NIU LAW REVIEW SYMPOSIUM

REPRODUCTIVE RIGHTS & JUSTICE

April 14, 2023
9 AM - 2 PM

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

Contact Us
NORTHERNILLINOISLAWREVIEW@GMAIL.COM
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
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 Klafla, 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 Hawaii 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 2002 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 of 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 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 Kلافeta

Ameri Kلافeta 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 & Emir 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 Sharwood 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 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.
Legal Summary

"After today, young **Women** will come of **Age** with fewer **Rights** than their **Mothers** and Grandmothers had."
- Dobbs SCOTUS Dissent

Dobbs v. Jackson et al

**Issue:**
Whether the Constitution, properly understood, confers a right to 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.

The Legal Landscape in Illinois post Dobbs

**Introduction**
**Dobbs v. Jackson**
**Illinois' Plan B**

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

Impact

**Response**
**Negative Impact:**

- **State Restrictions:** SCOTUS gave power back to the States & 95 became more Restrictive.

- **Criminal Liability:** Twelve States now have criminal statutes they can hold charging providers and those who help patients to access various situations.

- **Litigation:** Alliances for Abortion Medicine and US FDA et al. vs. Jane Roe decades forty years later.

**Pro-Choice Response**

- **Executive Admin:** Biden’s Administrative Commitments.

- **Pro-Choice States:** Eighteen States have State protections. Three States have State Constitutional Amendments.

- **Litigation:** US v. Idaho et al. EMTAL. Medicare mandates services for people in emergency conditions.

**PPIL since the Fall of Roe**

- Introduction to the landscape since the fall of Roe.

**The Legal Landscape in Illinois post Dobbs**

- **Dobbs v. Jackson:** Overview of the legal landscape in Illinois post-Dobbs.

- **Illinois’ Plan B:** Strategies and considerations following the Dobbs decision.
"Let me be clear, in Illinois abortion is and will remain Legal."

Jennifer Walter, PPIL CEO

Two Words:
Prepared & Committed

- Policy & Community Activism
- Remaining Diligent & Safe
- Navigating Patient Increases post Dobbs
- Relying on our Strong Partnerships

Planned Parenthood of Illinois

- Men’s Care
- Birth Control
- Cancer Screenings
- Reproductive and bombed Procedures
- Emergency Contraception
- HPV Testing and Prevention
- HPV Vaccines
- Pre- and Post-natal Care
- Adoption Services
- Contraception
- STI, HIV Testing, and Treatment
- Gender-Affirming Hormone Therapy
- Menopause Services

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One Word:
Strong
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
● 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_

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**Constitutional Backdrop: The Key Cases**

- Contraceptive law found to violate “right to marital privacy” in _Grannis v. Connecticut_ (1966)
- 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.”

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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

**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”
**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**

**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)
  - Ill. 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
Legitimates 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
Legitimates 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
Legitimating 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
Overview

• What is ACS?
• How is ACS advocating for abortion rights?
• How can you advocate at the local level for abortion rights?

What is ACS?
The American Constitution Society is a non-profit, non-partisan organization that supports and advocates for legal systems that strengthen our democratic legitimacy, uphold the rule of law, and repair the enduring inequities in our laws in pursuit of realized equality. We aim to do this by:

- Sustaining a Pipeline of Diverse Legal Leaders
- Driving Concrete Legal Reform to Advance an Inclusive, Truly Multiracial Democracy
- Promoting Equity Within the Legal System

How is ACS Advocating for Abortion Rights?

- Path to the Bench Initiative
- Volunteer and Pro Bono Projects
- Network and Public Education
- State Attorneys General Project
- Supreme Court Reform Advocacy
- Run, Vote, Work
- Long-term Thought Leadership and Development
- Amplification of Others’ Work
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

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

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

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
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.
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

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

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

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

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

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

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
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

State Pharmaceutical Regulation: Contraceptives

- “[T]o 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.
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.”

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

- “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.

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

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
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.

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

Thank you!

Questions/Comments?: awhelan@gsu.edu
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