



NORTHERN ILLINOIS UNIVERSITY
College of Law

NIU LAW REVIEW SYMPOSIUM

REPRODUCTIVE
RIGHTS & JUSTICE

April 14, 2023
9 AM - 2 PM

NIU Naperville Campus
1120 E. Diehl Rd., Naperville IL
60563

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LAW REVIEW

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NORTHERN ILLINOIS UNIVERSITY
College of Law

April 14, 2023

Dear Participant:

I am pleased to welcome you to the Annual Symposium sponsored by the Northern Illinois University Law Review. This year's program, "Reproductive Rights and Justice," addresses legal issues surrounding how the Dobbs decision has impacted the landscape of reproductive rights in the United States. Each of the symposium's speakers will present their unique, important perspectives on the subject, and we value their participation.

Pursuant to the law school's commitment to engagement, it is important for the law school to serve as an intellectual gathering place for attorneys, judges, and academics to discuss cutting-edge issues. As such, the symposium has been organized to permit active participation by everyone in attendance. You are encouraged to engage in the discussions during the question-and-answer sessions and panel break periods. These dialogues will ensure the sharing of a variety of perspectives on the expansive range of issues addressed by the speakers.

I am confident that your day will not only be enjoyable, but also enhance your knowledge in meaningful ways. We hope to see you again at next year's symposium and further College of Law events in the future.

Sincerely,

*Cassandra L. Hill
Dean and Professor*

Your Future. Our Focus.



NORTHERN ILLINOIS UNIVERSITY

College of Law

Reproductive Rights and Justice

April 14, 2023 | A Hybrid Event

NIU Naperville Campus & Zoom

AGENDA

- 8:30 am – 9:00 am Check-In & Breakfast
- 9:00 am - 9:10 am Welcome & Introduction
- 9:10 am - 10:00 am *The Legal Landscape in Illinois post Dobbs*
Michelle Wetzel
- 10:00 am - 11:15 am Prosecutorial Discretion & Reproductive Rights Panel
Miriam Krinsky, & Rebecca Blair
- 11:15 am - 11:45 am **Lunch**
- 11:45 am - 1:30 pm Constitutional Law & Reproductive Rights Panel
Ameri Klafeta, Evan Bernick, & Lindsey Langholz
- 1:30 p.m. - 2:00 p.m. Pharmaceutical Federalism & Abortion
Allison Whelan
- 2:00 p.m. Closing Remarks

MEET THE MODERATOR



Kim Ricardo

Kim D. Ricardo (née Chanbonpin) is a Director and Professor at UIC College of Law. She first joined the UIC faculty in 2008. Kim teaches Lawyering Skills, Criminal Law, Torts, Gender Race and Class, and National Security Law. She has also taught Introduction to the U.S. Legal System to LLM students in China's State Intellectual Property Office and at Masaryk University Faculty of Law in the Czech Republic. In 2014, she was a Visiting Professor at Seattle University School of Law.

Her scholarly writing considers redress and reparations law, policy, and social movements in the United States. Her work has appeared in the U.C. Irvine Law Review, the Northwestern Journal of Law & Social Policy, and the Mercer Law Review, among other publications. Kim is a member of the State Bar of California, and has been involved in several pro bono publico cases litigating a variety of legal issues, including post-conviction relief, Violence Against Women Act self-petitions, and police brutality claims. She sits on the Illinois State Bar Association's Criminal Justice Section Council. Kim is currently serving as Immediate-Past President of the Legal Writing Institute. She also proudly serves on the Board of Governors for the Society of American Law Teachers and on the board of the Chicago Dancemakers Forum.

Kim received her bachelor's degree in English from the University of California at Berkeley. She earned her J.D. from the University of Hawai'i at Mānoa, William S. Richardson School of Law, graduating cum laude with a Certificate in Asian-Pacific Legal Studies. After law school, she was a law clerk to the late Judge John S.W. Lim, Intermediate Court of Appeals in Honolulu. Kim also earned an LL.M., with distinction, and a Certificate in National Security Law at the Georgetown University Law Center. While in Washington, D.C., she interned at the World Bank. Prior to coming to John Marshall, Kim was a Westerfield Fellow at Loyola University New Orleans College of Law.

