

Center for Public Health Law Research

A Transformative Whole-of-Government Model to Reduce Opioid Use Harms and Deaths

THE LEGAL PATH TO A WHOLE OF GOVERNMENT OPIOIDS RESPONSE: PART 1

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Nicolas Terry, LLM Sterling Johnson, JD Jonathan Larsen, JD, MPP Scott Burris, JD

Introduction

The 2016 US Surgeon General's Report, Facing Addiction in America, provided an extraordinarily thorough and essentially irrefutable diagnosis of the country's drug problem. It also suggested a possible inflection point for drug policy: a transition from a (drug control policing) "war on drugs" to the embrace of (public health and health care) policies aimed at harm reduction, prevention, and treatment. Since then, the myriad of published federal and state strategies to combat substance use, including the Biden administration's 2022 National Drug Control Strategy (The White House Executive Office of the President, 2022), have agreed on some central tenets or policies that deploy resources to both supply side (law enforcement combating of production and trafficking and public safety) and demand side (prevention, harm reduction, treatment, and recovery) strategies.

However, the inflection point has not been fully embraced. Notwithstanding three decades of the overdose epidemic and renewed federal emergency declarations entering their sixth year (Administration for Strategic Preparedness and Response, 2022), drug harms and deaths keep increasing, with overdose drug deaths now exceeding 100,000 per year (Ahmad et al., 2023). The "war on drugs" continues, bringing with it law enforcement overreaching, disproportionate sentencing, overwhelmingly unequal consequences for people of color, and collateral consequences that linger long after incarceration (Drug Policy Alliance, 2015). During the past six years, successive federal and state administrations have expended considerable resources studying the problem and increasing public expenditures across the conventional policies. We know what to do to move beyond the lost war, but lack the political will to move decisively (New York Times Editorial Board, 2023). There have been some successes: innovations in treatment (Brooklyn & Sigmon, 2017), the deregulation of some treatment drugs (Substance Abuse and Mental health Administration, 2023), the elevation of harm

"Despite decades of expense and effort focused on a criminal justice—based model for addressing substance use-related problems, substance misuse remains a national public health crisis that continues to rob the United States of its most valuable asset: its people."

- Facing Addiction in America, Office of the Surgeon General, 2016

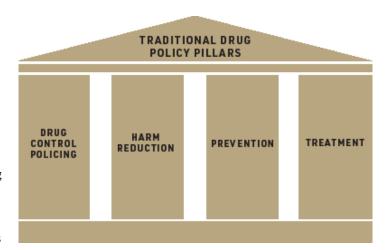


Figure 1: Traditionally, US drug policy has adopted a four-pillar approach to address harm: drug control policing, harm reduction, prevention, and treatment.

reduction (Weiland, 2022), and a better understanding of the role of social and structural determinants of health (Cohen et al., 2022; Galea, 2022; WHO Commission on Social Determinants of Health, 2008). However, given the resources expended, overall progress has been glacial (Gottschalk, 2023).

In this paper we introduce the Whole-of-Government (W-G) approach to reducing opioid use harms and deaths and how it should lead us to replace or seriously recalibrate conventional governmental drug strategies. These strategies embrace the coexistence of the traditional pillars prevention, harm reduction, treatment, and drug control policing (Macpherson, 2001: Government of Canada, 2016) (Figure 1). As currently implemented, these pillars frequently are oppositional, such that, to build on the public health funding paradox (Fleming et al., 2021), many of our drug policies are causing the very harms that other policies seek to address and, even when policies across (horizontal) and between (vertical) levels of government are not outright antagonistic, frequently they are seriously misaligned. Whether oppositional or misaligned, these strategies and the laws or policies through which they operate must be transformed.

The Whole-of-Government Model

Through the W-G approach, we gain an improved understanding of the design and implementation of conventional drug policy. The W-G perspective provides both a lens through which to critique current levels of alignment and misalignment between different levels of government or agencies at the same level, and a normative tool designed to structure reforms. Recognizing that the opioid crisis is the result of a poorly functioning complex ecosystem, lacking effective integration and riddled with contradictions, is accurate but incomplete (Bingham et al., 2016; Stein et al., 2023). The key is to understand how the dysfunction is largely caused by legal barriers and fundamental policy misalignments.

Complex, particularly "wicked problems" (Lee, 2018) such as addiction attract attention and regulation from multiple agencies distributed across one level of government, across different levels of government, or both. They are also dependent on multiple funding streams, not only in their sources (such as federal or state) but also their type (mandatory or discretionary), and their stability (such as consistent funding streams versus episodic grants). Not surprisingly, these multiple interrelationships and interdependencies at the least create friction, and at worst actively work against solving hugely complex problems. What is required is effective, comprehensive, coordinated government action across the different agencies at one level of government (be it federal or state), what we term horizontal W-G, and between different levels (federal.

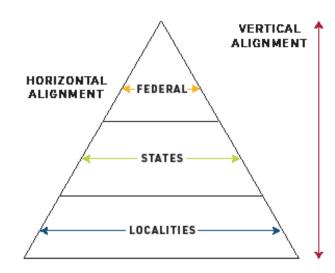


Figure 2: The Basic structure for Whole-of-Government alignment of laws and policies.

state, tribal, and local), what we term *vertical* W-G. Such co-ordination is essential "to eliminate situations in which different policies undermine each other, to make better use of scarce resources, to create synergies by bringing together different stakeholders in a particular policy area and to offer citizens seamless rather than fragmented access to services" (Christensen & Lægreid, 2017) (Figure 2).

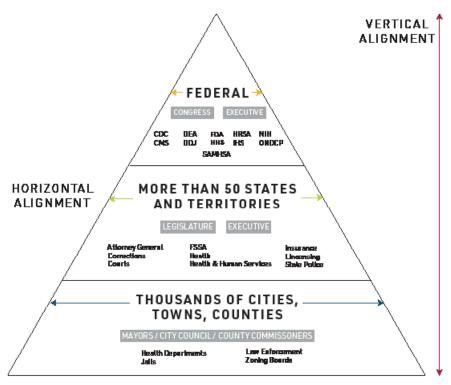
What we find in practice are fundamental exceptions from the W-G ideal. It is tempting to dismiss many of these as structural. It is of course the case that we have a complex governmental structure in which the federal government owns policymaking, financing, and implementation in relatively few domains. As a result, most of the time Congress funds policies or strategies but implementation devolves to state, local, and often, private actors. However, this does not excuse incoherence across multiple federal agencies, particularly their failures to agree on the nature of the problem and its causes (Worzala et al., 2018). Nor does federalism excuse repeated failures of federal, state, and local governments to work together and prioritize the removal of law and policy barriers that frustrate the downstream or upstream implementation of their policies. How else are we to interpret federal strategies that finally accept the overwhelming evidence-base supporting the funding of Syringe Services Programs (SSPs) (Centers for Disease Control and Prevention, 2022) but then condition state implementation on a certificate of need and prohibit the use of federal funds for purchasing syringes (Centers for Disease Control and Prevention, 2019)? Meanwhile, downstream, while most states begrudgingly have legalized SSPs, how many have fully rethought their drug paraphernalia laws to remove structural disincentives to using SSPs (Singer & Heimowitz, 2022)? Finally. why have state legislatures given veto powers to county health commissioners that encourages NIMBYism in the siting of SSP facilities (Ind. Code §16-41-7.5-5, 2021) (Figure 3)?

These fundamental derogations from W-G strategic alignment and the persistence of legal barriers inevitably cause failures to continue to mount. The response has been to double-down on the conventional strategies while occasionally recalibrating the percentage increases allotted to each, such as when one administration favors harm reduction over interdiction. That approach has led to unconscionable waste. The United States has spent more than \$1 trillion on the "war on drugs;" even as drug prices drop, the illegal drug supply gets more dangerous, and the deaths keep going up (Pearl & Perez, 2018).

Different and more ambitious thinking is needed. We must understand that there are better ways to fund initiatives and how conventional strategies hide conflicting or overlapping agencies, policies, and laws. And we must accept that many of the conventional approaches will be ineffective (or at least severely limited) without addressing upstream structural and social determinants. If federal or state agencies continue to press inconsistent or incoherent strategies that get in each other's way, they must be brought to heel by a central coordinating body. Further, both federal and state agencies must commit to performing gap analyses to root out policy misalignments and legal barriers. It is important to recognize progress such as the Biden administration's embrace of harm reduction. But, by itself, that represents only a pyrrhic victory if it is not accompanied by turning down the law enforcement heat (Schwartzapfel, 2021). Equally, if we were to decriminalize possession and stop warehousing drug users in our prisons, we will need to ramp up our treatment and social services while finding ways to allow those who use drugs and those who don't to share spaces in our cities.

A Transformative Model

Calling out legal barriers and policy misalignments while exhorting governmental and private actors to do better will not be enough. It is time to fundamentally rethink drug policies and implementation models. Many government agencies and commissions have set out policy frameworks built on a set of supposedly mutually supportive pillars, most commonly harm reduction, prevention, treatment, and drug control policing. These pillars are not complementary, but antagonistic. Once we accept that criminalization of drugs and drug users is not a supportive pillar, it is possible to suggest a very different, transformative model. The key component of transforming the drug policy landscape is decriminalization. The politicization of drug policy and the stigma surrounding drug users and those who treat them suggests that this will be a slow and likely decentralized process (in some places just turning down the heat on the "war on drugs" will be a victory. However, it is crucial to understand that ending the harm of criminalization must be accompanied by a difficult and process of building a new approach that does better. As we move away from warehousing drug users in prisons and the minimal treatment they receive, we must invest in the treatment, harm reduction, and safety net services they will require.



 $Figure \ 3: Examples \ of \ federal, state, and local \ government \ agencies \ that \ should \ interact \ to \ promote \ a \ Whole-of-Government \ approach.$

This transformative model reflects an interrelated set of approaches based in collaborative policymaking and a real, compassionate understanding of the nature of drug use (Figure 4). The components of the model are:

- 1. Reimagine federal funding of substance use strategies to promote long-term state strategies and coordinated spending.
- 2. Remove the final "war on drugs" impediments from the treatment domain.
- 3. Accept that harmful substance use is not only a chronic condition but one that requires redesigning health care.
- 4. Build a modern harm reduction system and allow it to do its job with sharply reduced interference from contrary federal policies, inconsistent state laws, and structural barriers.
- 5. Identify and remedy the upstream social and structural determinants that operate both as root causes of SUD and impediments to treatment and recovery.

1. Reimagine federal funding of substance use strategies to promote long-term state strategies and coordinated spending

Conventional policies of substance use amelioration are primarily funded by the federal government. A considerable share of that funding is spent on law enforcement (The 2021 federal budget for criminal justice responses to substance use was \$17.5 billion) and health care (in 2021 federal and state governments spent almost \$750 billion on Medicaid, by far the most important source of funds for state-provided opioid use disorder (OUD) treatment and improving social determinants). However, funding of harm reduction, treatment for the uninsured or underinsured, and reduction in social stressors such as lack of affordable housing, well-paying work, or education are more likely to be delivered under grant programs such as those operated by the Substance Abuse and Mental Health Services Administration (SAMHSA) (e.g., the Substance Abuse Prevention and Treatment Block Grant). This latter approach leads to states — and thereafter local communities and harm reduction organizations — receiving episodic and inconsistent funding. Funding

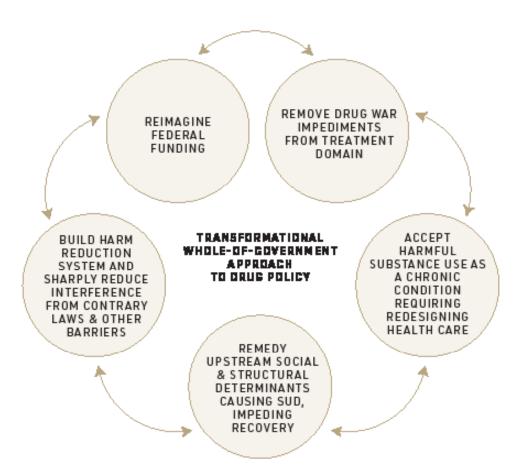


Figure 4: The components of a transformational Whole-of-Government approach to drug policy.

models should move away from annual applications and allow for longer spending horizons to encourage state spending on long-term plans and infrastructure. The federal government should also adopt the "braiding" approach to enable a coordinated spending framework for states (Bipartisan Policy Center, 2022). Recognizing that reimbursement gaps will persist in public and private insurance, attention should also be paid to designing a funding model for substance use disorder (SUD) prevention, treatment, and recovery services modelled on the "payer of last resort" used in the Ryan White HIV/AIDS Program (Kaiser Family Foundation, 2022).

2. Remove the final "war on drugs" impediments from the treatment domain

Continued criminalization of drug use creates a daunting barrier to real progress. In the meantime, at least some of the negative drug war impediments to treatment and harm reduction must be addressed. Federal drug policies on pharmacological treatments for substance use have dramatically lagged the evidence-base. The mindset and practices of criminalization have proliferated virtually every aspect of the overdose response, limiting the bounds of possible action with legal and attitudinal roadblocks rooted in the belief that supportive, public health approaches to drug use merely encourage or reward drug use. The Drug Enforcement Agency (DEA) and SAMHSA have moved too slowly in permitting mainstream prescribing of buprenorphine and methadone, resulting in unnecessary barriers faced by emergency room and general practitioners, while stigma and state laws continue to limit the number of providers. The DEA also needs to demonstrate that it is not the victim of agency capture by the opioid treatment programs (OTPs) industry. The Food and Drug Administration (FDA) was years behind the evidence in allowing over-the-counter naloxone (FDA News Release, 2023), but how access will be funded going forward is unclear. In parallel, new federal and state initiatives are erecting new barriers to pharmacy access to needed drugs (Jewett & Gabler, 2023). These "war on drugs" vestiges, that feed moral defect judgments and perpetuate stigma, also have permeated other institutions such as residential facilities, specialty courts, prisons, and jails where abstinence has been the preferred policy to the normalization of medication for opioid use disorder (MOUD) (Macomber, 2020).

3. Accept that harmful substance use is not only a chronic condition but one that requires redesigning health care

The challenge here is not limited to outdated federal and state policies "getting out of the way" of treatment, but that accepting that our legacy policy architecture is unable

to meet the challenges of access for and management of mental and behavioral health. Redesigning must occur in parallel to fixing other challenges facing healthcare. We must repair public and private health insurance to improve access: reduce care/recovery fragmentation with improved coordination of care, and upgrades in care delivery that focus on parity and equity (Levey et al., 2012). We must be prepared for the further coalescence of harm reduction and treatment services (Behrends et al., 2018). Syringe services increasingly will become valuable points of entry into the care continuum while some will morph into professionally staffed overdose prevention centers. Similarly, emergency department interventions are being reevaluated as being more than lifesaving but as opportunities to move patients toward treatment with, for example, early initiation of buprenorphine. Providers are also acting more like harm reduction services, meeting those who need treatment outside of traditional health care facilities using community mobile crisis intervention or rapid response teams. This transformational strategy also requires that we recognize that drug use, even illegal drug use, is not inherently dangerous or harmful, and so does not present a major threat to users or society. Our public aim should be to reduce the prevalence of harmful drug use through mechanisms that do not themselves produce harm.

4. Let harm reduction do its job without undue interference from contrary federal policies, inconsistent state laws, and structural barriers

The priority is to remove or minimize the federal and state laws and policies that make harm reduction strategies more difficult or illegal. Federal "crack-house" laws and outdated restriction on syringe funding, overbroad state paraphernalia laws, and layers of bureaucratic decision-making need to be excised. The priority must be to save lives and reduce sickness by meeting people who use

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drugs where they are, without interference. Getting to this state will require not only rethinking health care and its interface with public health strategies but also the role of law enforcement. Public safety initiatives such as providing amenity in civil spaces, teaming up with social services and gaining behavioral health skills must replace arrests and incarceration (Waal et al., 2014).

5. Identify and remedy the upstream social and structural determinants that operate both as root causes of SUD and impediments to treatment and recovery

While a realignment among federal agencies and between federal funding and state implementation across domains such as harm reduction, treatment, and interdiction will be considerably more successful in tackling SUD than narrow or uncoordinated government interventions, a true W-G approach also must identify and wield policy levers that address the deeper social drivers (or social determinants) of dangerous substance use. There is strong evidence of negative social determinants that impede improvements in the "Whole of Society," including structural racism (Miron & Partin, 2021) and educational attainment affecting population health, while differences in women's mortality between states correlate with social cohesion and economic conditions and education (Montez et al., 2016). There is also emerging research on the relationship between substance use and social vulnerabilities caused by stressors such as poverty, homelessness, and discrimination. We must "address the fundamental causes that create barriers to health and well-being" (Fleming et al., 2021) and recognize the multiplying effect of criminalization on adverse determinants. Often referred to as the "collateral consequences of conviction," state and federal law impose continuing barriers to successful reentry and the avoidance of recidivism. One of the many structural determinants that impede improvements in the "Whole of Person" is access to health care. Given the crucial role of Medicaid in providing health care to those with SUD, Medicaid expansion clearly decreased the number of uninsured low-income adults with SUD although, given the racial composition of non-expansion states, disparities among African Americans and Native Americans with substance use disorders increased.

Moving Forward

84 Steps Policymakers Can Take Today to Knock Down Legal Barriers to a Whole-of-Government Opioids Response

"Wicked problems" are wicked because they resist resolution through traditional approaches and often intersect with or are a part of another wicked problem (Camillus, 2008). W-G analysis supports this diagnosis of our national drug policy, highlighting inconsistent and inadequate funding, the destructive criminalization fault line between harm reduction and drug policing, a deeply-flawed healthcare system, and determinants that stand in the way of improvements in both the "Whole of Society" and the "Whole of Person." Resetting our policies and tactics with this suggested transformational model suggests a way forward.

The federal, state, and local governments are not sufficiently coordinating their efforts against OUD and overdose, either internally or with each other. Our White Papers explain how a "whole of government" effort should work vertically – better linking federal, state, and local efforts, and horizontally – linking efforts across governments at each level. An effective W-G approach requires improvements to the mechanisms used to fund state and local OUD projects with federal funding, the abandonment of the worst aspects of the discredited "war on drugs," and building a supportive, therapeutic, and preventive public health approach that embraces the whole person and addresses drivers of substance use across the whole society.

Our project has looked across our federal system to identify specific legal barriers and facilitators of this whole-of-government response. In conjunction with the fuller analysis of collaborative policymaking and a real, compassionate understanding of the nature of drug use in our White Papers, we have compiled a list of "shovel-ready" legal changes that policymakers can introduce tomorrow to promote effective cross-government action to reduce dangerous opioid use and its human and community toll.

OPPORTUNITIES TO KNOCK DOWN LEGAL BARRIERS TO A WHOLE-OF-GOVERNMENT OPIOIDS RESPONSE			
Opportunity	Domain	Secondary Domain	Government Level
DRUG POLICING			
Given the resources required and lack of general deterrence, DOJ can instruct federal prosecutors to abandon "Charging the Death," 21 U.S.C. § 841(b) (1)(C), in cases of low-level dealers or users who sell some of their own drugs.	Drug Policing	Decriminalization	Federal
Congress can amend 18 U.S. Code § 983 (civil forfeiture proceedings) as proposed by the Fifth Amendment Integrity Restoration Act of 2023 (FAIR), H.R.1525, 118th Congress (2023-2024), to change the burden of proof to "clear and convincing" evidence and reduce numerous abuses commonly associated with drug arrests.	Drug Policing	Civil Forfeiture	Federal
States can <u>repeal or amend their mandatory minimum sentencing laws</u> to stop incarcerating hundreds of thousands of nonviolent, low-level drug offenders, often with no chance of parole.	Drug Policing	Decriminalization	State
States can amend their drug possession laws to make offenses at most a misdemeanor (e.g., Colo. Rev. Stat. § 18-1.3-501) and enact other reforms to encourage probation or diversion sentencing (e.g., Massachusetts General Laws Part I Ch. 94C, § 34).	Drug Policing	Decriminalization	State
States can follow Oregon and decriminalize low-level drug possession in favor of a <u>civil citation model</u> , see the <u>Drug Addiction Treatment and Recovery Act (Measure 110)</u> passed as a ballot measure in November 2020. Approximately 10 states have seen bills introduced to <u>decriminalize possession</u> , see e.g., <u>Vermont House Bill 423</u> .	Drug Policing	Decriminalization	State
States can encourage help-seeking behavior during overdose events by repealing or providing immunity to Drug Induced Homicide (DIH) laws.	Drug Policing	Decriminalization	State
States can move away from War on Drugs policing practices such as pretextual stops, stop and frisk, and home invasions.	Drug Policing	Municipal Policing	State
States can reform child welfare laws and enforcement so that pregnant drug users are not afraid to seek prenatal and other care.	Drug Policing	Family Policing	State
States can abandon civil forfeiture in minor drug cases (See e.g., N.M. § 31-27-4).	Drug Policing	Civil Forfeiture	State
States can establish consistent appropriations policies to fund Law Enforcement Deflection Programs and consider enacting the Model Law Enforcement and Other First Responder Deflection Act. This model law encourages first responder deflection programming as well as related training, meant to steer people with SUD from the criminal justice system to evidence-based treatment.	Drug Policing	Deflection	State

