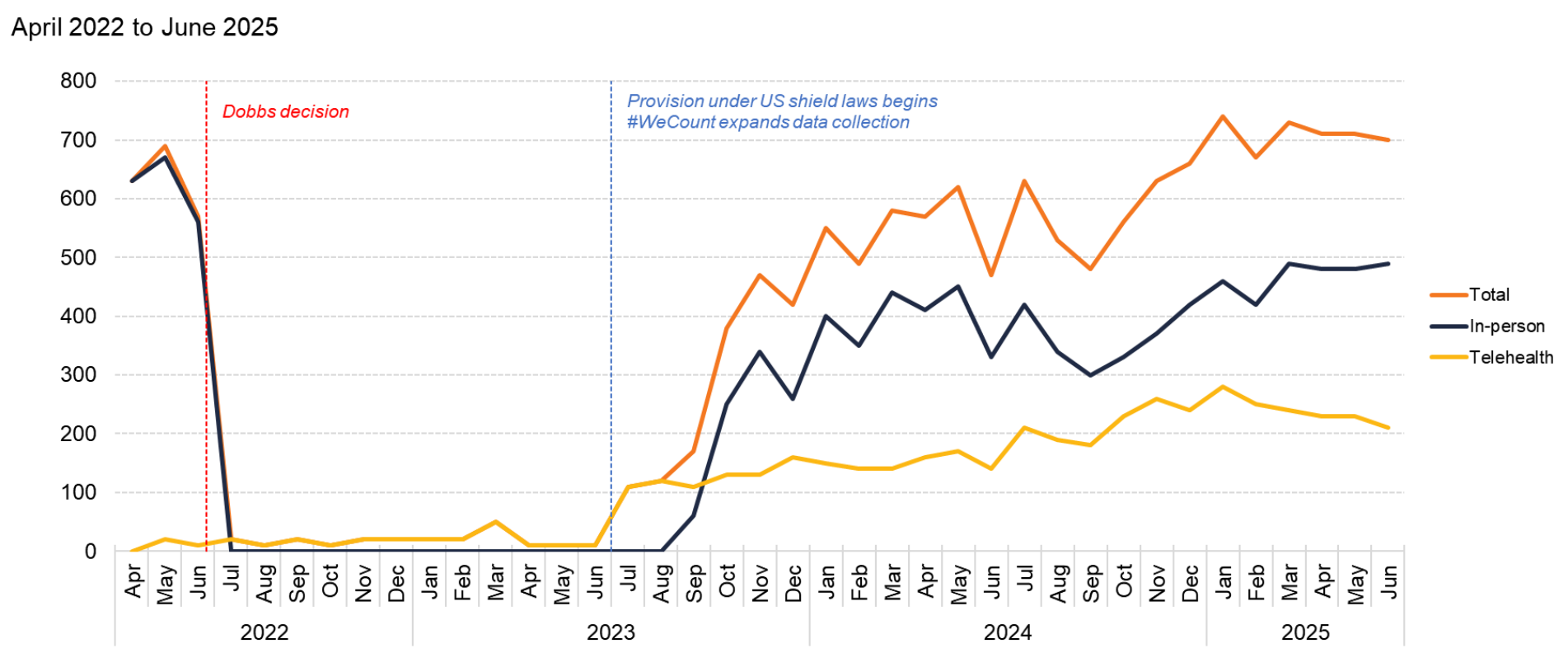
Wisconsin



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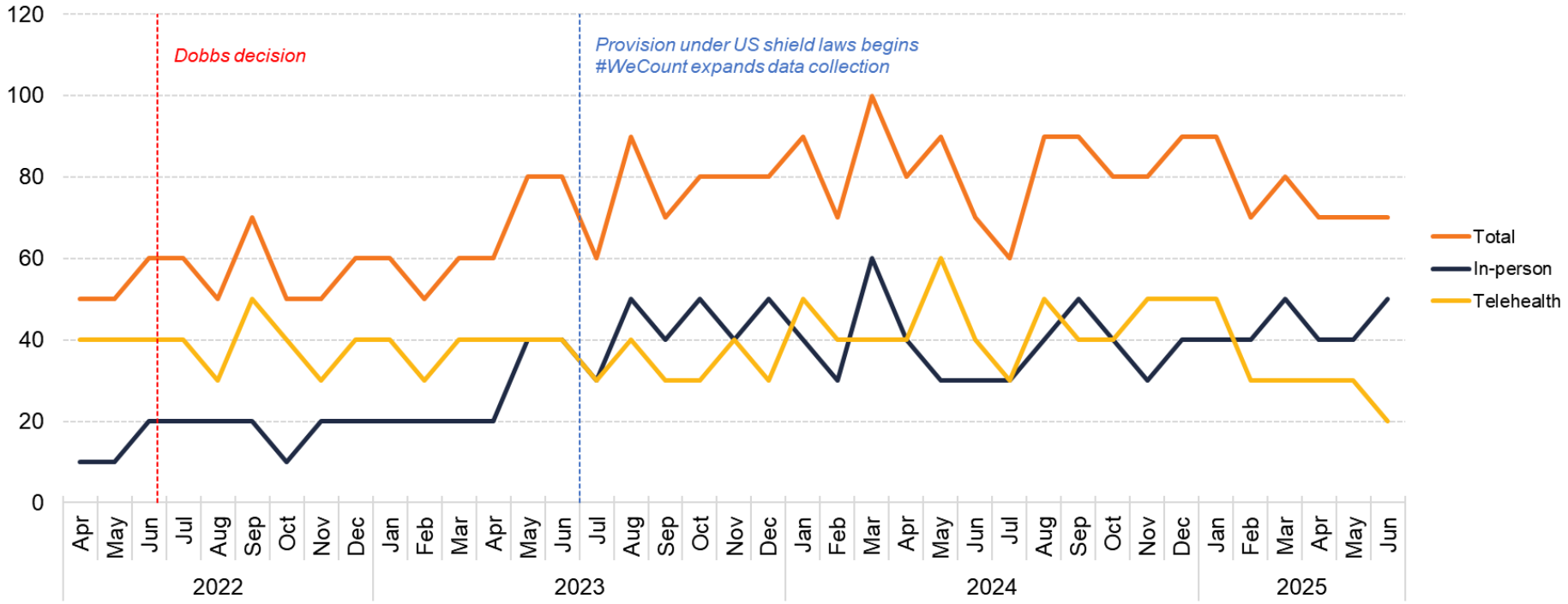
Wyoming

April 2022 to June 2025



Source: Society of Family Planning, December 2025

EXHIBIT 3

Abigail R. A. Aiken et al., Research Letter,
***Provision of Abortion Medications Using Online Asynchronous Telemedicine Under Shield Laws in the US*,**
334(15) JAMA 1388 (Oct. 21, 2025)

Letters

RESEARCH LETTER

Provision of Abortion Medications Using Online Asynchronous Telemedicine Under Shield Laws in the US

Despite the wave of state-level abortion bans following the overturn of *Roe v Wade*, recent data suggest that abortion rates have remained steady or even increased.[1] One plausible contributor is the rise of online asynchronous telemedicine abortion services—particularly those operating under shield laws, which allow US-licensed clinicians to provide abortion medications to patients in ban states with protection from legal liability.[2] To better understand usage of this care model, we analyzed 15 months of data from Aid Access, a nonprofit asynchronous telemedicine service that provides abortion medications to patients in all 50 states and the District of Columbia. Aid Access leverages shield laws to mail abortion medications to residents in 24 states with near-total or telemedicine bans, operating without the need for such protections in states where telemedicine abortion is legally accessible.[3]

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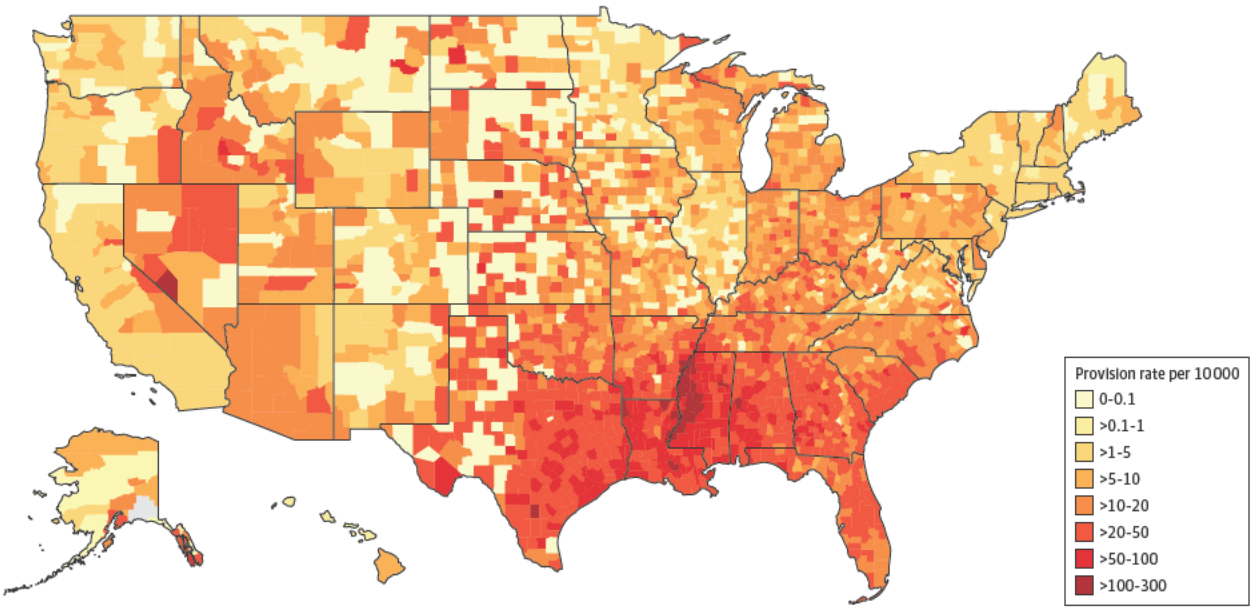
Supplemental content

Methods | During the study period, Aid Access was the only organization serving all states and offering a sliding-scale fee for patients experiencing financial hardship. Patients completed an online consultation reviewed by a US-licensed clinician, and if eligible, were provided with mifepristone and misoprostol, along with instructions and remote support.

We investigated how state abortion policy, travel distance, and poverty were associated with county-level provisions. State policies were classified as protective, telemedicine ban, or near-total ban (eAppendix in Supplement 1). Travel distance was measured from the population centroid of each county to the nearest abortion clinic[4]; poverty was measured as the percentage of residents living below the federal poverty line.[5] We calculated per capita provision rates and unadjusted rate ratios for each of these structural factors. To estimate adjusted rate ratios, we fit a bayesian negative-binomial regression model with fixed effects for policy, travel distance, poverty, and broadband access; state-level random effects; and a population offset. To avoid overadjustment and interpretive ambiguity, we did not include additional aggregate demographic variables. We used R version 4.3.1. All data were fully deidentified. (Patients provided consent for the anonymized use of their data for research purposes at the time of making a request to Aid Access.) The University of Texas at Austin Institutional Review Board approved the study.

Results | Between July 1, 2023, and September 30, 2024, Aid Access provided 118 338 medication abortion pill packs to

Figure. Geographic Variation in Aid Access Provision Rates of Abortion Medication via Telemedicine, July 1, 2023–September 30, 2024



County-level telemedicine abortion provision rates—defined as the number of medication abortion pill packs provided during the study period via online asynchronous telemedicine per 10 000 female residents aged 15 to 44 years—exhibit high geographic variability. The map shows provision rates across counties in the United States and the District of Columbia during the 15-month study period; darker shades indicate higher rates, with the highest concentrations in the South and Midwest, particularly in states with near-total bans.

Table. County-Level Provision Rates and Unadjusted and Adjusted Rate Ratios for Telemedicine Abortion Provision[a]

Variables	Provision rate per 10 000	Rate ratio	
		Unadjusted	Adjusted (95% posterior CrI)
State-level abortion policy			
Protective	5.7	1 [Reference]	1 [Reference]
Telemedicine ban	20.5	3.63	2.33 (1.57-3.38)
Near-total ban	41.3	7.31	3.12 (2.16-4.47)
Travel distance to nearest clinic, miles			
<50	10.1	1 [Reference]	1 [Reference]
50-99	15.9	1.58	1.03 (0.97-1.09)
100-250	25.6	2.53	1.18 (1.10-1.27)
>250	57.7	5.71	1.56 (1.36-1.79)
County residents living in poverty, %			
<5	5.3	1 [Reference]	1 [Reference]
5-9	10.4	1.95	1.47 (1.19-1.81)
10-20	20.3	3.8	1.63 (1.31-2.01)
>20	30.8	5.77	1.94 (1.55-2.42)
County households with ≥10 Mb/s broadband, %			
<60	19.4	1 [Reference]	1 [Reference]
≥60	17.8	0.92	1.19 (1.14-1.26)

Abbreviation: CrI, credible interval.

[a] Provision rates per 10 000 female residents aged 15 to 44 years, unadjusted rate ratios, and adjusted rate ratios were estimated from a negative binomial regression model of county-level telemedicine abortion provision, based on 118 338 abortions provided between July 1, 2023, and September 30, 2024, across 2649 US counties. The regression model includes state abortion policy, travel distance to the nearest clinic, county poverty level, broadband access, and state-level random effects, adjusting for county population via a log offset. Unadjusted rate ratios compare provision rates across categories without adjustment; adjusted rate ratios reflect associations after controlling for the other predictors in the regression model.

residents of 2649 US counties, of which 99 293 (84%) were in states with near-total or telemedicine bans (**Figure**). Unadjusted provision rates were higher in counties with more restrictive state policies, longer travel distances, greater poverty, and lower broadband access (**Table**). However, these structural factors were strongly correlated at the county level. The adjusted rate ratios in the Table reflect the association of each factor with provision rates, holding the other factors constant. After adjustment, provision rates were 3.12 times higher in near-total-ban states (95% posterior credible interval [CrI], 2.16-4.47), and 2.33 times higher in telemedicine-ban states (95% posterior CrI, 1.57-3.38) relative to protective states. Compared with counties within 50 miles of a clinic, provision rates were higher for counties 100 miles to 250 miles (rate ratio, 1.18; 95% posterior CrI, 1.10-1.27) and more than 250 miles (rate ratio, 1.56; 95% posterior CrI, 1.36-1.79) from a clinic. Provision rates also rose with poverty. Compared with counties with less than 5% poverty, counties with 5% to 9% poverty had 1.47 times higher provision rates (95% posterior CrI, 1.19-1.81); those with 10% to 20% poverty, 1.63 times higher provision rates (95% posterior CrI, 1.31-2.01); and those with higher than 20% poverty, 1.94 times higher provision rates (95% posterior CrI, 1.55-2.42). Counties with 60% or higher broadband access had 19% higher provision rates (rate ratio, 1.19; 95% posterior CrI, 1.14-1.26).

Discussion | Asynchronous online telemedicine abortion is widely used in the US. Provision under shield laws is strongly associated with structural barriers to in-clinic care—but even in states where abortion is protected and shield law protections are not required, telemedicine usage remains associated with distance and cost barriers. These findings underscore the public health importance of telemedicine, both as an alternative to the unsafe abortion methods that prevailed under abortion bans before *Roe v Wade*[6] and as a means of reducing access disparities.

Our analysis is limited by reliance on county-level rather than individual-level associations and by data that measure provision of abortion medications rather than completed abortions. Moreover, it does not capture the full scope of telemedicine in states without bans, where other abortion providers also operated during the study period.

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Author Contributions: Dr Aiken had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: All authors.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Aiken.
Critical review of the manuscript for important intellectual content: All authors.
Statistical analysis: Scott.
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Administrative, technical, or material support: Gomperts.

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Disclaimer: All authors agree to be accountable for all aspects of the work.

Data Sharing Statement: See Supplement 2.

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CLIMATE CHANGE AND HEALTH

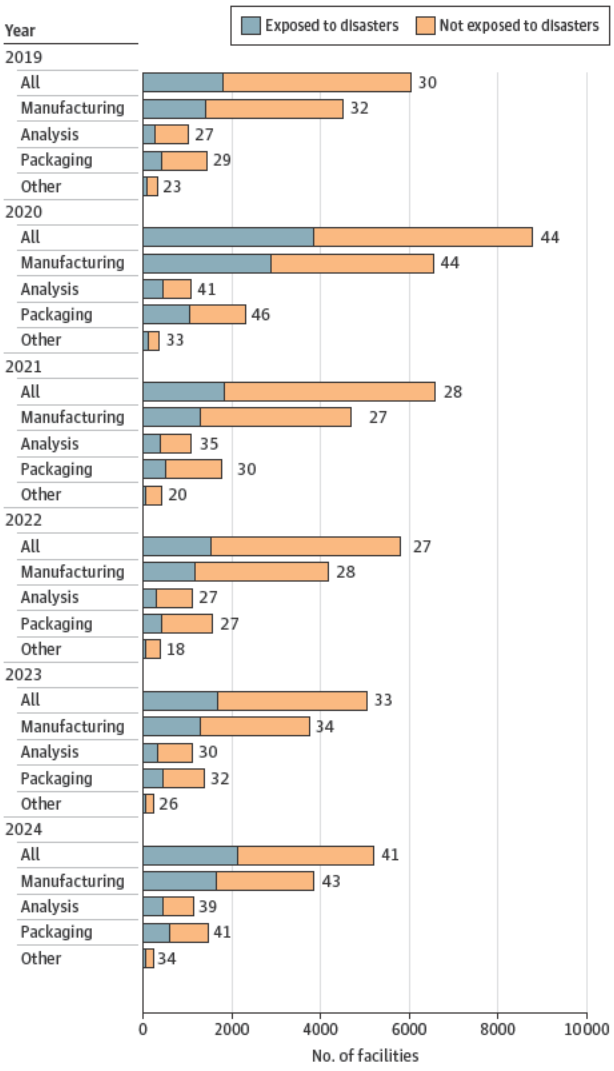
Threats of Weather Disasters for Drug Manufacturing Facilities in the US

In September 2024, Hurricane Helene triggered a nationwide shortage after hitting a Baxter facility in North Carolina that produces 60% of the country's intravenous (IV) fluids.[1] A similar IV shortage was caused when Hurricane Maria hit Puerto Rico in 2017. Climate change–driven extreme weather events impose new threats to established vulnerabilities in the US drug supply.[2] Those threats must be examined to be appropriately mitigated, especially in light of the current administration's recent executive order and policy proposals seeking to increase domestic pharmaceutical production.[3] This study assessed the frequency with which climate-related disaster events affected counties with US drug production facilities.

Supplemental content

Methods | We used archived versions of the US Food and Drug Administration (FDA) Drug Establishments Current Registration Site to identify all US-based drug production facilities that manufacture, prepare, propagate, compound, or process drugs distributed in the US from 2019-2024 (see eMethods in the Supplement). Counties with a Presidential Disaster Declaration from 2019 through 2024 were identified from the Federal Emergency Management Agency (FEMA) disaster declaration database. We included climate-related disaster events: fires, hurricanes, storms, tornadoes, and floods.[4] We calculated the number of facilities that were in counties impacted by disasters, by type of production activity and by type of disaster over time. We used logistic regression to calculate the relative odds of disaster impact, by whether a county had drug production facilities, with year fixed effects and errors clustered at the county level. We followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline, and the Harvard Pilgrim Health Care Institute's institutional review board determined the study to be nonhuman subjects research.

Figure 1. Number and Proportion of Drug Production Facilities in US Counties With at Least One Disaster Declaration



Manufacturing activities include facilities that list manufacture, active pharmaceutical ingredient manufacture, or positron emission tomography drug production in their list of activities. Analysis activities include facilities that analyze raw materials, active pharmaceutical ingredients, inactive ingredients, and the finished drug product. Packaging activities include facilities that pack, repack, or relabel. Other activities include facilities that list transfill, sterilize, particle size reduction, salvage, or distribution as their activities. "Exposed facilities" refers to facilities located in counties with at least one disaster declaration in a given year. Numbers next to the the bars represent percentages of facilities exposed to disasters

Results | There were 10 861 drug production facilities active from 2019 through 2024, ranging from 5063 in 2023 to 8790 in 2020, when 3860 facilities (43.9%) were in counties with at least one disaster declaration. Cumulatively, in the 6-year period, there were 6819 active facilities (62.8%) in counties when a disaster was declared, an average of 2146 active facilities (33.8%) annually over the study period (**Figure 1**). Facilities with all

EXHIBIT 4

Robin Wallace et al, *P040 - Expanding Access to Abortion with Mifepristone and Misoprostol Through 84 Days Estimated Gestational Duration*, 151 Contraception 111117 (Nov. 2025)

Results: Higher perceived abortion stigma predicted greater symptoms of depression, anxiety, and social anxiety. Social support moderated the associations between abortion stigma and symptoms of anxiety and social anxiety. Specifically, such stigma was positively associated with social anxiety symptoms at all levels of partner support (ie, low, moderate, high), but was strongest for those with low partner support. Additionally, perceived abortion stigma was positively associated with symptoms of anxiety and social anxiety for people with moderate and high maternal support (but not low). Abortion disclosure did not moderate the associations between this stigma and mental health symptoms.
Conclusions: This study adds to the emerging literature on perceived abortion stigma and mental health, and findings suggest that the effect of social support on this association may vary based on source.

https://doi.org/10.1016/j.contraception.2025.111116

P040

EXPANDING ACCESS TO ABORTION WITH MIFEPRISTONE AND MISOPROSTOL THROUGH 84 DAYS ESTIMATED GESTATIONAL DURATION

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S Diemert, O Ades-Lawlor, R Topp, H Simons

Objectives: We aimed to assess efficacy and safety of a combined medication abortion regimen, using mifepristone and repeat buccal misoprostol dosing, for patients seeking abortion at 78-84 days estimated gestational duration in an outpatient setting in the US.
Methods: We are conducting a secondary analysis of data from 14 US-based Planned Parenthood affiliates that provided medication abortion for eligible patients with an estimated gestational duration of 78-84 days from April 2024 to December 2024, with additional data through March 2025 expected. Affiliates reported the total number of patients receiving medication abortion at this gestational duration (n = 711) and available outcome data. Among medication abortions with known outcomes (n = 217), we will calculate the incidence rates and 95% confidence intervals for completed abortion, ongoing pregnancy, subsequent procedure, and emergency department or hospital visits associated with medication abortion.
Results: Out of 217 known outcomes of the 711 total medication abortions provided at 78-84 days estimated gestational duration, preliminary raw data includes 27 ongoing pregnancies, 22 aspirations performed for ongoing pregnancies, 10 aspirations performed for other reasons, and 21 visits to an emergency department or hospital.
Conclusions: Use of medication abortion at 78-84 days estimated gestational duration in our study's US-based outpatient health centers resulted in similarly low ongoing pregnancy and need for aspiration as shown by prior research conducted in international inpatient settings. Offering medication abortion with a combined regimen, including mifepristone followed 24-48 hours later by buccal misoprostol every four hours for 2-3 doses, may increase access to safe, effective abortion beyond 77 days of pregnancy.

https://doi.org/10.1016/j.contraception.2025.111117

P042

THE ROLE OF ABORTION RESTRICTIONS IN COUNSELING AT FETAL CARE CENTERS

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Objectives: Fetal care centers (FCCs) or hospital-based institutions focused on the diagnosis and management of congenital anomalies have increased over the past decade, but little is known about their abortion care practices including eliciting interest, counseling, and referrals, or how these practices are influenced by institutional or state policies on abortion care.
Methods: We conducted a cross-sectional study across US North American Fetal Therapy Network (NAFTNet) sites, including FCCs in states or institutions with restrictive and permissive abortion policies, as defined by the Guttmacher Institute. Providers were recruited via snowball sampling, and surveys were distributed electronically through REDCap. Semi-structured key interviews were performed among a subgroup of NAFTnet site representatives. Interviews were audio-recorded, transcribed and analyzed using grounded theory, with quantitative data summarized statistically.
Results: Twenty-three providers (3 pediatric surgeons, 20 maternal-fetal medicine (MFM) subspecialists) completed the survey, and 12 providers (1 pediatric surgeon, 11 MFMs) expressed interest in the interview. Among those interviewed, the majority were female (58.3%) and worked at FCCs located in settings with restrictive or partly permissive abortion policies (58.3%). Key themes from interviews by providers located in permissive settings included ease and comfort in abortion counseling, while providers located in hospital systems or states with restrictive abortion policies emphasized counseling practices based on institutional or state restrictions and conscientious provision.
Conclusions: Providers working at FCCs face unique issues in eliciting interest in and counseling about abortion care, which diverge based on institutional and state restrictions. Future research should investigate patient experiences of abortion care after consultation at an FCC.

https://doi.org/10.1016/j.contraception.2025.111118

P043

TRENDS IN MISOPROSTOL PRESCRIBING AND DISPENSING ACROSS NORTH CAROLINA PHARMACIES

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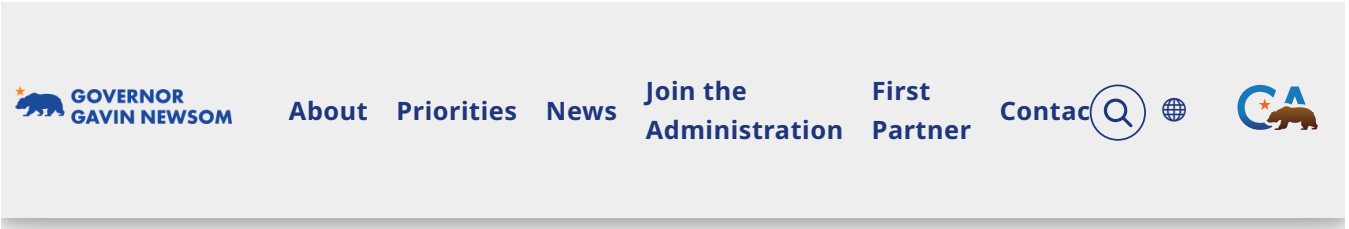
Objectives: The aim of this study is to assess misoprostol dispensing practices across North Carolina pharmacies. We sought to identify trends in misoprostol dispensing in low access healthcare counties, rural counties, and by pharmacy type.
Methods: We used a secret-shopper approach to assess whether pharmacies dispense misoprostol. The secret-shopper called in the role of clinic staff. Chi-squared tests and Fisher's exact tests were used for statistical analysis.
Results: Of the 100 counties in North Carolina, 94 (94%) counties were contacted. Ninety-nine (99%) counties had a chain pharmacy represented and 95 (95%) had an independent pharmacy represented. Some 173 (77.6%) pharmacies dispensed misoprostol, 12 (5.4%) had conditional dispensing practices, and 38 (17.0%) did not

EXHIBIT 5

Governor Newsom Signs New Landmark Laws to Protect Reproductive Freedom, Patient Privacy Amid Trump's War on Women,
Gov. Gavin Newsom (Sep. 26, 2025)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Sep 26, 2025

Governor Newsom signs new landmark laws to protect reproductive freedom, patient privacy amid Trump's war on women

What you need to know: Governor Newsom signed a series of bills, including AB 260 and AB 1525, to safeguard access to reproductive health care.

SACRAMENTO – In a significant effort to advance reproductive freedom, Governor Gavin Newsom today signed legislation to protect access to essential reproductive care and help shield health care providers, patients, and lawyers from adverse legal action.

Governor Newsom signed AB 260 (Cecilia Aguiar-Curry), offering health care providers the option to prescribe abortion care medication to patients anonymously, ensuring California-regulated health plans cover mifepristone regardless of FDA approval status, and strengthening protections for health care providers from criminal prosecution and other legal action for administering medication abortion drugs.

The Governor also signed AB 1525 (Committee on Judiciary), helping to shield attorneys assisting other states with access to reproductive care from State Bar discipline.

> *"California stands for a woman's right to choose. I'm proud to sign these bills to protect access to essential health care and shield patients and health care providers in the face of amplified attacks on the fundamental right to reproductive freedom."*
>
> Governor Gavin Newsom

"With the Governor's signature on AB 260, California will continue to be a national leader in protecting reproductive and privacy rights," **said Assembly Majority Leader and Legislative Women's Caucus Chair Cecilia Aguiar-Curry.** "I appreciate the partnership with the Administration as we fight for the sanctity of the patient-health professional relationship, and the safety of Californians and their health providers."

"Today, even in California, access to abortion and

reproductive health care hangs in the balance. President Trump's Administration and Republican members of Congress continue to attack reproductive health care access on all fronts, including ongoing threats to medication abortion and already successfully defunding all 109 Planned Parenthood health centers in California. And we know they won't stop there," **said Planned Parenthood Affiliates of California CEO and President Jodi Hicks.** "As Planned Parenthood fights to keep health centers open to provide the reproductive health care so many Californians rely on, Planned Parenthood Affiliates of California is grateful to the Governor for signing Assemblymember Aguiar-Curry's bill, AB 260. This significant policy will help safeguard access to medication abortion for many Californians and protect the ability of our state's abortion providers to continue providing this life-saving care."

Other bills the governor signed today include:

- **Assembly Bill 45** by Rebecca Bauer-Kahan (D-Orinda) – Privacy: health data: location and research.
- **Assembly Bill 50** by Mia Bonta (D-Oakland) – Pharmacists: furnishing contraceptives.

California's actions to protect reproductive freedoms

In the years since the Supreme Court's Dobbs v. Jackson decision, California has stepped up consistently to protect reproductive freedom, including:

- June 2025: The 25-26 budget expanded the authority of CalRx to purchase brand-name drugs. This change gives the state more tools to respond to supply chain disruptions, market manipulation, or politically motivated restrictions that could

threaten access to essential medications — including medication used for abortion care.

- May 2024: Governor Newsom signed SB 233 with the Legislative Women's Caucus, allowing Arizona abortion providers to temporarily provide abortion care to patients from Arizona who travel to California for care following the Arizona Supreme Court's ruling to reimpose a regressive 1864 law imposing a near-total abortion ban in their state.
- January 2024: The Reproductive Freedom Alliance, led by Governor Newsom, **filed an amicus curiae brief** with the U.S. Supreme Court in the case of Food and Drug Administration, et al., v. Alliance for Hippocratic Medicine, arguing that, if the Court allowed the Fifth Circuit's decision rejecting FDA's approval of mifepristone to stand, it would undermine Governors' ability to provide adequate healthcare services and would have far-reaching implications beyond reproductive healthcare. The Supreme Court sided with the FDA in June 2024.
- April 2023: Governor Newsom procured an **emergency stockpile of Misoprostol,** a **safe and effective medication abortion** drug, as legal challenges continue to move through the courts in an attempt to block abortion medication.
- March 2023: Governor Newsom joined 13 other Governors in calling on **major pharmacies to clarify plans for** dispensing Mifepristone and other actions they plan to take to safeguard access to reproductive health care drugs.
- February 2023: Governor Newsom launched the **Reproductive Freedom Alliance**, a coalition of 23 Governors fighting together to protect and advance reproductive freedom.
- November 2022: Voters pass Governor Newsom

and the Legislature's **Proposition 1**, an amendment to the state constitution to enshrine the right to reproductive freedom – including abortion care and contraception.