MEET THE SPEAKERS

Michelle Wetzel

Michelle Wetzel is currently serving as the General Counsel for Planned Parenthood of Illinois. Before joining Planned Parenthood in 2019, Michelle had a long career in legal aid, first with Prairie State Legal Services and then as an attorney with the Legal Assistance Foundation in their HIV/AIDS Project. She then became CEO of Bonaventure House, a supportive living facility for people with HIV/AIDS and struggling with addiction and mental health issues. In 2012 she became General Counsel for Howard Brown Health, where she worked for 7 years before becoming General Counsel for Planned Parenthood of Illinois. Michelle received her J.D. from DePaul University in 1999.



Miriam Krinsky

Miriam Krinsky is currently serving as the Executive Director at Fair & Just Prosecution. She previously served for 15 years as a federal prosecutor, both in Los Angeles and on an organized crime and narcotics task force in the Mid-Atlantic region. During her tenure as an Assistant United States Attorney in the Central District of California, Miriam served as Chief of the General Crimes Section (supervising the work of over 50 new prosecutors) and Chief of the Criminal Appellate Section (overseeing the Office's docket of over 1,000 criminal appeals); chaired the national Solicitor General's Advisory Group on Appellate Issues; served on the Attorney General's Advisory Committee on Sentencing; and received the Attorney General's highest national award for appellate work.

Miriam has extensive experience in system change and reform of criminal justice institutions, policies and practice. In 2012, she served as the Executive Director of Los Angeles County's Citizens' Commission on Jail Violence, charged with investigating allegations of excessive force by Sheriff's deputies in L.A. County jails and developing recommendations for reform. Thereafter, Miriam spent a year working inside the Sheriff's Department as the Special Advisor to the Sheriff, assisting in implementing reforms within one of the largest law enforcement agencies in the nation.

Miriam has been involved over the years in the legal community, including serving as President of the Los Angeles County Bar Association (the first lawyer from the public sector to hold that position), five years (including two years as President) on the Los Angeles City Ethics Commission, three years on the California Judicial Council, as a member of the California Blue Ribbon Commission on Foster Care and the American Bar Association's Youth at Risk Commission, and was appointed by the California Supreme Court to serve a three-year term on the California State Bar Board of Trustees. She also spent five years as the Executive Director of the Children's Law Center of Los Angeles – a 200-plus person legal services organization representing over 20,000 abused and neglected foster children – and has testified before national and state legislative, governmental and judicial bodies, authored over 50 articles, and lectured nationwide on criminal law, law enforcement oversight and reform, foster care, juvenile justice, and sentencing issues.





Rebecca Blair

Rebecca Blair is currently serving as the Senior Research, Policy, and Communications Associate at Fair & Just Prosecution. She comes to FJP with experience spanning research, advocacy, strategic planning, and communications, as well as a deep commitment to criminal justice reform. Prior to her role at FJP, Ms. Blair was a senior associate at Whiteboard Advisors, where she partnered with organizations working to promote equity and inclusion in education and labor. At Whiteboard Advisors, Ms. Blair spearheaded the firm's work to expand access to quality prison-based education and authored opinion pieces, on behalf of clients, that were published in outlets including The Washington Post, USA Today, NBC, Bloomberg, and TechCrunch. She also provided strategic planning and change management support to national nonprofits, leading due diligence, data modeling, policy research, and organizational design projects. Ms. Blair has volunteered to support incarcerated students since 2015 and currently serves as a Maryland co-chair of the Rikers Debate Project, an all-volunteer organization that offers debate classes in prisons and jails across the country. She received her B.S. in Industrial and Labor Relations from Cornell University.

Ameri Klafeta

Ameri Klafeta is currently serving as the Director of Women and Reproductive Rights Project at the ACLU Illinois. Prior to serving as the Director, Ameri was a Senior Staff Attorney at the ACLU Illinois.

Her work focuses on expanding access to comprehensive reproductive health care and improving gender equity.

Before joining the ACLU, Ameri worked as an Associate Attorney at Morrison & Foerster LLP & Eimer Stahl LLP. Just out of law school, she also served as a law clerk to the Honorable Mary B. Schroeder of the United States Court of Appeals for the Ninth Circuit.

Ameri received her J.D. from University of Chicago Law School in 2002.



Evan Bernick

Evan Bernick is an Assistant Professor at NIU College of Law. He joined the faculty in 2021. He teaches courses in constitutional law, criminal law, criminal procedure, administrative law and legislation.