States can remove barriers to layperson immunity (including "Good Samaritan"), such as requirements for calling or providing identities to law enforcement. See e.g., Indiana Code § 16-42-27-2(g).	Drug Policing	Good Samaritan	State
Local governments can establish law enforcement assisted diversion programs, to focus on better addressing unmet behavioral health needs or needs stemming from poverty, e.g. King County, Washington's Law Enforcement Assisted Diversion Program.	Drug Policing	Deflection	Local
<u>HEALTH CARE</u>			
The federal government can designate a single source of contact for the states within ONDCP to provide horizontal alignment across federal agencies and work with the states in aligning vertical implementation through amendments to the Office of National Drug Control Policy Reauthorization Act of 1998, 21 U.S. Code § 1701 et seq.	Health care	Agency Coordination	Federal
Congress can continue to provide additional fiscal incentives, as in the American Rescue Plan Act of 2021, amending Section 1905 of the Social Security Act (42 U.S.C. 1396d), to encourage the remaining 10 "hold-out" states to expand Medicaid under the Affordable Care Act (ACA).	Health care	Medicaid	Federal
Congress can extend the Support Act's mandate (42 U.S.C.1396d(a) (29)) that Medicaid plans should cover Medication-Assisted Treatment beyond 2025.	Health care	Medications for Opioid Use Disorder	Federal
CMS can enforce its reporting requirements and oversight of state Medicaid actions during the unwinding of the continuous enrollment condition attached to Families First Coronavirus Response Act § 6008 FMAP increases as provided by the Consolidated Appropriations Act of 2023 § 5131.	Health care	Medicaid	Federal
Congress can make permanent the SUPPORT Act's state plan amendment option (132 Stat. 3894 § 5052) to provide medical assistance for certain individuals who are patients in defined institutions for mental diseases (IMD) beyond the sunset date of September 30, 2023, by amending 42 U.S.C. § 1396n(l).	Health care	Institutions for Mental Diseases Exclusion Waiver	Federal
CMS can refuse to approve 1115 waiver applications that reduce enrollment, such as work requirements or block grants as inconsistent with Medicaid's primary purpose of provide health care coverage to populations that otherwise could not afford it (<i>Gresham v. Azar</i> , 950 F.3d 93 (D.C. Cir. 2020), vacated and remanded sub nom. <i>Becerra v. Gresham</i> , 212 L. Ed. 2d 576, 142 S. Ct. 1665 (2022), and vacated and remanded sub nom. <i>Arkansas v. Gresham</i> , 212 L. Ed. 2d 576, 142 S. Ct. 1665 (2022)).	Health care	Medicaid	Federal
DOJ can continue to enforce the Americans with Disabilities Act, 42 U.S.C. §§ 12101, et seq., against public and private entities (including hospitals, prisons, jails, and nursing homes) that unlawfully discriminate against people in recovery from opioid use disorder (OUD) who are not engaging in illegal drug use, including those who are taking legally-prescribed medication to treat their OUD pursuant to the current DOJ Guidance .	Health care	Americans with Disabilities Act Discrimination	Federal

CMS can enforce The Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S. Code § 1395dd, against hospital emergency departments that fail to stabilize patients with evidence-based services.	Health care	Emergency Departments	Federal
Congress can extend the liberalization (Consolidated Appropriations Act of 2023 (Public Law 117-328) § 4133) of telemedicine policies beneficial in the treatment of substance use and other behavioral health needs (including qualifying providers, geographic and originating site restrictions, and audio-only telehealth services) beyond the sunset date of December 31, 2024.	Health care	Telehealth	Federal
The DEA can extend the 72-hour rule (21 CFR 1306.07(b)) to allow emergency department doctors to prescribe and not merely administer buprenorphine or methadone to prevent pre-treatment withdrawal.	Health care	Medications for Opioid Use Disorder	Federal
Pursuant to the court's ruling in <i>City of Columbus v. Cochran</i> , 523 F. Supp. 3d 731 (D. Md. 2021), overturning the Trump administration's decision to cease oversight of network adequacy for marketplace plans pursuant to 42 U.S.C. § 18031(c)(1), CMS can publish national standards for network adequacy for marketplace plans and Medicare and Medicaid managed care plans, particularly for behavioral health services, adopting the three most common metrics for network adequacy, geographical distance, appointment wait time and provider-enrollee ratios, and also develop qualitative standards.	Health care	Private Health Insurance	Federal
Although the Consolidated Appropriations Act of 2021 amended to prohibit non-quantitative treatment limitations (NQTL) with respect to Mental Health or Substance Use Disorder SUD benefits, HHS and DOL can enact their proposed regulation on NQTLs and Congress should further strengthen the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), 42 U.S.C. 300gg–26(a), by granting the Department of Labor authority to impose civil monetary penalties on non-compliant health plans.	Health care	Private Health Insurance	Federal
Congress can repeal the monopoly enjoyed by certified and accredited opioid treatment programs (OTPs) as the only places permitted to dispense methadone for opioid use disorder treatment under the Controlled Substances Act (21 U.S.C. 823(g)(1); 42 CFR § 8.11) by permitting, for example, licensed physicians to prescribe methadone as provided for in the Modernizing Opioid Treatment Access Act, S.644 118th Congress (2023-2024). In the interim or alternative SAMHSA can remove other regulatory limitations on methadone treatment, such as the requirement to provide counselling as part of the treatment regime (42 CFR § 8.12(f)(5)) and move further than its current proposed changes, 87 FR 77330, to a default "take-home" approach to methadone maintenance treatment.	Health care	Medications for Opioid Use Disorder	Federal

To ensure that buprenorphine is available in free-standing and hospital pharmacies and to accelerate the reduction of stigma surrounding its prescribing, the DEA can amend its <u>Suspicious Orders Report System (SORS)</u> to "green light" rather than "red light" buprenorphine prescribing and the FDA can add the drug to the List of Essential Medicines, Medical Countermeasures, and Critical Inputs, Executive Order 13944.	Health care	Medications for Opioid Use Disorder	Federal
States can extend or make permanent Medicaid telehealth flexibilities adopted during the COVID-19 Public Health Emergency (PHE). Expanded coverages can include telephone and asynchronous services and allow the home to be the originating site.	Health care	Telehealth	State
States can address gaps in coverage from citizens returning from correctional settings by applying for Section 1115 waivers to expand Medicaid pre-release services. See e.g., California's 1115 waiver.	Health care	Medicaid	State
State correctional agencies can adopt policies assisting inmates in applying for applicable public or private health insurance and other expanded services pre-release including automatic Medicaid enrollment, peer Medicaid educators, building transition plans, and the transfer of medical records. (See: Ohio Department of Rehabilitation & Correction, Medicaid Pre-Release Program, 2023).	Health care	Medicaid	State
Alabama, Florida, Georgia, Kansas, Mississippi, South Carolina, Tennessee, Texas, Wisconsin, and Wyoming have yet to approve expansion of Medicaid under the Affordable Care Act. These states can do so to increase access to needed treatment for opioid use disorder. Where possible, those in favor of expansion can consider leveraging ballot initiatives.	Health care	Medicaid	State
State Medicaid agencies can <u>take</u> steps to minimize disenrollment to ensure access to Medicaid coverage caused by the termination of the COVID Public Health Emergency, particularly taking the <u>health</u> needs of high-risk populations into account when unwinding the emergency maintenance of eligibility rules.	Health care	Medicaid	State
State Medicaid agencies can submit 1115 waivers that include comprehensive services aimed at addressing health-related social needs (HRSNs), including but not limited to care coordination, peer support services, improved integration of behavioral health services, mobile crisis response services, and supportive housing services. (See: California's CalAIM Section 1115 waiver).	Health care	Medicaid	State
States can set aside special funds to assess and potentially supply treatment and other services to those unable to afford them modelled on Minnesota's so-called "Rule 25 Assessment" pilot that provided SUD health care services based on clinical and financial eligibility requirements. The Maine Office of Behavioral Health directly funds services for uninsured Maine residents and those not supported by federal grant programs or Medicaid.	Health care	Uninsured	State
States can dramatically increase their funding of equitable and data-driven behavioral health, e.g. <u>see behavioral payment reforms</u> in Maine, Me. Stat. tit. 22, § 3173-J.	Health care	Private Health Insurance	State

States can enact the National Association of Insurance Commissioners' Health Benefit Plan Network Access and Adequacy Model Act or enact a law like Colo. Rev. Stat. § 10-16-704, requiring health insurers to maintain an adequate provider network to assure access to all covered benefits without unreasonable delay.	Health care	Private Health Insurance	State
States can enact legislation to limit or ideally remove prior authorizations for SUD services and medications such as that passed in New York, see New York Insurance Law § 4303.	Health care	Private Health Insurance	State
States can enact strong parity laws requiring, for example, insurers to submit reports detailing its criteria in assessing and applying limitations on mental health and substance use disorder benefits as provided for in Connecticut, <u>An Act Concerning Mental Health And Substance Use Disorder Benefits</u> , <u>Pub. L. No. CT 19-159 (2019)</u> .	Health care	Private Health Insurance	State
States can revise their laws regulating physician and mid-level practitioner (e.g., nurse practitioner) dispensing of controlled substances to ensure their alignment with federal OUD strategies and policies. See Colo. Rev. Stat. § 12-255-112.	Health care	Scope of Practice	State
States can increase the effectiveness of their workforce by developing hub and spoke models of care (integrated care model for delivery of MOUD treatment) such as in Washington where federal funds were leveraged.	Health care	Medications for Opioid Use Disorder	State
States can modify any laws and regulations that create indirect barriers to or friction in providing methadone treatment, such as certificate of need laws and local zoning.	Health care	Medications for Opioid Use Disorder	State
States can reconsider any restrictions on opioid agonist therapy (OAT) prescribing by nurse practitioners <u>particularly in rural areas</u> that face a shortage of <u>qualified prescribers</u> .	Health care	Scope of Practice	State
States can pass legislation or amend regulations to permit disaggregated facilities ("medication units") to expand treatment options beyond fixed OTP locations (See Ohio Administrative Code Rule 5122-40-15).	Health care	Medications for Opioid Use Disorder	State
States can consider enacting the <u>Model Expanding Access to Peer Recovery Support Services Act</u> , which enables peer support to help people with SUD to recover through a peer support worker credentialing program and new funding.	Health care	Peer Support	State
States and localities can reconsider policies that hinder treatment with buprenorphine and methadone in prisons and jails.	Health care	Medications for Opioid Use Disorder	State
States can remove barriers to naloxone distribution, such as requirements that recipients provide their name and address, see required documentation from the West Virginia Department of Health and Human Services relating to naloxone distribution.	Health care	Naloxone Access	State
States can enact telecom fee laws to fund their 988 crisis services. See Colo. Rev. Stat. § 40-17.5-102, establishing dedicated funding for the 988-crisis line, which serves behavioral health crises. States having trouble funding and staffing their call centers can enact NASMHD Model Bill for Core State Behavioral Health Crisis Services Systems or legislation like Va. Code Ann. §§ 37.2-311.2, 37.2-311.3, and 37.2-311.4.	Health care	Mental Health Crisis	State

Health care	Medications for Opioid Use Disorder	State
Health care		State
Health care	Medications for Opioid Use Disorder	State
Health care		Local
Harm Reduction	Funding	Federal
Harm Reduction	Funding	Federal
Harm Reduction	Syringe Access	Federal
Harm Reduction	Overdose Prevention Centers	Federal
Harm Reduction	Private Health Insurance	Federal
Harm Reduction	Naloxone	State
Harm Reduction	Syringe Access	State
	Health care Health care Health care Harm Reduction Harm Reduction Harm Reduction Harm Reduction Harm Reduction	Health care for Opioid Use Disorder Health care Medications for Opioid Use Disorder Health care Funding Harm Reduction Funding Harm Reduction Syringe Access Harm Reduction Private Health Insurance Harm Reduction Naloxone Harm Reduction Naloxone

States can repeal "one-for-one" syringe exchange laws, e.g., Fla. Stat. § 381.0038(4)(b)(3).	Harm Reduction	Syringe Access	State
States can enact the <u>Model Syringe Services Program Act</u> that includes expanded SUD treatment provision and referral, measures to reduce needlestick injuries, data collection and reporting requirements for SSPs, immunity for criminal arrest, charge, and prosecution for possession, distribution, and furnishing of hypodermic needles and syringes, as well as harm reduction training for first responders, and funding to support programming.	Harm Reduction	Syringe Access	State
States can remove veto power or other review processes for operation of SSPs held by localities such as those found in, e.g., Ind. Code § 16-41-7.5-5r; W. Va. Code §16-64-2.	Harm Reduction	Syringe Access	State
States can enact legislation permitting Overdose Prevention Centers (OPCs) and hold participants harmless under state-controlled substances laws. (See e.g., R.I. Gen. Laws §23-12.10-1; New Mexico House Bill 263 (2023).	Harm Reduction	Overdose Prevention Centers	State
States can remove cost barriers by requiring Medicaid and private insurance to cover Naloxone, placing it in the lowest cost tier of formularies, etc., e.g., Mo. Rev. Stat. § 191.1165.	Harm Reduction	Naloxone Access	State
States can remove <u>various barriers to access to naloxone</u> and enact legislation based on the <u>Model Expanded Access to Emergency</u> <u>Opioid Antagonists Act</u> , that increases access to emergency opioid antagonists, including provisions for immunity for administering opioid antagonists, insurance coverage of opioid antagonists, and education to support use of opioid antagonists among other provisions.	Harm Reduction	Naloxone Access	State
States can pass legislation requiring naloxone co-prescribing with opioids. See e.g., Ariz. Rev. Stat. § 32-3248.01(D); Cal. Bus. & Prof. Code § 741.	Harm Reduction	Naloxone Access	State
Municipalities can use local health authority to authorize the use of OPCs, offering people who use drugs safe access to clinical services, like the center established in New York City.	Harm Reduction	Overdose Prevention Centers	Local
Local governments can integrate SSPs and remove any special zoning requirements for SSPs and OTPs.	Harm Reduction	Syringe Access	Local
City and County prosecutors can reduce prosecution of low-level crimes, e.g. See <u>Baltimore</u> , <u>Maryland's efforts to not prosecute low-level drug possession or prostitution</u> .	Harm Reduction	Decriminalization	Local
SOCIAL DETERMINANTS OF HEALTH			
CMS can encourage states to take advantage of optional Medicaid benefit categories that serve those with OUD/SUD such as rehabilitative or case management services, 42 U.S. Code § 1396n and apply for § 1115 waivers identified as supportive of substance use prevention or treatment and care transitions for incarcerated people.	Social Determinants of Health	Medicaid	Federal

Congress can broaden federal expungement to include more nonviolent crimes such as in the proposed Fresh Start Act of 2022, H.R.6667, 117th Congress (2021-2022).	Social Determinants of Health	Criminal Records	Federal
HUD can amend 24 CFR §982.553 to narrow public housing exclusions linked to drug use to situations in which a person's use of illegal drugs is causing observable harm to the premises or the community, and tighten key definitions to better guide local public housing agencies.	Social Determinants of Health	Housing	Federal
Congress can permanently expand the child tax credit that was first enacted temporarily by the American Rescue Plan Act of 2021.	Social Determinants of Health	Childcare Tax Credit	Federal
Congress can enhance the federal Earned Income Tax Credit (EITC) (26 U.S. Code § 32) by making the tax credit monthly.	Social Determinants of Health	Earned Income Tax Credit	Federal
States can increase <u>expungement</u> rates by amending laws to <u>apply</u> <u>automatic expungement to minor drug possession convictions and seal the records</u> . See N.Y. Crim. Pro. § 160.50 which automatically expunges certain cannabis possession and sale records.	Social Determinants of Health	Criminal Records	State
States can enact strong protections against predatory lending and high bank overdraft fees. See N.Y. Comp. Codes R. & Regs tit 3 §§ 32.1-32.2 for example of high bank overdraft protections. See N.M. Stat. 58-7-7 for example of predatory lending protections, including a 36% maximum annual interest rate cap on small loans.	Social Determinants of Health	Banking	State
States can provide sufficient funding for municipal and local court operations and can strictly limit excessive fees and fines or provide alternatives. (See e.g., Mo. Rev. Stat. §353; Cal Penal Code §688.5; Wash. Rev. Code §10.01.160; Tex. Crim. Proc. Code §45.049; Wash. Rev. Code §10.01.170; R.I. Gen. Laws §12-18.1-3).	Social Determinants of Health	Legal Administrative Fees	State
States can remove cash bail requirements, especially for low-level offenders in pretrial detention, See Washington D.C., Bail Reform Amendment Act of 1992 that ended cash bail for most justice-involved individuals.	Social Determinants of Health	Pretrial Detention	State
States can adopt "Ban the Box" laws, which give applicants with criminal records an opportunity to be considered for jobs based on their qualifications, not their conviction history. Access to stable employment is a driver of health. See D.C. Code § 1:620-42 and D.C. Code § 32:1342. DC prohibits any employer with more than eleven employees from asking about criminal history on a job application.	Social Determinants of Health	Criminal Records	State
States can establish earned sick leave laws. See N.Y. Lab. Law § 196-b, where employers must provide a certain amount of sick leave based on their size, following mandated accrual rates.	Social Determinants of Health	Employment	State
States can establish minimum wage laws to a level sufficient to allow a full-time worker to rise above the poverty line and obtain stable housing. See N.J. Stat. §34:11-56a et seq. States can also remove barriers to local governments setting a livable local minimum wage. See Colo. Rev. Stat. § 8-6-10.	Social Determinants of Health	Employment	State

Local governments can provide sufficient funding for municipal and local court operations, and can strictly limit excessive fees and fines. See, e.g., San Francisco Ordinance Number 131-18, which eliminated county criminal administrative fees, such as probation fees, electronic monitoring, and booking fees.	Social Determinants of Health	Legal Administrative Fees	Local
Localities can end cash bail, especially for low-level offenders in pretrial detention, See Washington D.C., Bail Reform Amendment Act of 1992 that ended cash bail for most justice-involved individuals.	Social Determinants of Health	Pretrial Detention	Local
Public housing agencies can narrowly specify grounds for denying housing based on drug-related behavior.	Social Determinants of Health	Housing	Local
Local governments can increase their minimum wage to a level sufficient to allow a full-time worker to rise above the poverty line and obtain stable housing.	Social Determinants of Health	Employment	Local
Local governments can provide temporary guaranteed income programs. See Stockton, California's <u>SEED Program</u> , providing no-strings-attached guaranteed income of \$500 a month for 24 months.	Social Determinants of Health	Universal Basic Income	Local

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ABOUT THE AUTHORS

Nicolas Terry, LLM is the Hall Render Professor of Law at the Indiana University Robert H. McKinney School of Law and executive director of the Hall Center for Law and Health.

Sterling Johnson, JD is a Law and Policy Analyst at the Center for Public Health Law Research at Temple University Beasley School of Law.

Jonathan Larsen, JD, MPP is a Legal Program Manager at the Center for Public Health Law Research at Temple University Beasley School of Law.

Scott Burris, JD is a professor at the Temple University Beasley School of Law and College of Public Health and director of the Center for Public Health Law Research at Temple University Beasley School of Law.

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Center for Public Health Law Research

A "Whole of Government" Approach to Reforming Opioid Use Disorder Legal and Policy Strategies

THE LEGAL PATH TO A WHOLE OF GOVERNMENT OPIOIDS RESPONSE: PART 2

November 2023

Nicolas Terry, LLM Scott Burris, JD

Executive Summary

The Whole-of-Government (W-G) perspective provides both a lens with which to critique current levels of alignment between different levels of government or agencies at the same level and a normative tool to drive reforms. Elsewhere we have applied a W-G lens to drug policing, harm reduction, and OUD treatment. A "wicked problem," such as the increase in serious opioid use disorder (OUD) and overdose deaths, requires multiple levels of government to mobilize their resources and expertise in an aligned and coordinated fashion. This should occur across multiple agencies either at one level of government (horizontal) or between different levels of government (vertical). It is clear that even when drug laws and policies across (horizontal) and between (vertical) levels of government are not outright antagonistic, frequently they are seriously misaligned.

A successful W-G strategy, particularly in a federal system with multiple overlapping agencies at different levels, requires agreement as to the problem and understanding the problem along with its causes. However, both the historic identification of the problem (people using drugs) and its cause (moral defect) have been proven false and created a stigmatizing feedback loop. The fallout has included impediments to treatment and harm reduction. The simplistic incarceration/moral defect approach also has slowed serious examination of how upstream factors such as structural and social determinants have caused or at least exacerbated our drug problem. An effective W-G strategy should identify the determinants that have the greatest impact on OUD issues and ensure that there is alignment between, for example, federal funding and state implementation in how they are approached.

W-G requires coordination and that is difficult when multiple agencies are involved. The natural coordinating agency is the Office of National Drug Control Policy (ONDCP). Yet, to be successful in that role ONDCP's director needs to be elevated to cabinet rank and the

agency's priorities moved away from "control" with a commitment to a public health and social welfare approach. Whichever coordinating agency is established or chosen, its brief must include vertical alignment between federal, state, tribal, and local governments and across multiple dimensions. Consistent policies and turning down the "heat" of the "war on drugs" will be key. There must be a concerted effort to improve the way the federal government funds and the states implement programs. Grant programs with time-limited spending horizons should be replaced with longer-term funding and increased coordination is required to "braid" multiple mandatory and discretionary funding streams to be more effective. Finally, attention must be paid to the many legal reforms that are overdue. For example, numerous state laws frustrate federal policies such as funded of Syringe Service Programs (SSPs). In contrast, states or municipalities wishing to innovate by establishing Safe Consumption Sites (SCSs) are looking to the federal government to remove barriers such as the "Crack House" statute.

Introduction

The Whole-of Government (W-G) approach to major health, social, or environmental challenges supposes that all the public agencies with something to contribute can help solve a recognized social problem if their efforts are aligned and coordinated. Sometimes referred to as "joined-up government" (Moseley, 2009), W-G connotes a systems-oriented conception of the matter at hand, in which many factors and agents drive problems, solutions, or both. Invoking W-G should be a sign of robust commitment from multiple levels of government and a potentially powerful model for mobilizing resources and expertise in a way that is attentive to side effects, feedback loops, and unintended consequences. Typically, it rests on and requires a clear, shared vision of the nature of the problem to be solved and the kind of action necessary to solve it.

We are now in the third decade of an overdose epidemic, and the fifth year of renewed federal emergency

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declarations, yet drug harms and deaths keep increasing (Spencer et al., 2023). As the demographics of the overdose epidemic shift from predominantly low-income white communities with sharp increases in deaths among individuals of color the opioid crisis becomes part of our racial justice debate (Friedman & Hansen, 2022; Joseph, 2022). Across our federal system, government agencies continue to follow narrow, partial visions of what to do, squandering precious resources as they get in each other's way. More than ever, it is imperative that we have effective, comprehensive, coordinated government action. In this article we describe key elements of an ideal W-G approach to opioid use disorder and drug problems generally, where W-G actually stands now, and how it needs to evolve.