- September 2022:
  - Governor Newsom **launched Abortion.CA.Gov** to ensure people across California, and the country, can access essential information regarding reproductive health care, including resources available to support access to care.
  - Governor Newsom, working with the Legislature, ensured California passed **the largest reproductive freedom bill package** in state history, building firewalls around California as a reproductive freedom state.

- June 2022:
  - Governor Newsom signed legislation to help **protect patients and providers** in California against radical attempts by other states to extend their anti-abortion laws into California, on the same day Roe v. Wade was overturned.
  - California invested over **$200 million in reproductive health care**.
  - Issued an **Executive Order** protecting state-held data and information from being used by out-of-state anti-abortion entities to target providers and patients.
  - Joined the Governors of Oregon and Washington to **launch a new Multi-State Commitment** to defend access to reproductive health care and protect patients and providers.

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EXHIBIT 6

US FDA Has Delayed Abortion Pill Safety Study,
Bloomberg News Reports,
Reuters (Dec. 8, 2025, at 14:23 PT)

US FDA has delayed abortion pill safety study, Bloomberg News reports

By **Reuters**

December 8, 2025 2:23 PM PST · Updated December 8, 2025

Signage is seen outside of the Food and Drug Administration (FDA) headquarters in White Oak, Maryland, U.S., August 29, 2020. REUTERS/Andrew Kelly/File Photo Purchase Licensing Rights

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Dec 8 (Reuters) - The U.S. Food and Drug Administration has delayed a review of safety data for the abortion drug mifepristone at Commissioner Marty Makary's request, Bloomberg News reported on Monday, citing people familiar with the matter.

Makary has told agency officials to delay the safety review until after the midterm elections, the report said.

"The FDA's comprehensive scientific reviews take the time necessary to get the science right and that's what Dr. Makary is ensuring," Department of Health and Human Services spokesperson Andrew Nixon said.

U.S. Health Secretary Robert F. Kennedy Jr. had said earlier this year that the review of mifepristone is ongoing.

Mifepristone is the first pill, followed by the drug misoprostol, for medication abortion in the first 10 weeks of pregnancy, and won FDA approval in 2000.

Reporting by Mariam Sunny and Sahil Pandey in Bengaluru; Editing by Maju Samuel

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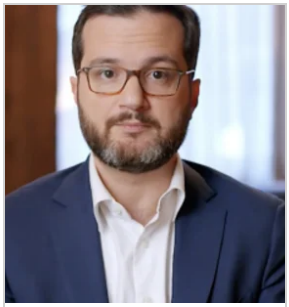

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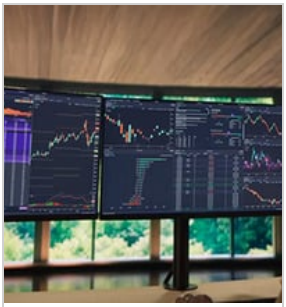

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Business · December 12, 2025 · 9:17 PM PST · 17 mins ago

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EXHIBIT 7

Elizabeth Troutman Mitchell, *EXCLUSIVE: Makary Responds to Report Saying He Slow-Walked Abortion Pill Safety Review*, Daily Signal (Dec. 9, 2025)

HEALTH CARE NEWS

EXCLUSIVE: Makary Responds to Report Saying He Slow-Walked Abortion Pill Safety Review

Elizabeth Troutman Mitchell December 09, 2025

Elizabeth Troutman Mitchell @TheElizMitchell

Elizabeth Troutman Mitchell is the White House Correspondent for "The Daily Signal." Send her an email.

FIRST ON THE DAILY SIGNAL—Food and Drug Administration Commissioner Dr. Marty Makary said the review of the abortion drug mifepristone is in the “data acquisition phase” following a report saying he is delaying the process.

“We do an ongoing review, but we’re also engaging in a robust study that can serve to validate or not validate other numbers that have been put out there in the literature,” he told The Daily Signal in an exclusive interview.

Makary and Secretary of Health and Human Services Robert F. Kennedy Jr. have pledged to do a review of the safety of abortion drugs following a study from the

Ethics and Public Policy Center, which showed 11% of women experience adverse effects after taking the pill regimen. Bloomberg reported that Makary is slow-walking the review, prompting calls from leading pro-life groups for him to be removed from his post.

Makary said he is personally responsible for the review.

”Ultimately, I’m responsible, and so this analysis is going to be done under my auspices, and it’ll be reported up to me,” he said, “and I’m going to be involved.”

The FDA is currently in the “data acquisition phase” of the abortion pill review.

“Appropriately, many members of Congress have said, ‘Hey, this is a good time to check in and do a robust study.’ So, part of a robust study is data acquisition,” he said. “And so, we’re in that data acquisition phase to get the right data to be able to do this study.”

Makary said he is unable to predict the “results or the timeframe” of the review.

“The shutdown was a little bit of a setback in that, but we’re gonna do it and whenever the results are available,” he said, “we’re gonna make them public.”

He laid out the plan for the review. Once the data has finished coming in, the FDA will review it and ensure there are no missing data fields that change the way the analysis is designed.

“If there are, then you change the design of the study and you account for how the landscape of the data actually is and the way it presents,” he said. “And then you look at the preliminary exploratory results, and then you change the analysis to account for confounding variables.”

Next, the FDA will “repeat and validate.”

“These are all routine steps in robust data analysis,” he said. “Studies are often repeated, done by multiple reviewers or statisticians. So, we’re going to do it the right way. And look, I know there are a lot of voices in this space, but I’m committed to doing this the right way.”

The former Johns Hopkins professor blamed the rumor mill for Bloomberg’s story saying he has slow-walked the mifepristone review.

“There’s a lot of rumors that are circulating out there,” he said. “We live in a very partisan time, and so you’re going to see the echo chambers of social media sort of magnify rumors, things that are just not true. There has been an ongoing review of mifepristone.”

The Risk Evaluation & Mitigation Strategies, or REMS, policy already requires the FDA to perform an ongoing review of medication, Makary said.

“There’s always an ongoing review of that medication, and we need to be open to the fact that maybe there’s a new drug interaction that was not appreciated,” he said.

Makary said it’s possible “there’s a complication that was not recognized previously” with the abortion pill. What the FDA finds in the study will join the “broader discussion nationally,” he said.

“We’re not going to decide what the results are before we’ve done the study,” he said. “We’re doing the study the right way. And when you do the study the right way, and I’ve done dozens of these studies as a Johns Hopkins professor, you gotta do the studies in data the right way with the right pace.”

The Ethics & Public Police Center study found that about 11% of women experience sepsis, infection, hemorrhaging, or another serious adverse event within 45 days following a mifepristone abortion. This has led to calls to reinstate the in-person dispensing requirement for mifepristone.

In April 2021, the Biden administration’s FDA stopped requiring that abortion drugs be dispensed to women in person, which allowed women to receive them through telehealth appointments and by mail. The FDA has not enforced the in-person dispensing requirement ever since.

Seven out of 10 American voters say they don’t think it’s safe for abortion drugs to be sent via mail, according to a McLaughlin & Associates poll.

When asked by The Daily Signal if it’s safe for women to take the abortion pill at home without seeing a doctor first, Makary said the Ethics & Public Police Center study “was done in claims data, so it didn’t have granularity into the patient characteristics in a way that many researchers would want to have.”

“Tha reasons why we are doing a bigger, more robust study,” he said.

EPPC abortion pill study authors, Ryan T. Anderson and Jamie Bryan Hall, responded that the study they conducted was "the biggest and most robust study conducted thus far—much more so than the studies the FDA has previously relied on—and we are confident that the FDA will find similar results to ours using real-world data."

"However, the FDA need not complete that study to reinstate the in-person doctor visit. We already have seen women coercively poisoned by boyfriends to kill their unborn babies," they told The Daily Signal. "This couldn't happen if the FDA once again required in-person doctor visits as they did during the first Trump administration."

The FDA approved a second generic version of the abortion pill on Oct. 2, shortly before the government shutdown, another move that sparked pro-life backlash. Makary said the FDA had to approve the drug or get sued.

"There's a law that requires the FDA to approve a molecule if it's similar to a branded molecule, so we had no discretion," Makary told The Daily Signal. "If we chose to look at that application and say, no, we're not going to approve this, we'd 100% get sued, and we'd 100% lose."

"It would all happen very quickly because the law is very clear now with drugs that we approve as new branded drugs," he said. "It's a very different law. So we have discretion to weigh risks and benefits. But when it comes to generic compounds, the law is pretty clear."

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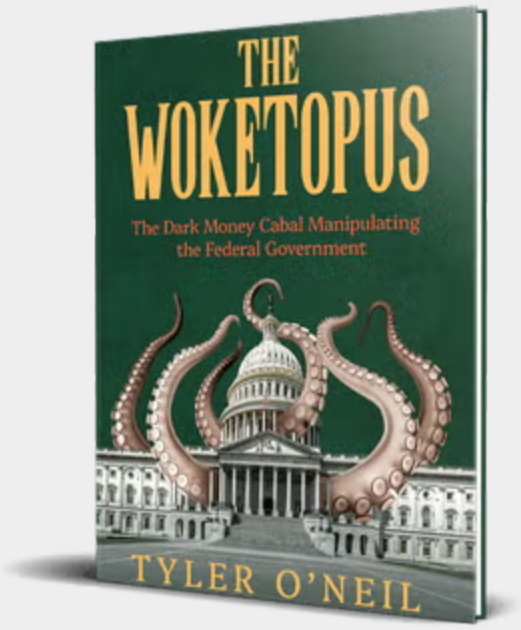

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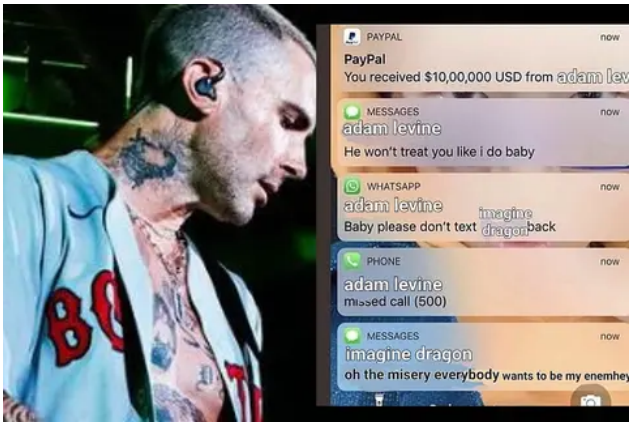

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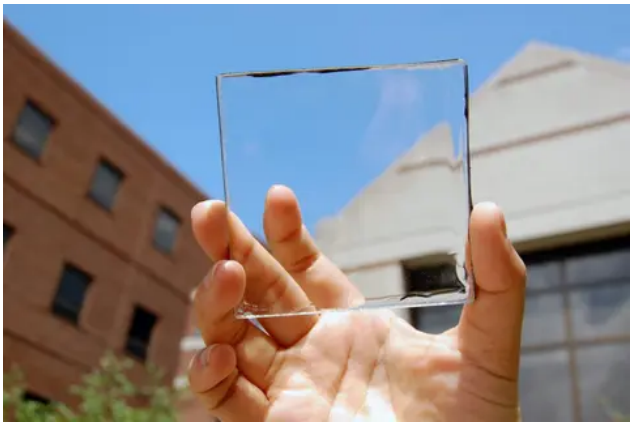

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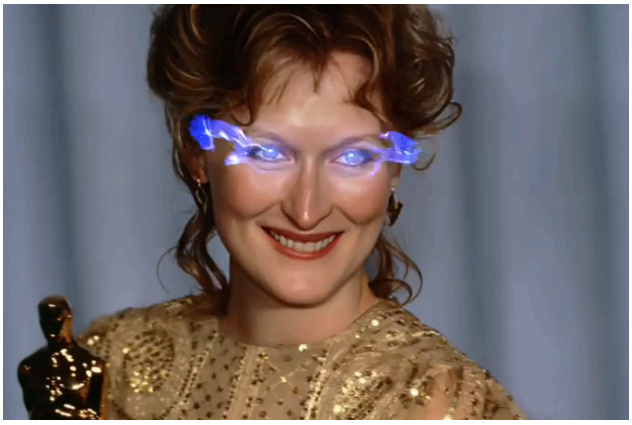

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EXHIBIT 8

Ian Lopez, *RFK Jr. Says Biden 'Twisted the Data' on Abortion Pill Safety*, BL (Sep. 4, 2025, at 12:45 ET)

RFK Jr. Says Biden 'Twisted the Data' on Abortion Pill Safety

Sept. 4, 2025, 12:45 PM EDT

US Health Secretary Robert F. Kennedy Jr. is accusing the Biden administration of having "twisted the data" on safety of the abortion drug mifepristone.

The Department of Health and Human Services chief told lawmakers at a Senate Finance Committee hearing Thursday that the Trump administration is committed to reviewing mifepristone safety and keeping politics out of his approach.

In May, Kennedy ordered Food and Drug Administration Commissioner Marty Makary to review mifepristone, prompting a request by Sen. James Lankford (R-Okla.) at Thursday's hearing for an update on the timing for the review.

Kennedy said he couldn't provide an exact timeline, though noted he spoke with Makary on Wednesday and that the HHS is frequently getting new data on the drug to review.

"We're getting data in all the time, new data on that, we're reviewing," Kennedy said. "We know that during the Biden administration, they actually twisted the data, to bury one of the safety signals, a very high safety signal, around 11%, so we're going to make sure that that doesn't happen anymore."

The safety of the drug has been a key focus of Republicans' anti-abortion efforts. A recent study from conservative think tank the Ethics & Public Policy Center claimed health data it reviewed on the medication warrants fresh FDA review of the drug.

The EPPC study drew quick pushback form public health policy experts who took issue with its methodology and described it as part of a broader effort to block access to medication abortion. The EPPC, however, billed the study as the "largest-known" on the drug, claiming it found that one in 10 users had a significant adverse health event.

Following up on the topic Thursday, Sen. Steve Daines (R-Mont.) pushed Kennedy as to whether the HHS plans to replicate other research critical of medication abortion. Kennedy, however, couldn't provide specifics, though noted that Makary said the topic was pressing.

Daines also asked about whether Kennedy would repeal Covid-era changes easing mifepristone restrictions that made the drug accessible via telemedicine. Kennedy, however, said he wasn't sure whether the White House had taken a position on that issue, and that he'd have to get back to Daines.

Republican lawmakers are taking increasingly aggressive approaches against mifepristone. On Wednesday, the Texas state legislature approved a bill that will allow any Texan to sue an abortion pill manufacturer or distributor.

The Senate Finance hearing focused on the HHS' shifting approach on vaccines under Kennedy's leadership, following his overhaul of the Centers for Disease Control and Prevention.

The attacks were largely from Democratic senators, though Republican Bill Cassidy (La.)—whose vote was crucial in securing Kennedy's confirmation as HHS secretary—took a critical tone with Kennedy.

Sen. Thom Tillis (R-N.C.) also took issue with Kennedy's commentary on Project Warp Speed, handling of HHS science, and the White House's firing of Susan Monarez from her role as CDC director.

To contact the reporter on this story: Ian Lopez in Washington at ilopez@bloomberglaw.com

To contact the editors responsible for this story: Zachary Sherwood at zsherwood@bloombergindustry.com; Brent Bierman at bbierman@bloomberglaw.com

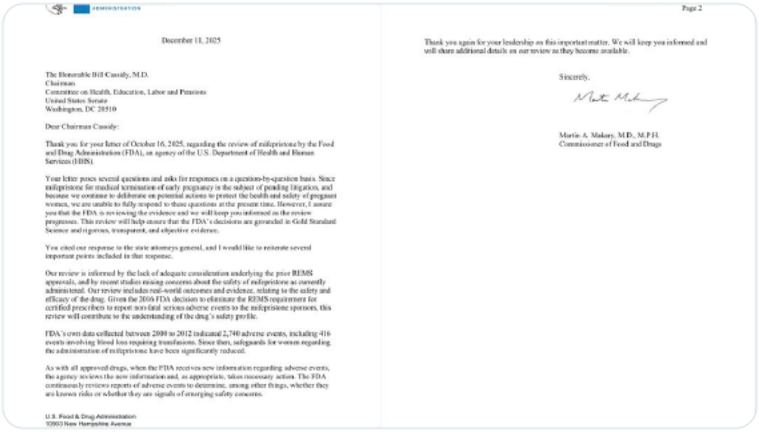
EXHIBIT 9

U.S. Senator Bill Cassidy, M.D. (@SenBillCassidy), X (Dec. 12, 2025, at 13:05 PT)

Post

U.S. Senator Bill Cassidy, M.D.
@SenBillCassidy

As chair of the HELP Committee and a strong pro-life conservative, FDA's response to Congress is unacceptable. Republicans have been pressing FDA to provide answers on the status of its promised safety study of the chemical abortion drug and information about the second generic's approval. The American people deserve to know why HHS and FDA continue to ignore their responsibility to safeguard mothers and unborn children from this harmful drug.



December 11, 2025

The Honorable Bill Cassidy, M.D.
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Dear Chairman Cassidy:

Thank you for your letter of October 16, 2025, regarding the review of mifepristone by the Food and Drug Administration (FDA), an agency of the U.S. Department of Health and Human Services (HHS).

Your letter poses several questions and asks for responses on a question-by-question basis. Since mifepristone for medical termination of early pregnancy is the subject of pending litigation, and because we continue to deliberate on potential actions to protect the health and safety of pregnant women, we are unable to fully respond to these questions at the present time. However, I assure you that the FDA is reviewing the evidence and we will keep you informed as the review progresses. This review will help ensure that the FDA's decisions are grounded in Gold Standard Science and rigorous, transparent, and objective evidence.

You cited our response to the state attorneys general, and I would like to reiterate several important points included in that response.

Our review is informed by the lack of adequate consideration underlying the prior REMS approvals, and by recent studies raising concerns about the safety of mifepristone as currently administered. Our review includes real-world outcomes and evidence, relating to the safety and efficacy of the drug. Given the 2016 FDA decision to eliminate the REMS requirement for certified prescribers to report non-fatal serious adverse events to the mifepristone sponsors, this review will contribute to the understanding of the drug's safety profile.

FDA's own data collected between 2000 to 2012 indicated 2,740 adverse events, including 416 events involving blood loss requiring transfusions. Since then, safeguards for women regarding the administration of mifepristone have been significantly reduced.

As with all approved drugs, when the FDA receives new information regarding adverse events, the agency reviews the new information and, as appropriate, takes necessary action. The FDA continuously reviews reports of adverse events to determine, among other things, whether they are known risks or whether they are signals of emerging safety concerns.

U.S. Food & Drug Administration
10903 New Hampshire Avenue

Page 2

Thank you again for your leadership on this important matter. We will keep you informed and will share additional details on our review as they become available.

Sincerely,

Martin A. Makary, M.D., M.P.H.
Commissioner of Food and Drugs

:05 PM · Dec 12, 2025 · **17.5K** Views

46 34 57 7

Read 46 replies

EXHIBIT 10

Video posted by Elizabeth Mitchell Troutman (@TheElizMitchell), X, at 02:02–2:19 (Dec. 9, 2025, at 14:56 PT)

Post

Elizabeth Troutman Mitchell
@TheElizMitchell

EXCLUSIVE ‼️: @DrMakaryFDA responded to a report saying he is delaying the review of the abortion pill.

The FDA is currently in the “data acquisition phase” of the review," he told @DailySignal.

“We do an ongoing review, but we’re also engaging in a robust study that can serve to validate or not validate other numbers that have been put out there in the literature."

"Ultimately, I’m responsible, and so this analysis is going to be done under my auspices, and it’ll be reported up to me," he said.

Makary said he is unable to predict the “results or the timeframe” of the review, and the shutdown was a "setback."

It’s possible “there’s a complication that was not recognized previously” with the abortion pill, he said.

2:56 PM · Dec 9, 2025 · **34.8K** Views

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Read 13 replies

EXHIBIT 11

T. Elliot Gaiser et al., *The Truth of Erasure: Universal Remedies for Universal Agency Actions*, U. Chi. L. Rev. Online (Aug. 28, 2024)

08/28/24 U. Chi. L. Rev. Online *1

The Truth of Erasure: Universal Remedies for Universal Agency Actions

T. Elliot Gaiser, Mathura Sridharan, & Nicholas Cordova[*]

* * *

Introduction

Courts, litigants, and scholars should not be confused by the ongoing debate about nationwide or so-called "universal" injunctions: the proper scope of remedies under the Administrative Procedure Act (APA) and other statutes providing for judicial review of agency action is "erasure." This Article aims to save scholars' recent progress in showing the legality of stays and vacatur under the APA from muddled thinking that conflates these forms of relief with other universal remedies that face growing criticism.

Begin with first principles. When a federal court reviews a legislative enactment that conflicts with a source of higher law (i.e., the Constitution), the court engages in what is essentially a choice-of-law analysis: the court chooses to apply the higher law to the parties in the case at hand and declines to apply the conflicting lower law to those parties. It does not "strike down" the lower law or repeal it, any more than a court choosing to apply Ohio law rather than Michigan law to a tort suit "strikes down" the unchosen Michigan law. To "strike down" the statute in this way would be to exercise legislative, not judicial

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[*] T. Elliot Gaiser is the Solicitor General of Ohio. He previously clerked for Associate Justice Samuel A. Alito, Jr., at the Supreme Court of the United States; for Judge Neomi Rao on the U.S. Court of Appeals for the D.C. Circuit; and for Judge Edith H. Jones on the U.S. Court of Appeals for the Fifth Circuit. He holds a J.D. from The University of Chicago Law School and a B.A. in Political Economy and Rhetoric & Public Address from Hillsdale College.

Mathura J. Sridharan is the Director of Ohio's Tenth Amendment Center and serves as a Deputy Solicitor General in the Ohio Attorney General's Office. She previously clerked for Judge Steven J. Menashi on the U.S. Court of Appeals for the Second Circuit and Judge Deborah A. Batts on the U.S. District Court for the Southern District of New York. She holds a J.D. from New York University School of Law, and an M.Eng. in Electrical Engineering & Computer Science and a B.S. in Electrical Engineering & Computer Science and Economics from Massachusetts Institute of Technology.

Nicholas A. Cordova is an associate at Boyden Gray PLLC and former Simon Karas Fellow to the Ohio Solicitor General. He previously clerked for Judge Paul B. Matey on the U.S. Court of Appeals for the Third Circuit. He holds a J.D. from Harvard Law School and a B.A. in Political Science from Waynesburg University.

power—and courts may only exercise the latter. Once the right law has been identified, the remedy is to apply that law to the parties in the case. Nationwide or "universal" injunctions that intend to deliberately affect parties beyond the case exceed the judiciary's equitable powers, and perhaps the judicial power altogether. But the increasing frequency of such overbroad remedies flows from the fallacy that a court, in finding that the legislative enactment must yield to a higher law in a given controversy, has "erased" the statute. Correct the fallacy, and the proper scope of the remedy comes into focus.

But the "erasure" conception of judicial review is not a fallacy in the context of federal agency action. Federal agency action is subject to review under statutes like the APA that authorize courts to "set aside," "postpone the effective date of," "reverse," or grant other relief directed at agency action itself, rather than at the officials responsible for carrying out agency action. These statutes reflect the principle that Article III courts review agency action analogously to decisions by Article I courts. Federal courts can thus review agency action much like a bankruptcy court's judgments or a magistrate judge's report and recommendations. This power to invalidate unlawful agency action exists in other places as well. For example, courts are also allowed to invalidate unlawful agency action taken under the Clean Air Act and the Securities Exchange Act of 1934. This Article's arguments defending universal remedies under the APA apply equally to agency action reviewed under these provisions.

Professor Mila Sohoni and others have shown that Congress designed judicial review of agency action under the APA to replicate the appellate review model, whereby a superior court judgment takes as its object the inferior court's judgment and invalidates that initial judgment if it is unlawful. Agency action reviewed under the APA and similar statutes essentially stands as an inferior-court judgment, subject to vacatur if the reviewing court finds it unlawful. This view is consistent with that of lawyer and academic Jonathan Mitchell, whose extensive work criticizing universal injunctions expressly carves out review of agency action. Congress's decision to subject agency action to these broad remedies is the result of its post–New Deal understanding that agency rulemaking is an exercise of nationwide quasi-judicial, quasi-legislative power that must be checked by judicial review of matching scope. Thus, stay and vacatur of agency action in these contexts are presumptively lawful and appropriate remedies, whereas universal injunctions of presidential action and universal injunctions against enforcement of statutes are not.

Part I of this Article surveys scholarship that shows that the APA authorizes federal courts to issue relief that undoes the agency action

under review. That work has established that vacatur is ordinarily the appropriate remedy for an agency rule found to be unlawful. Part II draws on that work to explain that the APA similarly authorizes universal *preliminary* relief from agency action. Part III shows why the Constitution not only permits, but requires, unlawful agency action to be subject to vacatur. Part IV applies the preceding discussion to contemporary debates about other forms of universal relief. This article aims to keep these debates from overspilling their proper doctrinal banks and disfiguring judicial review of federal agency action, where universal remedies should remain the norm as Congress intended.

I. The APA Instructs Courts to Invalidate Unlawful Agency Action

Scholars have demonstrated that courts truly "strike down" or "erase" unlawful agency action reviewed under the APA. Moreover, in both a recent stay grant and concurrence, Justice Brett Kavanaugh recognized that this distinguishes judicial review of agency action from judicial review of statutes, where universal injunctions are increasingly (and appropriately) suspect. And judicial practice wholeheartedly agrees that whatever may be said of universal injunctions involving statutes, courts should issue universal remedies for unlawful agency action. Every circuit has effectively recognized that the APA authorizes it to vacate a rule,[1] and the D.C. Circuit often does so "five times before breakfast." Because scholarship and practice firmly establish vacatur of federal agency action, this Part only summarizes the primary reasons—textual and historical—that others have advanced in support of it.

[1] *E.g.*, Harmon v. Thornburgh, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989); Nat'l Org. of Veterans' Advocs., Inc. v. Sec'y of Veterans Affs., 48 F.4th 1307, 1317 (Fed. Cir. 2022); N.H. Hosp. Ass'n v. Azar, 887 F.3d 62, 77 (1st Cir. 2018); Nat'l Black Media Coal. v. FCC, 791 F.2d 1016, 1020, 1024 (2d Cir. 1986); Prometheus Radio Project v. FCC, 652 F.3d 431, 453–54, 453 n.25 (3d Cir. 2011); N.C. Growers' Ass'n v. United Farm Workers, 702 F.3d 755, 759 (4th Cir. 2012); Chamber of Com. of the U.S. v. Dep't of Labor, 885 F.3d 360, 363 (5th Cir. 2018); Mason Gen. Hosp. v. Sec'y of Dep't of Health & Hum. Servs., 809 F.2d 1220, 1231 (6th Cir. 1987); H & H Tire Co. v. Dep't of Transp., 471 F.2d 350, 355–56 (7th Cir. 1972); Menorah Med. Ctr. v. Heckler, 768 F.2d 292, 297 (8th Cir. 1985); Nat. Res. Def. Council v. U.S. EPA, 526 F.3d 591, 594 (9th Cir. 2008); Zen Magnets, LLC v. Consumer Prod. Safety Comm'n, 841 F.3d 1141, 1155 (10th Cir. 2016); Alabama v. Ctrs. for Medicare & Medicaid Servs., 674 F.3d 1241, 1244 (11th Cir. 2012).

A. History Supports Continued Use of Vacatur

Reviewing the APA's history sets the stage for analyzing its text. Section 706 of the APA directs that "the reviewing court shall . . . hold unlawful and set aside agency action" that is "found to be" unlawful. When Congress was debating and drafting the APA, both Congress and the Executive Branch understood that the phrase "set aside" prescribed judicial invalidation of unlawful regulation. Just four years before the APA's enactment, the Emergency Price Control Act of 1942 gave an Emergency Court of Appeals exclusive jurisdiction "to stay, restrain, enjoin, or set aside, in whole or in part, any provision of th[e] Act . . . or any provision of any such regulation [authorized by the Act] . . . or to restrain or enjoin the enforcement of any such provision." This statute shows that Congress understood "set aside" to be an action against an entire provision of a statute or regulation, and distinct from an order "to restrain or enjoin" a provision's "enforcement" against plaintiffs to a lawsuit. Congress recognized these as different remedies and authorized both in the Emergency Price Control Act. Accordingly, Congress knowingly authorized the greater "set aside" remedy in Section 706 of the APA.

The Executive Branch shared this understanding that to "set aside" agency action meant to invalidate it wholly. The 1941 Attorney General's Report on Administrative Procedure, in discussing judicial review of agencies' formal rulemaking, explained that a "judgment adverse to a regulation results in setting it aside." That sentence shows then-Attorney General Robert H. Jackson's understanding that the object of the reviewing court's judgment is the regulation itself, not the regulation's application in the case at hand.

President Franklin D. Roosevelt used the term "set aside" to denote invalidation too. In an address designed to sell his court-packing scheme to Congress, Roosevelt lamented that "[s]tatutes which the Congress enacts are set aside or suspended for long periods of time" by federal courts. Roosevelt was upset that courts were preventing whole pieces of New Deal legislation from taking effect, not merely exempting individual plaintiffs from compliance. To him, and to the public he addressed, "set aside" meant to invalidate entirely.

B. The APA's Text Undergirds the Judicial Consensus Favoring Vacatur

That background informs the meaning of APA Section 706, which directs that "the reviewing court shall . . . hold unlawful and set aside agency action" that is "found to be" unlawful. The APA's definitions

section states that "'agency action' includes the whole or a part of an agency rule." As Mila Sohoni explained, "the statute makes agency action the *object* of the court's review." This posture replicates the "appellate review model" in which an appellate court takes an inferior court's judgment as the object of its review and sets it aside—that is, invalidates it—if the appellate court finds the judgment is unlawful.