From 2020 to 2021, Evan was a visiting professor at the Georgetown University Law Center and the executive director of the Georgetown Center for the Constitution. Before that, he served as a clerk to Judge Diane S. Sykes of the United States Court of Appeals for the Seventh Circuit. From April 2017 to April 2019, he was a visiting lecturer at Georgetown and a resident fellow of the Center for the Constitution.

His scholarship covers a range of topics, from constitutional law, to philosophy of law, to social movements, to law enforcement. He has published with the Georgetown Law Journal, the Notre Dame Law Review, the William and Mary Law Review and the George Mason Law Review, among other journals. His book, *The Original Meaning of the Fourteenth Amendment: Its Letter and Spirit* (2021), with Randy E. Barnett, was published by Harvard University Press under its Belknap imprint "for books of long-lasting importance, superior in scholarship and physical production, chosen whether or not they might be profitable."

Evan received his bachelor's degree in 2008 from the University of Chicago, where he studied philosophy and graduated with honors. He received his J.D. in 2011 from the University of Chicago Law School.



Lindsay Langholz

Lindsay Langholz currently serves as Senior Director of Policy and Program at the American Constitution Society (ACS). She is in charge of the "Democracy and Voting" and "Equality and Liberty" portfolios.

In this capacity, she works with legal scholars and advocates to protect and expand the right to vote, ensure that our elections are fair and accessible, and promote laws and policies that protect individual liberty and address inequality resulting from discrimination. She represents the organization in coalition meetings and works with experts in the field to develop issue briefs and blog posts.

Before joining ACS, Langholz directed voter protection programs on behalf of two presidential campaigns, a national party, and two state party organizations. She has also advised nonprofit voting rights organizations, managed several political campaigns, and worked as a campaign coordinator for the AFL-CIO.

Langholz received her J.D. from Vanderbilt University Law School and her B.A. in Politics from New York University.





Allison Whelan

Allison M. Whelan is an assistant professor of law at Georgia State University College of Law. She joined the faculty in the fall 2022. Her research and teaching encompass a broad set of medical, science, and social policy issues at the intersection of administrative law, health and FDA law, constitutional law, bioethics, and reproductive justice. Through her work, she aims to identify the public, private, and ethical factors that converge and influence the topics she writes about. In an era of political polarization and distrust, Allison probes whether ethical norms and expectations related to public and individual health are best policed and enforced at the public or private level. Her work also explores whether and how the administrative state can be used to promote justice and eliminate disparities among historically marginalized and vulnerable populations.

Prior to joining Georgia State Law, Allison was a Sharswood Fellow at the University of Pennsylvania Carey Law School and an Associate Fellow at the University of Pennsylvania's Leonard Davis Institute of Health Economics. She was also an associate at Covington & Burling LLP in Washington D.C. in the firm's Food, Drug, and Device Practice Group. At the firm, Allison established a particular area of focus and expertise advising clients on the research and development of medical countermeasures. She also co-chaired Covington's Food, Drug, and Device Rapid Response team during the COVID-19 pandemic. Allison developed an extensive pro bono practice, advising non-profit reproductive advocacy organizations, assisting low-income clients with applications for various government benefits, and protecting voting rights.

Allison clerked for the Honorable Guido Calabresi of the United States Court of Appeals for the Second Circuit and the Honorable William J. Kayatta, Jr. of the United States Court of Appeals for the First Circuit. She also served as the inaugural senior fellow for the Center for Biotechnology and Global Health Policy at the University of California, Irvine School of Law.

Allison is the author of numerous law review articles. Her work is published or forthcoming with the Vanderbilt Law Review, Minnesota Law Review, Cornell Law Review Online, Washington & Lee Law Review, Fordham Law Review, Illinois Law Review, UC Irvine Law Review, and the Journal of Law, Medicine & Ethics, among others. She is the co-author and co-editor of numerous book chapters and books, and she has published op-eds and commentary, including for the Harvard Bill of Health, Harvard Social Impact Review, Philadelphia Inquirer, and Ms. Magazine.

Allison graduated, summa cum laude and Order of the Coif, from the University of Minnesota Law School in 2014, where she served as Lead Note and Comment Editor for the Minnesota Law Review. She also holds a Master of Arts in Bioethics from the University of Minnesota.



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Legal Summary

"After Today, young Women will come of Age with fewer Rights than their Mothers and Grandmothers had."

- Dobbs' SCOTUS Dissent

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Dobbs v. Jackson et al.

Issue:
Whether the Constitution, properly understood, confers a right to obtain an abortion?

