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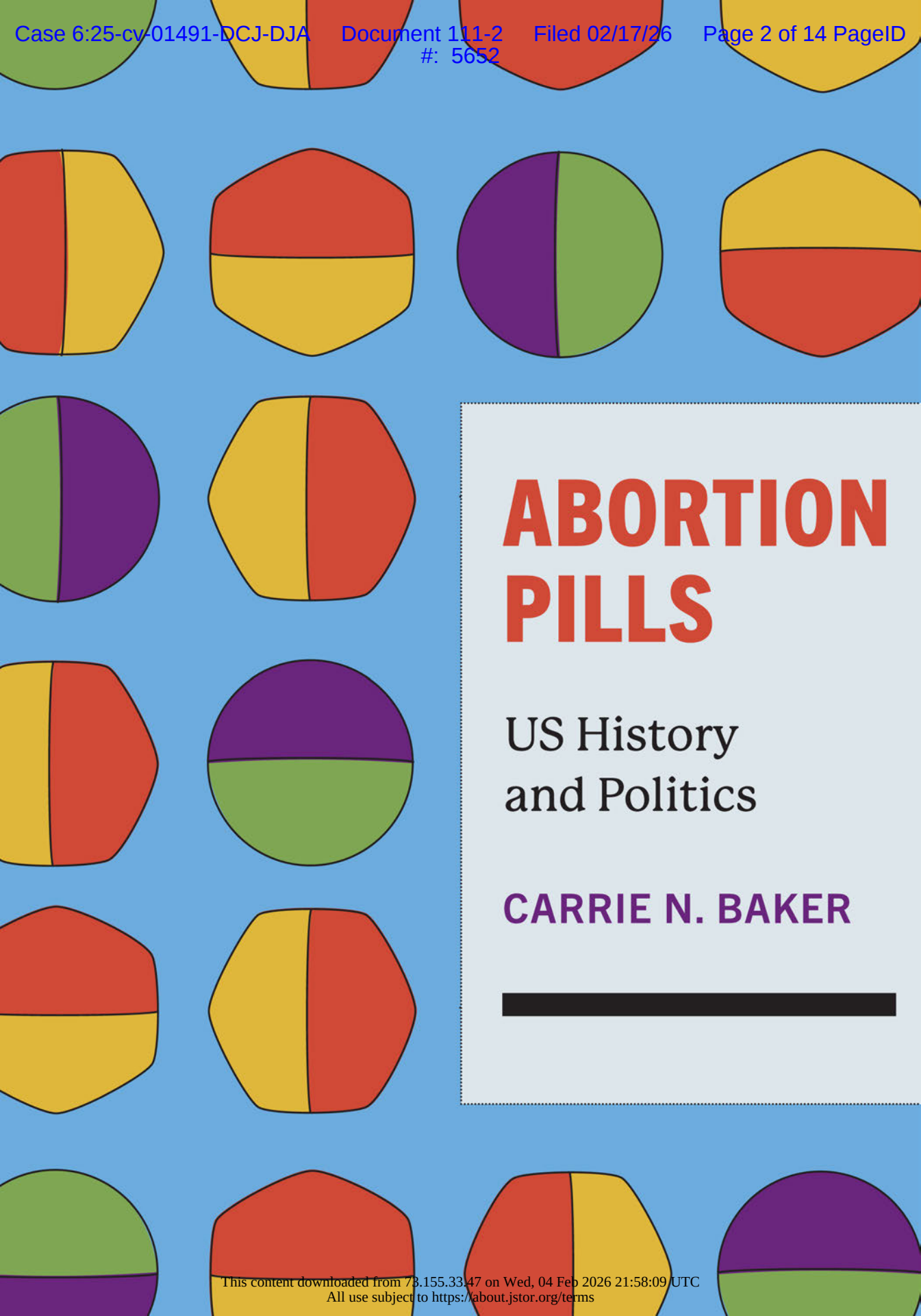