Another way to understand this review structure is by analogy to bankruptcy law. When a federal court reviews agency action under the APA, the relationship between the court and agency is like that between an Article III federal district court and the Article I bankruptcy court under its supervision. The inferior actor, be it an agency or bankruptcy court, takes the first shot at determining legal duties and obligations, but that determination has no force if the reviewing court finds it inconsistent with law. Both scenarios ensure that the final arbiter of legal rights and obligations is an actor that the Constitution itself creates and entrusts with Article III judicial power.

Jonathan Mitchell agrees that "[u]nlike judicial review of statutes, in which courts enter judgments and decrees only against litigants, the APA . . . [goes] further by empowering the judiciary to act directly against the challenged agency action." This statutory design "enables the judiciary to formally revoke an agency's rules . . . in the same way that an appellate court formally revokes an erroneous trial-court judgment."

In fact, the majority of the APA's drafters assumed that most administrative agencies would regulate through quasi-judicial adjudication, not rulemaking. As Professor Reuel Schiller observed, "[b]efore the 1960s agencies acted mainly through case-by-case adjudications," and "[m]ost traditional administrative actions—ratemaking, for example—were based on judicial models."[2] The New Deal expansion of administrative agencies may be understood as a proliferation of what looked to Congress like a cornucopia of Article I courts. Given that "[a]dministrative proceedings looked like mini-trials, where the rights of individual actors were adjudicated," it is not surprising that "critics of the Roosevelt administration, who aggressively pushed for the passage of the APA, focused their energies on making agency adjudications more like common law trials."[3] It is also clear that the judicial review provisions of the APA re-constitutionalized agencies by placing them in an appellate-review chain of command under Article III courts. When an Article III court sets aside an unlawful

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[2] Reuel E. Schiller, *Rulemaking's Promise: Administrative Law and Legal Culture in the 1960s and 1970s*, 53 ADMIN. L. REV. 1139, 1145 (2001).

[3] *Id.* at 1145–46.

agency action, be it a narrow adjudicatory order or a nationwide rule, that action ceases to have any force.

Contrary readings of Section 706's "set aside" language are implausible. Best read, it cannot mean, as Professor John Harrison argued, that a court should only decline to apply a rule to the parties who challenged it. The statutory text instructs courts to "set aside" an unlawful "rule," not enjoin agency personnel from enforcing the rule against parties. In defining "agency action," the APA equates an agency "rule" with an "order" produced through trial-like agency adjudication. It then instructs courts to "set aside" agency actions that are unlawful. Congress thus drew the easy analogy between judicial review of lower court orders and court-like agency adjudication orders and prescribed the same remedy for both. It then extended this appellate review analogy to review of agency rules as well.

The fact that everyone in 1946 expected agencies to do most of their regulating through court-like adjudication orders rather than quasi-legislative rulemaking does not mean that agency rulemaking stands outside the appellate-review model.[4] For one thing, agencies cannot skirt judicial review by regulating more people with less process than Congress expected in the 1940s. Moreover, by the time of the APA, agencies had long been promulgating regulations with nationwide scope through individual actions. They simply called these regulations "orders" instead of "rules," and courts had granted universal set-aside relief against them in at least three pre-APA cases. In the illustrative example of *United States v. Baltimore & Ohio Railroad Co.*, the Supreme Court affirmed a three-judge district court's ruling that an Interstate Commerce Commission "order" requiring railroads to install a power reverse gear on their locomotives be "vacated, set aside, and annulled," and that its enforcement be "perpetually enjoined." The Congress that passed the APA understood that courts would review and vacate agency action that sought to regulate nationally. Indeed, the APA commands courts to do so.

Another flawed textual argument against universal APA remedies is that the APA sets forth remedies in Section 703, not Section 706, and so Section 706's "set aside" language does not address remedies at all. Solicitor General Elizabeth Prelogar advanced this argument at oral argument in *United States v. Texas*, echoing Professor Harrison. Section 706, however, authorizes courts, in appropriate circumstances, to "compel agency action," which is most definitely a remedy. And the APA's structure leads one to expect to find final remedies in Section 706,

[4] *See* Samuel L. Bray, *Multiple Chancellors: Reforming the National Injunction*, 131 HARV. L. REV. 417, 425–45, 438 n.121 (2017).

right after Section 705 introduces (some universal) interim remedies. Section 703, on the other hand, is labeled "[f]orm and venue of proceeding," and makes no reference to remedies besides once using the word "injunction" to specify that the permissible "form[s] of legal action[ ] includ[e] actions for . . . writs of prohibitory or mandatory injunction or habeas corpus." Section 703's authorization of a specialized form of proceeding that happens to have the word "injunction" in its name does not make Section 703 a remedies provision, let alone an exclusive one. The APA's text and structure suggest that courts have been right all along—they should ordinarily vacate unlawful administrative rules and remand them to the agency for reconsideration.

II. The APA Authorizes Universal Interim Relief

Less has been written on the interim remedies available under the APA, although the importance of those remedies has only increased. Indeed, a growing number of high-profile challenges to agency action have reached the Supreme Court not through petitions for certiorari, but in an emergency posture.[5] As Justice Neil Gorsuch has observed, in this setting, interim remedies control the challenged action's fate for months or years during litigation, and often practically become final remedies when litigation outlives the challenged action. This Part shows that the APA grants courts authority to stay agency rules from taking effect pending appeal to the Supreme Court or denial of certiorari, even if

[5] *See, e.g.*, Ohio v. EPA, 144 S. Ct. 2040, 2058 (2024) (granting stay application for stay of ozone transport regulations); Garland v. Blackhawk Mfg. Grp., 144 S. Ct. 338 (2023) (challenging the regulation of gun parts as "firearms"); Biden v. Nebraska, 143 S. Ct. 2355 (2023) (rejecting student loan nullification); United States v. Texas, 143 S. Ct. 1964, 1980–86 (2023) (Gorsuch, J., concurring in judgment) (criticizing universal remedies in a challenge to immigration guidelines); Nat'l Fed'n of Indep. Bus. v. Dep't of Lab, 142 S. Ct. 661 (2022) (addressing the COVID-19 vaccine mandate). Still more high-profile litigation reaches the lower courts in an emergency posture. *See, e.g.*, The Enhancement and Standardization of Climate-Related Disclosures for Investors; Delay of Effective Date, 89 Fed. Reg. 25,804 (April 12, 2024) [hereinafter Climate-Related Disclosures; Delay of Effective Date] (staying rule requiring registrants to provide certain climate-related information in registration statements and annual reports in response to Eighth Circuit litigation seeking stay); Texas v. EPA, 2024 WL 3384818, at *1 (D.C. Cir. July 9, 2024); *see also* W.V. by & through Morrisey v. U.S. Dep't of Treasury, 59 F.4th 1124 (11th Cir. 2023) (granting a permanent injunction against a Treasury rule); Texas v. EPA, 662 F. Supp. 3d 739 (S.D. Tex. 2023), *appeal dismissed*, 2023 WL 8295928 (5th Cir. Oct. 6, 2023); Kentucky v. Fed. Highway Admin., 2024 WL 1402443, at *1 (W.D. Ky. Apr. 1, 2024).

courts lack authority to universally enjoin statutes and direct presidential action.

The textual argument for universal interim remedies under the APA is perhaps even stronger than that for universal final remedies. The APA's interim remedies provision, Section 705, grants that "the reviewing court . . . may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." This grant of judicial discretion to "postpone the effective date of an agency action" combines with the APA's definition of "agency action," which includes a "rule" or "order," to make a challenged agency action itself an object of interim remedies, just as agency action is the object of final remedies.

The operative language makes sense only in terms of a universal interim pause. "[P]ostpone the effective date of an agency action" is most naturally read to mean that the agency action—a rule or order—takes no effect as to anyone anywhere, not that it takes effect as to everyone but the parties to a legal challenge. And reason accords with text: only universal interim remedies match the scope of final relief available, as is necessary to protect parties adequately. Moreover, these universal remedies avoid the practical difficulties of carving individual parties or jurisdictions out of a rule or order applicable elsewhere. Put plainly, since Section 706 creates the universal final remedy of vacatur, it only makes sense that Section 705 would create a universal interim remedy capable of preserving the possibility of a universal final remedy. One would expect this congruence between interim and final remedies.

Moreover, when a court determines that tailored relief is practicable and otherwise appropriate, Section 705 authorizes the court to issue a preliminary injunction tailored as "necessary and appropriate . . . to preserve the status quo or rights pending conclusion of the review proceedings." The APA presents courts with injunctive relief as an *alternative option* to postponing a rule's effective date, which strongly suggests that a judicially postponed agency action is postponed universally, not only so far as necessary to preserve the status quo (whatever that might mean) or the rights of parties.

A final textual hint lies in Section 705's parallel grant of authority to an agency to "postpone the effective date of action taken by it, pending judicial review." The SEC recently exercised this power in response to legal challenges to its rule requiring companies to provide climate-related information in their registration statements and annual reports.[6] The agency decided to stay the rule on its own initiative

[6] Climate-Related Disclosures; Delay of Effective Date, 89 Fed. Reg. at 25,804.

pending final judicial review. Just as an agency may postpone its rule or order wholesale, so may a reviewing court. That is the only sensible reading of the APA's deployment of the same phrase in the same section to describe the interim relief available from agencies and courts.

Again, judicial precedent shows practice agrees with the text. The Supreme Court itself has universally stayed two agency actions pending final merits review in recent years, showing that it understands the APA to authorize interim relief that runs against a rule itself. In 2016, it stayed the EPA's "Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units." And in 2022, the Court stayed OSHA's vaccine mandate. In the latter case, the Court remarked without criticism that the Fifth Circuit had stayed the agency action universally in earlier proceedings. Justice Kavanaugh, joined by Justice Amy Coney Barrett, addressed this practice directly in his concurrence in the Court's narrowing of a district court's stay against an Idaho statute. He distinguished universal stays of statutes from stays against "new federal regulations, given the text of the APA."

The APA's text and the behavior of courts and agencies confirm that courts may issue universal interim remedies against unlawful agency action.

III. The Separation of Powers Requires the Availability of Universal Judicial Remedies for Unlawful Agency Action

Applying the plain meaning of the APA's text and history makes sense in the broader separation of powers scheme of the Constitution. The Constitution establishes the federal judiciary as a branch of government coequal with the legislative and executive. Thus, it is unsurprising that no provision of the Constitution authorizes the court to "set aside" the work of Congress when it reviews a statute for conflict with the Constitution. Instead, recall that constitutional review involves what are essentially choice-of-law principles. That is because both the Constitution and any duly enacted statute have the status of "law," but, as Justice Clarence Thomas has observed, one has a principled and textual right-of-way in any possible collision.

Administrative agencies, by contrast, are not creatures of constitutional creation, but statutory hybrids within the executive branch, exercising delegated powers that are considered mixed quasi-executive, quasi-judicial, and quasi-legislative in nature. And while an "agency action" might look like law because it has legal consequences for regulated parties, it is not "law" in the same sense that the Constitution and federal or state statutes are law. Rather, an agency action is the executive branch's enforcement of the laws enacted by Congress reduced

to a rule or an order. As the Supreme Court has noted, "an agency literally has no power to act . . . unless and until Congress confers power upon it." Thus no agency's regulation can "'operate independently of' the statute that authorized it."

Nevertheless, agency rulemaking binds parties with the force of legal consequences without undergoing the compromise-inducing ordeal of passage through both houses of Congress and presentment to the President. This constitutional process restrains exercises of pure legislative power and commands greater judicial respect for legislative commands that survive the process. Maintaining the Constitution's allocation of powers requires courts to counterbalance this relative lack of front-end checks on agency action with relatively greater judicial review on the back end.

To see why that is so, consider the alternative. If courts could not universally vacate agency action that unlawfully regulates with universal effect, then the Constitution's allocation of powers would be distorted by executive branch "lawmakers" insufficiently accountable to either congressional or judicial review. And indeed, there is much to be said for the argument that Congress has legislated relatively less as executive agencies have issued more rules.

It is, therefore, logically symmetrical that the APA authorizes courts to issue remedies running against an agency rule itself, even when courts may not issue universal remedies against statutes that are subject to greater front-end checks. Congress simultaneously gave agencies authority to make rules with universal effect and courts commensurate power to prevent the universal injustice of an unlawful rule by issuing universal relief. If the Constitution permits the first move, separation of powers requires, or at least permits, as Justice Byron White suggested, the second move as well. Otherwise, agency action would evade judicial review as to all regulated persons who do not join a successful lawsuit. Such a system would deny full protection of law to those without the resources and wherewithal to challenge unlawful regulation. It would also create a legal patchwork that would undermine the effectiveness of many rules and greatly complicate compliance and enforcement efforts.

Nevertheless, some, including Professor Samuel Bray and Chief Judge Jeffrey Sutton of the Sixth Circuit, have suggested that universal APA remedies exceed the limits of the judicial power that Article III vests in the federal judiciary.[7] These critics have argued that federal courts may not hand out remedies "in the abstract" because Article III empowers them only to resolve concrete "Cases" or "Controversies." A

[7] *See* Bray, *supra* note 4, at 433, 471–72.

universal remedy might exceed that limit to the extent it goes beyond redressing the injury in the case or controversy presented. Samuel Bray's work provides historical grounding for this critique by showing that principles of traditional equity did not permit universal injunctions.

Universal remedies under the APA, however, remain within Article III limits because they are legal, not equitable, remedies created by Congress and available only to resolve true cases or controversies. Critics of universal remedies are correct that the separation of powers generally prohibits remedies that reach beyond parties except where equity would have permitted at the Founding. Courts may not invent new equitable remedies that were unknown in England and America before the Founding because that would allow federal judges to unilaterally expand their own power into the legislative realm of general policymaking. Since only the legislature has the power to bind the sovereign people at large, Congress is the proper institutional actor to decide how far judicial remedies can reach before becoming quasi-legislative. These principles make remedies created by Congress (like stay and vacatur of agency action) presumptively constitutional and remedies invented by courts (like universal injunctions) constitutionally suspect.

History explains why remedies created by statute are presumptively lawful "legal" remedies in the fullest sense, whereas court-created remedies are best understood as remedies in "equity" and strictly conscribed. In medieval England, Parliament possessed absolute power to create new causes of action by statute.[8] No separation of powers concerns were conceivable because Parliament was both the legislature and the high court. Any expansion of judicial remedies approved by statute was, by definition, lawful. Equity, by contrast, was an extra-legal device by which the King's appointed Chancellor could, within broad limits, supersede the requirements of law that bound courts when he believed that justice so required. In this sense, the Chancellor could "make law" independent of the courts and Parliament.

When the U.S. Constitution created a separate legislature and judiciary, it also created a potential separation of powers problem by placing the powers of equity in the hands of federal judges. If courts expanded equity to include remedies unknown at the Founding, the federal judiciary would gain a share of legislative power. To avoid potential separation of powers problems, federal courts must respect the traditional limits on equitable remedies that Samuel Bray identified, which did not permit courts to issue sweeping injunctions impacting the

[8] See JOHN BAKER, AN INTRODUCTION TO ENGLISH LEGAL HISTORY 221, 354 (2019).

ability of a separate branch of government to enforce a statute.[9] Statutory remedies, by comparison, present fewer separation of powers concerns because they represent the legislature's judgment that those remedies do not encroach on legislative power. Thus, broad statutory remedies like those in the APA and Federal Rule of Civil Procedure 23, are not subject to the traditional limits of equity. They simply are not equitable remedies.

Some might argue that universal remedies might nonetheless exceed the judicial power of Article III. If so, even a statute could not authorize universal remedies because Congress may not expand the Constitution's limits on judicial power. And indeed, according to Supreme Court doctrine, Article III contains some limits on how far Congress can expand judicial remedies. Congress could not, for example, delegate to courts authority to write statutes in the form of judicial opinions addressed to the public at large, or to give government officials legal advice. But judicial review of agency action does not depend on Congress expanding Article III. It comports with Article III's case or controversy requirement, avoids advisory opinions, and gives courts no quasi-legislative power to create new, generally applicable legal obligations.

The Constitution bars Congress from authorizing courts to declare law independent of a concrete case or controversy because that would commingle legislative and judicial power by allowing courts to "prescribe[ ] the rules by which the duties and rights of every citizen are to be regulated" or to issue advisory opinions. But judicial vacatur of an unlawful agency rule never approaches these boundaries. It is available only if a party "aggrieved by [the] agency action" brings a concrete case, and it never declares new policies, just prevents new policies from taking effect. Nor does it purport to undo any act of Congress. It is inherently judicial power in the sense that it is a strictly negative power, activated only by a concrete dispute, to prevent subordinate actors from transgressing the boundaries of law. In this sense, the judiciary acts as a faithful agent of Congress in reviewing executive branch agencies' actions. And an opinion vacating a rule is not advisory. The very reason for recent objections to judicial vacatur is that it has too significant an effect. These essential characteristics of stay and vacatur of agency action show that it is precisely the type of power that Article III contemplates.

Some of the anxiety about the universal scope of APA remedies, which gets inaptly expressed as an Article III concern, may be resurfacing doubt about the constitutionality of agency rulemaking.

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[9] *See* Bray, *supra* note 4, at 420–21, 425–28.

Analyzing APA review through the appellate review model illustrates this point. In that model, a trial court judgment ordinarily affects only parties to the underlying suit. Thus, only those parties are affected when an appellate court invalidates that judgment. There is a correct intuition that the appellate court in this scenario could not act with nationwide effect without exceeding its authority. To reach nationwide results, the appellate court would need to reach beyond the trial-court judgment before it, by purporting to invalidate other similar trial-court judgments or decree binding rules of primary conduct in the abstract.

But the intuition that nationwide effect must exceed rightful judicial authority leads critics astray when a federal court sits in appellate-style review of agency action. Here, the judgment below—the agency rule under review—had a nationwide effect, unlike the party-bound effects of true court judgments. Thus, when a court invalidates an agency rule, that invalidation has a nationwide effect too. That may seem strange, but the strangeness lies in the scope of regulatory authority the "lower court" (the agency) exercised, not in the reviewing court's routine exercise of judging only the object placed before it. What really triggered the intuition that something illegal is ongoing was the agency action.

This again stands in contrast to statutes that have nationwide effect but came into being through procedures designed to ensure something like national consensus: bicameralism and presentment. Such federal law passes a gauntlet far more daunting than informal (notice-and-comment) rulemaking. So again, to reconstitutionalize Congress's choice to give an agency subordinate to a unitary executive (the President) the power to make nationwide pronouncements, Congress placed those agencies under the direct appellate-style review of the federal judiciary. If Congress has the power to adopt statutes that create agencies with nationwide quasi-legislative power, it surely has the power to adopt a statute that cabins such nationwide quasi-legislative power.

Also worth noting is that the injunctive class action mechanism from Federal Rule of Civil Procedure 23—a dramatic expansion of equitable remedies—is likely unconstitutional if Congress may not expand remedies beyond traditional limits. And there is no principled line to be drawn between Rule 23's expansion of injunctive relief to third parties only before the court in a representative capacity and the APA's choice to broaden relief by directing remedies at agency action itself, rather than expand the equitable tradition of enjoining the officers charged with carrying out agency action. If anything, Rule 23 is more suspect because it expands courts' power to bind private actors by

injunction, whereas the APA's universal remedies only create a power to negate agency action that was authorized by statute in the first place.

The APA's text, historical background, and constitutional principles all demonstrate that courts have correctly concluded that the "ordinary result" for unlawful rules is "that the rules are vacated—not that their application to the individual petitioners is proscribed."[10]

IV. Consequences Stemming from the Distinction Between Equitable Remedies and the APA Remedies of Stay and Vacatur

Contemporary debates surrounding universal injunctions and stays of new laws do not apply to APA remedies. It is easy to conflate the APA remedies of stay and vacatur of agency action with the equitable remedies of stay and injunction (preliminary and permanent) against statutes and presidential action. But, the APA's judicial review provisions create a unique remedies paradigm that is independent of courts' inherent equitable powers and general grants of statutory authority. This Part differentiates the universal remedies available under the APA from universal injunctions and from stays against state and federal statutes. It shows that concerns about the latter judicial inventions say nothing about the legality or propriety of the APA's universal remedies.

A. The APA Offers the Universal Remedies of Stay and Vacatur, Which Are Distinct from Preliminary and Permanent Injunctions

The universal remedies that the APA makes available are different in kind from universal injunctions. Courts and litigants have sometimes confused this distinction, especially in the context of interim remedies, by using the terms "preliminary injunction" or "temporary restraining order" interchangeably with "stay." For example, the Supreme Court recently decided an application for a partial stay of a rule implementing Title IX as though it were a request for a preliminary injunction. And the Eleventh Circuit has generated still more confusion by purporting to apply the traditional stay factors to applications for injunctions pending appeal, while also heightening the likelihood-of-

[10] *See also* Data Mktg. P'ship, LP v. Dep't of Lab., 45 F.4th 846, 859–60 (5th Cir. 2022); Regents of the Univ. of Cal. v. U.S. Dep't of Homeland Sec., 908 F.3d 476, 511 (9th Cir. 2018), *rev'd on other grounds, vacated in part sub nom.* Dep't of Homeland Sec. v. Regents of the Univ. of Cal., 140 S. Ct. 1891 (2020); Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Eng'rs, 781 F.3d 1271, 1290 (11th Cir. 2015).

success prong in apparent recognition of the extraordinary nature of preliminary injunctive relief. The Supreme Court's jurisprudence helps elucidate the difference between these remedies.

The Supreme Court's comparison of stays and preliminary injunctions in *Nken v. Holder* most visibly illustrates the important difference between stays and preliminary injunctions. To receive a stay, the Court explained, a party must show a likelihood of success on the merits, irreparable injury absent a stay, and that the private and public interests favor a stay (though it remains an open question whether the likelihood-of-success prong requires a showing of "certworthiness" for "emergency" stay applications in the Supreme Court). The Court has acknowledged that "[t]here is substantial overlap between these and the factors governing preliminary injunctions," but has maintained that stays are distinct from preliminary injunctions. "[A] stay operates upon" a "proceeding itself," the *Nken* Court noted, "either by halting or postponing some portion of the proceeding, or by temporarily divesting an order of enforceability." It does not directly bind any person to act or refrain from acting.

The *Nken* Court wrote in the context of a stay of a judicial proceeding, but the Court confirmed that the *Nken* standard applies to a request to stay administrative action this term in *Ohio v. EPA*, as other courts have done in the past. Section 705's grant of authority for courts to "postpone the effective date of an agency action" makes agency action the "proceeding" against which a stay operates. So, it is no surprise that the Supreme Court has recognized universal stays of agency action as an appropriate interim remedy. By contrast, an injunction, whether preliminary or permanent, "is a judicial process or mandate operating *in personam*." It "is directed at someone, [not something,] and governs that party's conduct." And because an injunction infringes the enjoined person's liberty, it must be as narrow as justly possible. As Samuel Bray has observed, historically, injunctions did "not control the defendant's behavior against nonparties."[11] Thus, a stay must be as broad as the action or proceeding it operates against, whereas the proper scope of an injunction is to prohibit the enjoined party (whether private actor or government official) from taking the unlawful action plaintiffs complained of.

Importantly, that distinction holds as to final APA remedies because vacatur, just like a stay, acts against agency action itself.

[11] Bray, *supra* note 4, at 421.

B. The APA's Universal Remedies Do Not Raise Significant Separation of Powers and Federalism Issues

The nature of the action that APA remedies run against is as significant as the nature of the remedies themselves when it comes to understanding why the APA's universal remedies are lawful. APA remedies run against agency action. And agency action is, at best, a quasi-constitutional chimera of quasi-legislative, quasi-executive, and quasi-judicial power, as the Court recognized in *Humphrey's Executor v. United States*, and as Justices Robert Jackson and White have suggested. This hybrid nature carries two important implications for the legality of universal APA remedies.

First, it means that judicial invalidation of agency action does not unbalance the tripartite separation of powers the Constitution establishes. Judicial suspension of or refusal to apply federal legislation always results in a clash of the coordinate departments of government since a statute (unlike an agency action) is the purely legislative act of a coequal branch of government. Universal remedies against enforcement of federal statutes interfere with what could reasonably be viewed as the Constitution's main focus—Congressional action. They tend toward power imbalance by shifting power from Congress to the courts. On the other hand, the APA's universal remedies reduce the power of governmental actors that are unknown to the Constitution. They serve to return the allocation of federal power closer to the Constitution's equilibrium point. They do this by using an enactment of Congress (the APA) to review and sometimes negative the actions of creatures of Congress (executive branch agencies). Universal APA remedies thus benefit separation of powers principles. In contrast, separation of power principles suffer when these universal remedies touch on federal statutes.

Second, the federal origin of agency action meaningfully distinguishes it from state laws that parties challenge in federal court. The APA directs review only of federal government action, so remedies that wholly incapacitate that action do no violence to federalism. When federal courts issue stays against enforcement of state laws, however, they irreparably infringe the States' retained lawmaking power, harming the Constitution's vertical balance. So, the federalism reasons to avoid federal court-issued remedies against state laws have no purchase when it comes to the APA's universal remedies.

C. The APA Does Not Authorize Courts to Enjoin Presidential Action

Equally important is that APA universal remedies face none of the problems unique to universal injunctions directed against presidential action. The APA authorizes universal remedies only against "agency action," which does not include presidential action. In fact, the APA does not authorize judicial review of presidential action at all. A different framework of constitutional review applies instead. So, the legal arguments against universal injunctions of presidential action do no harm to universal remedies against agency action under the APA.

The primary argument against universal injunctions of presidential action is that no source of law authorizes them. No statute grants district courts general power to issue universal injunctions, nor does the courts' inherent constitutional authority include any such power. Thus, courts lack general power to enjoin executive action. But courts do enjoy express statutory authorization to issue stays and vacatur of *agency* action under the APA. And this Article has already explained that these remedies are consistent with the separation of powers and Article III limits that might prevent Congress from authorizing universal injunctions against presidential action by statute. As elsewhere in the universal remedies debate, APA remedies stand above the fray. It should be little wonder, then, that courts have universally accepted without question that the APA provides universal remedies against agency action.

Conclusion

The APA is best understood as making universal remedies the default relief for unlawful agency action. The legal profession should not allow separate questions about universal injunctions to unsettle this consensus. APA remedies do not face the most serious legal problems that federal courts create when they enjoin enforcement of statutes beyond their jurisdiction (or, in the case of state laws, created by a separate system of government). If courts, lawyers, and scholars want to debate the legality of both universal remedies against agency action and universal injunctions, they must have two separate debates. This Article has focused on the APA debate to emphasize that that debate is largely settled, and rightly settled too.

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EXHIBIT 12

Letter from Elizabeth Warren et al. to FDA
(Nov. 18, 2022)

United States Senate
WASHINGTON, DC 20510

November 18, 2022

Dr. Robert M Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Califf:

In the wake of the Supreme Court's devastating decision in *Dobbs v. Jackson Women's Health Organization* to eliminate the right to an abortion,[1] we urge you to immediately act to defend Americans' fundamental reproductive rights. We respectfully request that you consider the following three actions to protect and expand access to medication abortion: (1) finalize the updated Risk Evaluation and Mitigation Strategy (REMS) for Mifepristone, (2) lift remaining medically unnecessary REMS restrictions, and (3) work with drug sponsors to add a miscarriage management indication for Mifepristone taken with misoprostol.

For over two decades, women have been safely and effectively using medication abortion – Mifepristone and misoprostol – to terminate a pregnancy.[2] But the Supreme Court's reckless decision to overturn *Roe v. Wade* now endangers millions of women in this country who are facing restrictions to lifesaving care and rights.[3]

Soon after the Supreme Court's *Dobbs* decision, in July 2022, President Biden released an Executive Order to protect access to reproductive health care services.[4] In August 2022, the Department of Health and Human Services (HHS) responded by publishing a report that provided an "action plan to protect and strengthen reproductive care."[5] The HHS report included a recommendation to expand access to medication abortion through FDA finalization of updated REMS for Mifepristone "that have been found to be safe and effective."[6] We are writing to ask you to consider the following recommendations, specifically, that you:

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[1] Dobbs v. Jackson Women's Health Organization, 597 U.S. _ (2022).
[2] Guttmacher Institute, "Medication Abortion," February 2021, https://www.guttmacher.org/evidence-you-can-use/medication-abortion.
[3] New York Times, "Medical Impact of Roe Reversal Goes Well Beyond Abortion Clinics, Doctors Say," Kate Zernike, September 10, 2022, https://www.nytimes.com/2022/09/10/us/abortion-bans-medical-care-women.html.
[4] White House, "FACT SHEET: President Biden to Sign Executive Order Protecting Access to Reproductive Health Care Services," press release, July 8, 2022, https://www.whitehouse.gov/briefing-room/statements-releases/2022/07/08/fact-sheet-president-biden-to-sign-executive-order-protecting-access-to-reproductive-health-care-services/.
[5] Department of Health and Human Services, "Health Care Under Attack: An Action Plan to Protect and Strengthen Reproductive Care," August 2022, p. 1, https://www.hhs.gov/sites/default/files/hhs-report-reproductive-health.pdf.
[6] Department of Health and Human Services, "Health Care Under Attack: An Action Plan to Protect and Strengthen Reproductive Care," August 2022, p. 6, https://www.hhs.gov/sites/default/files/hhs-report-reproductive-health.pdf.

1. **Finalize the Updated Risk Evaluation and Mitigation Strategy (REMS) for Mifepristone.** In December 2021, FDA conducted a scientific and evidence-based review of the Mifepristone REMS program and announced it would modify the existing REMS for Mifepristone, including eliminating the medically unnecessary in-person dispensing requirement.[7] This modification would expand access to medication abortion by allowing clinicians to dispense Mifepristone by mail order and/or for patients to obtain access to Mifepristone at retail pharmacies.[8] However, FDA is still processing the changes to the REMS and has not finalized them yet, despite the fact that manufacturers have already made their required submissions to FDA for approval.[9] We encourage you to finalize your review of manufacturers' plans to certify pharmacies and the updated REMS, especially as we advance closer to the 180-day deadline that FDA has to review or modify submissions.[10] It is crucial that you act as soon as possible to allow patients to access Mifepristone via certified mail delivery and at retail pharmacies. Until you finalize the updated REMS, we ask FDA to continue its policy of exercising enforcement discretion (put in place at the beginning of the COVID-19 pandemic) to protect access to medication abortion, regardless of when the COVID-19 public health emergency ends.[11]

2. **Consider Lifting Remaining Medically Unnecessary REMS Restrictions.** Distributing Mifepristone as a normal prescription, without REMS, is safe and effective.[12] As you prepare to finalize the updated REMS for Mifepristone that you announced almost a year ago, we ask that you continue to follow the science and reconsider the remaining REMS, lifting any remaining medically unnecessary restrictions.[13] FDA frequently reviews REMS "at periodic intervals following REMS approval."[14] You acknowledged in December 2021 that FDA modified the REMS for Mifepristone "after reviewing the data and information submitted by the applicant … and after taking into consideration the

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[7] Food and Drug Administration, "Mifeprex (mifepristone) Information," https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information.