Held:
The Constitution **does not** confer a right to abortion; Roe and Casey are **overruled**, and the authority to regulate abortion is **returned to the people** and their elected representatives

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The Legal Landscape in Illinois post Dobbs

- Introduction
- Consequences
- Q&A
- Dobbs v. Jackson
- Illinois' Plan B

7

Impact

"When it comes to Rights, the Court does not act "neutrally" when it leaves everything up to the States."

- Dobbs' SCOTUS Dissent

Response

8

Negative Impact:

- State Restrictions** SCOTUS gave power back to the States & 25 became more Restrictive
- Criminal Liability** Twelve States now have criminal statutes they uphold - charging providers and those who help patients based on various situations.
- Litigation** Alliance for Hippocratic Medicine et al. v. US FDA et al. - Texas Judge decides fate of Medical Abortion

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Pro-Choice Response

- Executive Admin** Biden's Administrative Commitments
- Pro-Choice States** Eighteen States have State protections - Three States now have Constitutional Amendments
- Litigation** US et al. v. Idaho et al. - EMTALA Medicare mandates services for people in Emergency Conditions
- Response Map

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PPIL since the Fall of Roe

Since the fall of Roe in late June 2022, patients from 34 states outside of Illinois + Canada for abortion care

CONFIDENTIAL

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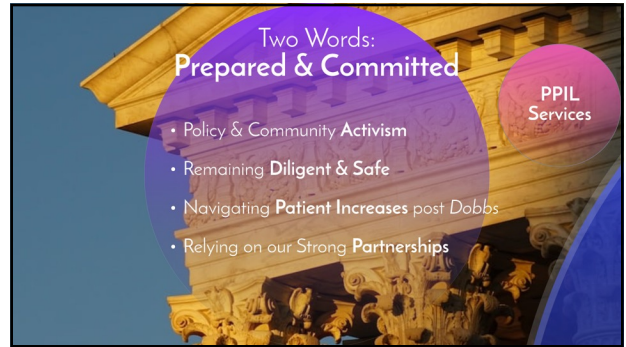
The Legal Landscape in Illinois post Dobbs

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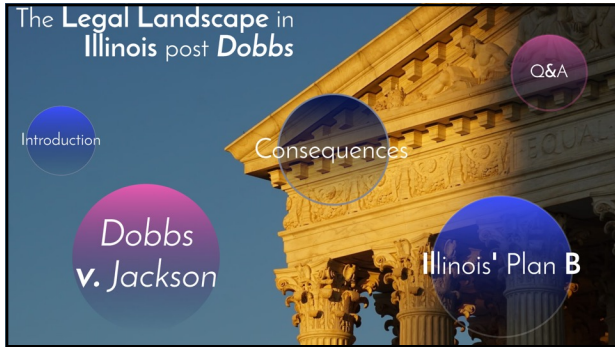
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NIU Law Review Symposium: Presentation Outline

Rebecca Blair & Miriam Krinsky

Introduction and brief overview

- Changes to the legal landscape since *Dobbs v. Jackson*
- Impacts of *Dobbs* on patient care in places where abortion remains legal
- Pregnancy criminalization pre-*Dobbs*
- Public safety and health risks of criminalizing pregnancy outcomes

Why is abortion a criminal justice issue?

- How abortion criminalization undermines public safety
- How abortion criminalization diverts resources away from the enforcement of serious crimes

The role of prosecutors: How can prosecutors engage and protect abortion access in a post-*Dobbs* world?

- Potential avenues for prosecutorial engagement
 - The use of prosecutorial discretion in the context of abortion bans
 - The prosecutor's role in educating partners and community stakeholders on relevant legal issues
- Avenues for supporting abortion access for system-involved pregnant people in states without legal abortion
- The use of strategic litigation to challenge abortion bans
- The prosecutor's role as a hub of resources and information

Challenges and pushback prosecutors face as they work to protect abortion access

- Supersession by attorneys general or other state actors
- Legislative attempts to strip abortion-related prosecution decisions from local elected prosecutors
- Efforts to remove prosecutors who choose not to use office resources to criminalize abortions
- *How are we already seeing this play out – in Florida, Texas, and elsewhere*

FJP's work and engagement

- Bringing key voices together
 - [Statement](#) signed by 90 elected prosecutors after the *Dobbs* decision was released, pledging not to use their offices' resources to criminalize personal healthcare decisions
 - Why these public pronouncements are important
- Litigation engagement