ABORTION PILLS

US History and Politics

CARRIE N. BAKER

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Acronyms

AAP	Abortion Access Project
ACLU	American Civil Liberties Union
ACOG	American College of Obstetricians and Gynecologists
ADF	Alliance Defending Freedom
AHT	Advances in Health Technology
ANSIRH	Advancing New Strategies in Reproductive Health
ARM	Abortion Rights Mobilization
CPC	crisis pregnancy center
CRR	Center for Reproductive Rights
EMAA	Expanding Medication Abortion Access
ETASU	Elements to Assure Safe Use
FDA	US Food and Drug Administration
FMF	Feminist Majority Foundation
FRC	Family Research Council
FTC	Federal Trade Commission
GLC	Generative Learning Community for self-managed abortion
HHS	Department of Health and Human Services
HIS	Indian Health Service
IND	Investigational New Drug
M+A Hotline	Miscarriage and Abortion Hotline
NAF	National Abortion Federation
NARAL	National Abortion Rights Action League
NAWHERC	Native American Women's Health Education Resource Center
NDA	New Drug Application
NOW	National Organization for Women
NRLC	National Right to Life Committee
NWHN	National Women's Health Network
OARS	Online Abortion Resource Squad

REMS	Risk Evaluation and Mitigation Strategy
RHEDI	Reproductive Health Education in Family Medicine
RHTP	Reproductive Health Technologies Project
SASS	Self-Managed Abortion. Safe and Supported
SHERo	Sisters Helping Every Woman Rise and Organize
SIA Legal Team	Self-Induced Abortion Legal Team
S.T.O.P.	Surveillance Technology Oversight Project
WRRAP	Women's Reproductive Rights Assistance Project

approval of a generic with the FDA. The head of the FDA at the time, Dr. Scott Gottlieb, was focused on increasing the number of generic medications on the market in order to encourage competition, especially for drugs in the REMS program.[219] On April 11, 2019, the FDA approved GenBioPro's generic mifepristone.[220] Coeytaux said the generic made a huge difference:

> The minute GenBioPro was in the act, all sorts of things started happening. Danco reduced its price because there was competition. All the stuff that we did with the providers during COVID—we couldn't have done it with Danco. Danco wasn't interested at all in anything innovative because they were happily doing their thing and already had their people on board. So having competition in the market was critical.[221]

FDA approval of the generic set price competition in motion: GenBioPro set their price lower than Danco, which then dropped their price. Lower prices and more options increased access to mifepristone for clinicians and patients across the country. The generic also established competition for new services from the drug sponsors, such as mail order at scale, but it also extinguished the rationale for Danco to pursue the miscarriage indication since most pharmacies could swap out brand-named mifepristone for the generic, regardless of what the prescription was written for.[222] Dr. Mitchell Creinin, however, believed that the drop in price had only a "marginal benefit" for patients because clinics did not drop their prices for medication abortion.[223]

But anti-abortion advocates pushed back against increasing access. In March of 2019, the Trump administration's FDA issued a warning letter to Dr. Gomperts, demanding that she stop "causing the introduction of a misbranded and unapproved new drug into interstate commerce."[224] The FDA threatened to seize the drugs. Gomperts explained what she did next: "I stayed in my bed for three days, researching and reading everything that existed on the FDA regulations, calling all the people I could call in the US. I came to the conclusion that it's okay, I can do this."[225] Then she fought back. In September 2019, Gomperts sued the FDA, alleging they had seized between three and ten doses of abortion drugs she had prescribed through Aid Access since March and that the government had blocked Aid Access from receiving payments from some patients.[226] The lawsuit was eventually dismissed, but Gomperts continued to mail the medication and did not experience any more interference.