Elements of an Effective Whole-of-**Government Strategy**

Few, if any major social problems are solved by a signature on an executive order or the bipartisan passage of legislation. Because of the systemic nature of "wicked problems" (Lee, 2018), the authority to address them tends to be distributed across multiple agencies either at one level of government (horizontal), across different levels of government (vertical), or both. W-G should be the counterweight to governmental "siloization" (Moseley, 2009). However, responses to OUD have too often demonstrated how decisions made by one agency or level of government can frustrate the work of others. W-G requires "horizontal and vertical co-ordination in order to eliminate situations in which different policies undermine each other, to make better use of scarce resources, to create synergies by bringing together different stakeholders in a particular policy area and to offer citizens seamless rather than fragmented access to services" (Christensen & Lægreid, 2017). This, in turn, requires agencies not only to work cooperatively but to think coherently about how the levers they can turn interact with the levers of the other agencies in the system and the evidence of what actions produce harms and what actions prevent or effectively prevent them. At the outset, we also must recognize that our call for aligned W-G will not sit well with many who view government as the problem rather than the solution.

In our federal system, central government attracts a lot of attention because of its visibility and how it sets and funds broad policies for the country. But most of the actual lifting on "federal" policy is done by state and local agencies, which take federal dollars and put them to work. However, the federal government cannot coerce states into accepting their largesse (National Federation of Independent Business v. Sebelius, 2012). This has led to substantial gaps in Medicaid expansion (Kaiser Family Foundation, 2023) and individual states, like Tennessee, pushing back against other types of federal health care funding (Edwards,

DEFINING WHOLE-OF-GOVERNMENT VERTICAL ALIGNMENT HORIZONTAL

FEDERAL ALIGNMENT STATES LOCALITIES

The Whole-of-Government (W-G) perspective provides both a lens through which to critique current levels of alignment and misalignment between different levels of government or agencies at the same level, and a normative tool designed to structure reforms. What is required for effective policy making is comprehensive, coordinated government action across the different agencies at one level of government (be it federal or state), what we term horizontal W-G, and between different levels (federal, state, tribal, and local), what we term vertical W-G.

2023). Across a broad range of substance use policies, the federal government's role is limited to discretionary funding, typically via grants administered by the Substance Abuse and Mental Health Services Administration (SAMHSA) (Substance Abuse and Mental Health Services Administration, 2020b). States and localities also bring to bear their own resources (NY Division of Budget, 2021) (sometimes reluctantly) and policies beyond and sometimes counter to what the federal agencies devise. That means that an ideal W-G strategy not only must be "horizontal" across governments at different levels but also "vertical," such that federal agencies are working well with their counterparts in states and devolved entities below.

The essence of W-G is independent but increasingly coordinated action by many different agencies toward the same goal. The biggest challenge for a W-G approach to OUD and drugs in the United States is finding that workable consensus. That consensus and so an effective W-G approach depends on several components, including agreement as to the problem, and understanding the problem along with its causes (Worzala et al., 2018). Effective coordination across a system as complex as

American federalism does not respond to top-down management. Rather, the many agencies at the different levels of government need a shared sense of what the problem is and the broad strategy for addressing it. Only then, with this shared "big idea," can they harmonize their work without direct day-to-day oversight.

Defining the Problem

For decades, drug policy in the United States has started from the explicit or implicit premise that certain drugs are illegal because they are bad, and therefore drug control depends on stopping the dealers and deterring (and punishing) the users. It follows, all too commonly, that people who use drugs are regarded as both criminal and morally defective. This deeply stigmatizing view has long powered a vertical (federal-state-local) criminal justice cooperation to suppress supply and demand while increasing incarceration. Criminalization has consistently put barriers in the way of harm reduction programs (Burris et al., 2009). More broadly, the continued acceptance of the flawed premises of criminalization has shaped a stunted, overly legalized approach to evidence-based treatment for Opioid Use Disorder (OUD) (Massing, 2000), added to the individual and communitylevel risks of drug use (Burris et al., 2004), and sucked billions of dollars from government budgets that might have been put to better use in a public health-based campaign (Gottschalk, 2023). Treatment to manage the consequences appears only late in the narrative and, in many corrections settings, not at all (Wakeman & Rich, 2015). Links between mental health and substance use disorders, and between social conditions and the prevalence of substance use, too frequently have been ignored (Interlandi, 2022).

The current overdose crisis stands as the best evidence that a punitive approach just does not work. Despite trillions of dollars spent over decades on police, courts, and prisons, criminalizing drugs and their possession has not suppressed supply or reduced demand (Pearl & Perez, 2018). Worse, reliance on criminal justice has itself been a tragic cause of harm, perpetuating racial subordination and disparities, coarsening our society and putting daunting barriers of stigma in the path of treatment and prevention (Human Rights Watch, 2016). Access to the most effective medications — methadone and until very recently buprenorphine — is still hampered by the stigma and regulatory strictures that are the legacy of criminalization. Harm reduction, a pragmatic, person-centered approach respects the choices and value of each individual — and it works to prevent the spread of diseases like HIV and to give drug users tools like overdose-reversing naloxone to save lives. But like treatment, harm reduction measures are hobbled or blocked by the moral defect narrative and the punitive drug laws that were built to express that disdain

(Williams, 2019). Our current state, therefore, is that of a public health paradox as government both funds a "war on drugs" that creates inequities and stigma and the harm reduction and treatment policies that are somehow meant to deal with them (Fleming et al., 2021).

Understanding the Problem and its Underlying Causes

Drugs are complicated. Most US adults use legal drugs, and about one-fifth of all adults in the United States use illegal drugs (Substance Abuse and Mental Health Services Administration, 2020a). People have always used drugs because they offer pleasure and dull pain and anxiety. Drugs pose a public health problem because along with these benefits come risks, but this risk is not tightly correlated with whether a drug is legal or illegal (Lachenmeier & Rehm, 2015; Nutt et al., 2007). Nor does the character of the drug — or its legal status — determine the impact it will have on any particular user. America's drug problems cannot be solved with a call for abstinence, or prohibition, or just saying "no." Rather, we need a smart, multifaceted and sustained campaign based on pragmatic — and attainable — public health and social welfare goals: reduce overall consumption of all drugs, reduce the harmfulness of the drugs and drug use, treat those with all types of substance use disorders (SUD) — and understand and address the root causes of unhealthy drug use.

The basic resources necessary for health include economic stability (including employment), a healthy environment (including secure, affordable housing), quality education, food security, social support networks, and access to health care (Artiga & Hinton, 2019; Hummer & Hernandez, 2013; Link & Phelan, 1995). Recent research has shown that directly addressing economic stress through mechanisms like the minimum wage (Komro et al., 2016), TANF, and the earned income tax credit can have life-saving impact on threats like low birth weight, women's health (Spencer et

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al., 2020), suicide (Kaufman et al., 2020), and HIV/AIDS (Cloud et al., 2019). More broadly, a compelling study from a team of demographers and political scientists found that life expectancy at the state level was tied to personcentered, supportive policies (Karas et al., 2020). Our drug crisis is a whole-of-society problem that calls on the whole of government to do all it can to create the conditions in which people have better options than unsafe drug use — to replace deaths of despair with lives of opportunity and hope. Though it runs directly counter to the sort of wholesale punitiveness of prohibition, the best way to turn back the long-term tide of SUD and overdose in America is to invest in making life easier, less humiliating, and less painful for those who have been shut out of security and prosperity over the past 50 years (Piketty, 2014; WHO Commission on Social Determinants of Health, 2008).

Coordination Across the Federal Government

Almost 20 federal agencies and departments are involved in drug policy. The national Commission on Combating Synthetic Opioid Trafficking (Trafficking Commission), established by Congress, reported that "Existing agencies retain specific areas of focus related to drug policy, but the sense of urgency of this quickly changing problem makes gaps in coordination more apparent" (US Department of Homeland Security, 2022). There is a twofold problem here: At the more micro level, a lack of coordination between agencies such as the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA) within a single department (Health and Human Services (HHS)), and the more macro question across departments, including HHS, the Department of Justice (DOJ) and the Drug Enforcement Agency (DEA). As has been noted, "[t]here's this tension between the federal agencies, where you've got SAMHSA and the ONDCP [Office of National Drug Control Policy] saying medications for opioid-use disorder are good... and then you've got the DEA, which it's just in its DNA to try and control controlled substances" (Mahr K, 2022). Therein lies one of the great ironies of the federal and state governments and how they have approached our drug problem; 50 years of drug policing has provided conclusive proof that W-G can be an effective model, as horizontally and vertically a wide range of agencies at all levels have exhibited considerable agreement as to what the problem is (drug possession and use) and its cause (the moral defectiveness of those who use drugs).

Recently, the Trafficking Commission recommended ONDCP "should establish itself more firmly as the central authority for policymaking and interagency coordination on all drug control policy matters" and that its director should be returned to cabinet level (US Department of

Homeland Security, 2022). This might make sense if ours was a "drug control" problem. ONDCP was established by the Anti-Drug Abuse Act of 1988 and is very much part of the "war on drugs" narrative. Today, our story is more complex. OUD and overdose are also health care stories. housing stories, stories of social mobility, education, and economic opportunity. They are stories of people who can't get housing at all, or whose housing comes with the monthly stress of paying a high rent on a low income. The Biden Administration's National Drug Control Strategy, also published in 2022, noted that ONDCP will lead the interagency process to implement its approach (The White House Executive Office of the President, 2022). As such the anointment of ONDCP as the point of coordination seems more like the culmination of a game of "you're it" than a well-thought exercise in choosing command and control based on regulatory powers, expertise, or influence. However, the need for horizontal and vertical alignment is chronic and a more robust ONDCP may succeed if it fully embraces harm reduction as a facet (or "pillar") of drug strategy, advocates for dramatic increases in treatment, and crucially starts to edge "drug control" through criminal law away from the center of the federal strategy. In short, the federal government should rebuild its hub as an Office of National Drug Policy, jettisoning the "control" and committing to a public health and social welfare approach. That rebuilt and restaffed office (with crucial staffing-up on budgetary policy) should have a single source of contact for the states that provides horizontal alignment and works with the states in aligning implementation.

Coordination Between the Federal Government and the States

There is much more to be done to enlist capacities across the federal government, but an effective W-G strategy demands more than horizontal alignment of policies and coordination of implementation across federal stakeholders. Vertical alignment also is required between federal, state, tribal, and local governments and across multiple dimensions. As a result, states also should institute cross-agency coordination specifically tasked with aligning state policies with federal initiatives and maximizing the use of federal funds.

While states do have their own initiatives and funding streams, most major programs are designed and funded by the federal government acting through distinct agencies. Although the federal government can attach conditions to its funding (e.g., Medicaid mandatory service categories) or refuse reimbursement for certain services (e.g., the frequently waived Institutions for Mental Disease (IMD) exclusion), application, implementation, and even program design (e.g., eligibility and services) typically is left to the states. Furthermore, in the OUD treatment domain,

states will frequently operate through private entities such as Medicaid Managed Care Organizations and Opioid Treatment Programs (OTPs).

The lack of vertical alignment between federal funding and state implementation pervades a number of domains. For example, while the federal government has earmarked funds for harm reduction strategies such as SSPs (Centers for Disease Control and Prevention, 2019), state and locality antipathy remain such that the majority have states have zero or some derisory number of facilities. Arguably, the most notable misalignment between federal policy and state implementation is the refusal by 10 states to expand Medicaid (Kaiser Family Foundation, 2023), funding to low-income adults notwithstanding evidence that coverage expansion has improved access and outcomes for persons with OUD (US Department of Health and Human Services, 2017). The so-called coverage gap in the non-expansion jurisdictions denies access to care for some two million people living in populous states such as Florida, Georgia, and Texas (Garfield et al., 2021).

Inconsistent Policies

Even as policymakers pivot toward emphasizing demandside strategies, they find it difficult to leave behind decades of prohibitionist policies and their consequences of "racial discrimination by law enforcement and disproportionate drug war misery suffered by communities of color" (Drug Policy Alliance). Inconsistencies also can be tracked within individual agencies. The Biden administration's Drug Enforcement Agency (DEA), while beginning to dismantle some of the barriers it had erected to MOUD access (Drug Enforcement Agency, 2022) (although it took Congressional action to deregulate buprenorphine prescribing (Consolidated Appropriations Act, 2023)) at the same time launched a major interdiction effort targeting "hotspots" characterized by criminal behavior and overdoses (Drug Enforcement Administration, 2022). While the rhetoric has shifted toward saving lives and funneling funds into treatment, for people who use drugs, law enforcement "solutions" (and budgets) still outpace harm reduction strategies (Gottschalk, 2023).

In addition to agreed-upon policies, governments at any level must have consistent strategies. However, in the world of substance use and, particularly, when it comes to harm reduction there are glaring inconsistencies. Take for example, federal funding of syringe services programs (SSPs). The Consolidated Appropriations Act of 2018 (Consolidated Appropriations Act, 2022) finally allowed federal funds to be used for SSPs yet the federal syringe rider (Centers for Disease Control and Prevention, 2019) contained in Continuing Appropriations legislation prohibits federal funding for syringes used for intravenous drug consumption but not, apparently, intramuscular

administration of naloxone (Substance Abuse and Mental Health Administration, 2022).

Law and Policy Barriers

The misalignment between federal and state policies and the inability or failure of states to spend down federal monies are not always the most serious impediments to W-G approaches. Federal initiatives can find themselves blocked by antagonistic state laws or policies (downstream barriers) while state initiatives may run into federal barriers (upstream barriers).

For example, the federal government supports (at least to some degree) harm reduction initiatives, such as funding SSPs, Fentanyl test strips, or overdose reversal drugs, that are frequently impeded by state laws or practices. These include over-restrictive drug paraphernalia laws (Singer, 2023), impractically stringent conditions for opening an SSP (W. Va. Code §16-64-3, 2021), or even the attitudes of local prosecutors to people who use drugs possessing naloxone (Chernoby & Terry, 2020). Although the federal government has recently deregulated the partial agonist buprenorphine, opening up a far larger pool of prescribers, a handful of states prohibit nurse practitioners (NPs) from prescribing buprenorphine even though those same states allow NPs to prescribe other drugs when in collaborative arrangements with physicians (Vestal, 2017). In some states, the vertical barriers can run deeper when, for example, federally funded SSPs, while legal under state law, are subject to final approval from county-level health directors (Ind. Code §16-41-7.5-5, 2021) or otherwise deterred by NIMBYism (Tempalski et al., 2007).

While federal-funded SSPs can be derailed by state of local downstream barriers, the opposite is true of safe consumption sites (SCSs). Underground, unsanctioned SCSs (Kral et al., 2020) have shown considerable potential for harm reduction. In 2019, after Philadelphia approved Safehouse, an SCS to be opened by a non-profit, the federal government sued to block the opening, arguing that it was unlawful under the so-called "Crack House Act" ("Maintaining drug-involved premises," 1986). A federal appellate court agreed noting, "(a)lthough Congress passed § 856 to shut down crack houses, its words reach well beyond them. Safehouse's benevolent motive makes no difference (United States v. Safehouse, 2021). Recently Rhode Island (R.I. Gen. Laws § 23-12.10-1, 2022) and New York City (Khurshid, 2022) have launched pilot programs, and the Biden administration has signaled a less combative approach (Peltz J. 2022), but this is a far cry from removing all barriers and adopting a vigorous positive policy. The "crack house law" remains on the books and could well be enforced again by a subsequent administration that recalibrates the federal supply-side/ demand-side strategy. In its shadow, the New York City

facilities are facing a budget debacle, and Rhode Island's facility has yet to open (Wernau, 2023). In California, successive governors have vetoed legislation that would allow cities to experiment with safe consumption sites (Cowan, 2022).

Reimagining Whole-of-Government

If a whole-of-government approach to SUD has not yet materialized, what should we be looking to build from the current law and policy wreckage? Clearly and at root, preventing and treating unhealthy drug use requires a new consensus on the drug problem and its solutions. We need a better "big idea" to guide the whole system than drug use as crime and the solution as punishment. In addition to agreement as to the problem, and understanding the problem and its upstream causes, we know that an effective W-G approach also depends on consistent funding, and coordination across stakeholders (Worzala et al., 2018).

Placing Social and Structural Determinants at the Heart of the Conversation

The assumption behind the W-G model is that alignment and coordination between federal agencies and between federal funding and state implementation across domains such as harm reduction, treatment, and interdiction is likely flawed because it fails to identify and wield policy levers that address the upstream social drivers (or social determinants) of dangerous substance use. When one person develops a substance use disorder, it is a tragic chapter in a hard life story (Eyre, 2020). When millions of people are using dangerous drugs and overdose is a leading cause of death, it is a failure of society to provide better options. Successful societies don't point fingers; they solve problems.

There is compelling evidence of the role of social determinants of health such as poverty, race, housing insecurity, lack of transportation and structural determinants such as stigma, and health care access or treatment (DiMario, 2022). As a result, any workable W-G strategy requires identifying the determinants that have the greatest impact on OUD issues and ensure that there is alignment between, for example, federal funding and state implementation to address those. The Biden administration's National Drug Control Strategy recognized that "[a]ddressing SDOH ... will require all sectors of Government and society to identify and improve factors that influence health outcomes" (The White House Executive Office of the President, 2022).

Indeed, some are openly skeptical about the linkage. For example, the Trafficking Commission report (US Department of Homeland Security, 2022) and the Stanford–Lancet Commission seemed to minimize the role

of social determinants in their recommendations. The latter went further, arguing that "Policy makers should attempt to alleviate poverty and inequality because of the human misery they cause. But they should not put forward the false promise that macroeconomic policy is a powerful or specific lever for reducing the prevalence of addiction" (Humphreys et al., 2022).

This is short-sighted. In an epidemic that has lasted two decades, it is folly to focus on short-term solutions that have not worked. There is strong evidence that negative social determinants, such as educational attainment (Kemp & Montez, 2020), lie behind the pejorative descriptors applied to regions of the country such as "tobacco nation" (Truth Initiative, 2019) or the "stroke belt" (Howard & Howard, 2020). States, reflecting polarized politics and policies, also operate as structural determinants (Krieger et al., 2022; Montez, 2020). For example, differences in women's mortality between states correlate with social cohesion and economic conditions (Montez et al., 2016) and education (Hummer & Hernandez, 2013), while disability rates are lower in states with greater income equality (Montez et al., 2017). Those indicators track to studies of overdose deaths. Generally, deaths are lower in counties with stable public-sector employment and higher levels of social cohesion and interaction (Monnat, 2018) and higher in areas of declining opportunities in the manufacturing sector (Seltzer, 2020). There is also emerging research on the relationship between substance use and social vulnerabilities caused by stressors such as poverty, homelessness, discrimination, and collateral consequences of conviction (Amaro et al., 2021).

A major structural determinant of substance use treatment is access to health care. Given the crucial role of Medicaid (Centers for Medicare & Medicaid Services) in providing health care to those with OUD, Medicaid expansion clearly decreased the number of uninsured low-income adults with SUD (Olfson et al., 2021), although, given the racial composition of non-expansion states, disparities among African Americans and Native Americans with substance use disorders increased (Andrews et al., 2015). Overall, however, Medicaid expansion appears to be associated with meaningful reductions in opioid-related hospital use (Wen et al., 2020), suggesting improved care in other settings. There is also a correlation between Medicaid expansion and uptake of buprenorphine and methadone medication-assisted treatment (Sharp et al., 2018).

The Biden administration's 2022 National Drug Control Strategy accepts the evidence, stating, "[A]ddressing SDOH is necessary to help improve health and reduce inequities in health outcomes—including in youth substance use, and this effort will require all sectors of Government and society to identify and improve factors that influence health outcomes" (The White House Executive Office of

the President, 2022). However, the "strategy" is silent as to how these goals should be pursued (or funded). Once again, this is a W-G problem requiring a W-G solution.

An Improved Funding Model

Given the importance of federal money, how the federal government chooses to deliver funding for harm reduction and treatment initiatives is crucial. The federal government's preferred approach has been through grant programs with time-limited spending horizons, such as those introduced by the 21st Century Cures Act, the SUPPORT Act, or the American Rescue Plan (Substance Abuse and Mental Health Services Administration, 2021). The grant-like mechanisms used in these initiatives favor short-term "fixes," making it difficult for states or smaller entities to build out necessary infrastructure or engage in long-term planning. These mechanisms also impose administrative burdens, and human service agencies typically juggle the administrative demands of applying for and spending funds from many uncoordinated government sources (Jaramillo et al., 2019). Furthermore, too many of the projects eschew bold, direct, and timely intervention (e.g., convene expert groups, request and fund studies, research, or reports), while favoring demonstration programs or pilot programs rather than long-term, sustainable W-G strategies, such as those addressing social determinants of health. Individual clients of government programs also have to cope with and overcome unnecessary administrative burdens (Fox et al., 2019). These mechanisms should be rethought, with the emphasis placed on longer-term, consistent, and coordinated resources provided to the states.

As we have discussed elsewhere, the Bipartisan Policy Center has recommended that SAMHSA and CMS provide states with a braiding framework whereby multiple mandatory and discretionary funding sources can be coordinated to support similar objectives and align programs (Bipartisan Policy Center, 2022). A successful vertical W-G strategy also must address funding gaps. Hundreds of thousands of people with OUD lack health insurance (Orgera & Tolbert, 2019). Congress should design a reimbursement model for OUD services modeled on the "payer of last resort" used in the Ryan White HIV/AIDS Program; a program specifically designed to fill funding gaps (Kaiser Family Foundation, 2022). The states also must step up investment of their own funds in improved behavioral health programs; few have made truly major investments (Maine Department of Health and Human Services, 2023; Washington Health Care Authority, 2023). As opioid litigation settlement funds become available, this is an opportunity to act, and the majority of states that have undertaken to spend their funds on opioid abatement and other approved uses (Distributor Settlement Agreement Schedule B Approved Uses, 2022) should be held to their promises (Vital Strategies, 2023).

Tackling social and structural determinants is a far more complex task than addressing their downstream effects. Taking on drivers of unhealthy drug use like economic inequality, housing, employment, education, and economic development dramatically implicates a wide range of legal levers and agencies. It demands that the system recalibrate to deal with individuals suffering from drug use as people who also have other economic, social, and medical needs. A W-G approach is essential not only because of the interaction of federal funding and state implementation and the need for alignment of policies but also because there must be a framework that aligns upstream levers addressing social determinants and downstream federal and state levers. Moving the emphasis upstream and placing the responsibility on the federal government rather than merely funding initiatives through block grants, while politically challenging, provides an opportunity to reverse the results of devolution and preemption that enabled state governments to have the dominant influence on the health of their citizens with profoundly negative consequences for the safety net, economic well-being, risky behaviors, and health care access in many states. Moreover, tackling OUD issues upstream signals that the problem is systemic or institutional, thus minimizing the individual responsibility, moral defect narrative and focusing attention on the necessary whole-of-government approach.