- *Amicus brief* in *Dobbs* signed by nearly 100 criminal justice leaders urging the Supreme Court to affirm *Roe* and protect abortion access
- Ongoing efforts to support prosecutors as they work to find ways that they can legally use their discretion to protect healthcare access in their communities and use their platform to advocate for better policies

Reference materials

- [FJP Joint Statement from Elected Prosecutors](#) (June 2022)
- [FJP amicus brief in the United States Supreme Court in *Dobbs v. Jackson Women's Health Organization*](#) (September 2021)
- The Guttmacher Institute's [interactive map](#) tracking abortion policies nationwide
- Abortion Finder's [State-by-State Guide](#) for accessing abortions
- Pregnancy Justice's "[Confronting Pregnancy Criminalization: A Practical Guide for Healthcare Providers, Lawyers, Medical Examiners, Child Welfare Workers, and Policymakers](#)" toolkit
- The Digital Defense Fund's [Guide to Abortion Privacy](#)

Post-Dobbs Legal Landscape

Ameri Klafeta

Director, Women's and Reproductive Rights Project

April 14, 2023

ACLU Illinois

Constitutional Backdrop: The Key Cases

- Contraceptive law found to violate "right to marital privacy" in *Griswold v. Connecticut* (1965)
- Right to abortion explicitly recognized in *Roe v. Wade* (1973)
- Right was reaffirmed and "undue burden" standard set out in *Planned Parenthood v. Casey* (1992)
- Until *Dobbs* decision:
 - Abortion bans prior to viability were unconstitutional.
 - Abortion restrictions were unconstitutional if they imposed an "undue burden" - law places "a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability."

ACLU Illinois

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Dobbs v. Jackson Women's Health: Mississippi 15-Week Abortion Ban

- Exceptions "only in medical emergencies or for severe fetal abnormality" -- no exception for rape or incest
- Blocked by lower courts
- Plainly unconstitutional under *Roe* and *Casey*
- Mississippi did not ask for *Roe* to be overturned until after RBG's SCOTUS seat became vacant

ACLU Illinois

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Dobbs v. Jackson Women's Health: The Decision

- Overturns *Roe* and *Casey*
- Justice Alito writing for the majority
 - Text of the Constitution does not mention abortion.
 - Abortion is not a right "rooted in the nation's history and tradition" when 14th Amendment was ratified
 - *Roe* was a "weak" decision and *Casey's* standard was "unworkable."
- Breyer, Kagan, and Sotomayor dissent "with sorrow"

ACLU Illinois

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Dobbs Puts the Issue Back to the States

- Chaotic and rapidly changing legal landscape over the summer
- “Trigger” laws came back into effect
- 13 states have full bans in effect right now
 - Georgia 6-week ban in effect
 - 8 states’ bans blocked by courts
- Litigation ongoing in several states

Legal Status as of 3/23/2023



Source: NY Times Abortion Tracker

Impact of *Dobbs* Beyond Abortion

- Threats to access to contraception, LGBTQ+ rights
- Justice Thomas invites Court to reconsider decisions regarding contraception, same-sex intimacy and marriage
- Dissent: “Either the majority does not believe in its own reasoning. Or if it does, all rights that have no history stretching back to the mid-19th century are insecure. **Either the mass of the majority’s opinion is hypocrisy, or additional constitutional rights are under threat. It is one or the other.**”

IL as a Model: Fundamental Rights

- In Illinois, it is a fundamental right to:
 - Make **autonomous decisions** about one’s own reproductive health – including to **use or refuse** reproductive health care
 - **Continue a pregnancy** and give birth or to have an **abortion** – and make autonomous decisions about **how** to exercise that right
- Rights apply to the whole spectrum of reproductive health care.
- “A fertilized egg, embryo, or fetus **does not** have independent rights under the laws of this State.”

IL as a Model: Legal “Shield” Protections

- Recently passed protections in IL include:
 - Restricting compliance with out-of-state subpoenas, summons and certain extradition orders;
 - Protecting IL medical licenses from being suspended or revoked; and
 - Allowing targets of abusive litigation to recover damages, including attorneys’ fees.
- Protections apply to reproductive health care and gender affirming care

Looking Ahead

- Anti-abortion organizations seek to prevent travel to other states, federal abortion ban
- Threat to medication abortion from Texas lawsuit challenging FDA approval
- Broad protections for religious or conscience objections
 - Broad exemptions/accommodations allowed for religious objections to ACA contraceptive mandate (*Hobby Lobby*, *Little Sisters*)
 - IL Health Care Right of Conscience Act being challenged in court.