Anti-abortion states also tried to block the increasing access by fighting for restrictions at the state level, including passing laws banning mailing of abortion pills, requiring ultrasounds which limited telemedicine access, and requiring that physicians alone may prescribe mifepristone. For three weeks in June of 2019, the Missouri health department required doctors prescribing abortion pills to conduct an extra medically unnecessary pelvic exam on their patients before the state-mandated waiting period so that patients had to have two pelvic exams to receive the pills—one when they initially

saw the doctor and a second when patients came back for the pills. In other words, doctors were forced by the state to insert their fingers into patients' vaginas while pressing their abdomens to feel their reproductive organs, for no medical reason. One doctor described the requirement as "state sanctioned, essentially, sexual assault."[227] After three weeks, doctors at the one remaining abortion clinic in Missouri, a Planned Parenthood clinic in Kansas City, refused to comply with the order, and the state health department backed down, rescinding the requirement.[228] During that time period, over one hundred women experienced invasive, medically unnecessary, and unwanted vaginal probes, by order of the state. In response, Planned Parenthood created a new clinic across the river in Illinois so as not to be subject to the Missouri Department of Health.[229] Meanwhile, states increasingly passed abortion bans, hoping to tee up a case for the Supreme Court to finally overturn *Roe v. Wade*. These developments spurred Plan C to push harder to make abortion pills available by telemedicine and mail. The declaration of a pandemic in March 2020 created new opportunities to make this vision a reality.

falsely deemed "nonessential," but the number of abortions in surrounding states increased, likely due to women traveling from restrictive states to find abortion health care. The Guttmacher report noted other factors that likely contributed to state variation and overall increase in the number of abortions, including increased fundraising by local and national abortion funds so they could help more people pay for their abortions, increased abortion restrictions and bans (twenty-five states enacted 168 laws between 2017 and 2020, some of which were blocked by courts), and seventy-five new provisions to protect abortion rights (repealing restrictions, expanding insurance coverage, and allowing more qualified clinicians such as nurse practitioners, physician assistants, or certified nurse midwives to provide at least some abortion care). "The Supreme Court is poised to overturn *Roe v. Wade* at a time when need for abortion care has been increasing," concluded the report. "This means the impact of the ruling could be even more devastating than predicted by prior analyses, particularly for people across the country who already struggle to access abortion care."[78]

In December of 2020, the Generative Learning Community (GLC) for self-managed abortion expanded, opening membership to more organizations. GLC grew to over seventy organizations and held meetings every other month as a "gathering space" for "shared learning and problem solving" on self-managed abortion. GLC also engaged in "culture change work" to normalize self-managed abortion.[79] GLC had two goals: "to give every person the option to end a pregnancy safely and with support, within the formal healthcare system, or outside it" and to "ensure no one risks punishment or imprisonment for their reproductive choices or for supporting a person who is self-managing the end of a pregnancy."[80] Their purpose was to normalize self-managed abortion by promoting a "positive narrative, and avoiding harmful messages, about self-managed abortion."[81] They focused on "developing tools and actions for use in communications" and committed to "do nothing that puts pregnant people, or those who support them, at increased risk of investigation, prosecution, and punishment for their reproductive choices." This limited approach later led to a break with Plan C because of their work to make pills available to people in states with abortion bans, which inevitably created some legal risks.[82]

The GLC focused primarily on normalizing abortion pills inside the reproductive health movement. "The medical community could get overly controlling about mifepristone," explained Kirsten Moore. "What the GLC did was hold a mirror up to the medical professionals and say, 'you know you're overthinking this, you're overtraumatizing this.' They consistently normalized the idea that patients can manage their abortions on their own," said Moore, noting that GLC held a full-day workshop on self-managed abortion at a NAF meeting in early 2022. "It's about getting the movement itself to move into the twenty-first century."[83]

THE PENDULUM SWINGS: BIDEN ADMINISTRATION EXPANDS ABORTION PILL ACCESS

Immediately after the 2020 election of Joseph Biden, reproductive rights advocates asked the new administration to review the FDA's abortion pill restrictions. "These restrictions place more of a burden than a benefit on providers and their patients," said Kirsten Moore, referring to the FDA standard for imposing the REMS restriction. "Based on opinion research we conducted last year, people like the idea that women have access to an option for ending an early pregnancy," said Moore. "And they like the idea that it's an FDA-approved drug that's been around for twenty years. We think it's time to revisit these restrictions and move forward."[84]