Removing Legal Barriers

A challenging pivot toward prevention, harm reduction, and treatment is absolutely necessary but it will also be insufficient. As we have detailed at length, healthier policies will not be successful until we reform our criminal justice approach to people who use drugs. That means aiming not just to reduce the harms of substance abuse, but also to reduce the harms caused by substance abuse policies. As long as we continue to criminalize drugs and their possession we will perpetuate stigma, disparities, and racial inequities. Without basic drug policy reforms, the W-G approach is in jeopardy. There will be continuous agency turf wars among those tasked with supply-side and those with demand-side strategies, while the inconsistent policies that inevitably follow further slow progress. The new "big idea" of unhealthy drug use as a health and social problem cannot co-exist with criminalization: it must replace it.

Job one for ONDCP should be to address all the law and policy barriers to the various parts of its OUD strategy that we have identified, particularly those impeding harm reduction and treatment, determine where the legal barriers lie — at federal, state, or local levels — and how

best to remove them. Given the complex nature of this "wicked problem" the remedies will have to be flexible and varied. But the federal government has a range of policy levers it can use, regulations, waivers, sub-regulatory guidance, DOJ non-prosecution memoranda, nudges from the bully pulpit, and so on.

Conclusion

Legal interventions such as broad harm reduction legislation (Good Samaritan Act, 2022), the Model Syringe Services Program Act promoted by the Biden administration, or even narrower provisions such as allowing naloxone standing orders (Meyerson et al., 2018) can have a positive impact on OUD and overdose deaths. However, many of the most needed legal interventions are more accurately viewed as corrective, necessary to reverse decades of unhelpful, even destructive policies. Characterizing drug addiction as a moral defect not only cruelly justifies criminalization and incarceration but also deprecates treatment for OUD in justice settings. Removing the legal and administrative legacy of Prohibitionist drug policy is a long-overdue way to improve delivery of interventions and services across government. It will also take a powerful cause of harm out of the system.

W-G as a solution is itself fraught with issues — competing bureaucracies, turf warfare, and fundamental disagreements as to policy. However, it is a positive step forward. Our complex, intertwined layers of laws and policies have to be reformed and for that federal, state, and local governments must commit to a W-G framework. That framework is complex and requires a far broader approach that looks at W-G from both horizontal and vertical perspectives. However, even with such a W-G commitment, federal and state stakeholders likely will achieve incomplete or short-lived success without also addressing the upstream social and structural drivers of OUD and overdose deaths. •

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ABOUT THE AUTHORS

Nicolas Terry, LLM is the Hall Render Professor of Law at the Indiana University Robert H. McKinney School of Law and executive director of the Hall Center for Law and Health.

Scott Burris, JD is a professor at the Temple University Beasley School of Law and College of Public Health and director of the Center for Public Health Law Research.

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Whole-of-Government and Drug Policing

THE LEGAL PATH TO A WHOLE OF GOVERNMENT OPIOIDS RESPONSE: PART 3

November 2023

Nicolas Terry, LLM Scott Burris, JD

Executive Summary

The long-standing "war on drugs" has demonstrated a strong whole-of-government approach to drug policing with considerable consensus across (horizontal) and between (vertical) levels of government as to the drug problem and its cause. Tragically, the evidence demonstrates that the consensus was built on fundamentally flawed policies. The result has been a sorrowful tale of mass incarceration, structural racism, and minimal improvement for treatment and harm reduction of drug use. While recent federal administrations and some state governments have increased funding for treatment and endorsed harm reduction, the war footing endures, with only a few states turning down the heat of the drug conflict. Addiction and substance use disorder is a chronic disease. A moral defect explanation of the condition that drives the "war on drugs" has fed upon itself and resulted in stigma that leads governments to over-criminalize acts far beyond drug possession and over-punish users. Drug-induced homicide (DIH) laws that allow prosecutors to "charge the death" after an accidental overdose and other overreaching laws such as prohibitions on paraphernalia have been combined with aggressive law enforcement tactics. Meanwhile, policies that establish and fund programs like specialty drug treatment courts meant to improve access to treatment and outcomes have actually made things worse. Although the end of the "war on drugs" may not yet be in sight, there are several changes in laws and policies that would improve harm reduction and treatment and perhaps the tenor of the drug war.

Federal laws could be changed to destigmatize treatment and increase access, and to better align with state laws that impact syringe services. Reports of successful programs in Europe and Canada have nudged some states to lower the criminal penalties associated with low-level possession or even adopt a civil citation model that provides a route to health screening.

Introduction

The Whole-of-Government (W-G) model posits an approach to providing effective, comprehensive, coordinated government action to solve difficult, complex, characteristically "wicked" problems (Camillus, 2008). It provides a lens through which to identify legal barriers or policy misalignment between agencies at the same level and between different levels of government. In our work in the harm reduction and treatment domains we have identified significant legal and policy barriers to effective W-G strategies to improve the health and well-being of people who use drugs. These barriers exist across multiple agencies either at one level of government (horizontal), across different levels of government (vertical), or across both. We have applied the W-G framework to identify misalignments and structural determinants in drug policy's traditional pillars (Government of Canada, 2016; Macpherson, 2001: US Department of Homeland Security. 2022), that have impeded harm reduction, prevention, and treatment, and we have identified policy barriers that can be removed or policy supports that can be erected to smooth the path to more integrated action. As we have noted, W-G strategies must be grounded on a clear, shared vision of the nature of the problem and the kind of action necessary to solve it. We have argued that the traditional pillars upon which decades of drug policy have been built (prevention, treatment, and drug control policing) are in fact antagonistic and should be rejected in favor of a transformational model built around effective W-G to better address our drug problem. That model calls for the removal of criminal law impediments to harm reduction and treatment while looking for upstream solutions rooted in removing social and structural determinants.

The conventional wisdom for addressing drug use and misuse in the United States is that law enforcement is the primary recourse for suppressing both supply and demand. Our analysis of drug control policing suggests a

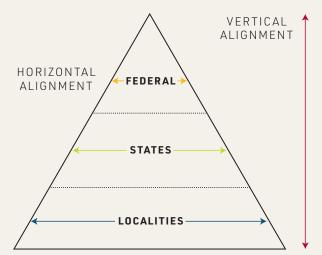
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strikingly different story. From a W-G perspective the drug policing domain is less about different agencies or levels of government getting in the way of policing, although no doubt as with all interagency or federal-state relationships there are plenty of examples of "sand in the gears" (Herd & Moynihan, 2019). Instead, ironically and tragically, the last 50 years of drug policing offers conclusive proof that W-G can be an effective model, as horizontally and vertically the criminal justice system has exhibited considerable agreement as to what the problem is (drug possession and use) and its cause (the moral defectiveness of those who use drugs). Thus, the problem here is not with the alignment of these processes but, rather, the demonstrably flawed underpinnings of that underlying consensus. Fifty years ago President Nixon opened the "war on drugs" when he said, "America's public enemy number one is drug abuse," to be fought by waging "a new, all-out offensive" (Smith, 2021). The war escalated during both the Reagan (Benson et al., 1995) and Clinton administrations (Murch, 2016a). Decades later the war is recognized as a disastrous failure (Coyne & Hall, 2017; Drug Policy Alliance, 2022a; New York Times Editorial Board, 2022), one that has resulted in mass incarceration and, as a textbook example of structural racism (Drug Policy Alliance, 2015; Rosino & Hughey, 2018; Tonry, 1994) gross exacerbation of racial disparities (Beckett & Brydolf-Horwitz, 2020; Pearl & Perez, 2018).

This paper applies a W-G lens to our federal and state drug policing laws, examines some of their internal contradictions and their corrosive impacts on our law and policy institutions, and provides a series of evidence-based recommendations to move forward. The "war on drugs" is examined not only for its direct effect on drug policing but how its endorsement of the moral defect theory of addiction has insinuated other drug pillars. Worse, there is circularity associated with moral disapproval and criminal law — as moral disapproval increases so do calls for more drug laws and enforcement that then reinforce the moral defect model and stigma (Boldt, 2010).

In addition to the direct impact on those arrested and their communities, the legal tools of the war on drugs had a pernicious indirect effect on efforts to provide harm reduction and treatment. We need transformational changes in law and policy to remove the "war on drugs" impediments to the treatment domain, permit harm reduction to do its job with sharply reduced interference from contrary federal policies and inconsistent state laws, and identify and remedy the upstream social and structural determinants that operate both as root causes of SUD and impediments to treatment and recovery. Difficult though it will be, "[w]e must not be satisfied with the norm, but work toward institutionalizing the demand for a standard of decency that values transformative change" (Taifa, 2021).

DEFINING WHOLE-OF-GOVERNMENT



Through the Whole-of-Government approach, we gain an improved understanding of the design and implementation of conventional drug policy. The W-G perspective provides both a lens through which to critique current levels of alignment and misalignment between different levels of government or agencies at the same level, and a normative tool designed to structure reforms. What is required for effective policy making is comprehensive, coordinated government action across the different agencies at one level of government (be it federal or state), what we term horizontal W-G, and between different levels (federal, state, tribal, and local), what we term vertical W-G.

A Whole-of-Government Exit from the War on Drugs?

The scale of the "war on drugs" and its continuing toll are well known. One of every nine arrests by state law enforcement is for drug possession, and possession arrests continue to average more than a million per year, notwithstanding a slight decline in overall imprisonment rates (Human Rights Watch, 2016; Pew Charitable Trusts, 2022). Reflecting on this period of our history it is understandable why some would conclude that "the core function of criminal law is normative, intended to stigmatize drug use and people who use drugs" (Beletsky, 2019). Indeed, it has been convincingly argued, "[l]ike Jim Crow (and slavery), mass incarceration operates as a tightly networked system of laws, policies, customs, and institutions that operate collectively to ensure the subordinate status of a group defined largely by race" (Alexander, 2010). There is also a self-reinforcing circularity at play; as more Black and brown people are

arrested, so their race becomes associated with criminality, leading to calls for more enforcement in their communities (Boldt, 2010). It is an indisputable understatement that as a result, "there are places in America today, particularly in Black and brown communities and other communities of color, where the bonds of trust are frayed or broken" (Biden, 2022).

To move beyond the mistakes of the past, the W-G approach requires policymakers to agree on the nature of the problem and its causes (Worzala et al., 2018). There is a political and legislative consensus about drug use, but it is wrong-headed and ignores the evidence. The political and legislative consensus about drug use is a loose but tenacious accord, bringing together hard right commentators who believe drug dealing is a violent crime (Bennett & Walters, 2016), fentanyl "hawks" who would use the military to attack the cartels (Press Release, 2023; Ward, 2023), and less committed politicians fearful of being seen as "soft-on-crime" (Gambino & Greve, 2022; Jouvenal & Berman, 2023).

The Biden administration has boosted harm reduction and treatment approaches to harmful drug use. However, it too has sent mixed messages (a feature of misalignment in horizontal W-G) as to what it believes are the problem and causes of the problem. In 2022, the administration launched "Operation Overdrive," a major interdiction effort targeting "hotspots" characterized by criminal behavior and overdoses (Drug Enforcement Administration, 2022). It also extended the 2018 class-wide scheduling of fentanyl analogue (Extending Temporary Emergency Scheduling of Fentanyl Analogues Act, 2021), which results in high sentences for mid-level dealers (Schwartzapfel, 2021). More recently, President Biden signaled additional crackdowns on fentanyl trafficking and border security (Yang, 2023). Some commentators, such as journalist Sam Quinones, continue to insist that the fentanyl crisis can only be overcome with "sustained engagement and collaborative enforcement" by the United States and Mexican governments (Quinones, 2023), while some politicians apparently believe that the United States should unilaterally bomb the cartels in Mexico (Ward, 2023).

Similar criminalization-focused agendas also surface in the states where the current increase in fentanyl deaths often lead to knee-jerk calls for additional and harsher criminalization rather than disaggregated policy and policing to apply criminal sanctions differently to people who use drugs rather than the traffickers who prey on them (Ovalle, 2023; Stern et al., 2023). The disparate impact of prescription opiates on white Americans and improvements in harm reduction and access to treatment could have led to states turning away from tactics used in the "war on drugs." Although states have been making penalties for possession more lenient, arrest rates have

remained roughly the same (Beckett & Brydolf-Horwitz, 2020). Overcoming a war footing during which public and private actors have taken ever more entrenched positions will be difficult, while agreeing on a postwar agenda will be harder still; "[w]hat has been shown to work is not always politically feasible, and what's politically popular often doesn't make for sound public health "(New York Times Editorial Board, 2022).

The primary W-G task that lies ahead for both federal and state governments is to recognize what the evidence has been telling us, that the "war on drugs" is a failure, and escalation will only double-down on that failure. A coordinated extraction from our present landscape will require the actors to abandon the "moral defect" view of those with substance use disorders and accept that its causes are similar to those that lie behind other chronic diseases. In the words of the Surgeon General's 2016 report:

Scientific breakthroughs have revolutionized the understanding of substance use disorders. For example, severe substance use disorders, commonly called addictions, were once viewed largely as a moral failing or character flaw, but are now understood to be chronic illnesses characterized by clinically significant impairments in health, social function, and voluntary control over substance use. Although the mechanisms may be different, addiction has many features in common with disorders such as diabetes, asthma, and hypertension. All of these disorders are chronic, subject to relapse, and influenced by genetic, developmental, behavioral, social, and environmental factors (Office of the Surgeon General, 2016).

Stepping back from our current approach to drug policing is simple in concept but complicated in execution. Politically it will be an immense task and, initially at least, will be measured in incremental rather than fundamental progress. It will be important to formally recognize not only the failure of the "war on drugs" but also its toll on the

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physical, mental, and familial health of those it swept up (Fleming et al., 2021; Malliori et al., 2015).

The "war on drugs" has created a complicated patchwork of overlapping crimes and interacting criminalization that not only corrodes our laws and legal institutions so that "drug offenses constitute the single most important manifestation of our tendency to criminalize too much and to punish too many," (Husak, 2008) but that the overwhelming pervasiveness also widely, negatively impacting key social determinants of health (Cohen et al., 2022). Primarily, we must recognize that "[n]othing has contributed more to the systematic mass incarceration of people of color in the United States than the War on Drugs" (Alexander, 2010). The collateral consequences of involvement with the criminal justice system seem cruelly designed to make the employment, housing and other social determinants (Alexander, 2010, Mogk et al., 2019; Upadhyay, 2022; White House Council of Economic Advisors, 2015) necessary for recovery from substance use more unattainable (Cohen et al., 2022).

Meanwhile, a compliant Supreme Court seemingly approved of drug war exceptionalism whenever law enforcement practices and tactics were subject to constitutional scrutiny. This was particularly the case with the well-documented erosion of Fourth Amendment protection, allowing profile and pretextual stops, sweeps, drug-testing without suspicion, and limitations on the expectation of privacy (Rudovsky, 1994). In parallel, the federal appellate courts have used qualified immunity to limit the civil liability (42 U.S.C. § 1983) of police officers and prosecutors (Harlow v. Fitzgerald, 1982; Hodson, 2018).

The federal government may have started the "war on drugs" but, international eradication, interdiction, and pursuit of high-level traffickers aside, it has delegated much of the war to the states. State and local law enforcement had relatively little interest in drug policing until the federal government purchased their enthusiasm with large grants and training assistance (Alexander, 2010). Federal largesse encouraged the states to increase the number of personnel, the lethal nature of their equipment, and a massive program to build correctional facilities (Eisen, 2019). For example, the federal government, through its "1033" and "1122" programs, asserted the reality of a war footing with supplies and equipment that promoted police militarization (Gamal, 2016). The federal money flowing to state law enforcement not only led to overall increases in arrests but an immediate increase in racial disparities in those arrests (Cox & Cunningham, 2021). Much of the federal money was used to establish Multi-Jurisdictional Drug Task Forces (MJTFs) (Cox & Cunningham, 2021), such is the power (misused as it was) of vertical W-G.

Today many assume that the end of the "war on drugs" is a "when" not an "if" (New York Times Editorial Board, 2022; Singer, 2018). Clearly, what the federal government ill-advisedly started it now has the obligation to reverse. The Clinton administration doubled down on the "war on drugs" to avoid being outflanked from the right as "soft on crime" (Murch, 2016b; Segura, 2016). It remains unclear even 30 years later where in Congress such a federal initiative to reverse that effort could arise. Without W-G leadership and vastly different targeted funding, it seems more probable that the end of the "war on drugs" will depend on a very gradual, possibly glacial series of reforms in progressive and moderate states.

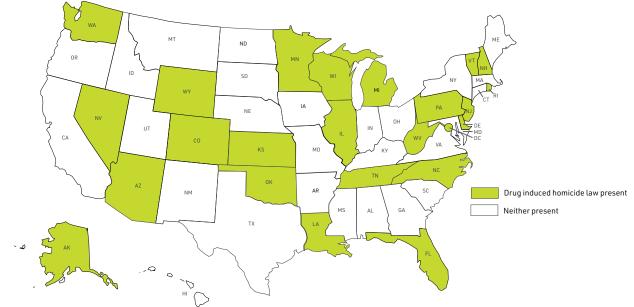


Figure 1: Approximately half the states have drug-induced homicide (DIH) laws that allow prosecution of persons who furnish or deliver controlled substances to another individual who dies as a result (PDAPS, 2019).

The War on Drugs in the States

Overall, states make far more drug crime arrests than federal authorities and most state arrests are for possession. In contrast, most drug arrests at the federal level are for drug trafficking. For example, when President Biden pardoned those convicted of federal marijuana no one among them was currently in federal prison for the offense (The White House, 2022). The states have participated with the federal government in a "successful" W-G operation, albeit one built around criminalization and stigma. The federal government with considerable alignment between its agencies (horizontal W-G) has waged war on the illicit supply and used its administrative powers, for example under the Controlled Substance Act, to curb licit access to drugs. The federal government then secured interagency cooperation and coordination (vertical W-G) with the localities, counties, and states through the funding of MJTFs and direct funding of police equipment and training.

States have also instituted novel or overlapping crimes in misguided attempts to deter the supply or use of drugs. Approximately half the states have drug-induced homicide (DIH) laws that allow prosecution of persons who furnish or deliver controlled substances to another individual who dies as a result (PDAPS, 2019). These strict liability drug homicide laws have been described as "a monstrosity, serving as an excellent illustration of the phenomenon of overcriminalization" (Husak, 2008). Worse, DIH prosecutions may disrupt a local drug market with unintended consequences and reduce the number of 911 "Good Samaritan" calls (Beletsky, 2019; Carroll et al., 2021; Carroll et al., 2020). Knee-jerk reactions to drug injuries can lead to further escalation; a recent increase

in fentanyl overdoses among teenagers in North Texas led to the Texas Senate passing a bill allowing prosecutors to charge fentanyl distributors with murder (Bella, 2023), and Virginia has amended its definition of "weapons of terrorism" to include a detectable amount of fentanyl.

Over policing (Bayley, 1996) and the budgets it attracts have been linked to aggressive tactics such as stop and frisk (H. L. Cooper, 2015) the criminalization of immigrants (Tosh, 2021), home invasions (H. L. Cooper, 2015), and police brutality (Hannah LF Cooper, 2015). Punishments have not only been carceral, driven by punitive minimum sentencing laws (Exum, 2021) but have extended to aggressive civil asset forfeiture (Drug Policy Alliance) that in some states has become particularly abusive (Jaglois & Baker, 2023). These in turn have fed in many places a pernicious W-G collaboration in which state legislators cut funding to municipalities and their courts with the tacit assumption that they will fill the gap by amping up fines and fees on local citizens (Martin, 2018; United States Department of Justice & Civil Rights Division, 2015).

As more public health-centered approaches to reducing drug harms have taken root, it seems at first sight that some have infiltrated the criminal justice system, suggesting a W-G win. For example, state legislatures have passed Good Samaritan Laws (GSLs) and are urged to fund specialty drug treatment courts (DTCs). Increasingly and perversely, research suggests these interventions may do more harm than good, delivering public health theater while unreformed drug policing endures. GSLs, which are now in 48 states and the District of Columbia, that encourage bystanders to call first responders during an overdose are notorious for the narrow grounds on

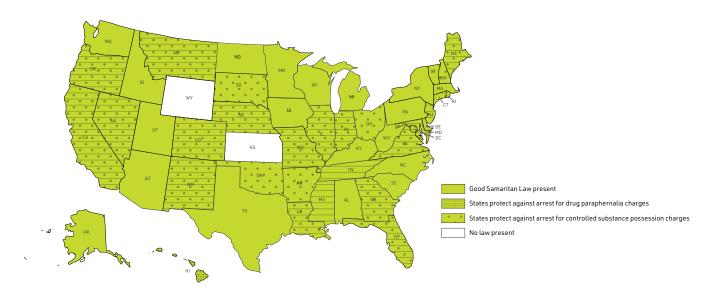


Figure 2: GSLs are now in 48 states and the District of Columbia, that encourage bystanders to call first responders during an overdose. 29 jurisdictions protect against arrest for controlled substance possession charges and 23 jurisdictions protect against arrest for drug paraphernalia charges (PDAPS, 2023).

which they are triggered (for example, administration of naloxone by the caller (Ind. Code § 16-42-27-2(g)) and the indeterminacy of police discretion (Pamplin et al., 2023). Overall, people who could benefit from these laws either have little knowledge of their existence or potential application (Schneider et al., 2020), or have had such negative experiences with law enforcement that they try to avoid any and all contact (Latimore & Bergstein, 2017; van der Meulen & Chu, 2022).