Questions?

For more information:

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Jane Crow Constitutionalism - Evan Bernick

Intro

Tens of thousands of women and girls are imprisoned in US jails and prisons every year. Nearly a million are on probation, parole, or pretrial release. This carceral control is unevenly distributed, being primarily exercised over poor women of color who are of reproductive age. And it is growing.

These realities are part of what has been conceptualized as “the New Jane Crow,” and *Dobbs v. Jackson Women’s Health* gives them the U.S. Supreme Court’s constitutional blessing. *Dobbs* celebrates the demise of *Plessy v. Ferguson*, upholding the constitutionality of “separate but equal,” as an example of the importance of overruling egregiously wrong precedents. But Justice Samuel Alito’s opinion for the Court in *Dobbs* has more in common with *Plessy* than its author recognizes. My remarks will detail how and why.

Part I: The Rise of the New Jane Crow

Genealogy of “New Jane Crow” as a concept

Pauli Murray

Michelle Alexander

Lynn Paltrow, Michele Goodwin

What the concept refers to today

All state control of reproduction that operates to maintain an racialized and gendered underclass

How/why it developed

Antebellum

Legitimized enslaved labor

Reconstruction Era

Legitimizes slavery-by-another name

War on Crime/Drugs

Legitimizes a carceral state that disproportionately imprisons, jails, surveils people of color, promotes their economic, civil, and political marginalization, and breaks up their families

Personhood Movement

Legitimizes the targeting of specifically women of color for harms to prenatal life

Common elements

Racialized stereotypes that associate Black people with crime/dangerousness

Racialized/gendered stereotypes that associate Black maternity with deviancy

Racialized/gendered state control of reproduction as a consequence

Present state

Women are fastest growing incarcerated population

Women of color of reproductive age are disproportionately impacted

Women of color are marginalized by and through state control of their reproduction

Part II: Dobbs as constitutionalization

Dobbs both directly and indirectly provides constitutional legitimation for the New Jane Crow

By denying that the right to terminate a pregnancy is a fundamental right

By broadly dismissing sex-discrimination arguments against restrictions on reproduction

By identifying race and gender as reasons FOR abortion restrictions

By not defining abortion with any precision and thereby enabling states to “weaponize” ambiguity surrounding pregnancy loss in favor of criminalization

Part III: Dobbs and Plessy

Dobbs shares what are widely regarded as some of the worst features of one of the Court’s worst decisions

Erasing Reconstruction

Both Dobbs and Plessy neglect Reconstruction and make no serious inquiry into how those who framed and ratified the Reconstruction Amendments understood discrimination

Erasing Social Reality

Both Dobbs and Plessy neglect the social meaning of laws that operate to create a racialized underclass despite being formally neutral

Legitimizing Political Economy

Both Dobbs and Plessy are written in terms that will be read to provide a constitutional endorsement not of a particular law but an entire way of life

Mississippi is consistently one of the worst performers in the nation when it comes to maternal and postnatal health care and incarcerates more of its population than any democracy in the world—and yet when it invokes the protection of “life at all stages” in defense of forcing pregnant people to give birth, the Court doesn’t even raise an eyebrow

Message: We’re generally OK with *all of this*

Part IV: What’s To Be Done?

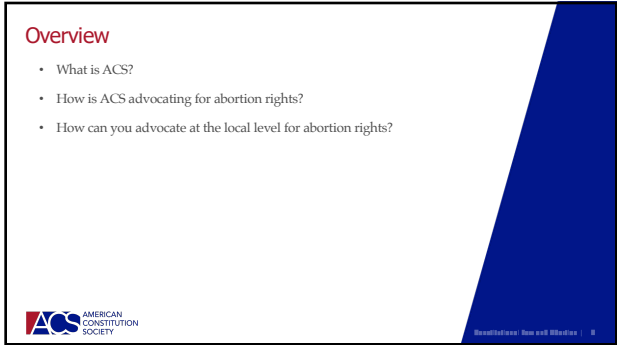
Reckon with the Court’s legacy, which isn’t as great as advertised

Learn from social movements that have arisen because of the Court’s marginalizing decisions—in particular, the reproductive rights movement