[8] The American College of Obstetricians and Gynecologists, "Understanding the Practical Implications of the FDA's December 2021 Mifepristone REMS Decision," news release, March 28, 2022, https://www.acog.org/news/news-articles/2022/03/understanding-the-practical-implications-of-the-fdas-december-2021-mifepristone-rems-decision; Congressional Research Service, "Medication Abortion: A Changing Legal Landscape," Jennifer A. Staman and John O. Shimabukuro, October 5, 2022, https://crsreports.congress.gov/product/pdf/LSB/LSB10706.

[9] Inside Health Policy, "Abortion Pill Makers Send FDA Detailed Proposal To Expand Access," Beth Wang, July 12, 2022, https://insidehealthpolicy.com/inside-telehealth-daily-news/abortion-pill-makers-send-fda-detailed-proposal-expand-access.

[10] New England Journal of Medicine, "Sixteen Years of Overregulation: Time to Unburden Mifeprex," Mifeprex REMS Study Group, February 23, 2017, https://www.nejm.org/doi/10.1056/NEJMsb1612526.

[11] Letter from Food and Drug Administration to American College of Obstetricians and Gynecologists, April 12, 2021, https://www.aclu.org/letter/fda-response-acog-april-2021; Washington Post, "Abortion Pills by mail are safe. The FDA finally acknowledged it," Daniel Grossman, December 20, 2021, https://www.washingtonpost.com/outlook/2021/12/20/telemedicine-abortion-fda-safe/.

[12] New England Journal of Medicine, "Abortion Safety and Use with Normally Prescribed Mifepristone in Canada," Laura Schummers, Elizabeth K. Darling, Sheila Dunn, Kimberlyn McGrail, Anastasia Gayowsky, Michael R. Law, Tracey-Lea Laba, Janusz Kaczorowski, and Wendy V. Norman, January 6, 2022, https://www.nejm.org/doi/full/10.1056/NEJMsa2109779.

[13] *Id.*

[14] Food and Drug Administration, "Frequently Asked Questions," https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems.

safety data that had become available since the initial approval of Mifeprex in 2000."[15] Given this example, we urge you to proactively review the remaining REMS to determine if any restrictions placed on the prescription and distribution of Mifepristone, including patient consent forms, are also medically unnecessary.[16]

3. **Work with Drug Sponsors to Add a Miscarriage Indication for Mifepristone with Misoprostol.** To further protect reproductive health and rights, we urge you to work with drug sponsors to add an additional indication to the Mifepristone with misoprostol label: use for miscarriage management.[17] As many as 26 percent of all pregnancies end in miscarriage,[18] and Mifepristone, when taken with misoprostol, significantly improves the management of early pregnancy loss and results in fewer complications.[19] Yet, many patients in states that have restricted access to medication abortion have reported being denied these medications to treat their miscarriages – to devastating effect.[20] Coordinating with drug sponsors to update the Mifepristone with misoprostol label will help ensure that patients experiencing miscarriages are not denied access to this medication.[21] Until you update the label, we ask FDA to exercise enforcement discretion regarding the use and distribution of Mifepristone under its current REMS and indication.

Since the Supreme Court overturned *Roe v. Wade,* states have continued to place radical bans and restrictions on abortion.[22] As states implement new restrictions, it is more important than ever that you take immediate steps to expand access to medication abortion. We encourage and support your efforts to protect access to abortion and reproductive rights across the nation. To continue coordinating our efforts, we request a staff-level briefing or written response by December 1, 2022 that provides a detailed update on FDA's actions regarding the REMS for Mifepristone and the Mifepristone with misoprostol label.

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[15] Letter Food and Drug Administration Center for Drug Evaluation and Research to American Association of Pro-Life Obstetricians and Gynecologists and American College of Pediatricians, December 16, 2021, https://www.regulations.gov/document/FDA-2019-P-1534-0016.

[16] New England Journal of Medicine, "Sixteen Years of Overregulation: Time to Unburden Mifeprex," Mifeprex REMS Study Group, February 23, 2017, p. 793, https://www.nejm.org/doi/10.1056/NEJMsb1612526.

[17] Citizen Petition from American College of Obstetrician and Gynecologists to Food and Drug Administration, October 4, 2022, https://emaaproject.org/wp-content/uploads/2022/10/Citizen-Petition-from-the-American-College-of-Obstetrician-and-Gynecologists-et-al-10.3.22-EMAA-website.pdf.

[18] National Library of Medicine, "Miscarriage," Carla Dugas and Valori H. Slane, June 27, 2022, https://www.ncbi.nlm.nih.gov/books/NBK532992/.

[19] American College of Obstetricians and Gynecologists, "Early Pregnancy Loss," practice bulletin, November 2018, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss; New England Journal of Medicine, "Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss," Courtney A. Schreiber, Mitchell D. Creinin, Jessica Atrio, Sarita Sonalkar, Sarah J. Ratcliffe, and Kurt T. Barnhart, June 7, 2018, https://pubmed.ncbi.nlm.nih.gov/29874535/.

[20] Politico, "Patients face barriers to routine care as doctors warn of ripple effects from broad abortion bans," Alice Miranda Ollstein and Daniel Payne, September 28, 2022, https://www.politico.com/news/2022/09/28/abortion-bans-medication-pharmacy-prescriptions-00059228.

[21] The 19th, "Label change for mifepristone could reduce barriers to care for miscarriages, advocates say in petition to FDA," Jennifer Gerson, October 4, 2022, https://19thnews.org/2022/10/mifepristone-miscarriage-label-change-fda-petition/.

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Thank you for your prompt attention to this urgent matter.

Sincerely,

Elizabeth Warren
United States Senator

Bernard Sanders
United States Senator

Mazie K. Hirono
United States Senator

Kirsten Gillibrand
United States Senator

Angus S. King, Jr.
United States Senator

Chris Van Hollen
United States Senator

Edward J. Markey
United States Senator

Ron Wyden
United States Senator

Brian Schatz
United States Senator

EXHIBIT 13

Aria Bendix, *Why Abortions Rose After* Roe *Was Overturned*, NBC News (Nov. 26, 2024, at 2:00 PT)

— Abortions rose in the U.S. last year – an unexpected trend. Xinyue Chen for NBC News

ABORTION RIGHTS

Why abortions rose after Roe was overturned

Contrary to many predictions, abortions did not decline nationally after the Supreme Court's Dobbs decision. Here's what's behind the trend.

Nov. 26, 2024, 2:00 AM PST

By Aria Bendix

It seemed only logical after the Supreme Court overturned Roe v. Wade that abortion rates would go down and births would go up.

Instead, the opposite happened: Abortions went up last year and the country's fertility rate hit a historic low.

More than 1 million abortions were recorded in the United States in 2023 – the highest in a decade, according to the Guttmacher Institute, a research group that supports abortion access. So far this year, abortion rates have remained about the same as in the last six months of 2023, preliminary data show.

"The post-Dobbs world wasn't as bad as we expected," said Diana Greene Foster, a reproductive health researcher at the University of California, San Francisco. "It happened that people were denied abortions before Dobbs. It's likely happening after Dobbs, but not to the extent that I, at least, was worried about."Foster predicted in 2022 that a quarter of women who wanted abortions in states with bans would give birth instead. Now, she thinks the share might be somewhere in the low single digits.

What happened to keep the abortion rates from falling?

To answer that question, NBC News sought out the people and systems behind the trend – spending a day at an Illinois Planned Parenthood clinic, meeting with the Dutch doctor whose work was crucial to preserving access to abortion pills in the U.S., and speaking with key players from all corners of the abortion rights landscape: providers, researchers, abortion fund directors, advocates, lawyers, policy experts and anti-abortion groups.

— An abortion rights advocate cries outside the Supreme Court after it overturned Roe v. Wade on June 24, 2022. Frank Thorp V / NBC News

Much of the story, it turns out, comes down to a small network of medical providers who found ways to prescribe and ship abortion pills around the country from places where they're still legal. That was only possible because of significant action taken by the Food and Drug Administration during the pandemic, which allowed the pills to be dispensed via telemedicine. Then, in the wake of the ruling in Dobbs v. Jackson Women's Health Organization, eight states passed laws that protected providers from being sued for prescribing abortion pills virtually to people from other states.

"The obstacles are actually lower than before Dobbs," said Dr. Rebecca Gomperts, the Dutch physician who founded Aid Access, an organization that mails abortion medications to individuals who request them. "For people that didn't have the financial resources or the infrastructure, the logistical structures in place to go to a clinic ... I think the landscape now is much better."

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HEALTH

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Outrage over the Dobbs decision also spurred a wave of donations and educational campaigns that helped expand access to in-person abortions at clinics. Funds that provide financial support to people seeking to end their pregnancies used that money to help discount or cover the cost of abortions, including travel and lodging for those who crossed state lines. Abortion providers, meanwhile, got an influx of funding that enabled them to set up new clinics and extend hours in states where abortion is still legal.

"It was kind of all hands on deck after Dobbs to get people the information and access to make sure that these abortion bans were not going to stop people from being able to access care," said Serra Sippel, executive director of The Brigid Alliance, a service that provides abortion seekers with support for travel, food, lodging and child care.

Abortions in the U.S.

In excess of a million abortions were estimated to be performed in 2023, more than the reported count in any of the years in the past decade where data is available.

Notes: Figures are rounded to the nearest 10.
Source: Guttmacher Institute
Graphic: Joe Murphy / NBC News

Donald Trump's election victory, however, could change that new status quo. Abortion pills are a target for anti-abortion activists, who hope the incoming administration might revoke provisions that allow the medications to be prescribed via telehealth and mailed nationwide. When asked about that possibility, Karoline Leavitt, a Trump-Vance transition spokeswoman, told NBC News that "President Trump has long been consistent in supporting the rights of states to make decisions on abortion."

Still, advocates on both sides of the issue said they are gearing up for a fight.

"We were under no illusions that Dobbs was going to solve the problem," said Randall O'Bannon, director of education and research for National Right to Life, an organization that opposes abortion. "The work is still very much going to need to be done, and we don't expect that the other side is going to give up or quit trying."

How pills preserved abortion access

Raised in a harbor town in the Netherlands, Gomperts has dedicated her life to preserving abortion access. Over coffee during a visit to New York City, she spoke about the subject with a clinical sensibility – perhaps because of her

background as a physician, perhaps because of how often she has to assert her viewpoint.

In 1999, Gomperts founded an organization that transported women from places with restrictions to a ship in international waters to obtain abortions. She launched a global telemedicine abortion service six years later, then in 2018 started Aid Access, which is headquartered in Austria.

“We know that people are scared,” Gomperts said. “Because of all the misinformation out there, they think that they’re breaking the law, which they’re not. It’s legal for women to do their own abortions.”

— Dr. Rebecca Gomperts in New York on Oct. 14. Elise Wrabetz / NBC News

To obtain pills via Aid Access, people fill out a questionnaire, sign a consent form, email an image of their ID and pay $150 – though the bill is adjusted on a sliding scale. The pills usually arrive within five days of being prescribed.Since the Dobbs decision, Gomperts said, Aid Access has seen a tenfold increase in demand.

The group's operating model relies on several FDA policies. In 2016, the agency enabled mifepristone – one of the two pills used in medication abortions – to be used up to 10 weeks' gestation instead of seven. Three years later, it approved a generic form, which increased supply.

Then came the biggest change: In 2021, the FDA eliminated the requirement to dispense mifepristone in person.

By last year, medication abortions accounted for 63% of abortions nationwide, up from 53% in 2020, according to the Guttmacher Institute. The institute does not disclose which providers are represented in its estimate, but some medication abortions are left out, including in states with bans, so the numbers are likely an undercount.

The pharmaceutical company that makes mifepristone, Danco Laboratories, said it does not publicly share its sales data. GenBioPro, the company that makes the generic version, also declined to provide such numbers. At the time of the Dobbs decision, 19 states banned or restricted telehealth prescriptions of abortion pills. Aid Access bypassed those laws because it was based overseas – physicians in Europe prescribed the pills to patients in the U.S. via a pharmacy in India.

Once post-Dobbs "shield" laws protected some providers who prescribe pills to patients in states where abortion is banned, Aid Access switched to partnering with a U.S. pharmacy and providers. Other telemedicine groups also began offering the pills nationwide, including A Safe Choice and the Massachusetts Medication Abortion Access Project, both of which said most of their patients are in states with abortion restrictions.

"Aid Access created and provided a model for other providers to replicate – not just replicate, but to expand upon," said Dr. Remy Coeytaux, a representative for A Safe Choice.

— Mifepristone and misoprostol pills.

Erin Hooley / Chicago Tribune via Getty Images file

“Had this small network of physicians not done this, there wouldn’t be access to telemedicine abortion” in states with bans, he added.It’s no surprise that anti-abortion groups are keen on stopping this work, and want to see the FDA changes rolled back.

“The ability of women to get these drugs online now, without an in-person visit, because of what the FDA did has essentially circumvented any law that a state might pass,” said Dr. Christina Francis, the CEO of American Association of Pro-Life OBGYNs, an anti-abortion group.

A surge in interstate travel for abortions

Although procedural abortions are harder to obtain post-Dobbs, out-of-state travel is another reason why abortions rose last year.

Nationally, more than 171,000 people crossed state lines to obtain an abortion in 2023 – roughly double the number in 2020, according to the Guttmacher Institute. Illinois has seen more out-of-state abortions than any other state, a 71% increase from 2020 to 2023.

Nekia, 25, traveled to Illinois from Whitestown, Indiana, to obtain an abortion last year; she asked that her last name not be published because of privacy concerns.

Nekia said she found out she was pregnant just after her state’s abortion ban took effect in August 2023. At the time, she added, she was pursuing a master’s degree and working full-time in marketing, and money was painfully tight.

“The last thing I could afford to do was to have a pregnancy,” she said. “That was a big motivating factor for me. I was like, ‘Regardless of how hard it is to figure this out, I’m going to get it figured out, and I’m going to make sure that I get to Illinois so I can get this done.’”

Not being able to afford a child is the most commonly cited reason for seeking an abortion, and the majority of women who do so are mothers already. About half are below the poverty line.

Nekia traveled to a Planned Parenthood clinic in Champaign, Illinois, about 2½ hours away, but said coming up with the money for gas and the procedure was a struggle.

“It was just stressful,” she said. “It was a lot of thinking, a lot of anxiety. ... Maybe I shouldn’t do this. Maybe I should just carry to term, because it just feels like there’s so many obstacles.”

To her relief, she said, Planned Parenthood gave her a prepaid gas card and discounted her procedure.

— Abortion rights demonstrator Amanda Herring and her 1-year-old son, Abraham, outside the Supreme Court on June 24, 2022. Hannah Beier for NBC News

Donations to abortion funds and clinics have helped enable travel for people like Nekia. Last year, abortion funds provided more than $36 million in aid to those seeking abortions, according to the National Network of Abortion Funds.At the same time, a new public spotlight on abortion has helped advocates promote resources for people seeking them.

“One of the positive consequences of the horrific decision overturning Roe, was that people became more aware of their rights, even as these rights were taken

away," said Julie Kay, executive director of the Abortion Coalition for Telemedicine Access.

However, leaders of abortion funds and networks said donations have waned significantly in the last year, raising questions about whether interstate travel for abortions will continue at the same pace in the future.

"To be able to remain open to serve multiple people, we have to put limitations on the amount that we support per client," said Stephanie Loraine Piñeiro, executive director of the Florida Access Network, an abortion fund.

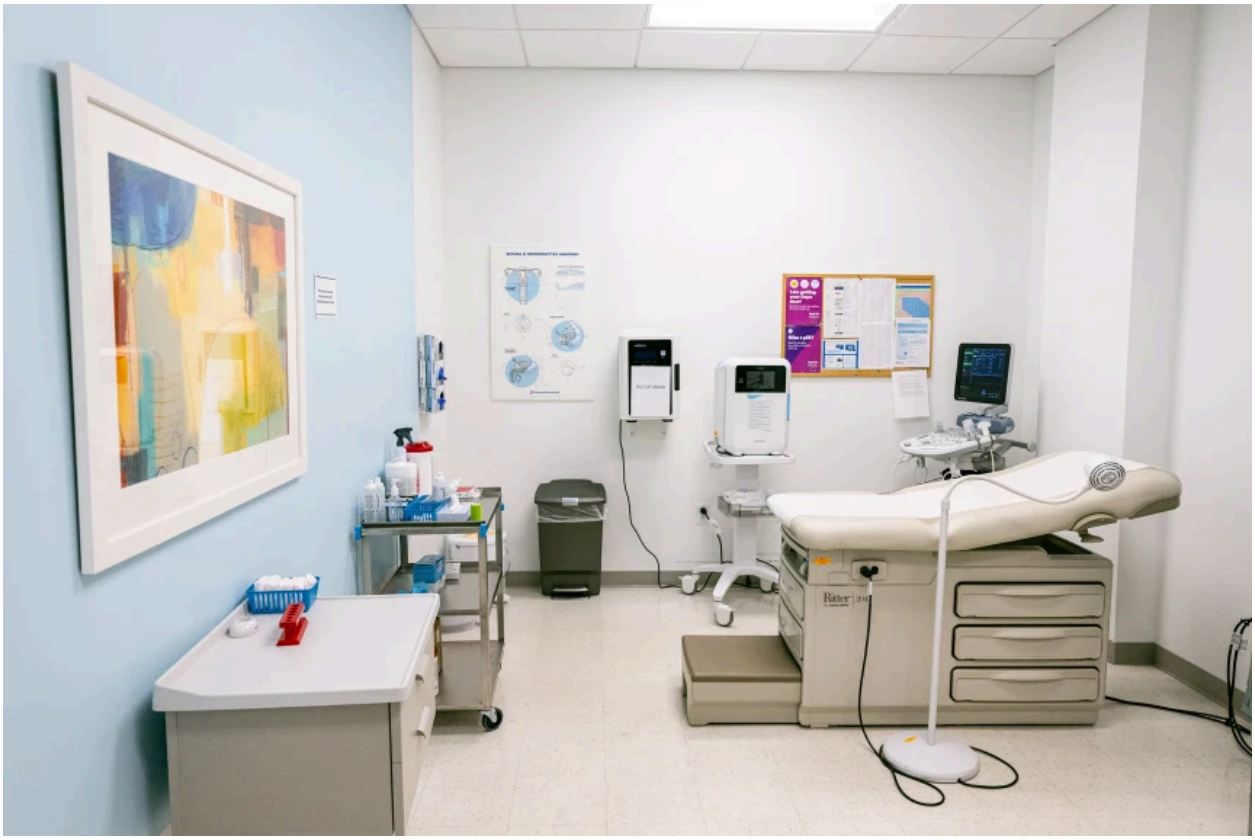
What the data hides

The nationwide rise in abortions can obscure the reality that some people who want abortions still can't get them – particularly low-income women of color.

Dr. Amy Whitaker, chief medical officer at a Planned Parenthood clinic in Flossmoor, Illinois, said the Dobbs decision has made it significantly harder for patients to reach her.

"Even the ones who make it to care, they just have had to go through so much more," she said.

Indeed, the waiting room at her clinic was packed on a Friday morning in September. Many patients travel long distances to get there from states with abortion restrictions – the clinic estimates they make up about 22% of its abortion patients.



An examination room at a Planned Parenthood Health Center in Louisville, Ky., in 2022. Jon Cherry / Getty Images file

Data isn't available on how many unwanted pregnancies have been carried to term since the Dobbs decision, but an April study found that abortion bans had resulted in a 2% average increase in births in the states that implemented them."You can clearly see that there is a little bit of an increase in childbearing relative to the nonban states," said Sarah Miller, a health economist at the University of Michigan.

Whitaker is known for her exuberance among her staff – sometimes dancing in the hallways between appointments – but the aftermath of the Dobbs decision has changed her demeanor.

"When you know your patients are struggling and suffering, it affects your day to day," she said. "I cry more often. I'm just so sad."

What comes next?

Advocates on both sides of the abortion rights issue don't think a federal ban is likely after Trump takes office, but they anticipate that the new administration could restrict abortion in other ways. One avenue they described is for the FDA

to rescind the licensing of mifepristone or roll back the changes that expanded its access.

“My expectation would be that his FDA would re-evaluate the Biden FDA’s decision to authorize mail-order abortion and determine that it was unlawful and dangerous to do so,” said Erik Baptist, senior counsel for the Alliance Defending Freedom, an anti-abortion legal group.

The attorneys general of Idaho, Kansas and Missouri also filed a lawsuit last month challenging the FDA actions that expanded mifepristone access. The case was filed in a federal court in Texas where the sole judge, Matthew Kacsmaryk, is a Trump appointee.

— Misoprostol tablets at a family planning clinic. Anna Moneymaker / Getty Images file

Kacsmaryk previously ruled in favor of abortion opponents who challenged mifepristone, but the Supreme Court said the plaintiffs lacked standing to sue. Reproductive rights lawyers said that this time, Trump’s Justice Department could choose not to appeal if Kacsmaryk sides with the attorneys general.Additionally, the lawyers raised the possibility that the next attorney

general could try to enforce the Comstock Act, an 1873 law that prohibits mailing and receiving "obscene" materials and those designed or intended to procure an abortion.

The Center for Reproductive Rights and the American Civil Liberties Union – the legal groups behind several major abortion rights cases – said they have strategies to counter any future changes to FDA rules or enforcement of the Comstock Act. The Center last year also filed a lawsuit challenging some remaining FDA restrictions on mifepristone. Planned Parenthood, meanwhile, has said it will continue fighting for abortion rights via state ballot measures.

To Gomperts, whose organizations have managed to skirt abortion restrictions around the world for decades, the election results aren't cause for panic.

"Whatever happens, people will get their abortion pills no matter what," she said. "I don't think that is ever going to go away."

This article was produced in collaboration with the USC Annenberg Center for Health Journalism's 2024 National Fellowship Fund for Reporting on Child Well-being.

Aria Bendix

Aria Bendix is the breaking health reporter for NBC News Digital.


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EXHIBIT 14

Complaint, *Rodriguez v. Coeytaux*,
No. 3:25-cv-00225, (S.D. Tex. July 20, 2025)

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

Jerry Rodriguez, on behalf of himself and others similarly situated, Plaintiff, v. **Remy Coeytaux**, Defendant.	Case No. 3:25-cv-225

COMPLAINT

Under the law of Texas, a person who assists a pregnant woman in obtaining a self-managed abortion commits the crime of murder and can be sued for wrongful death. *See* Texas Penal Code § 1.07; *id.* at § 19.02; *id.* at § 19.06 (murder statute); Tex. Civ. Prac. & Rem. Code § 71.001 *et seq.* (wrongful-death statute). It is also a state jail felony for anyone other than a Texas-licensed physician to provide an abortion-inducing drug for the purpose of inducing an abortion. *See* Tex. Health & Safety Code § 171.063(a); Tex. Health & Safety Code § 171.065(a).

In violation of these and many other laws, defendant Remy Coeytaux mailed abortion-inducing drugs into Texas that were used to murder Jerry Rodriguez's unborn child. Mr. Rodriguez sues to recover damages from Coeytaux for this wrongful death. Mr. Rodriguez also seeks an injunction to stop Coeytaux from distributing abortion-inducing drugs in violation of state or federal law.

JURISDICTION AND VENUE

1. The Court has subject-matter jurisdiction under 28 U.S.C. § 1332, as the parties are diverse and the amount in controversy exceeds $75,000.00.

2. The Court has personal jurisdiction over defendant Coeytaux because he purposefully and knowingly mailed abortion-inducing drugs into Texas in violation of state law, and Mr. Rodriguez's claim arises out of those minimum contacts with the forum state.

3. Venue is proper in this district and division because a substantial part of the events giving rise to the claims occurred in Galveston County. *See* 28 U.S.C. § 1391(b)(2). Venue is additionally proper because each of the defendants resides in Galveston County. *See* 28 U.S.C. § 1391(b)(1).

PARTIES

4. Plaintiff Jerry Rodriguez is a citizen of Texas.

5. Defendant Remy Coeytaux is a citizen of California, where he operates a solo medical practice.

STATEMENT OF FACTS

6. Plaintiff Jerry Rodriguez began dating Kendal Garza in June of 2024.

7. In July of 2024, Kendal became pregnant with Mr. Rodriguez's child.

8. Although Kendal was happy about the pregnancy and told Mr. Rodrigez that she planned to give birth, her estranged husband (Adam Garza) was displeased and wanted the baby murdered. Kendal had legally separated from Adam years before she started dating Mr. Rodriguez but had not yet divorced him.

9. On September 16, 2024, at 9:10 P.M. central time, Adam Garza ordered abortion-inducing drugs online from Coeytaux with the intent of using them to murder Mr. Rodriguez's unborn child. A Venmo receipt confirming Adam's purchase of the drugs from Coeytaux is attached as Exhibit 1. The receipt indicates that the drugs were purchased for $150.00 from "Remy Coeytaux MD PC" and describes the purchase as "'Aed axes Kendal Garza.'" The first two words ("Aed axes") are homophones

for "Aid Access," an organization that illegally ships abortion-inducing drugs into jurisdictions where abortion has been outlawed. Payment was made with a Visa Debit card whose last four digits are 1012. The payment was remitted to a Venmo account with the handle "@RemyCoeytaux."

10. After receiving this order, Coeytaux shipped the abortion-inducing drugs to Adam Garza's house in Galveston County, Texas.

11. On September 19, 2024, Kendal Garza used the drugs that Adam had purchased from Coeytaux to kill the unborn child that she conceived with Mr. Rodriguez. Kendal told Mr. Rodriguez that Adam Garza provided her with the abortion drugs, and that both Adam and her mother (Kim Crawford Williams) pressured her to kill the baby with the drugs obtained from Coeytaux. Kendal ingested the abortion-inducing drugs and killed Mr. Rodriguez's unborn child at Ms. Williams's house in Galveston County. Kendal was more than 10 weeks pregnant when she took the pills.

12. In late October 2024, Kendal became pregnant for a second time with Mr. Rodriguez's child. Kendal was again happy about the pregnancy and told Mr. Rodrigez that she planned to give birth to their child, a son. On January 18, 2025, Kendal and Mr. Rodriguez together went to a doctor's appointment and were provided with sonograms of the baby boy, which are attached as Exhibit 2.

13. But later in January Kendal killed Mr. Rodriguez's unborn son with abortion pills that were illegally obtained and provided by Adam Garza. This time Kendal took the abortion-inducing drugs at Adam's house in Galveston County. Kendal proceeded with this self-managed abortion even though she was nearly three months pregnant and even though Mr. Rodriguez pleaded with her not to do it. After the abortion, Kendal texted Mr. Rodriguez and told him that she had to cut the baby boy's umbilical cord and bury him (although she did not say where).

14. In May of 2025, Kendal became pregnant for a third time with Mr. Rodriguez's child. She is now two months pregnant. Mr. Rodriguez fears that Adam Garza

will again pressure Kendal to kill his unborn child and obtain abortion pills from Coeytaux to commit the murder.

CLAIM FOR RELIEF NO. 1 — WRONGFUL DEATH

15. The wrongful-death statute allows surviving parents to sue those who cause the death of an unborn child by a wrongful act, neglect, carelessness, unskillfulness, or default. *See* Tex. Civ. Prac. & Rem. Code § 71.002(b) ("A person is liable for damages arising from an injury that causes an individual's death if the injury was caused by the person's or his agent's or servant's wrongful act, neglect, carelessness, unskillfulness, or default."); Tex. Civ. Prac. & Rem. Code § 71.001(4) ("'Individual' includes an unborn child at every stage of gestation from fertilization until birth.").

16. Defendant Coeytaux caused the death of Mr. Rodriguez's unborn child through his wrongful acts, which violated the law in each the following respects:

17. Section 171.063(a)(1) of the Texas Health and Safety Code prohibits anyone other than a Texas-licensed physician from providing abortion-inducing drugs to a pregnant woman for the purpose of inducing an abortion. *See* Tex. Health & Safety Code § 171.063(a) ("A person may not knowingly provide an abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion in the pregnant woman or enabling another person to induce an abortion in the pregnant woman unless: (1) the person who provides the abortion-inducing drug is a physician"). A violation of section 171.063(a)(1) is a state jail felony. *See* Tex. Health & Safety Code § 171.065(a). Coeytaux is not a Texas-licensed physician, so he violated section 171.063(a)(1) by knowingly sending abortion-inducing drugs into Texas, which he knew would be provided to a pregnant woman for the purpose of inducing an abortion. Coeytaux is also criminally responsible for Adam Garza's violations of section 171.063(a)(1) because Coeytaux knowingly aided Adam's provision of abortion-inducing drugs to a pregnant woman. *See* Tex. Penal Code § 7.02.

18. Section 171.063(a)(2) of the Texas Health and Safety Code prohibits individuals from providing abortion-inducing drugs to a pregnant woman for the purpose of abortion unless they comply with the protocols in subchapter D of chapter 171 of the Texas Health and Safety Code. *See* Tex. Health & Safety Code § 171.063(a) ("A person may not knowingly provide an abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion in the pregnant woman or enabling another person to induce an abortion in the pregnant woman unless: . . . (2) the provision of the abortion-inducing drug satisfies the protocol authorized by this subchapter"). A violation of section 171.063(a)(2) is a state jail felony. *See* Tex. Health & Safety Code § 171.065(a). Coeytaux violated section 171.063(a)(2) by knowingly sending abortion-inducing drugs into Texas, which he knew would be provided to a pregnant woman for the purpose of inducing an abortion. Coeytaux is also criminally responsible for Adam Garza's violations of section 171.063(a)(2) because he knowingly aided Adam's provision of abortion-inducing drugs to a pregnant woman. *See* Tex. Penal Code § 7.02.