There are almost 4,000 DTCs spread across every state and the District of Columbia (National Drug Court Resource Center, 2021). The conventional wisdom is that these courts emphasize a non-adversarial, therapeutic, and treatment-oriented "team approach" (Hora et al., 1998) to address drug-related crimes. DTCs do work, but they do not work for everyone and bring with them hidden costs and tradeoffs (Bowers, 2007; Rodriguez Monguio et al., 2021). Indeed, "Far from serving as an alternative to incarceration, drug courts act as a sorting mechanism, carefully assessing which participants merit freedom and which should be locked up for an even longer time than before" (Kaye, 2019). Many participants fail out of the process. Many DTCs continue to focus on abstinence (Beckett & Brydolf-Horwitz, 2020) and are resistant to medication-assisted treatment (MAT) (Collins, 2020; Csete, 2020) There are also concerns that DTCs perpetuate drug use stigma by relying on a system of rewards and punishments (Woods, 2011); "[w]hen the court says treatment, it means discipline of individual offenders, rather than management of medical opportunities" (Miller, 2009). Questions also persist about the motivations of some judges because "problem-solving courts persist in part because they revive a sense of purpose and authority for judges in an era marked by diminishing judicial power [and] have become self-reinforcing institutions that are protected from meaningful external scrutiny" (Collins, 2020).

Damage to Other Drug Policy Pillars

The cruel irony is that "public health finds itself in a paradox: the government and taxpayers are subsidizing both policies that cause health inequities (such as overcriminalization and incarceration) and the work by public health agencies to address them" (Fleming et al., 2021). Prevention, harm reduction, treatment, and recovery have suffered in the wake of drug policing because of the "deontological perspective that conceives of drug use as wrongful or immoral (rather than by a more pragmatic conception that views drug addiction as a disease and drug use as a public health concern)" (Boldt, 2010). Facing a long road to the end of the "war on drugs," the immediate question is how do we disentangle the worst consequences of drug policing from harm reduction and treatment?

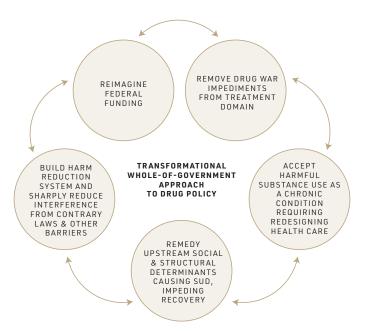


Figure 3: The components of a transformational Whole-of-Government approach to drug policy.

Harm Reduction

There are several changes in drug policing laws and policies that will positively impact harm reduction and treatment and simultaneously make for a somewhat kinder and gentler drug war (Beckett & Brydolf-Horwitz, 2020). Disagreements over harm reduction policies and implementation strategies exist at every level of government and between government and citizens. They include contrary federal policies, inconsistent state laws, and structural barriers that continue to exist notwithstanding that "[harm reduction] costs are less than the public health, law enforcement, and incarceration costs incurred under the current approach to substance use and abuse" (Singer, 2018). The priority is to remove or minimize the federal and state laws and policies that make harm reduction strategies more difficult or flat-out illegal. These include federal and state crack-house laws, outdated restrictions on syringe services, and overbroad state paraphernalia laws that discourage drug testing.

Treatment

That criminalization actively frustrates treatment is the fundamental W-G failure for opioid use disorder. Transformational changes in law and policy are required to remove "war on drugs" policies from the treatment domain. Because of "drug war logic" (Cohen et al., 2022) opioid agonist therapy (OAT) has suffered from federal restrictions simply not faced by prescription drug treatment of other chronic diseases. That overregulation created or at least perpetuated stigma and made it less likely general practitioners would participate even as legal controls are relaxed (Stringfellow et al., 2021). The failed war not only criminalized addiction but also erected significant barriers to treatment for people involved in the justice system, particularly the continuation or initiation of OAT (Fiscella et al., 2018; Grella et al., 2020). Drug courts and prisons maintain negative policies to evidence-based agonist treatments notwithstanding that drugs and alcohol are the third leading cause of death in US jails (Fiscella et al., 2020).

Public Safety and Competing Values

It is important to recognize that getting the police, courts, and prisons out of a primary role in reducing the social and individual harms of drug use does not mean that there is no role for police in a W-G effort. We must rebuild a real system of accessible mental and behavioral health care in this country, and that includes rethinking and rebuilding our first responders to reflect expertise in behavioral health and social work). If police retain some role in responding to drug issues (not an ideal solution) they need the training, support, and tools (like naloxone) to respond effectively. We must acknowledge that Interactions of people who use drugs with law enforcement officers almost always result in health and other harms for the former and should be minimized. (Davis et al., 2023). When we step back from a reflexive application of arrest and punishment in the drugs domain, it is also possible to appreciate the interest of communities more fully in civil order: moving away from arrest and punishment for drug use as such does not mean that communities need to tolerate open public consumption and intoxication or drug dealing. Over the last half-century, police as protectors of public order played an important, largely positive role in closing down open drug scenes in major European cities, finding ways to mix punitive crime control, bridges to care and maintenance of civil standards of behavior (Bancroft & Houborg, 2020; Olsen, 2017; Waal et al., 2014).

There are numerous evidence-based studies suggesting the very real potential of leveraging law enforcement in novel ways and to further different priorities. We should invest in law enforcement deflection programs (Ross & Taylor, 2022), train early and often (Rouhani et al., 2019), enact the legislation necessary to ensure stable financing, set standards, and facilitate the relationship between police and their emerging partners (Legislative Analysis and Public Analysis Association, 2021), while recognizing that on the streets there is a thin line between simple possession and drug trafficking (Xavier et al., 2022). Cooperation and partnerships also must be a two-way street. States should adopt state-local coordination

and staffing programs modelled, for example, on Maine's OPTIONS initiative, embedding clinicians in county public safety agencies (Carter et al., 2022) and other CIT and co-responder models (Krider & Huerter, 2020; Marcus & Stergiopoulos, 2022).

Elsewhere we have argued that decriminalization or partial decriminalization is unlikely to be effective without the vacuum being filled with treatment and recovery services and the construction of a true public health-oriented harm reduction system. Modern-day San Francisco serves as a difficult example with the city apparently ill-equipped to deal with homelessness and open-air drug markets. In 2022 the Mayor announced an emergency plan for the part of the city known as the Tenderloin because overdoses, drug dealing and street chaos were "totally out of control" (Westervelt, 2022) Following significant increases in overdose deaths because of fentanyl in. the first few months of 2023 (Leonard, 2023) the governor called in the National Guard and the California Highway Patrol to restore order and enforce trafficking laws (O. o. G. G. N. Press Release, 2023). The situation in San Francisco should not be used as evidence that decriminalization (there, of psychedelics) is a failure but rather that for decriminalization to succeed hard work must be put in to establish comprehensive harm reduction and treatment services, to understand how to maintain civil order, and address the social determinants of health that cause homelessness.

Meeting the Whole-of-Government Challenges

Despite modest shifts towards a public health frame, the policy and programmatic response to the crisis indicates that the change has remained largely rhetorical. Policymakers, prosecutors, and the police have continued to draw on the arsenal of carceral and punitive tools in mounting the response. These actions reflect established dynamics of policy theater (Beletsky, 2019).

Even when a more progressive state moves forward on issues such as harm reduction funding and increased treatment services, the price can be additional criminalization (Collins & Vakharia, 2020; Kenney, 2022) and the perpetuation of the public health paradox (Fleming et al., 2021; Gottschalk, 2023). Notwithstanding, there is evidence that the majority of Americans want to abandon the "moral crusade" of the "war on drugs" and adopt a public-health approach (The Lancet (Editorial), 2001). In 2018, Ohio narrowly rejected a ballot initiative that would have reduced minor drug offenses to misdemeanors and redirected savings from criminalization and incarceration towards drug treatment, crime victim, and rehabilitation

programs (Dew, 2019). Almost 40 percent of residents in this largely conservative state were in favor of the initiative. Gradual decriminalization slowly moving across the states (often in the footsteps of marijuana decriminalization) seems the most likely end to drug policing as we currently know it.

Some states, perhaps not ready to fully take on decriminalization, are making a start by reversing some of the legislative overreaching responsible for overlapping and ancillary crimes. For example, Minnesota recently revised several provisions of its criminal code that prohibited syringe possession, the bulk sale of syringes by, for example, pharmacies, the possession of residual amounts of drugs found in drug paraphernalia, and drug testing products (Minnesota S2909 Art. 16, Controlled Substances Policy, 2023). However, the only true decriminalization of possession in the legislation applied to marijuana.

Roughly half of the states still prosecute simple possession as a felony; most of the remainder classify it as a misdemeanor (Drug Policy Alliance, 2022b). Many states also classify simple possession of drug paraphernalia as a felony (Davis et al., 2022). Probably the most wellknown reform was California's 2014 "ballot 47" that downgraded simple drug possession and other nonviolent crimes to misdemeanors and also allowed for resentencing and reclassification to reduce collateral consequences (Ballotpedia, 2014). In states that cannot agree on a horizontal W-G approach, reform has devolved to some cities that approximate decriminalization with prosecutorial discretion. For example, Baltimore's decision to stop prosecuting low-level offenses such as drug possession did not seem to pose a threat to public safety or result in increased public complaints about drug use (Rouhani et al., 2021), and there is similar evidence coming out of Oregon (RTI International, 2023). A handful of states have considered bills that would take a similar approach (Drug Policy Alliance, 2022b; Vt. H.423, 2023). Conversely, conservative state legislatures have attempted to reign in such "rogue" prosecutors (Greenberger, 2023).

Washington State and Oregon have come closest to turning the page. In 2021, Washington's felony strict liability drug possession law was held to be unconstitutional (*State v. Blake*, 2021). Subsequently, the legislature replaced that law with a temporary simple misdemeanor provision but also enacted a substance use recovery services plan and a preference for diversion rather than arrest (WA SB 5476 (2021-22)). However, in 2023 the Washington legislature made drug possession and use are gross misdemeanors and, while expressing its preference, did not mandate referral or diversion. Nevertheless, the legislation fully preempted the field, blocking municipalities from introducing harsher laws while deregulating paraphernalia (Senate Bill 5536, 1st Special Session, 2023).

In contrast, in Oregon in 2020, following the approval of a ballot initiative, the state decriminalized low-level drug possession in favor of a civil citation model (Russoniello et al., 2023). The ticket's penalty fee can be waived if the recipient completes a health screening initiated through a recovery hotline" (OR SB 755 (2021 Regular Session)). The reforms in Washington and Oregon have significantly reduced possession arrests but have not resulted in increased arrests for other crimes. (Davis et al., 2023). Such initiatives could prove to be exemplars of horizontal W-G, ending the siloization of the harm reduction, treatment, and drug policing domains. Indeed, as criticism of the Oregon (Stephens, 2023, Westervelt, 2021) and its European exemplar (Faiola & Fernandes Martins, 2023) reforms have increased it has become obvious that criminal law reforms are inadequate in isolation. If we were to decriminalize possession and stop warehousing drug users in our prisons, we will need to ramp up our treatment and social services while finding ways to allow those who use drugs and those who don't to share spaces in our cities.

Conclusion

As has been noted, "something has gone seriously wrong with the legislative process in the criminal domain" (Husak, 2008). Even as policymakers pivot towards emphasizing demand-side strategies, they find it difficult to leave behind decades of prohibitionist policies and their consequences of "racial discrimination by law enforcement and disproportionate drug war misery suffered by communities of color" (Drug Policy Alliance).

Achieving a transformed state requires not only rethinking healthcare and its interface with public health strategies but also the role of law enforcement. Accusations that reform is surrender to criminals must be countered by a commitment to public safety initiatives such as providing amenity in civil spaces, teaming up with social services, and leveraging behavioral health skills to replace arrests and incarceration; in short reducing the role of police in addressing what are essentially societal problems (Human Rights Watch, 2020). Whole of Government got us into the "war on drugs" mess. Sooner or later, it must pick up the pieces and build something better. \blacklozenge

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ABOUT THE AUTHORS

Nicolas Terry, LLM is the Hall Render Professor of Law at the Indiana University Robert H. McKinney School of Law and executive director of the Hall Center for Law and Health.

Scott Burris, JD is a professor at the Temple University Beasley School of Law and College of Public Health and director of the Center for Public Health Law Research.

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Center for Public Health Law Research

Whole of Government and Opioid Use Disorder Health Care

THE LEGAL PATH TO A WHOLE OF GOVERNMENT OPIOIDS RESPONSE: PART 4

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Nicolas Terry, LLM Scott Burris, JD

Executive Summary

The treatment gap between people who need opioid use (OUD) treatment and those who receive it continues to grow — about two million people of the 20 million people diagnosed with substance use disorder in the United States. The barriers responsible for that gap are structural, policy, or legal misalignments that pervade all US health care, not just behavioral health. Deficiencies in health equity, bias, cost, access, and quality are not unique to those needing OUD treatment; it just so happens that the OUD cohort is particularly disadvantaged because of income and employment status. Fragmentation and lack of care coordination have a particular impact on chronic diseases that need constant care and management in and beyond the examination room. This paper uses a wholeof-government (W-G) approach to review the current landscape of opioid use disorder health care and outlines a series of evidence-based recommendations to improve access and remove barriers to essential care.

Among the top-level recommendations, we suggest that the US Department of Health and Human Services (HHS) (with a congressional assist) can and should improve health care access and service delivery and, as a result, greatly improve OUD treatment. However, by itself, that will be insufficient. Congress also must finish the work it has started in redesigning health care to elevate behavioral health away from its stigma-driven historical antecedents and finally build an integrated care model. Congress should strengthen parity laws and provide the Department of Labor with enforcement powers. Meanwhile the Centers for Medicare and Medicaid Services (CMS) must strengthen the regulation of health insurers to increase in-network coverage for behavioral care.

A major horizontal whole-of-government (W-G) approach by the federal government will be required to put the pharmacological treatment of opioid use disorder back on track. This must emphasize reducing regulatory burdens to opioid agonist treatment (OAT) and educating clinicians to reject stigma. A priority must be to safely increase the availability of methadone treatment. The Department of Justice must also keep up the pressure on health care entities, jails, and prisons with Americans with Disabilities Act enforcement that recognizes OUD as a protected disability. Congressional help will be needed to continue some of the mandates, such as Medicaid coverage for medication assisted treatment (MAT) and institutions for mental disease (IMDs) introduced by the SUPPORT Act of 2018. The federal government must work in a coordinated manner to improve the treatment continuum (prevention, treatment, and recovery) reversing the decades of policy that forced health care to follow the criminal justice playbook, and doing away with the final "war on drugs" regulatory impediments to treatment.

Making the health care system work better for people with and at risk of OUD will require federal and state horizontal W-G commitments to improving access to equitable care and reducing barriers to prevention, treatment, and recovery. In the absence of major health care reform, Medicaid is the key to increasing more and better prevention and treatment. Indeed, Medicaid is key, the largest payer of behavioral health services and with the largest percentage of those with substance use disorder (SUD) among all insures (Saunders, 2023). Medicaid expansion by holdout states and resisting political pressures to introduce work requirements are obvious. But states can do more such as submitting Section 1115 waivers for, care coordination, peer support services, improved integration of behavioral health services, prerelease services for the incarcerated, and supportive housing services. States also should encourage the shift to telehealth and invest in multi-disciplinary mobile teams that respond to crisis calls. Overall, health care must work better for people who use drugs.

Introduction

There are two million people who fall within a treatment gap of those who need SUD treatment but do not receive it (Substance Abuse and Mental health Administration, 2021). The United States spends considerably more per capita on health care than any other developed country (Kaiser Family Foundation, 2022). The relative lack of preventive mental health care and treatment for people who use drugs is a glaring failure. Many of our peer countries reach 50 percent or more of the high-risk opioid users with medications like methadone, while only 11 percent of Americans with opioid use disorder (OUD) report receiving those treatments (Baumgartner et al., 2022). There is no shortage of research pointing to dramatic improvements that are both necessary and possible. Many system enhancements have repeatedly been endorsed by federal and state commissions, reports, and strategies, including the 2016 Surgeon General's report (Office of the Surgeon General, 2016) and the 2022 Biden administration's National Drug Control Strategy (The White House Executive Office of the President, 2022). Yet, for all those exhortations, some sincere efforts, and growing expenditures, our health care system (from prevention through treatment to recovery) continues to fail people with opioid and other substance use disorders (OUD/SUD).

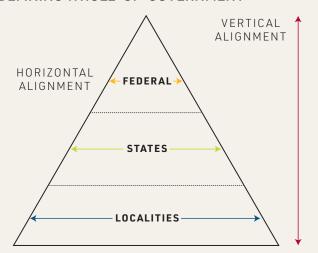
Whole-of-Government and Health Care

The whole-of-government (W-G) perspective provides both a lens with which to critique current levels of alignment between different levels of government or agencies at the same level, and a normative tool to drive reforms. Elsewhere we have applied a W-G lens to drug policing and harm reduction. The former highlights the "war on drugs," a failed 50-year program to eradicate drugs through criminalization, policing, and incarceration, the latter a public health initiative to provide coordinated services that "[e]nsure and improve the health and wellness of people who use opioids and other drugs" (Washington State Health Care Authority). The health care opioids W-G story itself is complex, First, health care continues to struggle with its own W-G demons, some of which overlap with its substance use fails. Second, historically health care was not designed or funded to deal with substance use, with behavioral health segregated away. Third, the "war on drugs" has severely hampered the pharmacological treatment of opioid use disorder, either directly through regulatory burdens or indirectly by stigmatizing those in need of treatment.

Health Care's Whole-of-Government Issues

The health care sector in the United States consists of an array of clinicians, hospitals and other health care facilities, insurance plans, and purchasers of health care services, all operating in various configurations of groups, networks, and independent practices. Some are based

DEFINING WHOLE-OF-GOVERNMENT



Through the Whole-of-Government approach, we gain an improved understanding of the design and implementation of conventional drug policy. The W-G perspective provides both a lens through which to critique current levels of alignment and misalignment between different levels of government or agencies at the same level, and a normative tool designed to structure reforms. What is required for effective policy making is comprehensive, coordinated government action across the different agencies at one level of government (be it federal or state), what we term horizontal W-G, and between different levels (federal, state, tribal, and local), what we term vertical W-G.

in the public sector; others operate in the private sector as either for-profit or not-for-profit entities. The health care sector also includes regulators, some voluntary and others governmental. Although these various individuals and organizations are generally referred to collectively as "the health care delivery system," the phrase suggests an order, integration, and accountability that do not exist. Communication, collaboration, or systems planning among these various entities is limited and is almost incidental to their operations (Institute of Medicine (US) Committee on Assuring the Health of the Public in the 21st Century, 2002).

Health care itself is riddled with horizontal and vertical W-G failures. Many of those failures are rooted in the absence of any national health policy, a critical disconnect between health care finance and delivery, and the overreliance on profit-driven private actors (Ameringer, 2018; Terry, 2020). The list of symptoms is long and includes access problems (particularly for the poor and the marginalized), high and increasing costs (including

insurance costs, prescription drug costs, and cost-shifting), substandard care coordination, a frequently incoherent health care delivery model involving multiple types of entities and financing or reimbursement models, and severe deficiencies in data management and sharing.

For almost a quarter of a century, reformist policymakers have highlighted health care system flaws (Institute of Medicine Committee on Quality of Health Care in, 2000), specifically system underperformance because of the disaggregated nature of health care individuals and entities, and their misaligned incentives. As a result, proposed reforms have focused on transforming health care from an underperforming aggregation of independent entities into a high performance "system" in which the participants recognize their dependence and influence on every other component of the system (National Academy of Engineering and Institute of Medicine, 2005). These reforms emphasize replacing individual with collective responsibility, aligning payment with quality or value (Porter, 2010), promoting evidence-based practice (Sackett & Rosenberg, 1995), strengthening clinical information systems (Institute of Medicine Committee on Quality of Health Care in, 2001), and improving system "learning" through evidence-generation and utilization (Institute of Medicine Roundtable on Evidence-Based, 2007).

Defects (many of the W-G type) in the US health care system are not solely responsible for the quantitative and qualitative treatment gap. But they are partly responsible. The makeup of the OUD cohort (frequently lower-income people, people of color) already places it in the vanguard for experiencing the failures of our health care system. Their stories are as familiar as they are unheeded. Ten states stubbornly refuse to adopt Medicaid expansion (Kaiser Family Foundation, 2018) notwithstanding the clear evidence that expansion dramatically increases the level of OUD treatment (Broaddus et al., 2018; Maclean & Saloner, 2019). These patients suffer from familiar obstacles, such as limited access, fragmentation, and health disparities (Buntin, 2021; Garson Jr, 2000; Stange, 2009; Terry, 2020). The increasing political polarization of the last few decades and, in particular, during the pandemic (Findling et al., 2022; Hegland et al., 2022), is making things worse. For example, Texas has the highest percentage of uninsured people in the nation and twothirds of its population favor expansion; yet, reportedly the state's executive leadership had maintained its hostile partisan position to all aspects of the Affordable Care Act (Krisberg & Leffler, 2022).

Other health care system defects deserve highlighting because of their serious impact on the behavioral health population. Fragmentation and lack of care coordination have a particular impact on chronic diseases that need constant care and coordination inside and outside of the

health care system (Chang et al., 2018; Frandsen et al., 2015). Care coordination is of particular importance for patients with more complex medical needs, like people with OUD, who interact with multiple health care providers (Pew Charitable Trusts, 2020). Many of these health care defects are products of path dependency, policy or structural choices, such as reliance on employer-provided health insurance, that prove inadequate today. It has been posited that universal health care, that favors treatment for painful conditions rather than management with opioids, and superior care coordination account for the reduced impact of OUD in Europe (Kalkman et al., 2022). In the United States, health care segregation (by income and insurance type) has been enshrined in policies and laws that continue to act as barriers to effective care and treatment, such as the previously mentioned overregulation of drugs used to treat OUD and the over-reliance on distinct opioid treatment providers. Still other barriers have become apparent as stakeholders have confronted the opioid overdose crisis as a "wicked problem" (Lee, 2018), one that is constructed out of numerous strands of law and policy, some intentional, some unanticipated, but all adversely affecting care, treatment, and recovery.