Don’t give up the Constitution to the Court—learn from constitutional movements that have succeeded in spite of the Court



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Advocating for Abortion Rights at the Local Level

- Work for officials or organizations who have an impact on increasing abortion access
- Incorporate pro bono cases or volunteer work into your practice
- Consider running for office



Stand for Women and Children

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Advocating for Abortion Rights at the Local Level

- Show up / speak out at local and state government meetings
 - City Council
 - Local Prosecutors
- Write and / or call your representatives
 - Hyde Amendment
 - Codification of *Roe*
 - Supreme Court Reform



Stand for Women and Children

6

Advocating for Abortion Rights at the Local Level

- Canvass and organize for candidates who are not only pro-abortion but have policies / plans for expanding access
- Engage with state court elections
- Vote in every election – there are no off-years



Stand for Women and Children

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Advocating for Abortion Rights at the Local Level

- Reach out to your local clinic and ask what volunteer needs they have
- Combat misinformation and disinformation in your network
- Donate to abortion funds and reproductive justice organizations




Stand for Women and Children

8

Final Thoughts


- There are numerous ways to get involved and every effort, big or small, can help
- Center the needs of marginalized people and others most directly impacted in your advocacy
- Many incredible organizations and leaders are already organizing and advocating – join them and follow their lead



Stand for our Bill of Rights

9

THANK YOU



601 13th Street NW, Suite 610 | Washington, DC 20005
202.393.6181 | info@acsclaw.org | acsclaw.org

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Preempting Inequities: Federal Preemption as a Tool to Combat State-Level Health Disparities

Allison M. Whelan
Assistant Professor, Georgia State University College of Law
April 14, 2023

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Overview

- Doctrine of Preemption
- Federal and State Regulation of Pharmaceuticals
- Examples
 - Medication abortion
 - Contraceptives
- Negative Consequences
- Preemption of State Regulation of Pharmaceuticals: Current Law, Policy, and Judicial Precedent
- Proposals

2


2

Overarching Problem: Entrenched Disparities in Healthcare Access and Outcomes

- Pervasive inequities contribute to excess morbidity and mortality among historically marginalized and vulnerable populations
- Deeply rooted discrimination and structural barriers contribute to disparities
- State of residence/geographic location also contributes


Why are pregnancy and childbirth killing so many Black women in Texas?

A deadly gap: Black women in Texas have twice as high a rate of death during pregnancy and childbirth. Why and what can be done?



Black women fear the steady rise in abortion restrictions across the US will worsen maternal health crisis

Black women are more likely to die from pregnancy-related complications than white women.



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Healthcare Federalism

- “Healthcare federalism” – division of power between the federal and state governments with respect to the provision of healthcare
- “Pharmaceutical federalism”¹ – division of power between the federal and state governments with respect to the regulation of pharmaceuticals – one component of healthcare federalism

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Preemption

- Article IV, clause 2 of U.S. Constitution (“Supremacy Clause”)
- Federal preemption - federal law supersedes conflicting state laws
- Express preemption - federal law or regulation contains explicit preemptive language
- Example: Medical devices, 21 U.S.C. § 360k:

“Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

 - (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
 - (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. . . .”

5

Preemption, Cont.

- Implied Preemption
 - Field Preemption: scope of a federal statute indicates Congress intended federal law to occupy field exclusively
 - Conflict Preemption
 - Impossibility preemption – Impossible to simultaneously comply with both federal and state law or regulation
 - Obstacle preemption – State law poses obstacle to accomplishment of Congress’s purposes and objectives

6

Federal vs. State Roles

- FDA statutory mandate includes “**protect[ing]** the public health by ensuring that . . . [human] drugs are safe and effective” and “**promot[ing]** the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.”
- Drugs must receive FDA approval prior to marketing
- FDA’s powers expand well beyond gatekeeping

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Federal vs. State Roles

- Police powers: “[A] state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there.”
- State bans and restrictions often driven by political or moral views with no basis in science
- Changing nature of medical practice, pernicious use of state regulations, and increasing health disparities raise questions about the logic of strong deference to state healthcare regulatory authorities

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State Pharmaceutical Regulation: Medication Abortion

- Restrictions well beyond requirements of FDA labeling and “Risk Evaluation and Mitigation Strategy”
- After *Dobbs*, states now ban abortion completely.
- General bans on abortion include bans on surgical and medical abortions
- More bans on the horizon
- Many state restrictions specifically considered, and removed or rejected, by FDA in its ongoing review

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Interactive Map: US Abortion Policies and Access After Roe

The abortion landscape is fragmented and increasingly polarized. Many states have abortion restrictions or bans in place that make it difficult, if not impossible, for people to get care. Other states have taken steps to protect abortion rights and access. Our interactive map groups states into one of seven categories based on abortion policies they currently have in effect. Users can select any state to see details about abortion policies, characteristics of state residents, and key abortion statistics, including access distances to the nearest abortion clinic. This map reflects state policies in effect as of March 12, 2023.