19. Section 171.0631 of the Texas Health and Safety Code prohibits any person from providing abortion-inducing drugs to a pregnant woman without complying with the informed-consent requirements of subchapter B of chapter 171 of the Texas Health and Safety Code, which include a mandatory ultrasound. *See* Tex. Health & Safety Code § 171.0631 ("A person may not provide an abortion-inducing drug to a pregnant woman without satisfying the applicable informed consent requirements of Subchapter B."). A violation of section 171.0631 is a state jail felony. *See* Tex. Health & Safety Code § 171.065(a). Coeytaux violated section 171.0631 by knowingly sending abortion-inducing drugs into Texas, which he knew would be provided to a pregnant woman for the purpose of inducing an abortion. Coeytaux is also criminally responsible for Adam Garza's violations of section 171.0631 because he knowingly

aided Adam's provision of abortion-inducing drugs to a pregnant woman. *See* Tex. Penal Code § 7.02.

20. Section 171.003 of the Texas Health and Safety Code prohibits anyone other than a Texas-licensed physician to perform abortions. *See* Tex. Health & Safety Code § 171.003 ("An abortion may be performed only by a physician licensed to practice medicine in this state."). Coeytaux is not a Texas-licensed physician, and he performed an abortion in violation of section 171.003 by arranging for the delivery and provision of the abortion pills that Kendal Garza used in her self-managed abortion. Coeytaux further violated section 171.003 by knowingly aiding an illegal self-managed abortion in Texas. *See* Tex. Penal Code § 7.02.

21. Section 171.011 of the Texas Health and Safety Code prohibits any person from performing an abortion without complying with the informed-consent requirements of subchapter B of chapter 171 of the Texas Health and Safety Code, which include a mandatory ultrasound. *See* Tex. Health & Safety Code § 171.011 ("A person may not perform an abortion without the voluntary and informed consent of the woman on whom the abortion is to be performed."). Coeytaux performed an abortion in violation of section 171.011 by arranging for the delivery and provision of the abortion pills that Kendal Garza used in her self-managed abortion, which did not comply with the mandatory ultrasound and other statutory informed-consent requirements in Texas law. Coeytaux has further violated section 171.011 by aiding an illegal self-managed abortion in Texas without complying with the mandatory ultrasound and other statutory informed-consent requirements.

22. Chapter 245 of the Texas Health and Safety Code requires abortions in Texas to be performed in licensed abortion facilities (subject to exceptions not applicable here). *See* Tex. Health & Safety Code § 245.002(2) ("'Abortion facility' means a place where abortions are performed."); *id.* at § 245.003(a) ("Except as provided by Section 245.004, a person may not establish or operate an abortion facility in this state

without an appropriate license issued under this chapter."). Coeytaux violated chapter 245 of the Texas Health and Safety Code by performing and assisting an abortion that took place outside a licensed abortion facility.

23. Federal law imposes criminal liability on any person who:

a. Knowingly uses the mails for the mailing, carriage, or delivery of abortion-inducing drugs;

b. Knowingly uses any express company, common carrier, or interactive computer service for carriage of abortion-inducing drugs in interstate or foreign commerce; or

c. Knowingly takes or receives abortion-inducing drugs from an express company, a common carrier, or an interactive computer service.

18 U.S.C. §§ 1461–1462. Coeytaux violated these federal criminal laws by sending abortion-inducing drugs into Texas with the intent of aiding an illegal abortion.

24. Articles 4512.1–4512.6 of the Texas Revised Civil Statutes make abortion a felony criminal offense unless the life of the mother is endangered. Violations of articles 4512.1–4512.6 are punishable by two to five years imprisonment. Coeytaux violated articles 4512.1–4512.6 by performing or assisting an abortion in Texas that was not needed to save the life of the mother.

25. Section 170A.002 of the Texas Health and Safety Code also makes abortion a felony criminal offense unless the abortion is performed to avert the risk of death or a serious risk of substantial impairment of a major bodily function. *See* Tex. Health & Safety Code § 170A.002. Violations of section 170A.002 are punishable by five to 99 years imprisonment. *See* Tex. Penal Code § 12.32. Coeytaux violated section 170A.002 by performing or assisting an abortion in Texas that was not needed to avert the risk of death or a serious risk of substantial impairment of a major bodily function.

26. Assisting a self-managed abortion in Texas is an act of murder. *See* Texas Penal Code § 1.07; *id.* at § 19.02; *id.* at § 19.06 (murder statute). Although Kendal

Garza cannot be charged with murder for her role in killing her unborn child,[1] her immunity does not shield Coeytaux from liability for aiding or abetting or directly participating in the murder. *See* Tex. Penal Code § 7.03 ("In a prosecution in which an actor's criminal responsibility is based on the conduct of another, the actor may be convicted on proof of commission of the offense and that he was a party to its commission, and it is no defense: (1) that the actor belongs to a class of persons that by definition of the offense is legally incapable of committing the offense in an individual capacity; or (2) that the person for whose conduct the actor is criminally responsible has been acquitted, has not been prosecuted or convicted, has been convicted of a different offense or of a different type or class of offense, or is immune from prosecution."). Coeytaux directly committed murder under section 19.02(b)(1) because he "intentionally and knowingly caused the death" of Mr. Rodriguez's unborn child by delivering abortion pills that he knew would be used in an illegal self-managed abortion. *See* Tex. Penal Code § 19.02(b) ("A person commits an offense if he: (1) intentionally or knowingly causes the death of an individual"). And Coeytaux directly committed murder under section 19.02(b)(2) because he "intended to cause serious bodily injury and committed an act clearly dangerous to human life that caused the death" of Mr. Rodriguez's unborn child. *See* Tex. Penal Code § 19.02(b) ("A person commits an offense if he: . . . (2) intends to cause serious bodily injury and commits an act clearly dangerous to human life that causes the death of an individual").

27. Coeytaux is also guilty of felony murder under section 19.02(b)(3) of the Texas Penal Code. Coeytaux's shipment of abortion pills to Adam Garza was a felony. *See* Tex. Health & Safety Code § 171.063(a); Tex. Health & Safety Code § 171.065(a); 18 U.S.C. §§ 1461–1462. Coeytaux also committed an act "clearly

1. *See* Texas Penal Code § 19.06 ("This chapter does not apply to the death of an unborn child if the conduct charged is: (1) conduct committed by the mother of the unborn child").

dangerous to human life that causes the death of an individual." Tex. Penal Code § 19.02(b)(3); Texas Penal Code § 1.07 (defining "individual" to include "an unborn child at every stage of gestation from fertilization until birth."). Coeytaux therefore committed felony murder under section 19.02(b)(3).

28. The manufacturers and distributors of the abortion pills that Kendal used are jointly and severally liable for the wrongful death of Mr. Rodriguez's unborn child, and they will be added as defendants once identified. The manufacturer and distributors caused the death of Mr. Rodriguez's unborn child through a "wrongful act" because they violated 18 U.S.C. §§ 1461–1462, which imposes federal criminal liability on anyone who knowingly sends or receives abortion pills through the mail or by using any express company, common carrier, or interactive computer service.

29. None of the exceptions in Texas's wrongful-death statute shield the defendants (or the manufacturers and distributors of the abortion pills) from liability. Sections 71.003(c)(2) and (c)(4) of the Texas Civil Practice and Remedies Code are inapplicable because assisting a self-managed abortion is not a "lawful medical procedure," nor is it a "lawful medical or health care practice or procedure." Section 71.003(c)(3) is inapplicable because the abortion pills were not dispensed or administered "in accordance with law." Coeytaux is therefore liable under section 71.003 and must pay damages to Mr. Rodriguez for murdering his unborn child.

30. Mr. Rodriguez seeks damages in excess of $75,000.00, the minimum amount in controversy required for diversity jurisdiction. *See* 28 U.S.C. § 1332(a).

CLAIM FOR RELIEF NO. 2 — INJUNCTION

31. Mr. Rodriguez has standing to seek injunctive relief against Coeytaux because Kendal Garza is again pregnant with his unborn child, and there is a substantial risk that Adam Garza will obtain abortion pills illegally from Coeytaux and provide those to Kendal. *See TransUnion LLC v. Ramirez*, 594 U.S. 413, 435–36 (2021)

("[A] person exposed to a risk of future harm may pursue forward-looking, injunctive relief to prevent the harm from occurring"). This risk is fairly traceable to the allegedly unlawful conduct of Coeytaux, who continues to send abortion pills into Texas in violation of state and federal law, and it will be redressed by an injunction that restrains Coeytaux from illegally distributing abortion-inducing drugs.

32. Mr. Rodriguez seeks this injunction on behalf of a class of all current and future fathers of unborn children in the United States. *See* Fed. R. Civ. P. 23(b)(2).

DEMAND FOR RELIEF

33. Mr. Rodriguez respectfully requests that the court:

a. certify the class described in paragraph 32;

b. order Coeytaux to pay nominal, compensatory, and punitive damages to for the wrongful death of Mr. Rodriguez's unborn child;

c. permanently enjoin Coeytaux from distributing abortion-inducing drugs in violation of state or federal law, including 18 U.S.C. §§ 1461–1462;

d. award Mr. Rodriguez court costs and attorneys' fees; and

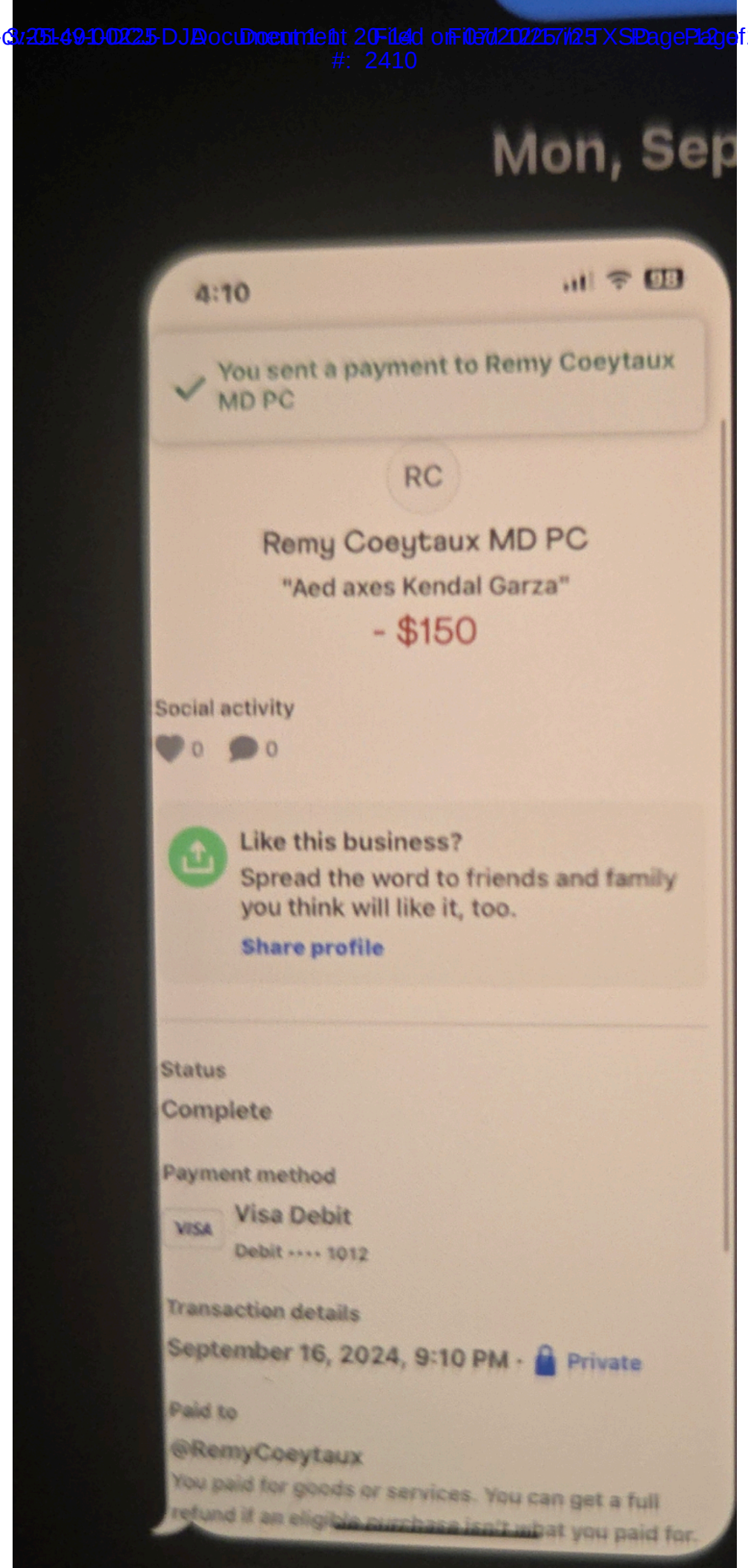
e. grant all other relief that the Court deems just, proper, or equitable.

Respectfully submitted.

/s/ Jonathan F. Mitchell
JONATHAN F. MITCHELL
Attorney in Charge
Texas Bar No. 24075463
S.D. Tex. Bar No. 1133287
Mitchell Law PLLC
111 Congress Avenue, Suite 400
Austin, Texas 78701
(512) 686-3940 (phone)
(512) 686-3941 (fax)
jonathan@mitchell.law

Counsel for Plaintiff and Proposed Class

Dated: July 20, 2025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98
You sent a payment to Remy Coeytaux MD PC
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Remy Coeytaux MD PC
"Aed axes Kendal Garza"
- $150
Social activity
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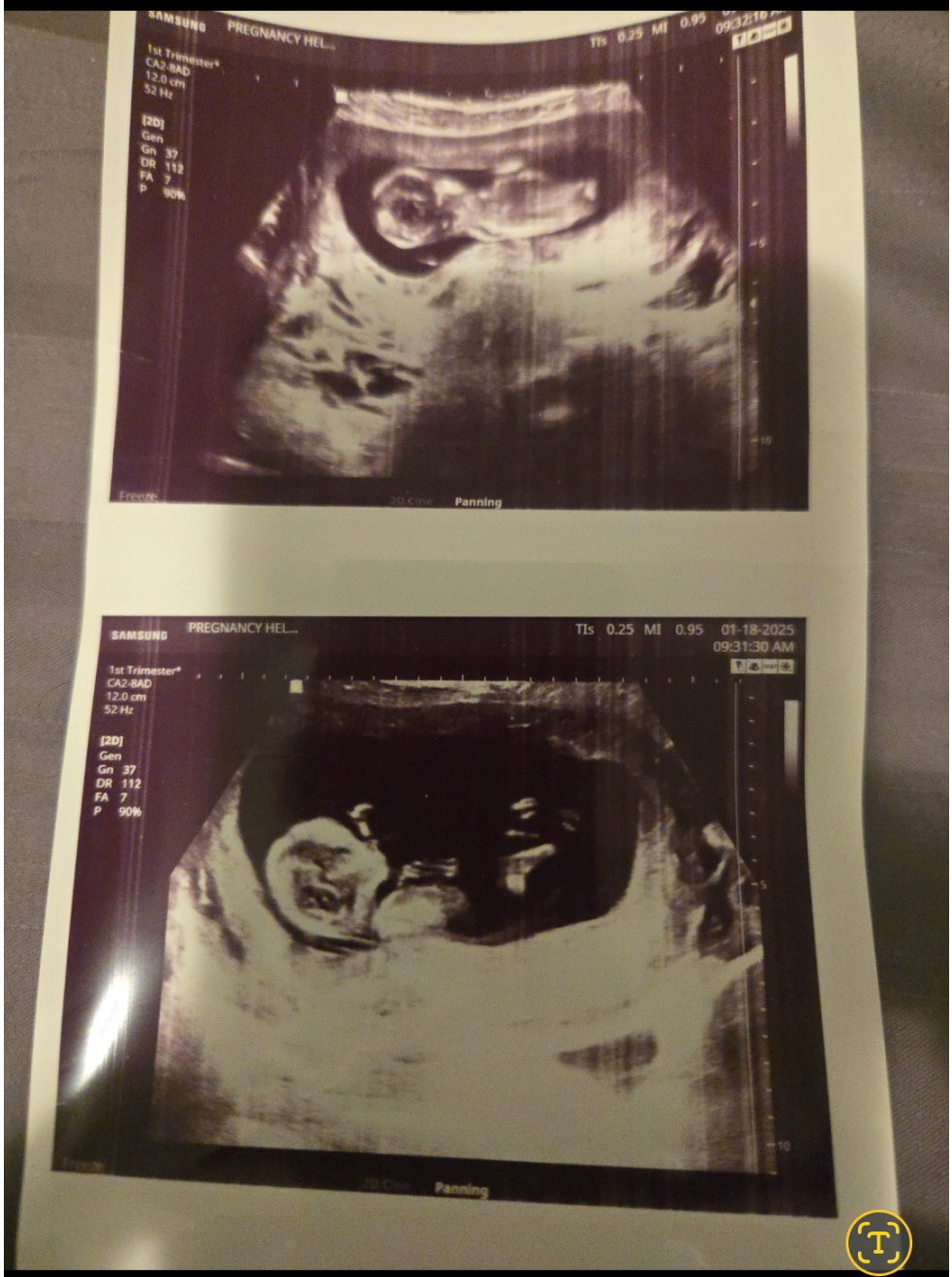
Like this business?
Spread the word to friends and family you think will like it, too.
Share profile
Status
Complete
Payment method
VISA
Visa Debit
Debit ···· 1012
Transaction details
September 16, 2024, 9:10 PM · Private
Paid to
@RemyCoeytaux
You paid for goods or services. You can get a full refund if an eligible purchase isn't what you paid for.


SAMSUNG
PREGNANCY HEL...
TIs 0.25 MI 0.95
1st Trimester*
CA2-BAD
12.0 cm
52 Hz
[2D]
Gen
Gn 37
DR 112
FA 7
P 90%
Freeze
2D Cine
Panning
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PREGNANCY HEL...
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1st Trimester*
CA2-BAD
12.0 cm
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Gn 37
DR 112
FA 7
P 90%
Freeze
2D Cine
Panning

EXHIBIT 15

Notice of Cease and Desist
from Ken Paxton, Att'y Gen. of Tex., to Remy Coeytaux
(Aug. 14, 2025)

KEN PAXTON
ATTORNEY GENERAL OF TEXAS

August 14, 2025

Via Certified Mail
7010 1060 0000 3703 4653

Remy Coeytaux
7765 Bodega Avenue
Sebastopo, California 95472

RE: Notice of Cease and Desist

Dear Mr. Coeytaux:

The Office of the Attorney General (OAG) has become aware that you have shipped abortion drugs into the State of Texas in violation of both state and federal laws. This letter serves as your notice to immediately **CEASE AND DESIST** this illegal activity.

You have been named in a recently filed lawsuit as having shipped abortion pills into the State of Texas via your affiliation with Aid Access. In *Rodriguez v. Coeytaux*, the plaintiff alleges that the abortion pills which caused the death of two preborn children were obtained from Aid Access via an order prescribed by you. Complaint at 2–3, No. 3:25-cv-00225 (S.D. Tex. Jul. 20, 2025), ECF No. 1.

This conduct violates multiple state and federal laws.

Performing, inducing, or attempting an abortion is prohibited in the State of Texas by the Human Life Protection Act, except for the rare circumstance when a woman has a life-threatening physical condition that poses a risk of death or serious physical impairment unless an abortion is performed. Tex. Health & Safety Code § 170A.002(a), (b); *see also* Texas Revised Civil Statutes Art. 4512.1–4512.6. Any person who "knowingly engages in conduct that aids or abets the performance or inducement of an abortion" is civilly and criminally liable for violating Texas's abortion laws. Tex. Health & Safety Code § 171.208; Tex. Health & Safety Code § 170A.004, Tex. Pen. Code § 7.02.

Furthermore, Texas law also specifically prohibits:

- Anyone not licensed as a physician in Texas from performing an abortion, Tex. Health & Safety Code §§ 171.003; 171.063(a)(1),
- A person from providing abortion-inducing drugs to a pregnant woman, Tex. Health & Safety Code § 171.063(a)(2);

- A manufacturer, supplier, physician, or any other person from providing to a patient any abortion-inducing drug by courier, delivery, or mail service, Tex. Health & Safety Code § 171.063(b-1).

In addition, the Comstock Act of 1873 prohibits the carriage in interstate commerce of "any drug, medicine, article, or thing designed, adapted or intended for producing abortion." 18 U.S.C. § 1462. Similarly, it prohibits the mailing of any "article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion." *Id.* § 1461.

Based on the allegations in *Rodriguez v. Coeytaux*, it appears that you are in violation of multiple state and federal laws. The Attorney General of Texas accordingly demands that you **IMMEDIATELY CEASE AND DESIST** from mailing abortion-inducing drugs into the State of Texas.

If you refuse to comply, a formal investigation will be initiated, and the Attorney General may bring a lawsuit against you for injunctive relief and civil penalties. If the Attorney General finds that you have committed violations of Texas's abortion laws, you will be prosecuted to the fullest extent permitted by law. The Attorney General may seek civil penalties for violations of the Human Life Protection Act of **not less than $100,000 per violation**.

Notify the OAG of the steps you have taken to remedy your violations of Texas law within 14 days of the date of this letter. Your response should be in writing and addressed to the address below. Alternatively, you may provide your response by email to Amy.Hilton@oag.texas.gov.

Thank you for your attention to this matter.

Sincerely,

/s/ Amy Snow Hilton

AMY SNOW HILTON
Chief, Healthcare Program Enforcement Division
KATHERINE PITCHER
Assistant Attorney General
Office of the Attorney General of Texas
Healthcare Program Enforcement Division
P.O. Box 12548, Capitol Station
Austin, Texas 78711-2548
Phone: (512) 936-1709
Amy.Hilton@oag.texas.gov
Katherine.Pitcher@oag.texas.gov
COUNSEL FOR STATE OF TEXAS

EXHIBIT 16

FDA, REMS Single Shared System for Mifepristone 200MG (May 2021)

Initial Shared System REMS approval: 04/2019
Most Recent Modification: 05/2021

Mifepristone Tablets, 200 mg

Progestin Antagonist

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

SINGLE SHARED SYSTEM FOR MIFEPRISTONE 200MG

I. GOAL

The goal of the REMS for mifepristone is to mitigate the risk of serious complications associated with mifepristone by:

a) Requiring healthcare providers who prescribe mifepristone to be certified in the Mifepristone REMS Program.

b) Ensuring that mifepristone is only dispensed in certain healthcare settings by or under the supervision of a certified prescriber.

c) Informing patients about the risk of serious complications associated with mifepristone.

II. REMS ELEMENTS

A. Elements to Assure Safe Use

1. Healthcare providers who prescribe mifepristone must be specially certified.
   a. To become specially certified to prescribe mifepristone, healthcare providers must:
      i. Review the Prescribing Information for mifepristone.
      ii. Complete a *Prescriber Agreement Form*. By signing a *Prescriber Agreement Form*, prescribers agree that:
         1) They have the following qualifications:
            a) Ability to assess the duration of pregnancy accurately
            b) Ability to diagnose ectopic pregnancies
            c) Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
         2) They will follow the guidelines for use of mifepristone (see b.i-v below).
   b. As a condition of certification, healthcare providers must follow the guidelines for use of mifepristone described below:
      i. Review the *Patient Agreement Form* with the patient and fully explain the risks of the mifepristone treatment regimen. Answer any questions the patient may have prior to receiving mifepristone.

ii. Sign the *Patient Agreement Form* and obtain the Patient's signature on the *Form*

iii. Provide the patient with a copy of the *Patient Agreement Form* and Medication Guide.

iv. Place the signed *Patient Agreement Form* in the patient's medical record.

v. Record the serial number from each package of mifepristone in each patient's record.

vi. Report any deaths to the Mifepristone Sponsor that provided the mifepristone, identifying the patient by a non- identifiable reference and the serial number from each package of mifepristone.

c. Mifepristone Sponsors must:

i. Ensure that healthcare providers who prescribe their mifepristone are specially certified in accordance with the requirements described above and de-certify healthcare providers who do not maintain compliance with certification requirements

ii. Provide the Prescribing Information and their *Prescriber Agreement Form* to healthcare providers who inquire about how to become certified.

The following materials are part of the REMS and are appended:

- *Prescriber Agreement Form for Danco Laboratories, LLC*
- *Prescriber Agreement Form for GenBioPro, Inc.*
- *Patient Agreement Form*

2. Mifepristone must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.

a. Mifepristone Sponsors must:

i. Ensure that their mifepristone is available to be dispensed to patients only in clinics, medical offices and hospitals by or under the supervision of a certified prescriber.

ii. Ensure that their mifepristone is not distributed to or dispensed through retail pharmacies or other settings not described above.

3. Mifepristone must be dispensed to patients with evidence or other documentation of safe use conditions.

a. The patient must sign a *Patient Agreement Form* indicating that the patient has:

i. Received, read and been provided a copy of the *Patient Agreement Form*.

ii. Received counseling from the prescriber regarding the risk of serious complications associated with mifepristone.

B. Implementation System

1. Mifepristone Sponsors must ensure that their mifepristone is only distributed to clinics, medical offices and hospitals by or under the supervision of a certified prescriber by:

a. Ensuring that distributors who distribute their mifepristone comply with the program requirements for distributors. The distributors must:

i. Put processes and procedures in place to:

a. Complete the healthcare provider certification process upon receipt of a Prescriber Agreement Form.

b. Notify healthcare providers when they have been certified by the Mifepristone REMS Program.

c. Ship mifepristone only to clinics, medical offices, and hospitals identified by certified prescribers in their signed *Prescriber Agreement Form*.

d. Not ship mifepristone to prescribers who become de-certified from the Mifepristone REMS Program.

e. Provide the Prescribing Information and their Prescriber Agreement Form to healthcare providers who (1) attempt to order mifepristone and are not yet certified, or (2) inquire about how to become certified.

ii. Put processes and procedures in place to maintain a distribution system that is secure, confidential and follows all processes and procedures, including those for storage, handling, shipping, tracking package serial numbers, proof of delivery and controlled returns of mifepristone.

iii. Train all relevant staff on the Mifepristone REMS Program requirements.

iv. Comply with audits by Mifepristone Sponsors, FDA or a third party acting on behalf of Mifepristone Sponsors or FDA to ensure that all processes and procedures are in place and are being followed for the Mifepristone REMS Program. In addition, distributors must maintain appropriate documentation and make it available for audits.

b. Ensuring that distributors maintain secure and confidential distribution records of all shipments of mifepristone.

2. Mifepristone Sponsors must monitor their distribution data to ensure compliance with the REMS Program.

3. Mifepristone Sponsors must audit their new distributors within 90 calendar days after the distributor is authorized to ensure that all processes and procedures are in place and functioning to support the requirements of the Mifepristone REMS Program. Mifepristone Sponsors will take steps to address their distributor compliance if noncompliance is identified.

4. Mifepristone Sponsors must take reasonable steps to improve implementation of and compliance with the requirements of the Mifepristone REMS Program based on monitoring and assessment of the Mifepristone REMS Program.

5. Mifepristone Sponsors must report to FDA any death associated with mifepristone whether or not considered drug-related, as soon as possible but no later than 15 calendar days from the initial receipt of the information by the applicant. This requirement does not affect the applicants other reporting and follow-up requirements under FDA regulations.

C. Timetable for Submission of Assessments

The NDA Sponsor must submit REMS assessments to FDA one year from the date of the initial approval of the REMS (04/11/2019) and every three years thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. The NDA Sponsor must submit each assessment so that it will be received by the FDA on or before the due date.

PRESCRIBER AGREEMENT FORM

Mifeprex® (Mifepristone) Tablets, 200 mg

Mifeprex* (Mifepristone) Tablets, 200 mg, is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Please see Prescribing Information and Medication Guide for complete safety information.

To set up your account to receive Mifeprex, you must:
1. complete, 2. sign, and 3. fax page 2 of this form to the distributor.

If you will be ordering for more than one facility, you will need to list each facility on your order form before the first order will be shipped to the facility.

Prescriber Agreement: By signing page 2 of this form, you agree that you meet the qualifications below and will follow the guidelines for use. You also understand that if you do not follow the guidelines, the distributor may stop shipping Mifeprex to you.

Mifeprex must be provided by or under the supervision of a healthcare provider who prescribes and meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the Prescribing Information of Mifeprex. The Prescribing Information is available by calling our toll free number, 1-877-4 Early Option (1-877-432-7596), or logging on to our website, www.earlyoptionpill.com.

In addition to meeting these qualifications, you also agree to follow these guidelines for use:

- Review the Patient Agreement Form with the patient and fully explain the risks of the Mifeprex treatment regimen. Answer any questions the patient may have prior to receiving Mifeprex.
- Sign and obtain the patient's signature on the Patient Agreement Form.
- Provide the patient with a copy of the Patient Agreement Form and the Medication Guide.
- Place the signed Patient Agreement Form in the patient's medical record.
- Record the serial number from each package of Mifeprex in each patient's record.
- Report deaths to Danco Laboratories, identifying the patient by a non-identifiable patient reference and the serial number from each package of Mifeprex.

ACCOUNT SETUP MIFEPREX® (Mifepristone) Tablets, 200 mg; NDC 64875-001-01

TO SET UP YOUR ACCOUNT:

1. Read the Prescriber Agreement on page 1 of this form.
2. Complete and sign this form.
3. Fax this page to the Danco distributor at 1-866-227-3343. Your account information will be kept strictly confidential.
4. The distributor will call to finalize your account setup and take your initial order.
5. Subsequent orders may be phoned or faxed and are usually shipped within 24 hours.

Mifeprex® (Mifepristone) Tablets, 200 mg
THE ORIGINAL EARLY OPTION PILL

BILLING INFORMATION

Bill to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

SHIPPING INFORMATION ☐ *Check if same as above*

Ship to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

ADDITIONAL SITE LOCATIONS *I will also be prescribing Mifeprex* at these additional locations:*

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

(Any additional sites may be listed on an attached sheet of paper.)

REQUEST ADDITIONAL MATERIALS

☐ **Medication Guides** ☐ **State Abortion Guides** ☐ **Patient Brochures** ☐ **Patient Agreement Form**

ESTABLISHING YOUR ACCOUNT *(required only with first order)*

Each facility purchasing Mifeprex must be included on this form (*see additional site locations box above*) before the distributor can ship the product to the facility.

By signing below, you agree that you meet the qualifications and that you will follow the guidelines for use on page 1 of the Prescriber Agreement.

Print Name _____ Signature _____

Medical License # _____ Date _____

FAX THIS COMPLETED FORM TO THE AUTHORIZED DISTRIBUTOR. FAX: 1-866-227-3343

Please fax any questions to the above number or call 1-800-848-6142.