Law and policy changes made during the COVID-19 public health emergency (PHE) decisively rebut the notion that we are incapable of addressing some of the flaws in our health care or OUD treatment systems. Various COVID aid statutes enacted in 2020, including The Families First Coronavirus Response Act (FFCRA) (Families First Coronavirus Response Act, 2020) and the Coronavirus Aid, Relief, and Economic Security Act (CARES) (Coronavirus Aid, Relief, and Economic Security Act, 2020) essentially extended COVID diagnosis, treatment, and vaccination to the uninsured, including the undocumented. For example, the FFCRA included a 6.2 percentage point increase in the federal share of certain Medicaid spending (Consolidated Appropriations Act, 2023) (§6008(a)) conditioned on ensuring continuous coverage for current enrollees, known

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as Maintenance of Enrollment (MOE) (Dolan et al., 2020). MOE was responsible, at least in part, for increasing Medicaid enrollment by approximately 20 million people (Tolbert & Ammula, 2023).

Those statutes, together with The American Rescue Plan Act of 2021 (ARPA) (American Rescue Plan Act. 2021). dramatically decreased the number of uninsured people by increasing spending on Medicaid and individual marketplace subsidies (Levitt, 2022). Furthermore, powers triggered by the PHE relaxed or waived many of the barriers to OAT (Amram et al., 2021; Davis, 2021). Many of these temporary reforms were unwound when the PHE expired in early 2023, (Cubanski et al., 2023; Executive Office of the President, 2023) although some improved access to health care through individual marketplace subsidies has been preserved (although again only temporarily) by The Inflation Reduction Act of 2022 (Gustafsson & Collins, 2022). Indeed, the unwinding of Medicaid itself is demonstrating a misalignment between federal and state governments. The Consolidated Appropriations Act of 2023 (Consolidated Appropriations Act, 2023) created a 12-month unwinding period so states could develop alternate financing or mechanisms for re-enrollment. However, some conservative-led states are executing an accelerated glide path that may leave millions of people without health insurance (Messerly, 2023).

There is conceptual overlap between urgently needed W-G approaches to OUD treatment and arguments for health care systems reform and. A key W-G OUD reform proposal is improved coordination across levels of government (horizontal) and among levels of government (vertical). Similarly, health care systems reform is dependent on an "integrator" responsible for redesign, management, and, of course, system integration (Berwick et al., 2008). However, most of the flaws identified by W-G run deeper and wider, frequently with exogenous factors, non-health care actors, policies, and practices, that promote friction or, worse, create barriers. Just as we need to broaden our analysis of the role of social determinants to include structural and other determinants (Galea, 2022), when it comes to treatment for OUD, key players are neither working together nor pursing the same ultimate goals.

The Behavioral Health Divide

Fixing some of health care's systemic defects would reduce the behavioral health treatment gap, but by not nearly enough. Improved access achieved by increasing Medicaid penetration and lowering costs of private insurance will only go so far to remedying a divide derived from deep structural impediments in our legacy health care system. As highlighted in the Surgeon General's Report in 2016, A coordinated W-G approach will require explicit and enthusiastic affirmation across government and the health care system that behavioral health is as important as any other kind of health care, and that we have major work to do over the next decade to build up human and institutional resources to provide the integrated care we so badly need. Tinkering at the margins is a sure path to circling back to where we are right now.

Despite the compelling national need for treatment, the existing health care system was neither trained to care for, nor especially eager to accept, patients with substance use disorders... [W]ith the exception of withdrawal management in hospitals (detoxification), virtually all substance use disorder treatment was delivered by programs that were geographically, financially, culturally, and organizationally separate from mainstream health care (Office of the Surgeon General, 2016, p. 6-5).

Restructuring and fixing previously detailed challenges facing health care must occur in parallel. It won't be enough to repair public and private health insurance to improve access or to reduce care/recovery fragmentation with improved coordination of care. We must encourage the further cooperation of harm reduction and treatment services. For example, emergency department interventions must be reevaluated as being more than lifesaving, but as harm reduction opportunities to move patients toward treatment with, for example, early initiation of buprenorphine. Increasingly, health care providers must resemble harm reduction services, meeting those who need treatment outside of traditional health care facilities through the use of community mobile crisis intervention or rapid response teams. This transformation also requires that we recognize that drug use, even illegal drug use, is not inherently dangerous or harmful, and so does not present a major threat to users or society. Some people who use drugs will not or are not yet ready to stop using. Our public aim should be to reduce the prevalence of harmful drug use through mechanisms that do not themselves produce harm.

A coordinated W-G approach will require explicit and enthusiastic affirmation across government and the health care system that behavioral health is as important as any other kind of health care, and that we have major work to do over the next decade to build up human and institutional resources to provide the integrated care we so badly need. Tinkering at the margins is a sure path to circling back to where we are right now.

Individual health insurance policies sold on the marketplace are narrower for behavioral health care than for primary care (Zhu et al., 2017) while private health insurance coverage generally is deficient in providing coverage for drug use treatment (Mojtabai et al., 2020). The contemporary legal responses to these deficiencies have been twofold: parity laws and narrow network laws. They have been unsuccessful because they lack adequate enforcement mechanisms and because they encourage a separate but equal mindset. Treating those with behavioral health issues differently from those with other medical needs itself is inequitable (Wong, 2022). Further, the burdens of mental health and substance use fall inequitably on the disabled (Thomas et al., 2023), the poor and people of color (Allen et al., 2022; Panchal et al., 2022; Satcher Health Leadership Institute, 2022). Race and poverty are also important structural determinants when it comes to prevention, treatment, and recovery. Take just one example, buprenorphine, itself a case study in over-regulation because of horizontal W-G failures stemming from the war on drugs. White people and those who self-pay or have private health insurance are far more likely to receive buprenorphine treatment (Lagisetty et al., 2019). Black patients are less likely to receive buprenorphine in emergency departments (Dong et al., 2023), while hospitals in areas with a high percentage of Black or Hispanic residents were significantly less likely to offer OUD services (Chang et al., 2022). Even when Black and Hispanic patients are started on buprenorphine their typical treatment regimen typically will be shorter than for white patients (Dong et al., 2023).

Structural determinants such as racial or economic inequities or the stigma attached to addiction also shape the distribution of social determinants (Crear-Perry et al., 2021), such as lack of transportation or a paucity of physicians or other resources, leading to OUD treatment disparities. During the period in which the X-waiver was required for buprenorphine prescribing there were considerable geographic disparities in access; in 2018, 40 percent of counties lacked any waivered providers (Health & Services, 2020). It is also unclear whether recent deregulation by itself will reduce disparities because of, for example, provider shortages, lack of training, inadequate reimbursement, and stigma (Stringfellow et al., 2021).

A series of federal parity laws beginning with the Mental Health Parity and Addiction Equity Act of 2008 (Mental Health Parity Act, 1996) have failed to deliver the levelling up they promised in large part because of provider shortages, a deficient regulatory scheme, and insurer business practices (Shana, 2020). There is evidence strong state parity laws are positively correlated with increases in SUD treatment rates (Wen et al., 2013). However, even effective state laws will be preempted by federal law in the case of self-insured employer provided insurance (known as ERISA plans). A 2022 Department of Labor report urged Congress to provide it with the authority to impose civil monetary penalties on non-compliant health plans and amend ERISA to provide the agency with authority to enforce parity laws against insurers providing Administrative Services Only (ASO) services to ERISA plans (Department of Labor, 2022).

Even when policies cover substance use, there are access problems. In 2022, the Government Accountability Office (GAO) reported that consumers faced serious challenges in finding in-network care, with providers not accepting new patients, long wait times, restrictive health plan approval processes, and coverage limitations (General Accounting Office, 2022). CMS should adopt the three most common metrics for network adequacy — geographical distance, appointment wait time, and provider-enrollee ratios — and states should align themselves with those standards (Weber, 2020).

Regulatory Burdens on Treatment

Federal drug policies on pharmacological treatments for substance use have dramatically lagged the evidencebase, depriving those with OUD of treatment and creating a generation of clinicians wary of treating those people. The Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) moved too slowly in allowing mainstream prescribing of buprenorphine and methadone, creating unnecessary barriers for emergency room and general practitioners. DEA has done little to reduce the appearance of agency capture by the Opioid Treatment Program (OTP) industry, while FDA was years behind the evidence in approving over-the-counter naloxone (Davis & Carr, 2020). These and other impediments are remnants of "war on drugs" and are both the product of and the nourishment for moral defect judgments that perpetuate stigma against people with OUD (Adams & Volkow, 2020; Kelly et al., 2015; Madden, 2019). Such moral judgments also have permeated other institutions such as residential facilities, specialty courts, prisons, and jails promoting abstinence over opioid agonist treatment.

The fundamental W-G failure for opioid use disorder has not been one of emphasis or miscalibration, but of misalignment. Governments at all levels have continued to fund both supply-side (e.g., criminal justice) and demandside (e.g., harm reduction and treatment) policies. This

is a characteristic of a public health paradox (Fleming et al., 2021), as criminalization actively frustrates treatment and harm reduction. Progress depends on recognizing that criminal justice, harm reduction, and treatment do not exist in a relatively benign triad. Criminal justice interventions do little to slow drug use and they worsen health outcomes (Jurecka & Barocas, 2023). Unless and until the United States pivots away from the criminalization of addiction, harm reduction will be slowed and the failure to get people into treatment and recovery will continue.

The criminal justice system erects both direct and indirect pervasive barriers to treatment. Direct barriers can be casual, such as the law enforcement officer hanging around outside a syringe service, or far more structural. After the declaration of the "war on drugs" in the 1970s, DEA used its powers under the Controlled Substances Act to establish multiple barriers to the medicinal uses of scheduled drugs to treat OUD, such as the partial agonist buprenorphine and the agonist methadone (Drug Abuse Prevention And Control, 2014). Because of "drug war logic" (Cohen et al., 2022) opioid agonist treatment has faced federal restrictions absent from prescription drug treatment of other chronic diseases.

The primary federal restriction on the normalizing of buprenorphine treatment was the requirement of the so-called "X-waiver" that required specialized training for clinicians before they could prescribe the drug. In April 2021, the Biden administration replaced the waiver with a simpler "notice of intent" to prescribe for clinicians treating up to 30 patients. The Consolidated Appropriations Act of 2023 removed even this requirement (Consolidated Appropriations Act, 2023) meaning that all DEA registered clinicians with Schedule III authority may now prescribe buprenorphine (Substance Abuse and Mental health Administration, 2023b). However, rigorous DEA scrutiny of "suspicious" prescribing activity (Drug Enforcement Agency), the continuing stigma associated with treating people who use drugs (Mendiola et al., 2018), a lack of training or information reaching physicians (Wakeman et al., 2016), and remaining DEA registration and reporting requirements (Dooling & Stanley, 2022, p. 31-34)) create serious doubts whether initial steps toward deregulation of OAT will be sufficient (Mahr K, 2023; Welland, 2023).

There are further barriers at the state level. For example, some states outright prohibit buprenorphine prescribing by nurse practitioners or limit it to nurse practitioners who have collaborative agreements with physicians, a significant barrier in states with few physicians willing to work with scheduled drugs (Vestal, 2017) or in rural areas that face a shortage of qualified prescribers (Andrilla et al., 2017). There is also evidence that patients face considerable difficulty in having their buprenorphine prescriptions filled at pharmacies (Weiner et al., 2023).

Methadone, a Schedule II drug, is even more highly regulated. A patient must receive the medication under the supervision of a practitioner along with counseling, tying methadone access to accredited and certified Opioid Treatment Programs (OTPs) (Federal opioid treatment standards, 2001). "At home" doses are permitted only after a period of stability, placing "liquid handcuffs" on the patient (Frank et al., 2021). The apparently successful liberalization of telemedicine access, take-home methadone doses (Amram et al., 2021), and other innovations, such as home delivery (Harocopos et al., 2021) and video observation of take-home doses (Hallgren et al., 2022) during the COVID-19 pandemic (Davis & Samuels.) 2020), led to calls for broader deregulation (American Telemedicine Association, 2022). Even factoring in recent deregulation, such as the liberalization of takehome criteria (Substance Abuse and Mental health Administration, 2023a), new guidance on split doses, and improved access through telemedicine (Centers for Medicare & Medicaid Services, 2022a; Janos, 2023), there are remaining state barriers that frustrate the W-G model. For example, some states layer additional requirements on top of the already stringent federal rules such as certificate of need, specialist licensure, or zoning limitations (Okla, Admin. Code § 450:70, 2021; Pew Charitable Trusts, 2022), while states have quite notably heterogeneous telemedicine laws and policies (Center for Connected Heath Policy / Public Health Institute, 2022). Further, it is arguable that the proposed deregulation goes far enough. Even with the recent liberalization OTPs retain a monopoly on distribution (Substance Abuse and Mental Health Services Administration, 2023), raising questions of agency capture by a predominantly for-profit industry (Redmond, 2022). Indeed, Nora Volkow, the director of the National Institute on Drug Abuse, has called for the broad deregulation of methadone to allow it to be prescribed by physicians and, in some situations, even pharmacists (Facher, 2022).

The failed "war on drugs" not only criminalized addiction but also erected significant barriers to treatment for people involved in the justice system, particularly the continuation or initiation of opioid agonist therapy (Fiscella et al., 2018; Grella et al., 2020). Drug courts and prisons maintain negative policies to evidence-based agonist treatments notwithstanding that drugs and alcohol are the third leading cause of death in US jails (Fiscella et al., 2020). Fewer than 5 percent of justice-referred clients receive agonist treatment, with courts and diversionary programs least likely to refer people to such treatment (Krawczyk et al., 2017). Some drug courts have policies against agonist use (Matusow et al., 2013) while many law enforcement officers, prosecutors, and court staff hold negative attitudes toward agonist treatments, particularly methadone (Andraka-Christou et al., 2019). Recently, the Department of Justice has published guidance (Department of Justice,

2022) pointing out that the failure to offer such services can run afoul of the Americans with Disabilities Act (ADA) because, while ADA does not protect those illegally using drugs, it does extend to "the use of a drug taken under supervision by a licensed health care professional" (42 U.S.C. §12210(d), 2008) and successfully settled a case it brought against the Massachusetts drug courts (US Attorney's Office, 2022).

OUD screening and access to treatment have been severely limited in US corrections facilities (Csete, 2019). Notwithstanding the evidence-base that clearly establishes benefits of carceral and post-carceral access to agonist treatment (National Commission on Correctional Health Care, 2021; Wakeman, 2017) only a minority of states have explicit MOUD treatment policies (Prescription Drug Abuse Policy System, 2022). Recent case law (Pesce v. Coppinger, 355 F. Supp. 3d 35 (D. Mass. 2018); Smith v. Aroostook Cnty., 376 F. Supp. 3d 146, 150 (D. Me.), aff'd, 922 F.3d 41 (1st Cir. 2019), 2019) and settlements (Kortlever et al. v. Whatcom County Settlement Agreement, 2022; Sclafani v. Mici, Settlement Agreement, 2020) based on constitutional claims and the ADA make it clear that jails and prisons refusing OAT are increasingly in legal peril (Macomber, 2020).

We must continue to take a long hard look at exactly what forces operating at a horizontal level and what vertical misalignments lead to our regulatory dysfunction. Federal and state policymakers, including those who recognize the W-G approach, have approached the opioid overdose and other substance use disorder crises as requiring adjustments in approach, recalibrating the criminal justiceharm reduction-treatment triad. However, recalibration is insufficient. The criminal justice system is responsible for too many barriers to treatment, direct and indirect, that the W-G imperative must be to get criminal justice and its detritus out of the way of treatment. First principles as voiced by Justice Douglas need to be restated, "We would forget the teachings of the Eighth Amendment if we allowed sickness to be made a crime and permitted sick people to be punished for being sick. This age of enlightenment cannot tolerate such barbarous action" (Robinson v. California, 82 S.Ct. 1417, 1426 (1962)).

Making Health Care Work for People with OUD

There are significant areas of the country, primarily in the west, that are effectively OTP deserts with no opioid treatment programs (OTP) that accept Medicare within a 60-minute driving time (Cantor et al., 2022). Indeed, large numbers of OTPs accept no insurance and are cash-only (Patrick et al., 2019; Van Zee & Fiellin, 2019) rendering them inaccessible for the majority of those suffering from OUD. Tying methadone distribution to OTPs (21

C.F.R.§1306.07(a), 2020) creates a barrier in that patients (absent take-home doses) are forced to travel daily to clinics for their doses, a constraint that may explain why many people are not in treatment (Amiri et al., 2018; Dooling & Stanley, 2022, p. 16). The COVID-19 pandemic provided an opportunity for some experimental deregulation (Davis & Samuels, 2020). However, in some states OTPs seemed to continue to operate as they always have and failed to offer their patients the flexibilities available during the PHE (Meyerson et al., 2022), raising questions about W-G vertical alignment after federal deregulation.

Historically, policymakers and lawmakers made the decision to allocate fewer resources to behavioral health, to allow toxic policing and penal policies to stigmatize those with OUD and hinder the availability of OAT. Those policies have combined with classism and racism to further disadvantage cohorts which overlap with those with OUD. As we discuss elsewhere, making health care work for people with OUD means reducing these inequities and barriers by rebuilding the behavioral health system, merging health care and social services, and addressing racism and bias in the system.

There are good emerging models for meeting those with OUD literally where they live. For example, in July 2021, DEA implemented a new regulation increasing the number of mobile methadone treatment facilities in an effort to expand access to treatment in remote and underserved communities (Whelan & Hazelton, 2023). ARPA (American Rescue Plan Act, 2021) provided for additional Medicaid reimbursement although only 20 states have applied for the funding (Centers for Medicare & Medicaid Services, 2022b). More fundamentally, the OTP monopoly needs to be rethought and consideration given to providing access to OAT treatments through rural safety net providers such as Federally Qualified Health Centers (FQHCs) or even chain retail pharmacies (Brooner et al., 2022; Iloglu et al., 2021; Wu et al., 2021).

If we truly can move on from the "war on drugs" then there are also opportunities for rethinking the roles of law enforcement and prisons. For example, mobile agonist treatment models can also be integrated into other first responder initiatives such as paramedicine and joint law enforcement-behavioral health teams (Firesheets et al., 2022; Traube et al., 2021). Many localities have created deflection programs, non-arrest pathways for people to access treatment and recovery services that reduce stigma and improve better services for people with OUD (Legislative Analysis and Public Policy Association, 2021b). Some type of deflection program exists in about half the states but differ as to definitions, funding sources, and liability protections (Legislative Analysis and Public Policy Association, 2021a). The Model Law Enforcement and Other First Responder Deflection Act (The Model Law

Enforcement and Other First Responder Deflection Act, 2022) is a well-constructed model for defining the purpose and reach of such programs, creating a funding model, training, and requiring including interagency agreements delineating the roles and responsibilities of the various organizations that need to partner on such initiatives. Here, SAMHSA and DOJ funding "nudges" should be employed.

Finally, if as discussed above, we can reform jails and prisons from places of withdrawal and abstinence to treatment and recovery, we need to better connect their populations with the outside world. Death from overdoses is the leading cause of death in the immediate post-release period (Binswanger et al., 2013; Waddell et al., 2020). Connecting people released from prisons and jails with health care (Guyer et al., 2019; Jannetta et al., 2017) and other social supports such as safe housing and employment (Hunter et al., 2023) is a priority. One promising initiative is to restart Medicaid for incarcerated individuals prior to their expected date of release as in California's Sec. 1115 waiver request recently approved by CMS; the agency making it clear that it will be encouraging other states to implement similar strategies (Centers for Medicare & Medicaid Services, 2023).

Structural determinants such as race and poverty impact many of the social determinants of health, key determinants include income and economic stability, education access and quality, and the social and community context (including family support and safety) (US Department of Health and Human Services). Indeed, "high opioid utilization and overdose are symptoms of structural dysfunction in American society" (Beletsky, 2019, p. 849). Health care itself is seldom a lever for changing these deep drivers, but the health care system can do a much better job of acknowledging and acting on the things in patients' lives that make it harder for them to access or maintain care. Sometimes negative determinants such as poverty, lack of community, or housing insecurity can become inseparable from someone's clinical diagnosis. Frequently, they will be part of the SUD diagnosis when persons in overdose present in emergency rooms or family members dial state hot lines seeking recovery services.

Medicalizing the social risk factors can encourage a more integrated approach to improving health care services (Webb & Matthew, 2018) and leverage continuing sources of funding. In this regard using Medicaid funds to address social determinants can be attractive to states

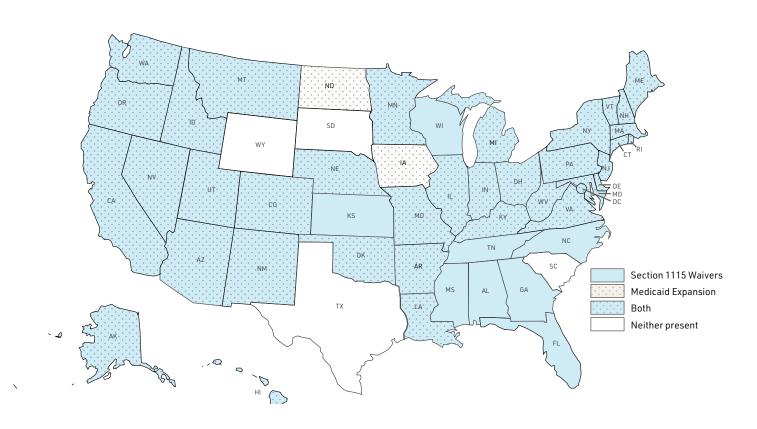


Figure 1: As of April 20, 2023, 45 jurisdictions received an approved Section 1115 Waiver. 39 jurisdictions adopted the Affordable Care Act Medicaid Expansion. 37 jurisdictions had both. (PDAPS, 2023).

(Daniel-Robinson & Moore, 2019; Kushner & McConnell, 2019). Examples include North Carolina's Healthy Opportunities Pilots program that uses Medicaid funding to address social risk factors such as food, housing. transportation, and interpersonal violence/toxic stress (Rapfogel & Rosenthal, 2022). California is fundamentally restructuring its Medicaid program through its "California Advancing and Innovating Medi-Cal" (CalAIM) project aiming to integrate health care with and providing reimbursement for a range of social services such as housing supports, medically tailored meals, and peer supports (Kelly, 2022). A major goal of CalAIM is to reduce fragmentation and promote integration for behavioral health services (Enos, 2022). Both of these programs involve Section 1115 Medicaid waivers (Kaiser Family Foundation, 2023) that, themselves are one of the best examples of effective vertical W-G policymaking.