Note: You may need to clear your browser's cache or open this page in an incognito window to ensure you are viewing the most recent version.

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State Pharmaceutical Regulation: Contraceptives

- “In future cases, we should reconsider all of this Court’s substantive due process precedents, including *Griswold* [right to contraceptives], *Lawrence* [right to same-sex intimacy], and *Obergefell* [right to same-sex marriage].” – Justice Thomas, Concurring
- “[N]o one should be confident that the majority is done with its work. The right *Roe* and *Casey* recognized does not stand alone. To the contrary, the Court has linked it for decades to other settled freedoms, including rights to contraception, same-sex intimacy, and same-sex marriage. – Justices Breyer, Sotomayor, and Kagan, dissenting.

Trump-backed Vos opponent wants to ban birth control

DePerno seeks to outlaw Plan B emergency contraceptive in Michigan, compares it to fentanyl

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Consequences

Woman Whose Fetus Had No Skull Travels 1,400 Miles for Abortion

Texas women almost die because she couldn't get an abortion

Bleeding and in pain, she couldn't get 2 Louisiana ERs to answer: Is it a miscarriage?

Medical Impact of the Revised Gase Will Expand Abortion Clinics, Doctors Say

Three Texas women are sued for wrongful death after allegedly helping friend obtain abortion medication

Patients worried IVF treatments could become illegal under abortion bans, doctors say

Blue states want to become abortion safe havens. It will cost them.

LGBTQ Agenda: Impact of Dobbs decision has already affected LGBTQ health care, study finds

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Preemption of State Pharmaceutical Regulation

- “Nothing in the amendments made by this Act to the [FDCA] shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.”
– 1962 Drug Amendments
- 40+ years later, Congress stated: “Different or additional requirements at the State or local level can... result in divergent public health protection throughout the country.”

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Preemption of State Pharmaceutical Regulation

- Supreme Court has not addressed issue explicitly
 - *Wyeth v. Levine* (2009): state law failure-to-warn claims against brand name drug manufacturer not preempted
 - *PLIVA v. Mensing* (2011): state failure-to-warn claims against generic drug manufacturer preempted
 - Holding reiterated in *Mutual Pharmaceutical Co. v. Bartlett* in 2013.
- “Stop-selling” argument – claims it is not impossible for a manufacturer to comply with both state and federal requirements because manufacturers can simply not sell their drugs in the more restrictive state
 - Argument rejected by majority in *Mutual Pharm.*

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Need for Clarity: Proposals

- Best option: amend FDCA to add express preemption provision
 - Include waiver/exception procedure to ensure balance of state and federal interests
- Include “savings clause” to mitigate concerns about preclusion of state tort claims
 - “Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.”
- Clarify that states can add different/additional remedies for injured plaintiffs

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Need for Clarity: Proposals, Cont.

- Possible methods:
 - Approval
 - Notification
 - Emergency Process
- In all cases, state must submit evidence to justify why an exemption is necessary to protect the public health and safety of its citizens and to indicate how long it intended the exemption to last.
 - Must show *state-specific* need

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Need for Clarity: Proposals, Cont.

- Non-legislative alternatives
 - Regulations
 - FDA guidance, policy statements, etc.
- Benefits: easier to enact regulations and issue guidance and policy statements than legislation
- Drawbacks: easier to challenge; easier to change (→ “flip-flopping”)
- Advocacy by those concerned about state restrictions: lobbying, citizens petitions, etc.

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Conclusions/Take-Aways

- Currently lack of clarity about preemptive effect of FDA laws and regulations
- State bans and restrictions → pernicious consequences, exacerbating historic inequities and disparities among populations and within and between states
- Statutory, regulatory, and policy reforms will be subject to challenge but provide potential pathways forward

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Thank you!

Questions/Comments?: awhelan@gsu.edu

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