*MIFEPREX is a registered trademark of Danco Laboratories, LLC.

Reference ID: 3909592

Reference ID: 4795916

Mifepristone Tablets, 200 mg, is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Please see Prescribing Information and Medication Guide for complete safety information.

To set up your account to receive mifepristone, you must:
1. complete, 2. sign and 3. fax page 2 of this form to the distributor.

If you will be ordering for more than one facility, you will need to list each facility on your order form before the first order will be shipped to the facility.

Prescriber Agreement: By signing page 2 of this form, you agree that you meet the qualifications below and will follow the guidelines for use. You also understand that if you do not follow the guidelines, the distributor may stop shipping mifepristone to you.

Mifepristone must be provided by or under the supervision of a healthcare provider who prescribes and meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the Prescribing Information for mifepristone. The Prescribing Information is available by calling our toll free number, 1-855-MIFE-INFO (1-855-643-3463), or logging on to our website, www.MifeInfo.com.

In addition to having these qualifications, you also agree to follow these guidelines for use:

- Review the Patient Agreement Form with the patient and fully explain the risks of the mifepristone treatment regimen. Answer any questions the patient may have prior to receiving mifepristone.
- Sign and obtain the patient's signature on the Patient Agreement Form.
- Provide the patient with a copy of the Patient Agreement Form and the Medication Guide.
- Place the signed Patient Agreement Form in the patient's medical record.
- Record the serial number from each package of mifepristone in each patient's record.
- Report deaths to GenBioPro, identifying the patient by a non-identifiable patient reference and the serial number from each package of mifepristone.

ACCOUNT SETUP

Mifepristone Tablets, 200 mg; NDC 43393-001-01

TO SET UP YOUR ACCOUNT:

1. **Read the Prescriber Agreement on Page 1 of this form.**
2. **Complete and sign this form.**
3. **Fax this page to the GenBioPro distributor at 1-877-239-8036.**
   Your account information will be kept strictly confidential.
4. **The distributor will call to finalize your account setup and take your initial order.**
5. **Subsequent orders may be phoned or faxed and are usually shipped within 24 hours**

BILLING INFORMATION

Bill to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

SHIPPING INFORMATION ☐ *Check if same as above*

Ship to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

ADDITIONAL SITE LOCATIONS *I will also be prescribing mifepristone at these additional locations:*

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

(Any additional sites may be listed on an attached sheet of paper)

REQUEST ADDITIONAL MATERIALS

☐ **Medication Guides** ☐ **State Abortion Guides** ☐ **Patient Brochures** ☐ **Patient Agreement Form**

ESTABLISHING YOUR ACCOUNT *(required only with first order)*

Each facility purchasing mifepristone tablets must be included on this form (*see additional site locations box above*) before the distributor can ship the product to the facility.
By signing below, you agree that you meet the qualifications and that you will follow the guidelines for use on page 1 of the Prescriber Agreement.

Print Name _____ Signature _____

Medical License # _____ Date _____

FAX THIS COMPLETED FORM TO THE AUTHORIZED DISTRIBUTOR. FAX: 1-877-239-8036

Please fax any questions to the above number or call 1-877-239-8036

PATIENT AGREEMENT FORM Mifepristone Tablets, 200mg

Healthcare Providers: *Counsel the patient on the risks of mifepristone. Both you and the patient must sign this form.*

Patient Agreement:

1. I have decided to take mifepristone and misoprostol to end my pregnancy and will follow my provider's advice about when to take each drug and what to do in an emergency.
2. I understand:
   a. I will take mifepristone on Day 1.
   b. My provider will either give me or prescribe for me the misoprostol tablets, which I will take 24 to 48 hours after I take mifepristone.
3. My healthcare provider has talked with me about the risks, including:
   - heavy bleeding
   - infection
   - ectopic pregnancy (a pregnancy outside the womb)
4. I will contact the clinic/office right away if in the days after treatment I have:
   - a fever of 100.4°F or higher that lasts for more than four hours
   - severe stomach area (abdominal) pain
   - heavy bleeding (soaking through two thick full-size sanitary pads per hour for two hours in a row)
   - stomach pain or discomfort, or I am "feeling sick," including weakness, nausea, vomiting, or diarrhea, more than 24 hours after taking misoprostol
5. My healthcare provider has told me that these symptoms could require emergency care. If I cannot reach the clinic or office right away, my healthcare provider has told me who to call and what to do.
6. I should follow up with my healthcare provider about 7 to 14 days after I take mifepristone to be sure that my pregnancy has ended and that I am well.
7. I know that, in some cases, the treatment will not work. This happens in about 2 to 7 out of 100 women who use this treatment. If my pregnancy continues after treatment with mifepristone and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy.
8. If I need a surgical procedure because the medicines did not end my pregnancy or to stop heavy bleeding, my healthcare provider has told me whether they will do the procedure or refer me to another healthcare provider who will.
9. I have the MEDICATION GUIDE for mifepristone. I will take it with me if I visit an emergency room or a healthcare provider who did not give me mifepristone so that they will understand that I am having a medical abortion with mifepristone.
10. My healthcare provider has answered all my questions.

Patient Signature: _____ **Patient Name** (print): _____ **Date**: _____

The patient signed the PATIENT AGREEMENT in my presence after I counseled the patient and answered all questions. I have given the patient the MEDICATION GUIDE for mifepristone.

Provider's Signature: _____ **Name of Provider** (print): _____ **Date**: _____

After the patient and the provider sign this PATIENT AGREEMENT, give 1 copy to the patient before the patient leaves the office and put 1 copy in the medical record.

EXHIBIT 17

REMS Compliance Program,
FDA (Sep. 22, 2022)

← Risk Evaluation and Mitigation Strategies | REMS

REMS Compliance Program

FDA conducts inspections to evaluate compliance with risk evaluation and mitigation strategies (REMS) requirements to ensure the drug's health benefits outweigh the risks for patients. Inspections are prioritized using a risk-based approach.

The agency will take action if issues found during the REMS inspections are not promptly and adequately corrected. Failure to comply with REMS requirements may result in enforcement action such as product seizure, injunction or civil money penalties.

FDA also reviews REMS assessment reports to evaluate compliance with legal and regulatory requirements. The agency takes appropriate regulatory action for noncompliance, which may include warning letters or untitled letters, to address serious safety concerns and mitigate risks to patients.

Additional resources

- REMS@fda
- REMS compliance program guide
- Webinar: Risk Evaluation and Mitigation Strategies (REMS) compliance program
- Webinar: Postmarketing drug safety and inspection readiness

Guidances

- FDA's application of statutory factors in determining when a REMS is necessary
- Development of a shared system REMS
- REMS assessment: Planning and reporting
- Format and content of REMS
- Medication guides – Distribution requirements and inclusion in REMS
- REMS: Modifications and revisions
- Providing regulatory submissions in electronic format – Content of the REMS document using Structured Product Labeling
- Use of a drug master file for shared system REMS submissions
- Waivers of the single shared system REMS requirement
- Survey methodologies to assess REMS goals that relate to knowledge
- Policy for certain REMS requirements during the COVID-19 public health emergency

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Content current as of:

09/22/2022

Regulated Product(s)

Drugs

Was this page helpful? *

◯ Yes

◯ No

Submit

An official form of the United States government. Provided by Touchpoints

EXHIBIT 18

Declaration of John Voltz, M.D.
(Nov. 17, 2025)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*.	Case No.: 6:25-cv-01491-DCJ-DJA Judge David C. Joseph Magistrate Judge David J. Ayo

DECLARATION OF DR. JOHN VOLTZ

I, John Voltz, M.D., a citizen of the United States of America and a resident of the State of Louisiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge. I am fully competent to make this declaration. If called to testify, I could and would testify competently to these facts.
2. I am a board-certified obstetrician and gynecologist. I graduated from Menard High School in Alexandria in 2006. I attended Louisiana State University, graduating in Civil Engineering in 2010. After graduation, I served as a full-time uniform Patrol Deputy in the East Baton Rouge Sheriff's Office.
3. I received my medical degree from Louisiana State University Health Sciences Center–Shreveport in 2018 and completed my residency at Saint Louis University in 2022. I returned home to Louisiana after residency, and I have practiced medicine in Louisiana since 2022.
4. I am a practicing obstetrician and gynecologist with admitting privileges at a large local general medical center in Lafayette, Louisiana.
5. I provide general OB/GYN care. I provide, among other things, labor and delivery care, prenatal care, preventative care, preconception counseling, and minimally invasive and vaginal gynecologic surgery, along with treatment for abnormal bleeding, infertility, pelvic pain, and menopause. I specialize in multiple births, high-risk pregnancies, and vaginal births after a cesarean section. I deliver approximately 300 babies per year.
6. I am on call as an emergency room consultant at the local general medical center in Lafayette.
7. Seventy percent of my patients are enrolled in Medicaid and pay for my services through Medicaid.

8. I have witnessed firsthand how the abortion drug mifepristone has hurt women in Louisiana.

9. I have treated a Louisiana patient who suffered complications after taking mifepristone in 2025.

10. The patient I treated was at five weeks gestation. I performed a dilation and curettage procedure due to an incomplete abortion and severe bleeding. This patient was on private insurance.

11. I presume this patient received the mifepristone by out-of-state mail because abortion drugs are illegal in Louisiana and no in-state provider could dispense the drugs in Louisiana.

12. Another patient—pregnant in her teenage years—came to my office with her mother. Her mother wanted her to take abortion drugs. At one of her ultrasound appointments, the unborn baby was no longer in the uterus. She had taken prescription mifepristone and misoprostol. The patient and her mother showed me the envelope the drugs were mailed in—with a New York sending address.

Executed this 17TH day of NOVEMBER 2025.

By _____
John Voltz, M.D.

EXHIBIT 19

Declaration of Kathleen Richard, LMSW
(Nov. 12, 2025)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*.	Case No.: 6:25-cv-01491-DCJ-DJA Judge David C. Joseph Magistrate Judge David J. Ayo

DECLARATION OF KATHLEEN RICHARD

I, Kathleen Richard, a citizen of the United States of America and a resident of the State of Louisiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge. I am fully competent to make this declaration. If called to testify, I could and would testify competently to these facts.
2. I am the executive director of Life Choices of North Central Louisiana, a pregnancy resource center in Ruston, Louisiana. I have witnessed how the abortion drug mifepristone has hurt women in Louisiana. Life Choices encounters women considering abortion and women who have had an abortion—including by mifepristone.
3. Since 2022, Life Choices has regularly encountered women who took abortion drugs, who have received abortion drugs in the mail, and many who sought treatment for complications after taking them.
4. These women are either Louisiana residents or college students living in Louisiana.
5. In 2024, Life Choices encountered approximately 75 abortion-minded or undecided pregnant women. At least 65% of these women had abortion drugs in their possession or knew where they could get the drugs. Most of the women received their drugs from out-of-state providers through the mail. They identified Plan C (https://www.plancpills.org/) as the most common source for the drugs.
6. Women call Life Choices once or twice per month asking for a follow-up ultrasound after taking mifepristone.
7. Life Choices has encountered several Louisiana women who suffered mifepristone complications. Many of them come to Life Choices to share their experiences and seek counseling. For example, mifepristone complications sent one woman to the

emergency room and hospital with excessive bleeding after she passed out. Her abortion-drug provider told her not to tell doctors that she had taken mifepristone. She is on Medicaid.

8. A second woman took mifepristone, suffered from excessive bleeding, and had two ultrasounds at her healthcare provider confirm that products of conception were in her uterus. She is on Medicaid.

9. A third woman who took mifepristone passed out at home but did not go to the emergency room.

Executed this 12 day of Nov, 2025.

By Kathleen B Richard, LMSW
Kathleen Richard, LMSW

EXHIBIT 20

Declaration of Kathleen Willis, M.D.
(Dec. 15, 2025)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants.*	Case No.: 6:25-cv-01491-DCJ-DJA Judge David C. Joseph Magistrate Judge David J. Ayo

DECLARATION OF KATHLEEN WILLIS, M.D.

Pursuant to 28 U.S.C. § 1746, I, Kathleen Willis, M.D., affirm under penalty of perjury:

1. I am over the age of 18, have personal knowledge of the matters set forth herein, and am competent to make this Declaration.

2. I serve as the Associate Medical Director for Louisiana Medicaid in the Louisiana Department of Health ("LDH"). I completed medical school and residency at LSU School of Medicine in New Orleans and served as Chief Resident of the Internal Medicine Residency Program in my final year. I am board certified in Internal Medicine and a lifetime member of the AOA Honor Medical Society. I've been a physician for 26 years with over 20 years of leadership experience in healthcare delivery, quality improvement, and healthcare administration.

3. I help oversee the clinical and medical policy aspects of the State's Medicaid program, which runs through LDH's Bureau of Health Services Financing. My responsibilities include developing and evaluating medical policies to ensure they are evidence-based and cost-effective; reviewing coverage decisions, prior authorization criteria, and clinical guidelines used by Medicaid and its Managed Care Organizations ("MCOs"); providing clinical guidance to Medicaid leadership on

program operations, benefits, and emerging health issues; and collaborating with MCOs, providers, and LDH divisions to align care standards and address medical or utilization concerns.

4. Louisiana Medicaid provides healthcare coverage to eligible low-income individuals as part of a cooperative effort between the State of Louisiana and the federal government, who jointly fund the program. Louisiana Medicaid covers a broad set of services, including hospital and physician care, prescriptions, labs and imaging, long-term care, behavioral health, and more.

5. Louisiana Medicaid also covers emergency services at *any* hospital emergency room ("ER"), whether or not the hospital is in the patient's Medicaid MCO network. We follow federal Medicaid laws that require LDH to cover emergency care. When an individual covered by Medicaid goes to an ER, the hospital will run the patient's Medicaid ID through the State's electronic eligibility system, but emergency care cannot be delayed while the provider is verifying coverage. As part of Medicaid coverage, and under EMTALA, the ER must, at a minimum, perform a medical screening exam, stabilize the patient, and provide any necessary treatment. Louisiana Medicaid and all MCOs prohibit prior authorization for emergency services: The hospital treats the patient first, bills later. After treatment, the hospital submits the claim to the appropriate MCO (or Medicaid fee-for-service, if applicable), and payment goes directly from the plan/Medicaid to the provider. The patient typically has no copay, unless a small copay applies under their specific plan.

6. In 2021, the Department of Health and Human Services estimated that the average cost of a Medicaid-covered ER visit was $600—a number we can safely assume has increased in the past 4 years due to inflation and rising healthcare costs generally. In June 2023, approximately 2 million people were enrolled in Louisiana Medicaid. As of June 2024, the number dropped slightly to just over 1.6 million, as States across the country have seen the overall number of Medicaid enrollees decline from the extreme uptick during the COVID-19 pandemic. However, the decline has stopped: As of June 2025, the number of Louisiana Medicaid enrollees remained around 1.6 million, a number that

surpasses pre-pandemic data. As of January 1, 2023 (the most recent data of its kind available), 534,294 women from ages 15 to 44 were enrolled and 538,139 women from ages 15 to 44 were recipients.[1]

7. The FY 2025 Medicaid budget for Louisiana is about $21.2 billion, with the State covering about 25% of these costs and the federal government covering the remainder. Louisiana Medicaid accounts for roughly 38% of the State's total budget. In FY 2023 (the most recent data available), Louisiana Medicaid cost the federal and State government a combined $16.6 billion.[2]

8. I am familiar with the U.S. Food & Drug Administration's 2023 Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone. I understand that women who ingest mifepristone may end up in the emergency room to treat and remedy side effects of the drug.

9. When such women are covered by Medicaid, the resulting services are paid for by the State (and the federal government) under Medicaid. The patients often do not absorb the costs.

10. These emergent situations and associated Medicaid costs will continue to be a problem in Louisiana because of mifepristone that is being mailed into Louisiana.

11. In 2025, a Louisiana woman on Medicaid—Jane Doe #1—received emergency medical care at a Louisiana regional medical center after ingesting FDA-approved mifepristone that she received in the mail from AidAccess.org. She delivered a dead fetus in the emergency room. As a result of the services rendered by the Louisiana medical center to Jane Doe #1, the total cost billed to Medicaid was over $17,500 and the total amount paid was over $4,500.

12. In 2025, another Louisiana woman covered by Medicaid—Jane Doe #2—ingested FDA-approved abortion drugs in Louisiana that she received in the mail from AidAccess.org. Two

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[1] The information in this paragraph comes from *Louisiana Medicaid 2023 Annual Report*, Louisiana Department of Health, p.26 (https://ldh.la.gov/assets/medicaid/AnnualReports/MedicaidAnnualReport2023.pdf) (last visited Dec. 9, 2025).

[2] *See, e.g.*, *Medicaid Enrollment Declines*, PAR Louisiana (July 28, 2025) (https://parlouisiana.org/wp-content/uploads/2025/07/Medicaid-Enrollment-Declines2.pdf).

days later, she arrived at a Louisiana emergency room with severe abdominal pain and delivered her baby alive. The baby needed emergency treatment and a prolonged hospitalization. As a result of this emergency room visit, the total cost billed to Medicaid for the mother's treatment was over $24,000 and the total amount paid was over $7,500. The total cost billed for the baby's treatment was over $299,500 and the total amount paid was over $80,000.

13. These women are just two examples of many women believed to have suffered adverse health consequences requiring emergency medical care at Louisiana's hospitals, paid for by Louisiana Medicaid, as a result of ingesting FDA-approved supplies of mifepristone.

14. These figures almost certainly understate the true harm, owing to incomplete hospital reporting, miscoding or false reporting of complications as "miscarriages," and concealed shipments. Louisiana Medicaid covers miscarriage treatment and reimburses for miscarriage treatment and care.[3]

15. Because the amount of mifepristone illegally prescribed and shipped to Louisiana women is unlimited and increasing, there is no doubt that the number of adverse health consequences requiring emergency medical care in Louisiana hospitals will only increase as well, as will the associated costs borne by Louisiana Medicaid.

Executed in Baton Rouge, Louisiana, this 15th day of December, 2025.

Kathleen Willis, M.D.

Kathleen Willis, M.D.

[3] *See LaMOMS*, Louisiana Department of Health (https://ldh.la.gov/medicaid/lamoms) (last visited Dec. 9, 2025).

EXHIBIT 21

Declaration of Christina Francis, M.D.
(Dec. 12, 2025)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants.*	Case No.: 6:25-cv-01491-DCJ-DJA Judge David C. Joseph Magistrate Judge David J. Ayo

DECLARATION OF CHRISTINA FRANCIS, M.D.

I, Christina Francis, M.D., a citizen of the United States of America and a resident of Indiana, declare as follows:

1. I am over eighteen years old and make this declaration on personal knowledge. I am fully competent to make this declaration. The opinions expressed in this report are my own and do not represent the views of any organization with which I am associated.

I. Background

2. I am a board-certified Obstetrician and Gynecologist (OB/GYN) in good standing and licensed to practice in Indiana and Virginia. I have been practicing for 17 years, and I have been board-certified for thirteen years. I have worked for the last nine years as an OB/GYN Hospitalist in Fort Wayne, Indiana, which is where I work now.

3. I graduated from medical school at Indiana University in 2005 and completed my obstetrics and gynecology residency at St. Vincent Hospital in Indianapolis in 2009.

4. As an OB/GYN Hospitalist, my practice is primarily hospital-based. I manage both high- and low-risk pregnancies and deliveries, obstetric critical care, gynecological emergencies presenting to our Emergency Department, and inpatient obstetric and gynecologic consultations.

5. I am a member of the Board of Directors and the CEO of the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), a national professional organization of approximately 8,000 pro-life medical practitioners.

6. AAPLOG is the largest nonsectarian organization of pro-life medical practitioners in the world and is headquartered in Indiana. AAPLOG includes more than 70 members in Louisiana. AAPLOG members oppose elective induced abortion and are committed to the care and well-being of their patients, including both pregnant women and their preborn children. AAPLOG members are concerned about the adverse impacts of chemical abortions—including chemical abortions using mifepristone and misoprostol—on their practice of medicine. I am familiar with AAPLOG, its policy positions, its members, and its members' interests and concerns.

7. I am familiar with chemical abortion drugs, their use, and the complications that accompany chemical abortions. I am also familiar with FDA's regulation of chemical abortion drugs, including mifepristone and misoprostol.

II. Pregnancy and the development of the human person

8. The childbearing years for women typically range from ages 14 to their mid-40s.

9. A new human life begins at the moment of fertilization. It is a scientific fact that a distinct, living, and whole human being comes into existence at the moment of fertilization. At fertilization, a sperm from a male meets an ovum from a female, and their genetic material combines to form a new, unique human being. From the moment of sperm-egg fusion and onward, the embryo exhibits all of the characteristics of a new living organism. Put another way, at fertilization, a new single-celled entity is formed that is distinct from the sperm or the egg, and her development and metabolic activity are radically unlike that of a sperm or egg cell.

10. The sperm and ovum unite to form a single-celled human being called a zygote. The zygote begins dividing immediately and continues developing as an embryo through the first eight weeks of gestation. After the eighth week, the developing human is termed a fetus, a designation that

continues for the remainder of the pregnancy. A pregnancy usually lasts about 280 days, after which a woman gives birth, and the new baby continues growing and developing outside the uterus.

11. At every stage of development—zygote, embryo, and fetus—there is a human being with its own unique DNA. Even a zygote has self-directed growth and development. And, although nutrients and protection are required, the new embryo or fetus is self-integrated and oriented toward her own survival. The organism goes on to have one continuous biological existence throughout her developmental stages, from zygote through embryo, fetus, newborn, toddler, child, teen, adult, and aged adult, until death. Each of us begins our existence as a human embryo. Each of us was carried in our mother's uterus through the early stages of development.

12. As a physician, I recognize that each human life has equal dignity and value from the moment of fertilization throughout her entire lifespan. As a physician, my oath compels me to provide care towards health and healing for all of my patients, regardless of their age or level of development. The age of a human being does not determine her humanity or whether she has value.

13. Intentionally ending the life of any human being goes against the basic tenets of medical ethics that have steered the practice of medicine for millennia. Since its introduction, the Hippocratic Oath has distinguished the practice of medicine from any act intended to end human life. Induced abortion violates the basic tenets of medical ethics because it intentionally takes a human life.

14. As a physician, I know that when I care for pregnant women, I care for two distinct patients. My duty is to protect and preserve both mother and child. Our medical system and our society have a duty to support women throughout and after their pregnancies. All pregnant women and their preborn children deserve excellent healthcare.

15. I understand that many states, like Louisiana, recognize the scientific reality that life begins at the moment of fertilization. They thus protect human life from the moment of fertilization. Through their laws and their healthcare programs, like Medicaid, they ensure that all pregnant women and preborn children are valued and protected.

III. The nature and known risks of mifepristone and misoprostol

16. The FDA-approved chemical abortion regimen involves two drugs: mifepristone and misoprostol.

17. Mifepristone is a synthetic steroid that blocks the release of progesterone, a hormone that is critical for the development of a preborn child. Progesterone is essential to achieve and maintain a healthy pregnancy. It prepares the uterine lining to allow implantation and stimulates glands in the lining to secrete nutrients for the early embryo. During the first 8 weeks of pregnancy, progesterone is produced by the corpus luteum (a cyst on the ovary during pregnancy), but between 8 and 12 weeks the placenta takes over this role and maintains the pregnancy thereafter.[1] Mifepristone binds to progesterone receptors,[2] thereby blocking the action of progesterone. This causes the uterine lining to deteriorate, cutting off oxygen and nutrients to the preborn child and causing her to die.

18. Misoprostol, a prostaglandin analogue, is then taken 24 to 48 hours after mifepristone to induce uterine contractions intended to expel the embryo or fetus and other pregnancy tissue. Bleeding can last from several hours to over 30 days. Chemical abortions of this type are approved by FDA for use through the 10th week of gestation.

19. By removing the in-person dispensing requirement from its chemical abortion-drug protocol, FDA authorized abortion drugs to be prescribed to patients remotely and sent to them via the mail—even without any in-person contact or real-time interaction (even virtual) with a medical professional. FDA also authorized dispensing from certified pharmacies that can ship medications in the mail. This transformed mifepristone from a drug that required visiting a specialized medical site like a clinic, medical office, or hospital, to one that could be obtained from online sites, some of which have minimal or asynchronous medical oversight.

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[1] Arri Coomarasamy et al., *PROMISE: First-Trimester Progesterone Therapy in Women with a History of Unexplained Recurrent Miscarriages—A Randomized, Double-Blind, Placebo-Controlled, International Multicenter Trial and Economic Evaluation*, 20(41) Health Technol. Assess. (May 2016).

[2] Oskari Heikinheimo et al., *The Pharmacokinetics of Mifepristone in Humans Reveal Insights into Differential Mechanisms of Antiprogestin Action*, 68(6) Contraception 421, 421 (Mar. 17, 2003). *Contraception* is a journal affiliated with the Guttmacher Institute and Planned Parenthood, or Obstetrics organizations well known for their abortion advocacy.

IV. The importance of in-person doctor care

20. It is my professional opinion that the proper standard of care is an in-person doctor's visit before receiving mifepristone and misoprostol.

21. It is also my professional opinion that in-person dispensing of abortion drugs enhances the safety and well-being of women taking these drugs and leads to better-informed medical decisions. Requiring an in-person doctor visit ensures that each woman is able to give truly informed consent, can be screened for coercion and potential contraindications to the drugs, and can have her preborn child's gestational age, pregnancy location, and other risks accurately assessed.

22. A pre-abortion ultrasound (or appropriate physical examination) is the best way to rule out ectopic pregnancy and to confirm the gestational age of the preborn child.

23. Eliminating the in-person dispensing requirement increases the risk that an ectopic pregnancy will go undetected. This can cause women serious and life-threatening complications, such as rupture of the fallopian tube and secondary hemorrhage. Ectopic pregnancies are not rare, occurring in 1 in 50 pregnancies. Some emergency room studies have reported a higher incidence of 8–9% of pregnancies.[3] Approximately 50% of women with an ectopic pregnancy will have no risk factors for it, so screening for this condition based on risk factors is not adequate. The symptoms women experience when they have a rupturing ectopic pregnancy (vaginal bleeding and abdominal pain) are the same as those experienced by women undergoing a chemical abortion. This similarity can cause a delay in seeking care if women have taken mifepristone and misoprostol as they will assume these are normal symptoms of a chemical abortion. This delay in care can increase her risk of morbidity and mortality.

24. An in-person test is necessary in early pregnancy to determine a mother's Rh factor. If the mother's Rh factor is negative, she can form antibodies against an Rh-positive baby's blood cells, which can be prevented by administering Rho(D) immunoglobulin (Rhogam) preventatively, after delivery, or after any event that could mix maternal and fetal blood—such as miscarriage, abortion,

[3] Carlos A. Link, M.D. et al., *Diagnosing Ectopic Pregnancy Using Bayes Theorem: A Retrospective Cohort Study*, 119(1) Fertil. Steril. 78, 82 (2023).

ectopic pregnancy, prenatal testing, or trauma. About 15% of North Americans have an Rh-negative blood type.[4] If these women are not appropriately administered Rhogam, they may experience isoimmunization, which threatens future pregnancies. If an Rh-negative woman is left untreated and she becomes isoimmunized, her future baby will have a 14% chance of being stillborn and a 50% chance of suffering neonatal death or a brain injury.[5]

25. In-person care is also important as a way to obtain informed consent and to ensure that there is no coercion. The process of obtaining informed consent involves assessing the individual patient in front of you—her exact clinical situation (gestational age and location of pregnancy, number of fetuses, placental location, etc.) and her individual medical history—to inform her of her specific risks, benefits, and alternatives. This can only truly be done with an in-person assessment to confirm these details.

26. Medical professionals are the first line of defense for women who are being coerced, abused, or trafficked. We regularly screen women for abuse or coercion to ensure decisions are informed and voluntary. If we detect abuse or coercion, we can provide support, secure the patient's safety, or connect the patient with appropriate resources or authorities. Mail-order abortion increases the risk of coerced abortion. When abortion drugs are dispensed in-person, a prescriber can confirm that the person seeking the abortion drugs is actually a pregnant woman. And the prescriber has an opportunity to see whether the pregnant woman is freely choosing to have an abortion or whether she is facing outside pressure or threat.

27. Not so with mail-order abortion. The prescriber may never see the person ordering the abortion drugs and thus cannot determine whether it is a pregnant woman or some other bad actor ordering the drugs. And even if it is a pregnant woman ordering the drugs, there is no way to fully assess whether she is freely choosing to have an abortion and is sure about her decision or is

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[4] *American College of Obstetricians and Gynecologists Practice Bulletin No. 181: Prevention of Rh D Alloimmunization*, 130(2) Obstet. Gynecol. e57, e58 (Aug. 2017) (ECF 1-17).

[5] *Id.*

being coerced by a third party. This is music to the ears of abusive boyfriends, rapists, and human traffickers.

28. Mail-order abortion can enable human traffickers and sexual abusers force their victims into getting abortions while preventing the authorities from identifying these victims.[6] In fact, the State of Texas has recognized that "[d]ue to the potentially high number of trafficking victims who undergo abortion procedures, abortion facility employees are uniquely situated to identify and assist victims of sex trafficking."[7] Physicians are trained in ways to screen for trafficking and abuse; part of this involves observing body language and how a patient interacts with her partner (when the partner is with her). In person assessment also gives us the opportunity to ensure we talk to her alone if we suspect abuse or coercion—something that cannot be reliably done through a virtual interaction and certainly not when women have zero interaction with a medical professional.

V. Complications from mifepristone and misoprostol

29. Women who take chemical abortion drugs can experience significant complications.

30. There are many intense side effects for women who take chemical abortion drugs, including labor-like abdominal pain, heavy bleeding, nausea, vomiting, and fevers.[8]

31. FDA's own label states that roughly 1 in 25 women who take mifepristone as directed will end up in the emergency room,[9] with up to 7% requiring a "surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding."[10] These statistics apply when

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[6] Laura J. Lederer & Christopher A. Wetzel, *The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities*, 23 Annals Health L. 61 (2014); *Id.* at 73, 77–78 (noting that survivors in study "reported that they often did not freely choose the abortions they had while being trafficked," these "[s]urvivors [ ] had significant contact with clinical treatment facilities, most commonly Planned Parenthood clinics," and that "these points of contact with healthcare represent rare opportunities for victim identification and intervention.").