Conclusion

How we treat those with OUD has clearly evolved over the past two decades. There are clinical as well as W-G opportunities to improve paths to treatment, access to and availability of care, and an extended continuum of care that stretches from prevention to recovery. The W-G agenda must be to make criminal justice read from the health care playbook, not vice versa.

Success in the effort to reduce OUD and the harm it causes will require dramatic change built on a commitment across government, between layers of government, and the health care system to address OUD through prevention, treatment, and harm reduction. We have identified some key priorities for federal and state policymakers that go beyond fixing health care's own collection of problems: first, recognize that substance use is a health care issue that requires something more than the recalibration of "health care as usual," but the re-architecting of health care to elevate behavioral health away from its stigma-driven historical antecedents; second, remove the final "war on drugs" regulatory impediments (and their incidental stigmatization) from the treatment, care, and recovery domain; third, make the health care system work better for people with and at risk of OUD by improving access to equitable care and reducing impediments to prevention, treatment, and recovery, thereby making health care work better for the "Whole of Society" and for the "Whole of Person." •

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ABOUT THE AUTHORS

Nicolas Terry, LLM is the Hall Render Professor of Law at the Indiana University Robert H. McKinney School of Law and executive director of the Hall Center for Law and Health.

Scott Burris, JD is a professor at the Temple University Beasley School of Law and College of Public Health and director of the Center for Public Health Law Research.

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Whole of Government and Harm Reduction

THE LEGAL PATH TO A WHOLE OF GOVERNMENT OPIOIDS RESPONSE: PART 5

November 2023

Nicolas Terry, LLM Scott Burris, JD

Executive Summary

Harm reduction is beset by law and stigma. Stigma powers the urge to be punitive and law provides the means. The effects ripple through every harm reducing action the government does at all levels. To achieve its full potential in reducing the toll of overdose and dangerous drug use, harm reduction must be allowed to do its job without undue interference from contrary federal policies, inconsistent state laws, and structural barriers. Using a whole-of-government (W-G) approach, this paper details the challenges, current policy misalignments and legal barriers to implementing harm reduction strategies for drug use. The recommendations that follow articulate a series of opportunities for governments at all levels to realign and recommit to harm reduction.

The federal government needs to do more to make hard reduction work. The Centers for Disease Control and Prevention and the National Institutes of Health should fund the research that further demonstrates its costeffectiveness. Those and other health and human services agencies together with the Office of National Drug Policy (ONDC) and the Drug Enforcement Agency (DEA) must better align their horizontal whole-of-government policy levers. Harm reduction requires not only positive policy signals but a far more sophisticated approach to federal funding to avoid funding gaps, insecurity, and siloes. Congress can make progress on vertical wholeof-government (W-G) by endorsing a new financing framework ("braiding") where multiple mandatory and discretionary funding sources that flow vertically from the federal government to the states can be coordinated. Congress must also intervene to remove numerous legal roadblocks such as those that impede the funding of access to clean syringes and the establishment of Overdose Prevention Centers.

State governments must move beyond the "war on drugs" (such as eliminating drug induced homicide charges against street-level dealers and people sharing drugs with others)

and address the legal rules that create persistent barriers to harm reduction, such as state drug paraphernalia laws that impede federal-funded initiatives such as naloxone distribution, fentanyl test strips, and syringe services programs. State executives also must ask themselves whether they are making sufficient progress on structural barriers such as the attitudes of local prosecutors to people who use drugs, the links between homelessness and drugtaking, and efforts to reduce stigma. State governments must also find a consistent institutional "home" for harm reduction. There must be aligned appropriations from the federal and state budget (and opioid lawsuit settlements) that are both big and flexible enough to allow states and localities to construct a true "harm reduction system," one that is tailored to local needs, but with a firm floor of decriminalization, destigmatizing, non-discrimination elements that nudge states towards a public health and non-punitive approach to Opioid Use Disorder.

Introduction

Harm reduction emphasizes working directly with people who use drugs in a non-judgmental and non-coercive manner (National Harm Reduction Coalition, 2020b) to prevent overdose and infectious disease transmission and, overall, to improve their well-being (The White House Executive Office of the President, 2022). While the Council of Economic Advisers has estimated the cost of the opioid overdose crisis at 3.4 percent of the US GDP (\$2.5 trillion from 2015 to 2018) (Council of Economic Advisers, 2019), a Cato Institute analysis observed, "harm reduction has a success record that prohibition cannot match" (Singer, 2018). Notwithstanding, this track record and an excellent return on investment (Harm Reduction International, 2020), harm reduction is beset by horizontal and vertical whole-of-government (W-G) challenges.

Ignoring the evidence-base underpinning harm reduction strategies, many of its critics (who frequently will have influence or control over some level of government) see harm reduction engagement as encouraging or perpetuating unlawful drug use. This is not news for those involved in harm reduction. Indeed, many of those who staff harm reduction services such as syringe services programs (SSPs) are themselves people in recovery, surviving not only the physical and mental challenges but also rampant stigma (Birtel et al., 2017; Pytell et al., 2022). Historically, many programs have started underground. Today, in many cities overdose prevention centers (OPCs) operate "off the grid" ("Dozens and dozens' of underground safe injection sites in Seattle," 2018) and, no doubt, safe supply services will follow, only to emerge once law and policy catch up with the evidence-base their underground activities inevitably help to establish.

Blunt disagreements over harm reduction policies and implementation strategies exist at every level of government and between government and citizens. Take, for example, OnPoint's community outreach teams (mobile SSPs) and its OPC in New York that have provoked anger from civic groups who feel overburdened by drug use in their locales even as the programs increasingly reduce deaths and illness (Interlandi, 2023).

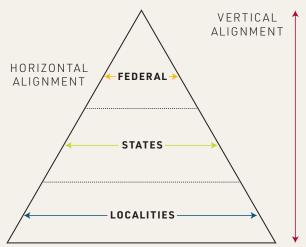
To achieve its full potential reducing the toll of overdose and dangerous drug use, harm reduction must be allowed to do its job without undue interference from contrary federal policies, inconsistent state laws, and structural barriers (including those sometimes erected by local law enforcement). Getting there will require not only rethinking health care and its interface with public health strategies but also the role of law enforcement. Public safety initiatives that provide amenity in civil spaces, team up with social services and gain behavioral health skills must replace arrests and incarceration. To paraphrase Justice Douglas in Robinson v. California, we can no longer allow sickness to be viewed as a crime or sick people punished for being sick (*Robinson v. California*, 82 S.Ct. 1417, 1426 (1962)).

This paper details the W-G challenges, current policy misalignments and legal barriers faced by harm reduction and offers recommendations for all levels of government.

Harm Reduction's Whole-of-Government Failure

Even the Biden administration's signature harm reduction program designed to channel \$30 million into harm reduction strategies (Substance Abuse and Mental Health Services Administration, 2021) has attracted controversy. The Substance Abuse and Mental Health Services Administration (SAMHSA) grants for harm reduction announced pursuant to the American Rescue Plan Act can be used to fund products such as infectious-disease testing kits, condoms, and hepatitis vaccinations (Substance Abuse and Mental Health Services Administration, 2021). The

DEFINING WHOLE-OF-GOVERNMENT



Through the Whole-of-Government approach, we gain an improved understanding of the design and implementation of conventional drug policy. The W-G perspective provides both a lens through which to critique current levels of alignment and misalignment between different levels of government or agencies at the same level, and a normative tool designed to structure reforms. What is required for effective policy making is comprehensive, coordinated government action across the different agencies at one level of government (be it federal or state), what we term horizontal W-G, and between different levels (federal, state, tribal, and local), what we term vertical W-G.

list of covered products (including "safe smoking kits" containing, for example, alcohol swabs and lip balm) led to a political storm, fueled by conservative news outlets, accusing the US Department of Health and Human Services (HHS) of funding and distributing "crack pipes" (Jones, 2022). Before long, legislation was introduced to further restrict products that could be purchased with federal funds (Preventing Illicit Paraphernalia for Exchange Systems Act, 2022), with one of its sponsors proclaiming, "We need to do more, but sending drug paraphernalia to addicts is not the answer" (Rubio, 2022).

Syringe services, while finally granted a funding stream under the Consolidated Appropriations Act of 2018, remain hampered by a congressional federal rider contained in continuing appropriations legislation (Centers for Disease Control and Prevention, 2019) that prohibits federal funds being used to purchase syringes. As if to highlight the confusion and friction that can flow from these restrictions, a September 2022 letter to state agencies from SAMHSA opined that it was permissible

to use federal funds for the purchase of syringes for the intramuscular administration of the overdose reversal drug naloxone. These inconsistencies reflect a government that is not serious about harm reduction, allowing pervasive internal barriers at all levels of government to hamper the use of the proven, effective strategy.

The interaction of harm reduction and government is fraught, strewn with legal barriers that make the job of saving lives harder. A broad W-G approach is necessary to harness diverse sources of funding but exposes harm reduction strategies to actors who frequently initiate or defend horizontal and vertical misalignments and barriers.

Federal Horizontal Whole-of-Government Issues

Harm reduction is institutionally under-represented at the federal agency level and currently lacks an advocate agency that can harness and promote the necessary W-G solutions.

Of our public health agencies, the US Centers for Disease Control and Prevention (CDC) is focused on testing, education, surveillance, and data. SAMHSA, the lead federal body and one of the few that self-describes as a public health agency, is currently focused on providing "access to a comprehensive continuum of mental and substance use disorder services, including high-quality, evidence-based prevention, treatment, and recovery support services" (Substance Abuse and Mental Health Services Administration, 2022). Other than a commitment to improving access to naloxone, the strategies advocated by SAMHSA arguably are more aligned with improving the treatment continuum than public health interventions such as syringe services or overdose preventions centers. This treatment orientation is consistent with its origin story and its advocacy and support for treating mental health illnesses (Duff, 2020). But is it conducive to an effective harm reduction strategy? The country's lead agency on funding state OUD strategies should be front and center in promoting and funding effective harm reduction. In contrast, laws and policies that create misalignments and barriers (whether intended or not) have strong advocates in DEA and among congressional criminal justice hawks. SAMHSA and the Office of National Drug Control Policy (ONDCP) both had their origins in the early years of the "war on drugs."

Overall, harm reduction needs stronger leadership within the federal government to raise its profile and offer a counterbalance to supply-side strategies. Both agencies should be advocates for harm reduction and forcefully argue against FDA over-caution and DEA/Department of Justice (DOJ) over-regulation. Although the Biden administration has publicly supported harm reduction (The White House, 2022), the ONDCP Director is still not

a member of his cabinet (Choi, 2023). Arguably the most effective counterpoints to agencies that have not committed to harm reduction are, within HHS, the evidence-driven National Institute on Drug Abuse and, outside of government, national advocacy organizations such as the Drug Policy Alliance (DPA) (Drug Policy Alliance, 2022a), the National Harm Reduction Coalition (National Harm Reduction Coalition, 2020a), and the Network for Public Health Law (The Network for Public Health Law, 2023b).

Spending on harm reduction has increased during the Biden administration, and the American Rescue Plan Act of 2021 included \$30 million for harm reduction (American Rescue Plan Act, 2021 § 2706; Substance Abuse and Mental Health Services Administration, 2021). In September 2022, HHS announced \$1.6 billion in funding to be distributed by SAMHSA's State Opioid Response (SOR) and Tribal Opioid Response (TOR) grant programs and the Health Resources and Services Administration (HRSA) rural communities opioid response programs (US Department of Health and Human Services, 2022). This overall increase in funding is positive. However, these funding programs are spread across prevention, harm reduction, treatment and recovery support. Indeed, historically they have skewed towards treatment and, as far as harm reduction goes, naloxone distribution. Even with overall funding increases harm reduction struggles to maintain current levels of service, let alone expanding to meet unmet need.

Because of harm reduction's emphasis on survival over abstinence and its acceptance (but not necessarily approval) of illicit conduct, its strategies can face strong push-back. At the federal agency level, harm reduction frequently attracts friendly fire from other agencies or Congress that for political, policy, or social (stigma) reasons lean toward "moral defect" explanations of drug use and illnesses. It is all too easy for critics to beat the drum of criminalization, arguing that harm reduction helps deviant people do illegal things.

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State Horizontal Whole-of-Government Issues

In response to the sharp increase in heroin and fentanyl overdoses from 2016 through 2018 (Baumgartner & Radley, 2021), many states appointed study commissions or task forces to create state action plans. Most of these state initiatives addressed the familiar prevention/ early intervention, harm reduction, treatment, and recovery domains. Harm reduction tended to concentrate on naloxone distribution and training, with limited receptiveness to establishing syringe services. Some more recent state-level initiatives have addressed additional strategies such as drug-checking, OPCs, and joint public safety-public health programs. However, there has been only limited willingness to address the legal rules that create persistent barriers to harm reduction (Davis et al., 2019). Federal funding for the overdose reversal drug naloxone or fentanyl test strips frequently are impeded by state drug paraphernalia laws (Singer, 2023) (albeit with a growing number of exceptions (New Mexico Department of Health, 2022)) or the attitudes of local prosecutors to people who use drugs (Chernoby & Terry, 2020).

Like the federal government, harm reduction does not have a consistent institutional "home" in state governments. Many programs have found homes alongside infections disease programs within public health agencies, in the same divisions that deal with HIV, STDs, and viral hepatitis (California Department of Public Health, 2022; Indiana Department of Health). In other states the programs appear to be less programmatic and more communications oriented (Georgia Department of Public Health, 2023) or narrowly focused on licensing private harm reduction

organizations such as SSPs (West Virginia Bureau for Public Health, 2018). And, of course, there are still other states without any harm reduction programs, having committed themselves to the continued criminalization of the possession and distribution of supplies for drug use and drug testing (Dey, 2022). Several governors have appointed cabinet level officials to "drug czar" positions such as a director of recovery (Governor of Ohio) or a director for drug prevention, treatment and enforcement (NextLevel Recovery Indiana). However, some clearly have been appointed to further a drug policing strategy rather than harm reduction agenda (Bailey, 2023). Most states rely on the federal government to fund harm reduction (state appropriations for harm reduction are rare (Co. HB22-1326 Fentanyl Accountability And Prevention, 2022) and community organizations to provide it (Coalition; North America Syringe Exchange Network (NASEN)).

The conventional (and quite modest) state law harm reduction playbook features laws relaxing syringe possession and distribution, improved naloxone access (including statewide standing orders) and some variant on "Good Samaritan" overdose protections (The Network for Public Health Law, 2023a). However, not every state has legalized SSPs (Kaiser Family Foundation, 2022b) and (as discussed below) there are considerable variations in syringe laws. Naloxone distribution is frequently burdened by incomplete immunity provisions, lack of insurance or out-of-pocket charges (Legislative Analysis and Public Analysis Association, 2020; New York State Department of Health AIDS Institute), while few states have enacted naloxone-opioids co-prescribing laws (Ariz. Rev. Stat. § 32-3248.01(D); Cal. Bus. & Prof. Code § 741).

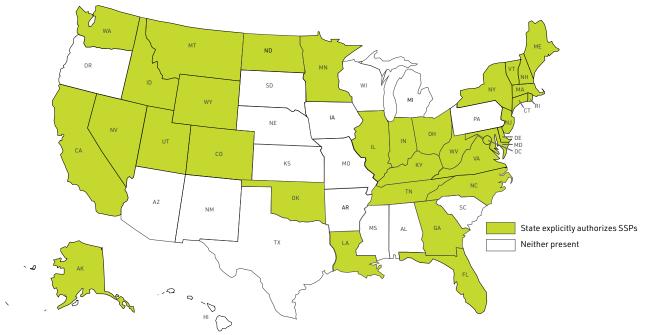


Figure 1: 34 states explicitly authorize syringe service programs as of August 1, 2021 (PDAPS, 2021).

A prevailing sense of criminalization with harm reduction and treatment exceptionalism reappears in state government. The criminalization fault line generally is replicated across state government with legislatures leaning toward more conservative positions while many state public health and Medicaid agencies push for harm reduction and treatment policies. Some state legislatures, such as Georgia, have gone so far as to propose legislation allowing centralized or concurrent jurisdictions designed to thwart local prosecutors who have decided not to bring minor drug cases (Blakinger, 2022). There are, however, few consistent patterns. For example, in 2019, 39 attorneys general acting through the National Association of Attorneys General sent a letter to congressional leaders requesting the federal government correct vertical misalignments such as the federal over-regulation of buprenorphine and restrictions on Medicaid funding of some residential treatment facilities (National Association of Attorneys General, 2019).

Vertical Whole-of-Government Issues

Few harm reduction strategies illustrate the W-G misalignments and barriers more vividly than strongly evidence-based SSPs (Bartholomew et al., 2021). One horizontal federal misalignment, the syringe rider, is discussed above. Additional signs of vertical friction are found in other appropriations language that makes eligibility for SSP funds dependent on a state, local, tribal, or territorial health departments satisfying a CDC Certificate of Need. This Certificate of Need is premised on a "risk for significant increases in hepatitis infections or an HIV outbreak (Centers for Disease Control and Prevention, 2022).

Once this obstacle is scaled (as it has been by 44 states and the District of Columbia, one tribal nation, and on territory (Centers for Disease Control and Prevention, 2022)), additional legal and policy barriers or, at best, friction are found downstream in state legislatures or agencies. Most, but not all, states now allow SSPs (Kaiser Family Foundation, 2022b). However, some SSP-enabling legislation itself can lead to further direct barriers. For example, some states push additional approval processes even further downstream to local public health officials who must certify a hepatitis C or HIV risk causes by intravenous drug use (Ind. Code §16-41-7.5-5, 2021; Fla. Stat. § 381.0038(4)(a), 2018). Other state statutes have potentially onerous requirements for programs, such as requiring the presence of a licensed health care provider (W. Va. Code § 16-64-3(a), 2021) or "one-for-one" syringe exchange (Bartholomew et al., 2021; Fla. Stat. § 381.0038(4)(b)(3), 2018; W. Va. Code §16-64-3(a), 2021).

State laws also create indirect barriers to the successful implementation of SSPs. For example, while states have passed legislation curtailing law enforcement from arguing probable cause merely because someone attended an SSP

(Ind. Code § 16-41-7.5-9, 2021), possession of syringes may still create jeopardy under outdated paraphernalia laws (Ga. Code Ann. § 16-13-32.2, 2021). Even states that seek to exclude only SSP-obtained syringes or drug residue left in exchanged syringes can muddy the waters by placing the burden on the person who injects drugs to establish proof that a particular syringe was exchanged at an SSP (N.C. Gen. Stat. § 90-113.27(c), 2020). Additional indirect barriers can involve broad structural determinants (such as law enforcement harassment of drug users) (Tempalski et al., 2007) as well as more explicit NIMBYism such as zoning laws to keep SSPs from opening in a neighborhood in the first place (Sawicki, 2022; Strike & Miskovic, 2017).

SSPs illustrate primarily downstream W-G barriers and misalignments. In contrast, overdose prevention centers (OPCs), safe spaces for the consumption of drugs under medical supervision (Drug Policy Alliance), currently trigger upstream vertical issues. Underground, unsanctioned OPCs have shown considerable potential for harm reduction (Armbrecht et al., 2021) as have studies on a large number of sites outside the United States (Drug Policy Alliance, 2022b). An NIH/NIDA report noted, "drug use supervision and overdose management have the potential to provide health benefits to at-risk [people who inject drugs] as well as economic advantages to the larger community," concluding that "the evidence suggests these sites are able to provide sterile equipment, overdose reversal, and linkage to medical care for addiction, in the virtual absence of significant direct risks like increases in drug use, drug sales, or crime" (National Institutes of Health, 2021, p. 11). Notwithstanding, in 2019 after the City of Philadelphia approved an OPC to be opened by a non-profit, the federal government successfully sued to block the opening, arguing that it was unlawful under the Anti-Drug Abuse Act of 1988 (referred to as the "Crack House Law") a position endorsed by the Third Circuit Court of Appeals, which noted, "Although Congress passed § 856 to shut down crack houses, its words reach well beyond them. Safehouse's benevolent motive makes no difference" (United States v. Safehouse, 2021). The Biden administration has signaled a less combative approach than its predecessor (Peltz J, 2022). However, the "Crack House Law" remains on the books and could well be enforced again by a subsequent administration that is less inclined to favor harm reduction.

States have been slow to follow the Biden administration's example. The governors of California (Cowan, 2022) and Vermont (Vermont governor vetoes safe injection sites for drug users, 2022) vetoed bills that were favorable to OPCs. However, a comprehensive 2023 bill introduced in New Mexico (House Bill 263, 56th Legislature (Lujan & Hochman-Vigil), 2023) may find approval from the governor, and similar legislation is being considered in Colorado (Young, 2023). Rhode Island has passed legislation allowing a pilot program (dependent on

downstream municipal approval (R.I. Gen. Laws § 23-12.10-1, 2022) but, with no OPC yet opened, is running into the sunset date for the pilot program (Smollen, 2023)). Although New York City has opened two OPCs (Khurshid, 2022), funding is running out (Wernau, 2023), and the governor of New York has refused to use opioid settlement moneys to fund OPCs, citing state and federal laws (Lombardo, 2022).

Even where federal/state/locality misalignments can be navigated, the friction they generate burns resources and hinders harm reduction strategies from getting to scale. Small breakthroughs such as the establishment of 402 SSPs scattered across 43 states (Kaiser Family Foundation, 2022b) represents a disproportionate use of resources, including lobbying and advocacy. Yet even that is a hollow victory. Only 13 states have 10 or more SSPs and they account for 253 of the 402 nationwide. The remaining 149 SSPs are spread across 31 states and the District of Columbia. Similar questions arise regarding OPCs. There may now be two open in New York City (NYC Health) but what about the rest of the state that has an opioid burden event (opioid overdose deaths, non-fatal outpatient ED visits and/or hospital discharges involving opioid overdose, abuse, dependence and unspecified use) at a rate of 250.5 per 100,000 population (New York State Department of Health, 2021, p. 41)?

The harm reduction strategy that logically will follow on from SSPs and OPCs are safe supply programs that have been piloted in Ontario (Lew et al., 2022) and British Columbia (Tyndall, 2020). An array of federal barriers (the Controlled Substance Act, off-label prescribing, DEA sanctions against physicians) would be complemented by state and local laws such as those that have slowed the adoption of SSPs.