Even before the election, medical professionals and activists were calling on Biden to reverse the Trump policy and end the FDA restriction on the abortion pill altogether. A coalition of more than ninety women's rights organizations released a "Blueprint for Sexual and Reproductive Health, Rights and Justice" that made two demands with regard to mifepristone. The first was that President Biden issue an executive order on his first day in office directing the Secretary of Health and Human Services to lift the in-person distribution requirement for mifepristone during the pandemic. The second demand was that within ninety days of assuming office, the president direct the FDA to review the mifepristone REMS to determine whether it should be modified or removed to "best reflect scientific evidence and real-world use."[85] On January 27, 2021, Guttmacher Institute's president and CEO Herminia Palacio and Dr. Daniel Grossman of ANSIRH wrote an op-ed in *The Washington Post* urging Biden to remove the in-person distribution requirement. "Facts matter, and the facts couldn't be clearer," they wrote. "In this moment, when the country is looking to the administration to heed public health experts, it must suspend this requirement for the duration of the public health emergency and direct the FDA to ensure its medication abortion policies are aligned with the scientific evidence."[86] At a more personal level, Sarah Christopherson of NWHN found people to speak directly with President Biden about mifepristone. "I spent some time organizing high-net-worth major donors. I had some leftover contacts and some leftover favors to call in from people I knew would be receptive and get it, and be good spokeswomen for it," said Christopherson.[87]

On February 9, 2021, eleven female Democratic members of the House Committee on Oversight and Reform wrote a letter to the Acting Commissioner of the FDA Janet Woodcock[88] urging her to lift the in-person abortion pill distribution requirement. In the letter, they emphasized the FDA's illogical policy on mifepristone: "Of the more than 20,000 drugs regulated by FDA, mifepristone is the only drug that FDA requires patients to obtain in person at a hospital, clinic, or medical office, but it does not restrict the ability of patients to self-administer—unsupervised—at home or at a location of

their choosing." They described a strong safety record of mifepristone, and the risks imposed on patients by the in-person distribution requirement. They concluded, "In light of the clear danger that the reinstated requirement poses to people seeking comprehensive reproductive health care at the height of the coronavirus pandemic, we urge you to immediately eliminate the medically unnecessary in-person dispensing requirement for mifepristone."[89]

On March 18, fifty-five reproductive health, rights, and justice groups sent a letter to President Biden urging his administration to lift FDA restrictions on mifepristone. The letter emphasized the burden of the FDA restrictions on marginalized communities:

> Consistent with your important commitment to follow the science in responding to COVID-19, as well as your critical promise to tackle issues of systemic equity across the government, it is imperative that your administration prioritize safe access to medication abortion. Burdensome restrictions on medication abortion, which are not based in medical evidence, deepen the health inequities already experienced by those who are struggling to make ends meet, particularly people of color, who comprise a majority of medication abortion patients and are now being hit hardest by the COVID-19 pandemic.[90]

Along with the letter, they delivered a petition with over 200,000 signatures of supporters.

On April 12, 2021, under the leadership of Dr. Janet Woodcock, the FDA finally lifted the in-person distribution requirement for the duration of the COVID-19 public health emergency, allowing clinicians to resume telemedicine abortion services.[91] In a letter to ACOG and the Society for Maternal-Fetal Medicine, Dr. Woodcock wrote that the FDA would waive the requirement that clinicians dispense mifepristone to their patients in a clinic or hospital setting. The letter said research studies on telemedicine abortion "do not appear to show increases in serious safety concerns occurring with medical abortion as a result of modifying the in-person dispensing requirement during the COVID-19 pandemic."[92] ACOG issued a statement praising the new guidelines: "We are pleased to see mifepristone regulated on the basis of the scientific evidence during the pandemic, rather than political bias against comprehensive reproductive health care, and we look forward to working with policy makers to ensure this principle governs post-pandemic care."[93] Advocates celebrated the decision for following the science. "We know from twenty years of research that medication abortion is extremely safe—even safer than some over-the-counter medications. It's past time to permanently lift the restrictions and make medication abortion more accessible for those who need it," said Dr. Grossman of ANSIRH. Online pharmacies resumed distribution of mifepristone by mail. Sarah Christopherson said all the strategies contributed toward their success: "I don't think any one strategy would have been sufficient on its own. I think it took all of them. It took the medical studies, proving how safe it was. It took EMAA