[7] House Committee Report, H.B. 3446, 84th Leg., C.S. (Tex. 2015), https://perma.cc/KF4N-P3W2 (a subsequent, similar version was codified at Tex. Health & Safety Code § 245.025).

[8] FDA-Approved Label for Mifepristone (Mifeprex) at 7 (Jan. 2023) (ECF 1-9) ("Mifeprex 2023 Label") ("Uterine bleeding and cramping are expected consequences of the action of MIFEPREX and misoprostol as used in the treatment procedure. Most patients can expect bleeding more heavily than they do during a heavy menstrual period.").

[9] *Id.* at 8, Table 2.

[10] *Id.* at 17.

a woman has had an in-person evaluation before taking mifepristone—something that is not occurring in many cases today. The label also includes a black box warning that "[s]erious and sometimes fatal infections and bleeding" may occur.[11]

32. FDA also agrees that the risks of complications and emergency surgeries increase with gestational age.[12] FDA's label notes that the percentage of surgical interventions for ongoing pregnancies is ten times higher for women at 64–70 days' gestation than for women at less than or equal to 49 days' gestation.[13] And one study on which FDA previously relied[14] found that—as compared to those who take mifepristone before nine weeks' gestation—almost four times as many women who take it after nine weeks' gestation experience an incomplete abortion, nearly twice as many suffer an infection, and over six times as many require surgical evacuation.[15] In fact, the study suggests that upwards of 10% of women who take these drugs will need follow-up medical treatment for an incomplete or failed chemical abortion.[16] An average of 39% of women require surgery if taken in the second trimester.[17]

33. One study showed that nearly 14% of women who took this mifepristone-misoprostol combination from 10–11 weeks required surgical intervention.[18] This is consistent with larger studies, which show that the further along in pregnancy a woman is when she takes these drugs, the higher

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[11] *Id.* at 1.

[12] 2021 FDA Letter to AAPLOG and Am. Coll. of Pediatricians denying in part and granting in part 2016 Citizen Petition, Docket No. FDA-2019-P-1534 at 9 (Dec. 16, 2021) (ECF 1-10) ("We agree that the failure rate of medical abortion regimens, including the currently approved regimen, generally increases with increasing gestational age."); Mifeprex 2023 Label, *supra* note 8, at 13, Table 4.

[13] Mifeprex 2023 Label, *supra* note 8, at 13, Table 4.

[14] Center for Drug Evaluation and Research, Application Number: 020687Orig1s020 Summary Review at 19 (Mar. 29, 2016) ("FDA 2016 Summary Review") (ECF 1-11).

[15] Maarit Niinimäki et al., *Comparison of Rates of Adverse Events in Adolescent and Adult Women Undergoing Medical Abortion: Population Register Based Study*, 342 BMJ 5 (April 20, 2011) (ECF 1-12).

[16] *Id.* at 4.

[17] Maarit J. Mentula et al., *Immediate Adverse Events After Second Trimester Medical Termination of Pregnancy: Results of a Nationwide Registry Study*, 26(4) Hum. Reprod. 927, 931 (Apr. 2011).

[18] Ilana G. Dzuba et al., *A Non-Inferiority Study of Outpatient Mifepristone-Misoprostol Medical Abortion at 64-70 Days and 71-77 Days of Gestation*, 101(5) Contraception 302, 305, Table 2 (2020).

her risk of complications.[19] Mifepristone is in fact known to increase risk of hemorrhage due to its effect on the spiral arteries of the pregnant uterus.[20]

34. A recent review of large-scale insurance claims data concluded that the "real-world rate of serious adverse events following mifepristone abortions is at least 22 times as high as the summary figure of 'less than 0.5 percent' in clinical trials reported on the drug label."[21] Nearly 11% of women "experience sepsis, infection, hemorrhaging, or another serious adverse event within 45 days following a mifepristone abortion."[22] This review provides preliminary information. It warrants serious concern and suggests the need for further investigation. It also suggests that FDA was right when it predicted that women in the real world would experience significant complications from abortion drugs.

35. Another recent study also suggests that the complication rate may in fact be nearly 15%. In that study, "Out of 217 known outcomes of the 711 total medication abortions provided at 78-84 days estimated gestational duration, preliminary raw data includes 27 ongoing pregnancies, 22 aspirations performed for ongoing pregnancies, 10 aspirations performed for other reasons, and 21 visits to an emergency department or hospital."[23] Medical professionals and regulatory agencies like FDA should follow important safety signals like this. This study suggests that mifepristone's complication rate in the real world is much higher than what is indicated on the label.

36. Of the women who end up in the emergency room after taking abortion drugs, many suffer severe injuries. A study testing the severity of emergency department visits for Medicaid-eligible women following various pregnancy outcomes found that "an [emergency department (ED)] visit following a [mifepristone] abortion was significantly more likely to have a severe or critical acuity

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[19] Mentula, *supra* note 17, at 927–32.

[20] Ralph Miech, *Pathopharmacology of Excessive Hemorrhage in Mifepristone Abortions*, 41(12) Ann. Pharmacother. 2000, 2004 (Dec. 2007).

[21] Jamie Bryan Hall & Ryan T. Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event* 1, Ethics & Pub. Pol'y Ctr. (Apr. 28, 2025) (ECF 1-13).

[22] *Id.*

[23] Robin Wallace et al., *P040 - Expanding Access to Abortion with Mifepristone and Misoprostol Through 84 Days Estimated Gestational Duration*, 151 Contraception 111117 (Nov. 2025).

rating than a visit following surgical abortion, live birth, or an ED visit at any time by a woman who was never pregnant."[24] The study also found that ED visits coded severe or critical for women who underwent a chemical abortion increased by 4,041.1% between 2004 and 2015, compared to a 450.6% increase for surgical abortion subjects and 20.9% for live birth subjects.[25]

37. All of this assumes accurate reporting in the ED, notwithstanding that some abortion activists encourage women to tell emergency room staff that they are having a miscarriage if they suffer abortion-drug complications requiring urgent care. I know that many women suffering complications from chemical abortions tell their doctors that they are experiencing miscarriages.[26] This phenomenon—regardless of why it occurs—means that doctors cannot be certain of what their patients have taken or are experiencing. This kind of inaccurate information also means that the true number of incidences of complications from chemical abortions are significantly underreported or not fully known.

38. FDA used to require that women seeking care for an abortion drug complication bring the Medication Guide with them to the ED. Removing this requirement places women at heightened risk of cascading complications and impedes physicians' ability to treat them. The Medication Guide protection ensures that physicians have critical information that helps them recognize and manage adverse effects, reduce delays in treatment, and make safer and more informed decisions for patient care. Without the Medication Guide, it is harder for physicians to treat complications because these patients also do not present with their medical records from a pre-abortion visit or document what they were given. This is, in fact, crucial because of the unique risk of clostridial sepsis from mifepristone that is not present in women having first-trimester miscarriages (and is what precipitated the black box warning for infection on the mifepristone label). This is a very difficult infection to

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[24] James Studnicki et al., *Comparative Acuity of Emergency Department Visits Following Pregnancy Outcomes Among Medicaid Eligible Women, 2004–2015*, 5(2) Int'l J. Epidemiol. & Pub. Health Rsch. 1, 1 Aug. 20, 2024 (ECF. No. 1-14).

[25] *Id.* at 2.

[26] *Will a Doctor Be Able to Tell if You've Taken Abortion Pills?*, Women Help Women Blog (Sep. 23, 2019), (ECF 1-15); *How Do You Know if You Have Complications and What Should You Do?*, Aid Access (ECF 1-16).

diagnose, requiring physicians to have a high index of suspicion—something they can only do if they know a woman has taken mifepristone.[27]

39. Claims that mifepristone is "safer than Tylenol" have no basis in reality. *First*, acetaminophen (Tylenol) toxicity is nearly exclusively caused by not following the directions—for example, not taking the FDA-approved dose.[28] Not so for mifepristone. *Second*, mifepristone still has a black box warning attached to it due to the risk of hemorrhage and infection (specifically sepsis from clostridium sordellii which causes an insidious sepsis picture and has caused the deaths of several women who took mifepristone).[29] Tylenol has no such warning. *Third*, FDA's own data shows that approximately 1 in 25 women who take mifepristone for an induced abortion as directed by the label will seek care for complications in the ED—and this was when women were still being evaluated in person prior to receiving this.[30]

40. In addition, beyond the known physical risks, women have described their abortion-drug experiences as harming their mental health and leaving them feeling unprepared, silenced, regretful, or trapped.[31]

41. Remotely-dispensed abortion drugs present even greater risks to women because, without an in-person examination, prescribers cannot confirm and therefore are more likely to misdate the gestational age of a baby or fail to detect an ectopic pregnancy—with potentially fatal consequences. The American College of Obstetricians and Gynecologists (ACOG) states that "A pregnancy without an ultrasound examination ... before 22 0/7 weeks of gestational age should be

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[27] AAPLOG, Dangers of Clostridial Infection after Mifepristone Ingestion for Induced Abortion: A Public Health Concern (Aug. 2025), perma.cc/YK2A-AQZQ.

[28] Suneil Agrawal et al., *Acetaminophen Toxicity*, StatPearls Publishing (April 10, 2025), perma.cc/8XL9-TJVQ.

[29] CDC, Clostridium Sordellii *Toxic Shock Syndrome After Medical Abortion with Mifepristone and Intravaginal Misoprostol—United States and Canada, 2001–2005*, Morbidity & Mortality Weekly Rep. (July 29, 2005), perma.cc/5MVR-HN94.

[30] Mifeprex 2023 Label, *supra* note 8, at 8, Table 2.

[31] Katherine A. Rafferty & Tessa Longbons, #AbortionChangesYou*: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives*, 36 Health Commc'n 1485 (2021) (ECF 1-18).

considered suboptimally dated."[32] This is because 40–50% of women will be wrong about their gestational age based on their last menstrual period alone.[33] As the number of mifepristone-induced mail-order abortions continues to increase, so will the overall number of women seeking emergency care in hospitals.

VI. My experience with abortion-drug complications

42. Since FDA's 2000 approval of Mifeprex (the chemical abortion drug regimen consisting of mifepristone and misoprostol), medical professionals have needed to treat women and girls who have suffered from chemical abortion and experienced complications.

43. Mifepristone and misoprostol are high-risk drugs that should not be administered in combination for induced abortion without medical supervision. FDA's actions to eliminate the necessary supervision of these drugs harm women and remove fully informed consent.

44. The most common physical complications resulting from chemical abortions are hemorrhage, retained tissue (incomplete abortion), and infection. These often necessitate treatments such as admission to the hospital, intravenous antibiotics, dilation and curettage (D&C) to remove retained tissue or control bleeding, or blood transfusion. Less commonly, more significant surgery can be necessary, such as hysterectomy in the case of clostridial infection.

45. I have seen first-hand the complications that can result from the use of these high-risk drugs. Although Fort Wayne does not have an abortion facility, and the majority of abortions are illegal in Indiana, I personally have seen several women present with complications after seeking chemical abortions with mifepristone and misoprostol, and my group has seen many more.

46. As an example, an AAPLOG-member partner and I cared for a patient who suffered complications from a chemical abortion. I had taken care of her when she was hospitalized for hyperemesis gravidarum at 9 weeks 5 days gestation. She was discharged home in good condition after

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[32] American College of Obstetricians and Gynecologists Committee on Obstetric Practice, *Committee Opinion No. 700: Methods for Estimating the Due Date*, 129(5) Obstet. Gynecol. e150 (May 2017), https://doi.org/10.1097/AOG.0000000000002046.

[33] *Id.*

significant improvement with medications. During that hospital stay, she had an ultrasound, which showed a healthy pregnancy with no apparent complications and a strong fetal heart rate. During her hospitalization, she expressed to me that she was considering abortion because of experiencing hyperemesis, but was unsure. About a week after her discharge, the patient presented back at our emergency room with heavy vaginal bleeding and unstable vital signs as a result of taking chemical abortion drugs. One of my partners was able to detect a fetal heartbeat. However, due to the amount of bleeding that she was experiencing and evidence of hemodynamic instability, my partner had no choice but to perform an emergency D&C. The patient needed to be hospitalized overnight for close observation after the D&C. Not only did my partner need to provide several hours of critical care for this patient, but she also needed to call in a backup physician to care for another critically ill patient. And because the preborn baby still had a heartbeat when the patient presented, my partner felt as though she was forced to participate in something that she did not want to be a part of–completing the abortion.

47. I also cared for a woman who had undergone a chemical abortion approximately one month prior. She had had no follow up with the abortion provider. She presented to our hospital two days before I saw her with complaints of abdominal pain and ongoing vaginal bleeding. One of my partners evaluated her and determined that she had retained tissue from her chemical abortion. She was taken to the operating room for a D&C procedure to complete her abortion and then discharged home after her surgery. She returned to our hospital two days later with persistent abdominal pain as well as worsening nausea and vomiting. Repeat ultrasound did not show any retained tissue, but she had evidence of endometritis on exam as well as a significantly elevated white blood cell count, consistent with a bacterial infection. She required treatment with multiple IV antibiotics and was hospitalized for multiple days before being able to be discharged home.

48. The experience of one other patient who came to me through the Abortion Pill Reversal Network highlights the dangers of women not being seen in person before these drugs are dispensed. She was pregnant with an unplanned, but not unwanted, child. Her boyfriend, however,

wanted her to get an abortion and she felt threatened by him if she did not go through with it. She ordered the drugs online, thinking that while she waited for them to arrive she could convince him to support her in continuing her pregnancy. However, when the drugs arrived in the mail, her boyfriend continued to insist that she have an abortion. Fearing that he would hurt her if she did not go through with it, she took the mifepristone. Shortly after taking it, she went into the bathroom and forced herself to vomit, hoping that would rid her of the drug meant to end the life of her child. She called the Abortion Pill Reversal Network after not being confident that that had occurred and that is how I spoke with her. She told me how much she wanted her baby and desired to try to halt the effects of mifepristone—which she had only taken because of her boyfriend forcing her to. I administered progesterone treatment, and the baby survived.

49. As an OB/GYN who has seen many women with unplanned pregnancies early in their pregnancies, I have had patients tell me that they wanted information about abortion. My standard first question in this situation, as it would be in any situation in which a patient is requesting a certain intervention, is "Can you tell my why you feel that is the best option for you?" Not only does this give me insight into where she is at and what she is experiencing, but it also helps screen for pressure or coercion. It is not uncommon for a patient's response to be that her parents, boyfriend, or someone else is pressuring or forcing her to consider abortion. This kind of screening and personal interaction, with ensured privacy, is not happening with online dispensing.

VII. Reporting abortion-drug complications

50. I am aware of FDA's actions that require prescribers to report only deaths and no other complications associated with chemical abortion. However, non-fatal complications still have a significant impact on my patients as well as our healthcare system. FDA should require reporting of these complications again. This is the only way for physicians to accurately assess public health impact as well as have accurate information to inform patient choices. The current reporting system is cumbersome for busy physicians to report these complications: it takes a significant amount of time and does not collect all of the pertinent information.

51. To report complications to the abortion-drug manufacturer, a form must be printed, filled out by hand, and then either mailed or scanned and emailed back. Much of the information required by this form is impossible to obtain by the physician seeing the patient if they were not the one who dispensed the chemical abortion drugs (such as lot number and dosage), forcing me to leave several fields blank. I have never received confirmation from the manufacturer that the complications I reported were recorded or reported to FDA.

52. In addition to reporting to the manufacturer, the process of reporting to the FDA Adverse Event Reporting System (FAERS) is also cumbersome. The actual form to be filled out is hard to find online, requiring several steps to access it. It once took me two hours to get the website to accept submission of the form, taking me away from the care of my other patients. The minimum amount of time I have spent reporting a mifepristone complication to FAERS is thirty minutes—valuable time that should be spent in patient care.

53. Due to inadequate adverse event reporting, the true rates of risks associated with chemical abortion drugs remain unknown and undercounted. This lack of information impedes informed consent for women, and it should have raised serious questions for FDA before it approved sending mifepristone through the mail or other remote means.

I declare under 28 U.S.C. § 1746 and under penalty of perjury that this declaration is true and correct based on my personal knowledge.

Executed December 12, 2025.

Christina Francis, M.D.

EXHIBIT 22

Declaration of Michael J. New, Ph.D
(Dec. 15, 2025)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*.	Case No.: 6:25-cv-01491-DCJ-DJA Judge David C. Joseph Magistrate Judge David J. Ayo

DECLARATION OF MICHAEL J. NEW, PH.D.

I, Michael J. New, Ph.D., a citizen of the United States of America, declare as follows:

STATEMENT OF OPINIONS AND THE BASES FOR THEM

I have been hired as an expert witness in the case *Louisiana et al. v FDA et al.* Case No 6:25-cv-01494 W.D Louisiana. This case involves the 2023 Risk Evaluation and Mitigation Strategy for the Abortion Drug Mifepristone.

In this declaration, I show that the state of Louisiana has a compelling interest in eliminating mail-order abortion drugs so it can enforce its pro-life laws and prevent economic harm. This is for several reasons. *First*, mail-order abortions increase the incidence of abortion in Louisiana. *Second*, women on Medicaid are more likely to obtain abortions. *Third*, Louisiana's state Medicaid program will incur costs treating Louisiana women who obtain mail-order abortions. *Fourth*, in the absence of mail-order abortion drugs, Louisiana women who are carrying pregnancies to term can obtain pregnancy assistance from a range of public and private sources. *Fifth*, an increase in the incidence of abortion in Louisiana is detrimental to Louisiana's economic and fiscal health.

1) Mail-order Abortions Increase the Incidence of Abortion.

The Supreme Court's June 2022 *Dobbs* decision allowed states to place legal limits on abortion. Many states have done this in the aftermath of the decision. Louisiana has been enforcing a law that largely bans all elective abortions since July 29, 2022 (Hilburn 2022).

The best data on the impact of recent pro-life laws comes from Texas. Texas was able to enforce a Heartbeat Act, on September 1, 2021. Data from the Texas Department of State Health Services found that immediately after the Heartbeat Act took effect the number of abortions performed on Texas residents fell by nearly 2,500 a month (Texas Health and Human Services Commission 2025).[1]

Meanwhile, the study by White et al. (2025) found that out-of-state abortions among Texas women increased by about 1,160 per month. Three separate studies of the Texas birthrate indicate that in the months after the Heartbeat Act took effect, the number of children born in Texas increased by approximately 1,000 per month (New 2022; Bell et al, 2023; The University of Houston Institute for Research on Women, Gender, and Sexuality 2024).

Since Texas' in-state abortion decline was not completely offset by combined increases in births and increases in out-of-state abortions, it seems very likely that hundreds of Texas women were obtaining mail-order abortions.

A research letter that appeared in the *Journal of the American Medical Association* on October 21, 2025 obtained data from Aid Access to analyze the mailing of 118,388 abortion pill packs between July 1, 2023 and September 30, 2024. They found that states with a near-total ban on abortion, which includes

[1] In the 8 months before the enforcement of the Texas Heartbeat Act (January 2021 to August 2021) 41,147 abortions were performed on Texas residents. In the 8 months after the enforcement of the Texas Heartbeat Act (September 2021 to April 2022) there were 21,173 abortions performed on Texas residents. Data obtained from Texas Health and Human Services Commission. Calculations by author.

Louisiana, had a county-level provision rate that was more than seven times higher than states with permissive abortion policies. The map that accompanies the article indicates that nearly all Louisiana counties had an above-average provision of mail-order abortions (Aiken et al. 2025).

The Society of Family Planning's #WeCount project finds that between July 2023 and June 2025, 15,420 mail-order abortions occurred in Louisiana. In calendar year 2024, the #WeCount project estimates 7,530 mail-order abortions took place in Louisiana (Society of Family Planning 2025).

Data from the Centers for Disease Control (CDC) indicates that in both 2020 and 2021, the two full years prior to the *Dobbs* decision, about 7,400 abortions were performed in Louisiana (Kortsmit et al. 2023; Ramer et al. 2024). The Guttmacher Institute estimates that in 2020, 7,610 abortions were performed on Louisiana residents (Jones et al. 2022). As such, because the number of abortions before Louisiana's abortion ban took effect are similar to the number of abortions after it took effect, it's clear that a very large percentage of women who would have obtained chemical or surgical abortions in Louisiana are obtaining mail-order abortions.

Recent data from the Society of Family Planning's #WeCount project indicates that 5,410 abortions were performed via mail-order in Louisiana in the first 6 months of 2025. According to the Society of Family Planning's Data, 100 percent of the abortions obtained in Louisiana in 2025 were done via mail-order. (Society of Family Planning 2025).

In the absence of mail-order abortions, it is impossible to say how many additional Louisiana women would carry pregnancies to term. However, a substantial body of political science, economics, and public health research shows that the incidence of abortion is sensitive to its effective cost (Cook et al. 1999; Hansen 1980; Haas Wilson 1993, 1996, 1997; Meier and McFarlane 1994; Blank 1996; Meier et al. 1996; Korenbrot, Brindis, and Priddy 1990; Levine, Trainor, and Zimmerman 1996; Lundberg and Plotnick 1990; Matthews, Ribar, and Wilhelm 1997; Medoff 1999, 2007; Morgan and Parnell 2002; Trussell et al. 1980). As such, eliminating mail-order abortions would reduce the incidence of abortion, resulting in more Louisiana births, and an increase in Louisiana's fertility rate.

2) Women on Medicaid Are More Likely to Obtain Abortions.

Women on Medicaid are more likely to obtain abortions compared to women who are not enrolled in Medicaid. As such, access to mail-order abortions means that Louisiana's Medicaid program will have to pay for any physical health complications or mental health complications caused by mail-order abortions.

At the outset, it is important to note, a body of research shows that low-income women are more likely to obtain abortions than high-income women. Since Medicaid is a program that typically provides health insurance for low-income earners, it is unsurprising that women enrolled in Medicaid would have a higher incidence of abortion than women not enrolled in Medicaid.

Data from the Guttmacher Institute's 2021-2022 abortion patient survey found that 41.4% of all women seeking abortions had incomes that were less than 100% of the federal poverty level (Jones 2024).

Guttmacher also conducted an abortion patient survey in 2014. That year, women whose incomes were less than 100% of the federal poverty level had an abortion rate of 36.6 per thousand women of childbearing age (15-44). Conversely, in 2014 women whose incomes were between 100% and 199% of

the federal poverty level had an abortion rate of 19.1 per thousand women of childbearing age (15-44), and women whose incomes where above 200% of the federal poverty level had an abortion rate of 6.0 per thousand women of childbearing age (15-44) (Jones and Jerman 2017).

The results from Guttmacher's 2008 abortion patient survey are similar. This survey found that women whose incomes were less than 100% of the federal poverty level had an abortion rate of 49.5 per thousand women of childbearing age (15-44). Conversely, in 2008 women whose incomes were between 100% and 199% of the federal poverty level had an abortion rate of 28.0 per thousand women of childbearing age (15-44) and women whose incomes were above 200% of the federal poverty level had an abortion rate of 9.5 per thousand women of childbearing age (15-44) (Jones and Jerman 2017).

A 2024 study in *Health Services Research* analyzed lifetime abortion incidence among women in Alabama, Delaware, Maryland, Iowa, Ohio, and South Carolina. They used 2016-2019 pre-*Dobbs* data from the Survey of Women studies and obtained data from 8,972 women aged 18-44 residing in the study areas. The authors obtained data on the incidence of abortion using a double list experiment which may improve reporting on sensitive behaviors (Jackson and Rendall 2024).

Among the states whose Medicaid programs did not cover elective abortion (Alabama, Delaware, Iowa, Ohio, and South Carolina) women on Medicaid had a 6.0 percent greater probability of having had an abortion in their lifetimes compared with women with another insurance status. This finding reaches conventional standards of statistical significance (Jackson and Rendall 2024).

The results from these states provide an apt comparison to Louisiana since Louisiana's Medicaid program does not cover abortion. As such, it is very likely that women on Medicaid in Louisiana are more likely to obtain abortions than women in Louisiana who are not on Medicaid.

3) Women who obtain abortions, particularly chemical abortions, frequently need subsequent medical assistance.

The FDA's medication guide for Mifeprex indicates that anywhere from 2.9 percent of women to 4.6 percent of women using mifepristone will visit an emergency room (U.S. Food and Drug Administration, 2025).

A 2025 study authored by Ethics and Public Policy Center analyzed 865,727 prescribed mifepristone abortions from 2017 to 2023. They found 10.93 percent of women experienced a serious adverse event (Hall and Anderson 2025).

A study analyzing over 54,000 abortions that were covered by California's Medicaid program in 2009 and 2010 found that chemical abortions have a complication rate that is four times higher than first trimester surgical abortions (Upadhyay et al. 2015).

A study of over 4,900 induced abortions in Skaraborg Hospital in Sweden between 2008 and 2015 also found that surgical abortions had a higher complication rate than first-trimester surgical abortions. This difference achieved conventional levels of statistical significance.[2] The study also found that the complication rate for chemical abortions increased from 4.2% in 2008 to 8.2% in 2015 (Carlsson, Breding, and Larsson 2018).

[2] A Wald Independent Samples Proportion Test was also performed by the author using SPSS 30.0.

A 2021 study in the journal *Contraception* analyzed over 1,100 women who obtained mail-order abortions during the pandemic. They found that 6 percent reported an emergency room or an urgent care visit related to the abortion (Chong et al. 2021). This is a higher emergency room visit rate than the U.S. Food and Drug Administration reports for women who obtain chemical abortions (U.S. Food and Drug Administration, 2025).

A recent study in the *International Journal of Women's Health Care* analyzed the mental health of women between the ages of 41 and 45. Of women who had obtained abortions (20 years previously on average), 24.1 percent reported high levels of post- abortion distress (Sullins 2025).

A 2025 study in the *Journal of Psychiatric Research* analyzed over 28,000 Canadian women who obtained abortions and over 1.2 million Canadian women who gave birth between 2006 and 2022. The authors found that the rate of mental health hospitalization was more than double following induced abortions than other pregnancies. The study also found that abortion was associated with higher rates of hospitalization for psychiatric disorders and suicide attempts (Auger et al. 2025).

Issues of Law and Medicine published an analysis of the abortion breast cancer link in 2014. Of the 72 studies they considered, 45 studies found a positive correlation between abortion and the incidence of breast cancer. In 19 of these studies the correlation was both positive and statistically significant. This 2014 article also considered three meta analyses of the abortion and breast cancer link. Two of the three meta-analyses found that the correlation between abortion and breast cancer was both positive and statistically significant (Lanfranchi and Fagan, 2014).

4) Assistance is Available to Pregnant Women in Louisiana.

Research shows there is a substantial amount of assistance available to pregnant women in Louisiana. Women who are unable to obtain mail-order abortions can receive both public and private assistance if they carry their pregnancy to term.

Louisiana's Medicaid Program provides coverage for pregnant women whose income is equal to or less than 138 percent FPIG (Federal Poverty Income Guidelines) (Louisiana Department of Health, 2025a). As of April 1, 2022 pregnant Medicaid beneficiaries are provided coverage for 12 months postpartum (Louisiana Department of Health, 2025b).

The Charlotte Lozier Institute obtained survey data from 19 pro-life pregnancy help centers in Louisiana. These centers were located in diverse locations throughout the state including Alexandria, Baton Rouge, Bogalusa, Hammond, Houma, Lafayette, Lake Charles, Leesville, Mamou, Natchitoches, New Orleans, Opelousas, Ruston, Shreveport, and Thibodeaux.

In 2024, these 19 centers served 7,025 clients, performed 5,355 pregnancy tests, performed 3,589 ultrasounds, and performed 1,543 STI tests. They had 2,355 clients attending parenting and prenatal education classes, had 67 clients receiving post-abortion support, and gave Sexual Risk Avoidance and Education presentations to 705 students.

These pregnancy centers gave out 9,605 packs of diapers, 10,107 packs of baby wipes, 408 new car seats, 20,666 clothing outfits, 138 strollers, 226 cribs, and 2,255 cans of infant formula.

Overall, these 19 pro-life pregnancy centers in Louisiana provided $2,303,127.52 worth of goods and services to women, children and families in 2024.

The Charlotte Lozier Institute was not able to obtain data from all of the pro-life pregnancy help centers in Louisiana. According to Heartbeat International, there are 37 stand-alone pro-life pregnancy centers in Louisiana. If the figures from the 19 pregnancy help centers for which Lozier has data are extrapolated to a total of 37 pregnancy help centers, that would mean that pro-life pregnancy centers in Louisiana assisted over 13,680 clients and provided over $4.4 million of goods and services to women, children, and families.[3]

5) Increases in Abortion and Reductions in Fertility Will Hurt Louisiana's Economic and Fiscal Health.

In *Alliance for Hippocratic Medicine v. FDA*, the government argued that "eliminating access to medication abortion" would increase health care costs and therefore "increase the costs imposed on taxpayers." Case No. 2:22-cv-00223-Z, ECF 28-2, Declaration of Jason Lindo. But the impact on taxpayers and the public fiscal health is exactly the opposite. Indeed, although the birth of a child may result in public assistance and safety-net costs, the eventual economic (and tax) contribution of that child will quickly exceed those costs.[4]

A 2022 report from the Republicans on the U.S. Senate Joint Economic Committee analyzed the cost of the 629,989 legal abortions reported by the Centers for Disease Control (CDC) in 2019. To calculate the cost of abortion, they use a value of a statistical life (VSL). This estimate observes the amount of wealth an individual must be provided in return for accepting an increased risk of mortality. For example, if the average individual is willing to accept $10,000 to incur a 1 in 1,000 chance of death, the corresponding VSL would be $10 million.[5]

Using estimates from academic journals, the U.S. Department of Transportation uses a value of a statistical life estimate of $10.9 million. Multiplying the 629,898 lives lost to abortion by the $10.9 million value of statistical life estimate, the Joint Economic Committee found that the economic cost of abortion to society was nearly $6.9 trillion. (Joint Economic Committee Republicans 2022).

Economists Danielle Sandler and Nichole Szembrot estimate that for the average mother, earnings fall by a total of approximately $26,000 over the first six years of the first baby's life (Sandler and Szembrot 2019). However, the $6.9 trillion economic cost to society of aborting unborn children greatly exceeds any estimated earning loss experienced by women in the first six years after giving birth (Joint Economic Committee Republicans 2022).

Also, the authors of the Joint Economic Committee report noted that "abortion imposes additional costs not reflected in the estimate." Specifically, they add that "In the long run, abortion shrinks the labor

[3] Calculation by author.

[4] Not to mention the fact that the presence of a child may lead to an increased sense of responsibility, thus increasing economic productivity. Rebecca Glauber, *Trends in the Motherhood Wage Penalty and Fatherhood Wage Premium for Low, Middle, and High Earners*, 55 Demography 1663 (2018), https://read.dukeupress.edu/demography/article/55/5/1663/167918/Trends-in-the-Motherhood-Wage-Penalty-and.

[5] $10,000*1,000= $10,000,000

force, stunts innovation, and limits economic growth. It also weakens the solvency of social insurance programs like Social Security and Medicare that rely on workers to support a growing elderly population." (Joint Economic Committee Republicans 2022).

The most recent data from #WeCount indicates that approximately 7,530 mail-order abortions are performed annually in Louisiana. Using the $10.9 million value of a statistical life estimate that was utilized by the Joint Economic Committee, this means the annual cost to society of aborting unborn children in Louisiana is approximately $82,077,000,000. In fact, the government's argument in *AHM v. FDA* on the impact to taxpayers is not only wrong but also too narrow. Mail-order abortions also have a negative impact on Louisiana's income, sales, and property tax revenue (Felix and Watkins 2013; Governor's Office of State Budgeting and Planning 2022; Pew Charitable Trusts 2022; Brighton et al. 2021).

In addition to leading to a possible decline in tax revenue, fertility rate reductions could reduce states' federal funding. Several federal programs—including Children's Health Insurance Program, and Head Start—allocate money to states according to formulas that incorporate population counts (Pew Charitable Trusts 2022). A reduction in Louisiana's fertility rate would reduce the amount of federal funds that Louisiana receives for these programs.

STATISTICAL WORK

Excel spreadsheet version 2108 was used for various calculations that were used in this analysis.

A Wald Independent Samples Proportion Test to compare chemical abortion complication rates to surgical abortion complication rates in a study conducted in Sweden was done using SPSS 30.0.

FACTS OR DATA SUPPORTING MY OPINIONS

The opinions in this declaration are my expert opinions, based on my education, training, and research in both Political Science and Statistics. All of the opinions provided in this report are based on my personal knowledge and are provided to a reasonable degree of certainty.

EXHIBITS USED TO SUMMARIZE OR SUPPORT MY OPINIONS

None.

LIST OF CASES WHERE I HAVE SERVED AS AN EXPERT

Served as an expert witness in *The People of the State of California vs. Heartbeat International Inc. and RealOptions Inc.* in the Superior Court of the State of California County of Alameda (Testimony submitted September 9, 2025).

Served as an Expert Witness in *Planned Parenthood Great Northwest, Hawai'i, Alaska, Indiana, Kentucky et al. v. State of Alaska, et al.* in the Superior Court for the State of Alaska Third Judicial District at Anchorage (Testimony submitted August 1, 2022).

Served as an Expert Witness in *Planned Parenthood of Wisconsin, et al. v. Joshua Kaul, et al.* in the United States District Court for the Western District of Wisconsin (Testimony submitted February 28, 2020).

Served as an Expert Witness in *Yashica Robinson M.D., et al. v. Steven Marshall* in the United States District Court for the Middle District of Alabama Northern Division (Testimony submitted August 29, 2019).

Served as an Expert Witness in *Planned Parenthood Federation of America, et al. v. Center for Medical Progress, et al.* in the United States District Court Northern District of California San Francisco Division (Testimony submitted April 15, 2019).

Served as an Expert Witness in *Whole Women's Health, et al., v. Ken Paxton, et al.,* Case No. A-17-CV-690-LY. In the United States District Court for the Western Division of Texas Austin Division.

Served as an Expert Witness in *Springfield Right to Life et al., v. Felicia Norwood*, Director of the Department of Health Care and Family Services, et al., Case No. 2017-MR-1032 in the Circuit Court for the Seventh Judicial Circuit Court Sangamon County.

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White, Kari, Gracia Sierra, Brooke Whitefield, Kristina Tocce, Samuel L. Dickman, and Vinita Goyal. 2025. "Changes in Facility-Based Abortion Care Among Texas Resident Minors and Young Adults After a 2021 Abortion Ban: September 2020 – May 2022." *American Journal of Public Health*: e1-e4.

QUALIFICATIONS AND PUBLICATIONS

I provide these facts and opinions as someone as an expert in the field of Political Science with an extensive background in Statistics. I hold a Ph.D. in Political Science and a M.S. in Statistics both from Stanford University. After I completed my Ph.D., I completed a two year post-doctoral fellowship at the Harvard-MIT Data Center. I have had full time, academic positions at the University of Alabama, the University of Michigan – Dearborn, and Ave Maria University. I am currently an Assistant Professor of Practice of Social Research at The Catholic University of America.

My areas of expertise include fiscal policy and direct democracy. I have a specific interest in the issue of abortion – specifically the impact of both abortion regulations and contraception programs on the incidence of abortion. For more than 20 years, I have conducted research on these topics and published my findings in policy papers and peer reviewed political science journals. I have also presented my findings at numerous professional and academic conferences. In 2012, I testified in front of a Congressional Subcommittee on the Child Interstate Abortion Notification Act (CIANA). In 2017, I was hired by the State of Texas to serve as an expert witness during litigation over Texas Senate Bill 8, which prohibits dilation and evacuation abortions. I have also been hired as an expert witness by the state of Wisconsin, the state of Alaska, and the state of Alabama in cases involving litigation over abortion regulations and restrictions. I have also been hired as an expert witness in a California case involving the legality of abortion pill reversal.

Four of my papers on the impact of anti-abortion legislation have appeared in peer reviewed journals. Two of these papers have been published in *State Politics and Policy Quarterly*, which is considered to be the best state politics journal in the country. In 2007, I was one of only four junior (untenured) faculty members asked to serve on the editorial board of *State Politics and Policy Quarterly.* I served as a section chair at the 2008 meeting of the Midwest Political Science Association, which is typically the second largest political science conference in the country. During my academic career, I have been asked to review manuscripts for 14 different academic journals.

COMPENSATION

I will be compensated at the rate of $300.00 an hour for my work in this case.

I declare under 28 U.S.C. § 1746 and under penalty of perjury that this declaration is true and correct based on my personal knowledge.

Executed December 15, 2025

EXHIBIT A

Curriculum Vitae of Michael J. New, Ph.D.

Michael J. New

The Catholic University of America
The Busch School of Business
620 Michigan Ave. NE
Washington, DC 20064
newm@cua.edu

Employment

The Catholic University of America
Assistant Professor of Practice, August 2022 - present
Research Associate, August 2020 – August 2022
Visiting Assistant Professor, July 2018 – August 2020

Ave Maria University
Associate Professor, July 2017 – July 2018
Visiting Associate Professor, July 2015 – July 2017

University of Michigan – Dearborn
Assistant Professor, August 2011 – June 2015

University of Alabama
Assistant Professor, August 2004 – August 2011

Harvard-MIT Data Center
Post-Doctoral Research Fellow, August 2002-August 2004

Education

Stanford University
Ph.D. Political Science, June 2002
Dissertation: *A Comparison of Fiscal Discipline Measures Passed Through The Citizen Initiative To Fiscal Discipline Measures Enacted Through Other Means.*
Reading Committee: Morris Fiorina, Simon Jackman, John Cogan
Fields: American Politics, Political Organizations, Political Economy (GSB sequence)

Stanford University
M.S. Statistics, January 2002

Dartmouth College
B.A. with High Honors, Government, June 1997
B.A. Economics Modified with Mathematics, June 1997
Magna Cum Laude, Phi Beta Kappa Society

Selected Courses Taught

Undergraduate Courses
"Social Research 101: Foundations of Economic Thought I." The Catholic University of America, Fall 2019, Fall 2020, Fall 2021, Fall 2022, Fall 2023, Fall 2024

"Social Research 260: Game Theory and Strategic Thinking." The Catholic University of America, Spring 2019, Spring 2020, Spring 2021, Spring 2022, Spring 2023, Spring 2024, Spring 2025

"Social Research 325: Public Policy and Federal Budgets." The Catholic University of America, Spring 2019, Fall 2020, Fall 2021, Fall 2022, Fall 2023, Fall 2024

Teaching Interests

Economics
Microeconomics, Macroeconomics, Game Theory, Fiscal Policy
American Politics
Introduction to American Politics, State and Local Government,
Statistical Methods
Introductory Statistics, Intermediate Statistics

Research Interests

Economics
Economics of the Family, Morality Policy, Public Finance, Fiscal Constitutions, Health Policy
American Politics
State and Local Politics, Budgetary Politics, Direct Democracy

Published Academic Papers

"Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes." *Ave Maria Law Review*. Summer 2015.

"Analyzing the Effect of State Level Anti-Abortion Legislation in the Post *Casey* Era: A Re-Assessment." *State Politics and Policy Quarterly*. September 2014.

"Analyzing the Effect of State Level Anti-Abortion Legislation in the Post *Casey* Era." *State Politics and Policy Quarterly*. March 2011.

"State Education Investments and Economic Growth in America: A Path Analysis with Cross-National Controls" with Norman Baldwin and Stephen Borrelli. *Social Science Quarterly.* March 2011.

"U.S. Tax and Expenditure Limitations: A Comparative Political Analysis." *State Politics and Policy Quarterly.* Spring 2010.

"Direct Democracy, Public Opinion, and Public Policy." *PS: Political Science and Politics*, October 2009.

"Starve the Beast: A Further Examination." *Cato Journal.* Fall 2009.

"Using Natural Experiments to Analyze the Impact of State Legislation on the Incidence of Abortion." *Catholic Social Science Review*. Fall 2009.

"Analyzing The Welfare Caseload Decline from 1996-2002." *Cato Journal*. Fall 2008.

"Analyzing the Effect of Anti-Abortion Legislation on the Incidence of Abortion Among Minors." *Catholic Social Science Review*. Fall 2007.

"The Effect of State Regulations on State Health Insurance Premiums." *ICFAI Journal of Insurance Law*. May 2006.

Academic Book Reviews

Review of David Primo's *Rules and Restraint*. *Public Choice*. July 2009.

Academic Letters to the Editor

"Preventing Unintended Pregnancies by Providing No-Cost Contraception." With David Paton. *Obstetrics and Gynecology*. April 2013

Papers in Preparation For Review at Academic Journals

"Analyzing the Effect of Anti-Abortion Parental Involvement Laws" (Previously Received a Revise and Resubmit at *Social Science Quarterly*)

"The Citizen Initiative, Public Opinion, and State Fiscal Outcomes" (Previously Received a Revise and Resubmit at *Social Science Quarterly*)

Selected Papers Presented at Academic Conferences

"Using Birth Data From Texas to Analyze the Impact of the Texas Heartbeat Act." Presented at the Annual Meeting of the American Political Science Association. September 2024, Philadelphia, PA and at annual State Politics and Policy Conference, May 2025, Boston, MA

"Using Birth Data to Analyze the Impact of Anti-Abortion Laws." Presented at the Annual Meeting of the American Political Science Association. September 2024, Philadelphia, PA.

Selected Professional Consulting

Hired by the State of Florida to testify and assist with the drafting of the Financial Impact Statement on Amendment 4. (Oral testimony presented July 1st and July 8th. Written testimony submitted the week of July 1st and July 8th)

Served as an Expert Witness in *Planned Parenthood Great Northwest, Hawai'i, Alaska, Indiana, Kentucky et al. v. State of Alaska, et al.* in the Superior Court for the State of Alaska Third Judicial District at Anchorage (Testimony submitted August 1, 2022)

Served as an Expert Witness in *Planned Parenthood of Wisconsin, et al. v. Joshua Kaul, et al.* in the United States District Court for the Western District of Wisconsin (Testimony submitted February 28, 2020)

Served as an Expert Witness in *Yashica Robinson M.D., et al. v. Steven Marshall* in the United States District Court for the Middle District of Alabama Northern Division (Testimony submitted August 29, 2019)

Served as an Expert Witness in *Planned Parenthood Federation of America, et al. v. Center for Medical Progress, et al.* in the United States District Court Northern District of California San Francisco Division (Testimony submitted April 15, 2019)

Served as an Expert Witness in *Whole Women's Health, et al. vs. Ken Paxton, et al.* in the United States District Court for the Western District of Texas Austin Division (Testimony submitted October 4, 2017)

Compensated Expert on a Department of Health and Human Services (HHS) Project on the Sexual Health of Adolescents and Young Adults. Assisted with the Development of Models of Sexual Risk Avoidance and Sexual Risk Cessation (2018-2020)

Amicus Brief

Brief: On Writ of Certariori in *Zubik v. Burwell* in Support of Petitioners (U.S. Supreme Court argued March 23, 2016; Filed January 11, 2016)

Selected Editorials

"Gann, not Gavin, Is Responsible for Tax Relief in California" *Washington Examiner,* May 25, 2021

"The Trump Administration's Protect Life Rule in a Win for Women" *Washington Examiner*, August 27, 2019

Selected Presentations

"Public Opinion and the Pro-Life Brand." Presentation given at Notre Dame's Vita Institute in 2025, South Bend, IN.

"Pro-Life Success in the States: Strategies for the *Dobbs* Era." Presentation Given at annual convention of the National Right to Life Committee in Arlington, VA on June 29, 2024. Similar presentations given at the 2023 Convention of the National Right to Life Committee, Harvard University (2025), University of New Hampshire (2023), and other university campuses.

"Abortion Access and the Flourishing of Women: A Discussion of the Turnaway Study" Presentation given at Notre Dame's Vita Institute in 2024, South Bend, IN.

"Domestic Politics and Political Messaging on Abortion?" Presentation given at Notre Dame's Vita Institute in 2023, South Bend, IN.

"Analyzing the Effect of State Level Anti-Abortion Legislation in the Post *Casey* Era." Presentation given at Notre Dame's Vita Institute annually from 2011 to 2017, South Bend, IN.

"An Analysis of State Level Contraception Mandates." Presentation given at "The Future of the Families and Family Law." Brigham Young University Law School, October 10, 2014, Provo, UT.

"Taming Leviathan: Do Tax and Expenditure Limits Work?" American Enterprise Institute Policy Forum. June 12, 2013, Washington, DC.

Comments on John Lott's *Freedomnomics*. Cato Institute Book Forum. August 14, 2007, Washington, DC.

"Process and Institutions: Approaches to Responsible Budgeting." Goldwater Institute Fiscal Policy Conference, February 3rd, 2005. Phoenix, AZ.

"Tax Limitation after California's Prop 13." Cato Institute Policy Forum. June 19, 2003, Washington, DC.

Research Grants

$10,000 from the Charlotte Lozier Institute to Analyze State Level Contraception Mandates. Spring 2014

Fellowships

Witherspoon Institute, Bradley Fellow 2008-2009 academic year

American Political Science Association, Centennial Center Visiting Scholar, Summer 2009

Hoover Institution on War, Revolution, and Peace, Academic Fellowship, May 2007

Weaver Fellow, Intercollegiate Studies Institute, 2001-2002

Honors and Awards

Society of St. Sebastian Person of the Year Award, 2023

Society of St. Sebastian's Person of the Year Award, Honorable Mention, 2020

George Mason University Foundation Award, 2005

Intercollegiate Studies Institute's Director's Award, 2000

Disciplinary Service

Chair, Public Administration Section, Annual Conference of the Midwest Political Science Association, Spring 2008. Chicago IL

Editorial Board Member, *State Politics and Policy Quarterly* (2007-2011)

Invited by the General Social Survey (GSS) to write a memo suggesting topics for updated survey questions on various sanctity of life issues

Referee, *American Journal of Political Science*

Referee, *Journal of Politics*

Referee, *Political Research Quarterly*

Referee, *American Politics Review*

Referee, *Eastern Economic Journal*

Referee, *Public Budgeting and Finance*

Referee, *Publius*

Referee, *State Politics and Policy Quarterly*

Referee, *State and Local Government Review*

Referee, *Journal of Policy Analysis and Management*

Referee, *Journal of Women, Politics, and Policy*

Referee, *Social Forces*

Referee, *The Review of Black Political Economy*

Referee, *National Tax Journal*

Discussant, Midwest Political Science Association Meetings, 2022, 2019, 2014, 2013, 2008, 2006, 2003

Discussant, American Political Science Association Meetings, 2005

Discussant Southern Political Science Association Meetings, 2005

University and Departmental Service

The Catholic University of America
Faculty Advisor, Catholic University of America College Republicans, 2019-2020, 2020-2021, 2021-2022, 2022-2023, 2023-2024, and 2024-2025 Academic Years

Faculty Advisor, Catholic University of America Young Americans for Freedom (YAF), 2019-2020, 2020-2021, 2021-2022, 2022-2023, 2023-2024, and 2024-2025 Academic Years

Failed Grades Committee (Busch School of Business), Spring Semester 2023 (partial), 2023-2024 academic year

Ave Maria University
Program Director, Political Economy and Government, 2016-2017 and 2017-2018 Academic Year

Member, Honor Council, 2015-2016, 2016-2017, and 2017-2018 Academic Years

Search Committee for Faculty Member in Economics, 2017-2018 Academic Year

Member, Sophomore Success Committee, 2016-2017 Academic Year

Search Committee for Faculty Member in Business, 2016-2017 Academic Year

Member, Institutional Review Board, Spring Semester 2016

University of Michigan -- Dearborn
Co-Director, University of Michigan Dearborn's Social Science Research Colloquium Fall 2011-Fall 2014

Member, CASL Curriculum Committee, Winter Semester 2014 and Winter Semester 2015

Member, Social and Behavioral Analysis Learning Outcomes Subcommittee, 2013-2014 Academic Year

Graduate Integrity Board, 2013-2014 Academic Year

Search Committee for Assistant Professor in Environmental Politics and Policy, 2012-2013 Academic Year

The University of Alabama
Director, University of Alabama's Washington Experience Summer Internship Program, 2005 – 2011

Vice-President, Phi Beta Kappa Society, 2009-2010 Academic Year

Acting Director, University of Alabama's Masters in Public Administration (MPA) Program, Spring 2006

Dissertation Committee, Sam Clovis. "Federalism, Homeland Security, and National Preparedness: A Case Study in the Development of Public Policy."

Dissertation Committee, Justice Kali. "Innovation Diffusion and the Reinvention of Domestic Violence Policy Within State Welfare Programs: Influences of Adoption of the Family Violence Option and Domestic Violence Policy."

EXHIBIT 23

Declaration of Angela Parise, M.D.
(Dec. 11, 2025)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*.	Case No.: 6:25-cv-01491-DCJ-DJA Judge David C. Joseph Magistrate Judge David J. Ayo

DECLARATION OF DR. ANGELA PARISE

I, Angela Parise, M.D., a citizen of the United States of America and a resident of Louisiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge. I am fully competent to make this declaration. If called to testify, I could and would testify competently to these facts.
2. I am a board-certified obstetrician and gynecologist with more than 20 years of experience.
3. I am a fellow in the American College of Obstetrics and Gynecology.
4. I received my medical degree from State University of New York Downstate Health Sciences University in 2001 and completed my residency at Ochsner Medical Center (New Orleans) in 2005. I have practiced in Louisiana ever since.
5. I am a practicing obstetrician and gynecologist in private practice and on call at a major health center network in New Orleans, Louisiana. Our health centers are part of the leading nonprofit healthcare provider in the Gulf South. Our facilities provide

labor and delivery, emergency OB/GYN interventions, newborn care, women's health, and maternal-fetal medicine for high-risk pregnancies.

6. I provide general OB/GYN care. I also specialize in minimally invasive procedures and robotic surgery with an interest in routine obstetric care, adolescent gynecology, and advanced gynecologic surgery such as hysteroscopic endometrial ablation, total laparoscopic hysterectomy, and uterine fibroid surgery.

7. I provide emergency care to patients seeking OB/GYN care.

8. I have witnessed firsthand how the abortion drug mifepristone has hurt women in Louisiana.

9. Since 2022, I have personally treated and cared for approximately fourteen patients who suffered complications after taking mifepristone.

10. These fourteen women were Louisiana residents.

11. Of those fourteen patients, I treated approximately eleven patients for an incomplete abortion and three patients for infection. The incomplete abortions required emergency medical intervention by me, including dilation and curettage (D&C) for eight patients and supportive management, ultrasounds, and antibiotics for the other three patients.

12. At least 80% of the patients I have personally treated for mifepristone complications received the drugs through the mail.

13. In a recent two-month span, my team—including the junior partners and nurse practitioners I oversee—treated at least 30 women who suffered mifepristone complications. These complications included hemorrhaging, blood transfusions, the need for D&C, and hospital stays, just from April through May 2025. Among the colleagues in my network, I am aware of women seeking treatment for mifepristone complications every day.

14. Approximately half of the patients my team or I have treated for mifepristone complications were on Medicaid. That means Louisiana Medicaid likely paid for that treatment.

15. In 2024, a patient came to me with what she initially labeled a miscarriage. She was bleeding and septic. I performed a suction D&C. I later discovered that this patient had taken mifepristone that she received in the mail. She took the mifepristone at approximately 19 weeks gestation.

16. In 2025, I managed the treatment plan for a patient suffering mifepristone complications. She ordered mifepristone from Abuzz, who mailed the drugs to her Louisiana home. She took the drugs in Louisiana. After she took the drugs, she bled for three weeks and came to the hospital after she started experiencing lightheadedness at the end of that three-week period. She was at approximately 7 or 8 weeks gestation when she came to the hospital. My partner performed a suction D&C and a blood transfusion. In the operating room, the patient started hemorrhaging. She was on Medicaid.

17. Patients often hide the fact that they took mifepristone.

18. In the last six months, I have personally treated four patients for post-abortion care after they took mail-order mifepristone.

19. Every day, women contact my team because they have abnormal bleeding, cramping, pain, nausea, and fever from mifepristone, and they often do not know the gestational age of their unborn children.

20. The number of Louisiana women whom we treat for mifepristone complications has dramatically increased since January 2023. If the FDA had not formally authorized a national mail-order abortion-drug regime, few, if any, women in Louisiana would be harmed by mifepristone. Based on my experience, the number of women harmed under this regime will continue to increase unless the FDA reverses course or the courts hold the FDA accountable for its reckless actions.

Executed this 11th day of December, 2025.

By _____
Angela Parise, M.D.

EXHIBIT 24

Declaration of Lindsey Sikes
(Dec. 15, 2025)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA by and through its Attorney General, Liz Murrill, and Rosalie Markezich, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants.*	Case No.: 6:25-cv-01491-DCJ-DJA Judge David C. Joseph Magistrate Judge David J. Ayo

DECLARATION OF LYNDSEY SIKES

I, Lyndsey Sikes, a citizen of the United States of America and a resident of the State of Louisiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge. I am fully competent to make this declaration. If called to testify, I could and would testify competently to these facts.
2. I am the executive director of Life Choices Pregnancy Resource Center in Monroe, Louisiana. I have witnessed how the abortion drug mifepristone has hurt women in Louisiana. Life Choices encounters women considering abortion and women who have had an abortion—including by mifepristone.
3. Before mid-2022, Life Choices rarely encountered women who had ordered or taken abortion drugs. Now the center encounters women who have ordered or taken abortion drugs on a daily basis.
4. These women are Louisiana residents.
5. Most of Life Choices' clients who ordered or took abortion drugs ordered the drugs through Aid Access.

6. One Life Choices client received her drugs through Aid Access from Dr. Margaret Carpenter.

7. Approximately one out of seven Life Choices clients bring their abortion drugs with them to the center.

8. Life Choices encounters two or three women suffering from mifepristone complications every month. These complications include hemorrhaging, cramping, bleeding, fever, and incomplete abortions that require ultrasounds by our nurse practitioner on-site and referrals to the emergency room.

Executed this 15th day of Dec, 2025.

By_____
Lyndsey Sikes

EXHIBIT 25

Declaration of Gabriella McIntyre
(Dec. 16, 2025)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*.	Case No.: 6:25-cv-01491-DCJ-DJA Judge David C. Joseph Magistrate Judge David J. Ayo

DECLARATION OF GABRIELLA MCINTYRE

I, Gabriella McIntyre, declare as follows:

1. I am above the age of 21. I am fully competent to make this declaration.

2. I am Legal Counsel at Alliance Defending Freedom (ADF) and counsel for the State of Louisiana and Rosalie Markezich in this action.

3. These facts are within my personal knowledge and are true and correct. If called to testify, I could and would testify competently to these facts.

4. I caused to be accessed the listed documents through the specified web links in the form in which they appeared at the time of access:

Complaint ECF Number	**Description**
ECF 1-1	Society of Family Planning, *#WeCount Report April 2022 to June 2024* (Oct. 22, 2024), https://societyfp.org/wp-content/uploads/2024/10/WeCount-Report-8-June-2024-data.pdf, also available at perma.cc/WRW3-PMWK (archived July 23, 2025)

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MPI Exhibit Number	**Description**
1	#WeCount Report April 2022 to June 2025 (Dec. 9, 2025), https://societyfp.org/wecount-report-10-june-2025-data/, also available at https://perma.cc/AYJ2-FYJ2 (archived Dec. 15, 2025)

2	#WeCount Report Summary Slides with National and 51 State-Level Findings April 2022 to June 2025 (Dec. 9, 2025) https://perma.cc/83U9-TC79 (archived Dec. 15, 2025)
3	Abigail R. A. Aiken et al., Research Letter, Provision of Abortion Medications Using Online Asynchronous Telemedicine Under Shield Laws in the US, 334(15) JAMA 1388 (Oct. 21, 2025), https://jamanetwork.com/journals/jama/article-abstract/2837546, also available at https://doi.org//10.1001/jama.2025.11420
4	Robin Wallace et al, *P040 - Expanding Access to Abortion with Mifepristone and Misoprostol Through 84 Days Estimated Gestational Duration*, 151 Contraception 111117 (Nov. 2025), https://www.contraceptionjournal.org/article/S0010-7824(25)00308-7/abstract, also available at https://perma.cc/KXC7-9TFA (archived Dec. 15, 2025)
5	*Governor Newsom Signs New Landmark Laws to Protect Reproductive Freedom, Patient Privacy Amid Trump's War on Women*, Gov. Gavin Newsom (Sep. 26, 2025), https://www.gov.ca.gov/2025/09/26/governor-newsom-signs-new-landmark-laws-to-protect-reproductive-freedom-patient-privacy-amid-trumps-war-on-women/, also available at perma.cc/SB5E-V4QB (archived Dec. 12, 2025)
6	*US FDA Has Delayed Abortion Pill Safety Study, Bloomberg News Reports*, Reuters (Dec. 8, 2025, at 14:23 PT), https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-has-delayed-abortion-pill-safety-study-bloomberg-news-reports-2025-12-08/, also available at perma.cc/DH8S-89TM (archived Dec. 12, 2025)
7	Elizabeth Troutman Mitchell, *EXCLUSIVE: Makary Responds to Report Saying He Slow-Walked Abortion Pill Safety Review*, Daily Signal (Dec. 9, 2025), https://www.dailysignal.com/2025/12/09/exclusive-makary-responds-report-saying-he-slow-walked-abortion-pill-safety-review/, also available at perma.cc/AXP5-XTYS (archived Dec. 12, 2025)
8	Ian Lopez, *RFK Jr. Says Biden 'Twisted the Data' on Abortion Pill Safety*, BL (Sep. 4, 2025, at 12:45 ET), https://news.bloomberglaw.com/health-law-and-business/rfk-jr-says-biden-twisted-the-data-on-abortion-pill-safety, also available at perma.cc/ST5H-94H6 (archived Nov. 20, 2025)
9	U.S. Senator Bill Cassidy, M.D. (@SenBillCassidy), X (Dec. 12, 2025, at 13:05 PT), https://x.com/senbillcassidy/status/1999586351172485625?s=42, also available at perma.cc/LR7T-9UZT (archived Dec. 13, 2025)

10	Video posted by Elizabeth Mitchell Troutman (@TheElizMitchell), X, at 02:02–2:19 (Dec. 9, 2025, at 14:56 PT), https://x.com/TheElizMitchell/status/1998527302011924941?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1998527302011924941%7Ctwgr%5E3d356988d5d37f2987180f0d963894e34808456a%7Ctwcon%5Es1_c10&ref_url=https%3A%2F%2Fwww.dailysignal.com%2F2025%2F12%2F09%2Fexclusive-makary-responds-report-saying-he-slow-walked-abortion-pill-safety-review%2F, also available at perma.cc/Q9CV-8FDN (archived Dec. 12, 2025)
11	T. Elliot Gaiser et al., *The Truth of Erasure: Universal Remedies for Universal Agency Actions*, U. Chi. L. Rev. Online (Aug. 28, 2024), https://lawreview.uchicago.edu/sites/default/files/2024-08/The%20Truth%20of%20Erasure%20UCLR.pdf, also available at perma.cc/Y4C6-G7ZX (archived Nov. 20, 2025)
12	Letter from Elizabeth Warren et al. to FDA (Nov. 18, 2022), https://www.warren.senate.gov/imo/media/doc/2022.11.18%20Letter%20to%20FDA%20re%20medication%20abortion.pdf, also available at perma.cc/Y6RB-XDPT (archived Dec. 12, 2025)
13	Aria Bendix, *Why Abortions Rose After* Roe *Was Overturned*, NBC News (Nov. 26, 2024, at 2:00 PT), https://www.nbcnews.com/health/womens-health/abortions-rose-roe-overturned-why-rcna181094, perma.cc/QP3F-U82N (archived Dec. 12, 2025)
15	Notice of Cease and Desist from Ken Paxton, Att'y Gen. of Tex., to Remy Coeytaux (Aug. 14, 2025), https://www.texasattorneygeneral.gov/sites/default/files/images/press/Coeytaux%20Cease%20and%20Desist.pdf, also available at perma.cc/P7NE-7RTH (archived Dec. 12, 2025)
16	FDA, REMS Single Shared System for Mifepristone 200MG (May 2021), https://www.fda.gov/media/164651/download, also available at perma.cc/W522-9F7G (archived Dec. 15, 2025)
17	REMS Compliance Program, FDA (Sep. 22, 2022), https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/rems-compliance-program, also available at perma.cc/KE9P-UKGU (archived Dec. 15, 2025)

Each listed exhibit is a true and accurate copy of the document as downloaded.

I declare under 28 U.S.C. § 1746 and under penalty of perjury that this declaration is true and correct based on my personal knowledge.

Executed this 16th day of December, 2025, at Lansdowne, Virginia.

Gabriella McIntyre

Counsel for Plaintiffs State of Louisiana and Rosalie Markezich