In short, as Herd and Moynihan (2019) note, "federalism... creates opportunities for different levels of government to work at cross-purposes." Regulators and legislatures manipulate here policy misalignments and legal barriers to calibrate their views of policies or strategies. Thus, passing or enforcing a broad drug paraphernalia law heightens their control over harm reduction, or vice versa. Worryingly, the vertical misalignment in health and public health has been hardened by political polarization over the last few decades and, in particular, during the COVID-19 pandemic (Findling et al., 2022; Hegland et al., 2022). What is becoming clear is that some states will reject federal funding of evidence-based health or public health strategies because they disapprove of the conditions imposed by the federal government (such as non-discrimination policies), as exemplified by Tennessee's recent rejection \$9 million destined for HIV/AIDS prevention (Cha & Nirappil, 2023) and more generally by a small government vision of public health precipitated by the COVID-19 pandemic (NACCHO & The Network for Public Health Law, 2021).

Finally, the mechanisms by which the federal government appropriates funding and states apply for funds for harm reduction strategies are flawed. The federal

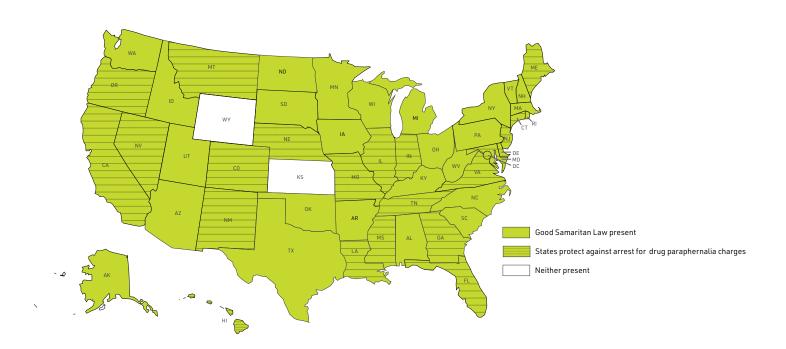


Figure 2: GSLs are now in 48 states and the District of Columbia, that encourage bystanders to call first responders during an overdose. 3 jurisdictions protect against arrest for controlled substance possession charges. (PDAPS, 2023).

government defaults to a "feast or famine" model for discretionary spending. States will be starved of resources until a change in administration or policies triggers a substantial appropriation. As a result, states and the harm reduction organizations they support receive episodic and inconsistent funding with short spending horizons that discourage spending on staffing, long term plans, or infrastructure. This phenomenon occurred during the Ebola and Zika outbreaks and was vividly illustrated during the COVID-19 public health emergency. In all cases, the federal government adopted the same type of grant-based funding; state public health agencies were underfunded as the pandemic began but, by the time federal funding arrived, the emergency was past its peak with grant funds unspent (LaFraniere, 2023).

Meeting the Whole-of-Government Challenges

Bringing the W-G approach to bear on a complex problem depends on several components, including agreement as to the problem, understanding the problem, and the causes of the problem (Worzala et al., 2018). For many involved in government at all levels, the harm reduction challenge unfortunately falls at the first of those hurdles. *Implicitly*, harm reduction recognizes that the predominant component of the "war on drugs," the criminalization of drug use, has been a failure and that the future depends on demand-side strategies, such as harm reduction and treatment. Explicitly, harm reduction characterizes the addictive use of drugs, whether alcohol, tobacco, or opioids, as a public health problem, not a justice system issue. These challenges to the criminalization fault line create a barrier to the adoption (sometimes even the mere toleration) of harm reduction strategies. These challenges must be met with a reduction in legal and policy barriers, including: (1) an overhaul of funding mechanisms, (2) the removal of criminal justice barriers to harm reduction, and (3) the construction of a harm reduction system.

Overhaul Funding Mechanisms

After establishing effective leadership, the next step is funding. Harm reduction properly led and with workable strategies, deserves a proper funding mechanism. Not only has there been chronic underinvestment in harm reduction strategies (Baumgartner et al., 2022) but also the financing mechanisms are awash in funding insecurity (Jaramillo et al., 2019); periodic grant applications, limitations on use, spending horizons. Funding mechanisms must be overhauled to promote long-term state strategies, building out necessary infrastructure, and coordinated spending. Recently the Bipartisan Policy Center (BPC) recommended that Congress revisit the State Opioid Response Grants and Substance Abuse Prevention

and Treatment Block Grants overseen by SAMHSA, revisit its funding formula, and allow multiyear authorizations (Bipartisan Policy Center, 2022).

In addition to funding insecurity, states and other organizations that rely on federal and other funds for harm reduction (and treatment) must cope with funding siloes. Funds may be provided from different SAMHSA "buckets," as well as from the Centers for Medicare and Medicaid Services (CMS), CDC, HRSA, NIH, and FDA; 70 opioid-related discretionary funding streams.(Bipartisan Policy Center, 2022, p. 35). This is the financial equivalent of the horizontal W-G fail (fragmentation and lack of coordination) across the federal government. Thereafter, this fragmentation and lack of coordination across the federal horizontal plane means states and their public and private dependents face difficulties analogous to vertical W-G barriers as they seek to apply funds to various harm reduction and treatment purposes (Butler et al., 2020, p. 6-8). Budget flexibility and coordination of funding sources are improved by either braiding together grants or other sources into a virtual fund or actually blending them into a single pool (Butler et al., 2020, p. 8-9). BPC has recommended the braiding approach to improve OUD funding. First, SAMHSA and CMS should provide states with a braiding framework whereby multiple mandatory and discretionary funding sources can be coordinated to support similar objectives and align programs.(Bipartisan Policy Center, 2022, p. 41-42). BPC did not go so far as to recommend the federal government blend their funding sources (presumably because of the mandatorydiscretionary divide) it did recommend braiding discretionary funding through close cooperation across agencies and recommended that Congress should add instructions that agencies better coordinate their spending and braid funding from multiple programs (Bipartisan Policy Center, 2022, p. 41-42).

Finally, funding gaps must be addressed. Large numbers of people with OUD, particularly those in non-expansions states (Kaiser Family Foundation, 2023), do not have health insurance. While more of a treatment than harm reduction issue at this time, it will become more important as harm reduction programs (SSPs and OPCs) begin to blend into treatment programs. As such attention should be paid to designing a reimbursement model for OUD services modeled on the "payer of last resort" used in the Ryan White HIV/AIDS Program; a program specifically designed to fill funding gaps (Kaiser Family Foundation, 2022a).

Remove Criminal Justice Barriers to Harm Reduction

Nationally, law enforcement officials exacerbate rather than ameliorate the harms associated with drug use, confiscating naloxone, opposing SSPs, and prosecuting

syringe possession or drug-induced homicides (Fair and Just Prosecution, 2019, p. 4). Harm reduction must be allowed to do its job with sharply reduced interference from contrary federal policies, inconsistent state laws, and structural barriers. A recent editorial in the Journal of the American Medical Association summarized our current state: "Studies have demonstrated that intensified drug enforcement laws have little deterrent effect on substance use and may worsen health outcomes" (Jurecka & Barocas, 2023). Leaders at all levels, federal agencies, Congress, state legislatures, the National Governors Association, and others must provide a final, transparent assessment of the "war on drugs" and recalibrate the criminalization fault line to exclude most people who use drugs, making harm reduction and treatment the dominant systems they encounter. This is not legalization, nor is it the capitulation of the country to the cartels. Neither does it follow that public safety should be sacrificed; that itself is an essential part of everyone's right to public health.

Congress should not only commit more strongly to longterm harm reduction funding but also resist calls to maintain impediments such as carve-outs for syringes. The Biden administration's harm reduction strategies must (along with steadily improving treatment initiatives) become the dominant themes in a freshly framed "war on death and disease" with all the federal agencies pulling together in the same direction. Although the FDA has approved its first OTC naloxone product (FDA News Release, 2023), but itself that will not cure and may even exacerbate fundamental cost-based, access problems (Bowman, 2023; Lovelace Jr., 2023). Federal agencies also must reach consensus on repealing or at least limiting the "Crack-House" law and fund innovative public safety/public health partnerships. States and localities must examine their own laws and policies to remove barriers to drug testing and SSPs, while encouraging public safety/public health partnerships such as law enforcement deflection and community mobile crisis intervention programs.

A recent New York Times editorial (2023) said,

Criminal justice still has a role to play in tackling addiction and overdose. The harm done by drugs extends far beyond the people who use them, and addictive substances — including legal ones like alcohol — have always contributed to crime. There is a better balance to strike, nonetheless, between public health and law enforcement.

Striking that balance is not without difficulty but there is some low-hanging fruit that will further harm reduction. Approximately half the states have drug-induced homicide laws (PDAPS, 2019) that primarily ensnare family members and friends rather than hardened criminals, create barriers to calling for help, and are "perhaps the

most vivid illustration of a larger structural problem" (Beletsky, 2019). Next, states need to reassess their overbroad approach to drug paraphernalia. For example, Colorado no longer includes drug-testing products (CO Rev. Stats. Title 18. Criminal Code § 18-18-426) and New York has decriminalized the possession or sale of hypodermic needles or syringes (NY SB 2523 (2021-22)).

The next question that must be addressed is whether it is sound policy to continue prosecuting drug users. Some cities are approaching this with prosecutorial discretion. For example, Baltimore's decision to stop prosecuting low-level offenses such as drug possession did not seem to pose a threat to public safety or result in increased public complaints about drug use (Rouhani et al., 2021), and there is similar evidence coming out of Oregon (RTI International, 2023). A more advanced model, and illustrative of a W-G success in Canada, has been the granting of an exception to the federal Controlled Drugs and Substances Act (1996) to the province of British Columbia that decriminalizes possession of up to 2.5 grams of certain illegal drugs for personal use (Health Canada, 2023). In the words of a former mayor of Vancouver, "it gets the police out of the lives of drug users..." (Ling, 2023).

In the United States, Washington and Oregon have come closest to the British Columbia model. In 2021, the Supreme Court of Washington ruled the state's felony strict liability drug possession law was unconstitutional (State v. Blake, 2021). Subsequently, the legislature replaced that law with a misdemeanor provision but also enacted a substance use recovery services plan and a preference for diversion rather than arrest (WA SB 5476 (2021-22)). Following the approval of a ballot initiative Oregon went further, decriminalizing low-level drug possession and instituting a "ticketing" system of fines that are waived if a health assessment is completed (OR SB 755 (2021 Regular Session)).

Construct Harm Reduction Systems

Currently OUD harm reduction is defined by W-G barriers and misalignments — but what happens if you take those away? What's left? The federal government funneling money to state purchases of naloxone? States supporting non-profit community SSPs and eventually OPCs? However, a collection of programs is not a system. Neither is it sufficient to nominate (our still inadequate) access to treatment and recovery services. Of course, harm reduction services (syringes, HIV-testing, police deflection programs, etc.) increasingly are recognized as non-stigmatizing entry points for some health care services and products and as pathways into treatment (US Department of Homeland Security, 2022). Some harm reduction programs such as syringe services are becoming increasingly medicalized, providing naloxone and buprenorphine, and engaging

their clients in support services. Parallel lessons have been learned by those rooted in the treatment domain. First responders now carry and administer naloxone and, increasingly, emergency department interventions are being reevaluated as being more than lifesaving but as opportunities to move patients toward treatment with, for example, early initiation of buprenorphine. Providers are also acting more like harm reduction services, meeting those who need treatment outside of traditional health care facilities through the use of community mobile crisis intervention or rapid response teams (Weiner, 2022).

However, fundamentally a harm reduction frame is different and accepts that the treatment gap between those with SUD and those being treated is not simply or even primarily caused by unaffordable or unavailable treatment services. People who use drugs are exercising choices. Modern harm reduction was founded during the identification of HIV/AIDS in the 1980s. Then, as now with OUD, treatment access or prevention were not the only priorities, with illicit conduct, stigma, and a lack of trust muddying the waters. OUD harm reduction strategies can mitigate or reverse those concerns, including but not requiring nudging people who use drugs towards treatment (The White House Executive Office of the President, 2022). Harm reduction also rejects the binaries that populate treatment (recovery vs. relapse) or the justice system (lawful vs. unlawful). The lessons learned from HIV/AIDS are that harm reduction should not be judgmental about drug use and must be prepared to meet people who use drugs where they are, psychologically and geographically. Today, we should design coordinated services that "[e]nsure and improve the health and wellness of people who use opioids and other drugs" (Washington State Health Care Authority).

According to a recent New York Times (2023) editorial:

In the United States, syringe service programs and would-be supervised consumption sites have largely been left on their own, forced to design vital public health programs from scratch, then operate them in a legal morass, with little guidance or support. The Office of National Drug Control Policy could help if it worked to stitch organizations together into a national network, bound to a set of standards and guided by the same policies and procedures.

Indications of what a national harm reduction system could look like have come from jurisdictions that have moved the closest to decriminalization. Washington State has favored a system designed to move people toward treatment and recovery through a substance use recovery services plan designed to pull together existing and newly funded state resources. Although treatment and recovery oriented, the plan is notable for its emphasis on inclusion and lived lives together with plans for recovery housing,

transport assistance, and education and employment pathways (WA SB 5476 (2021-22)). Oregon's reforms have gone further with a network of Behavioral Health Resource Networks (BHRNs), entities or groups of entities to be established in every county and tribal area (OR SB 755 (2021 Regular Session); Russoniello et al., 2023). Services are provided free of charge using a payer of last resort model and include screening, individualized intervention plans, case management, harm reduction, peer support, and housing (Oregon Health Authority, 2023). We must radically increase our funding of harm reduction, embracing increased and additional services such as OPCs and pathways to treatment and make progress against persistent social determinants of health such as homelessness and unemployment.

Conclusion

It's time to end the blunt disagreements over harm reduction policies and implementation strategies that exist at every level of government and between government and citizens to enable horizontal and vertical W-G in the harm reduction space. Public safety and public health must cease being confrontational. The overwhelming priority is to allow harm reduction to do its job without undue interference from contrary federal policies, inconsistent state laws, and structural barriers. However, in parallel, additional consideration must be given to more effective leadership, far more responsive funding mechanisms, and the construction of harm reduction systems. •

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ABOUT THE AUTHORS

Nicolas Terry, LLM is the Hall Render Professor of Law at the Indiana University Robert H. McKinney School of Law and executive director of the Hall Center for Law and Health.

Scott Burris, JD is a professor at the Temple University Beasley School of Law and College of Public Health and director of the Center for Public Health Law Research.

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Center for Public Health Law Research

Whole of Government, Society and Person

THE LEGAL PATH TO A WHOLE OF GOVERNMENT OPIOIDS RESPONSE: PART 6

November 2023

Scott Burris, JD Nicolas Terry, LLM

Executive Summary

Having a drug problem is not just about the drugs. A person with an opioid or other substance use disorder may have many other challenges as well as countervailing strengths and resources for coping and returning to full well-being. A strong, well-coordinated public response to substance use disorder (SUD) and overdose considers the whole person involved and aims to address all their challenges and support all their strengths. Effective drug treatment is important to recovery, but so are housing, a vocation, family ties, community reintegration, and a sense of hope for the future. Likewise, dangerous drug use is not simply an individual failing. The United States has an unparalleled rate of drug use and drug death, which can only be properly understood as reflecting conditions in our whole society. Overcoming unhealthy drug use in America requires Whole of Government action across domains of health care, drug policy, public health, housing, education, economic development, and tax policy to change the social conditions that impel too many people into risky and selfharming behavior. In this final paper in our series, we turn to the question of how social structural factors influence the opioid epidemic — and what law can do about them.

Introduction

So far, the reports in this series have addressed the many ways law can get in the way of (or support) a "Whole of Government" (W-G) response to substance use disorders and drug overdose. W-G is shorthand for broad efforts that are well-coordinated. Looking beyond better cooperation between health and criminal justice agencies explicitly tasked with drug-related work, W-G points to other sectors like housing, education, social support, and economic development as having important contributions to make. In that way, W-G also widens the lens on the opioid crisis; it points to the deeper social drivers of unhealthy individual drug use — such as economic and racial inequality — and to the broader set of challenges individual drug users face — homelessness, inaccessible mental health care, criminal

records — as they struggle with dangerous drugs and substance use disorder. In this final paper in our series, we turn to the question of how social structural factors influence the opioid epidemic — and what law can do about them.

We begin by introducing a simple framework showing how a Whole-of-Government strategy can support action addressing both the Whole Person and the Whole Society. We then show how a Whole Person approach recognizes that individuals with SUD are more than just their diagnosis: they have a broader range of needs that may interfere with their recovery and important capacities that may support it; the tools of law can be used to support comprehensive and flexible responses that can work with people in all their complexity. Looking beyond the individual, we then show how a Whole Society approach looks upstream at how our social and economic conditions produce so much downstream SUD, and how law can both change unhealthy structural factors and reduce their negative effects.

SUD: Seeing the Whole Person in the Whole Society

A person who has been using opioids unsafely for a while is not just at risk of overdose, and they don't just have a drug problem. Their use could be causing, or be caused by, untreated mental illness. Their mental illness could be related to economic distress: not having a job or worrying about money — or adverse child experiences visited upon them by parents facing these kinds of troubles. Chances are, if they are having money problems, they are having housing problems, or they have lost their housing, and all that will be complicating or sundering their social support networks. If some part of their identity — their race, class, gender identity, disability, sexual orientation — is stigmatized along with their drug use, they will be facing rejection and blame as they seek help and support. If they have been using drugs for a long time, they likely have multiple health problems from hepatitis to serious

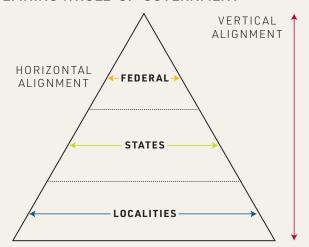
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wound infections, and they also probably have some record of police involvement, maybe even convictions that bar them from certain housing and other benefits. Providing that person with a slot in drug treatment, no matter how effective that treatment mode is, will not address the other problems that have gotten them into or helped keep them in a chronic pattern of unhealthy drug use. This person doesn't just need treatment — they need an intervention approach that aims to deal with all their interlocking challenges and the resources of strength and resilience that have kept them going this long — a response that addresses the whole person, not just the drug user.

The idea of "whole person health" (also called "whole health" or "whole person") has been gaining traction for some time. It may be defined as "an approach that considers multiple dimensions of the patient and their context, including biological, psychological, social, and possibly spiritual and ecological factors, and addresses these in an integrated fashion that keeps sight of the whole" (Thomas, Mitchell, Rich, & Best, 2018). Promoting this approach, Surgeon General Vivek Murthy has emphasized "providing the tools and resources that individuals and communities need to face today's challenges before they develop downstream consequences" (Murthy, 2023). The approach is applicable to any condition, from diabetes to hypertension, because no person is just their disease and even something as theoretically simple as adhering to a medication plan actually depends on all sorts of contextual factors driving the patient's behavior. A whole person viewpoint also recognizes that people using drugs also have something to contribute to their own health and that of others. Current and former drug users have long taken active roles in treatment (e.g., 12 step and other peer recovery support models (Eddie et al., 2019)) and harm reduction (Kerr et al., 2006), and it important to see past the stigma to the many strengths, forms of expertise and motivation that drug users can contribute.

Like people with SUD, the United States doesn't just have a drug problem. The United States has far more people suffering from their drug use than peer countries (Baumgartner, Gumas, & Gunja, 2022; Ho, 2019). Looking at the country invites the same sort of inquiry as a look at the individual: what else is going on? Why is there so much more drugrelated mortality here than anywhere else? The flood of oxycodone that pharma companies unleashed under lax Food and Drug Administration (FDA) and Drug Enforcement Agency (FDA) oversight was a uniquely United States factor but doesn't explain why the country was so vulnerable or why the crisis persists. The individual risk factors do provide a guide to other social drivers or the way our society is organized in ways that make it so hard for people to be healthy (Galea & Vlahov, 2002; Link & Phelan, 1995).

DEFINING WHOLE-OF-GOVERNMENT



Through the Whole-of-Government approach, we gain an improved understanding of the design and implementation of conventional drug policy. The W-G perspective provides both a lens through which to critique current levels of alignment and misalignment between different levels of government or agencies at the same level, and a normative tool designed to structure reforms. What is required for effective policy making is comprehensive, coordinated government action across the different agencies at one level of government (be it federal or state), what we term horizontal W-G, and between different levels (federal, state, tribal, and local), what we term vertical W-G.

People feel stress, depression, and anxiety because, for too many, America has become a very hard place to thrive. Chronic stress is a predictable problem in a country where people can work 40 hours each week and still not make enough money to address their basic needs, where their working hours are unpredictable and their housing takes half their pay or more, and where their kids are not safe at school. They may be in despair about what has happened with their communities, cut off from their neighbors and worried that nothing can get better. People facing serious stress or mental illness have trouble getting mental health care because they live in a place with a broken mental health system. Feckless politicians are whipping up anxiety about just about every aspect of society, and undermining trust in government. Meanwhile, a culture of blame and stigma persists about substance use disorders, in which the barriers and challenges people face are projected onto them as moral failings, poor decisions, or racial or class characteristics. These attitudes become justifications for social inaction and disdain. Recognizing that the whole

society can and should make changes points to legal levers we can pull to address the social factors that drive what have been aptly called "deaths of despair" (Case & Deaton, 2021).

This big picture can feel overwhelming. It is hard enough to provide basic health care and drug treatment for people at risk of overdose. How can health, social service, or criminal justice workers deal with so many other problems for an individual patient, let alone change society? These are hard questions, and despite the broad impact of the "deaths of despair" research on how people think about the crisis, many experts write off action addressing social factors as unlikely to make a difference (Humphreys et al., 2022). That's wrong, both morally and practically.

We think Americans can and should take on the social drivers of our opioid problem for two very good reasons. First, it is possible to treat each patient as a whole person and deal with the broader set of challenges they face. That's how many of our peer countries manage drug problems, and how many health care providers and social workers try to work in spite of our uncooperative health care and social service systems (Bourgois, Holmes, Sue, & Quesada, 2017). We will highlight a whole set of actionable policy changes already referenced in other reports in this series that can help the health system treat the whole person and also begin to reduce the structural pressures on people that drive unsafe opioid use. The second reason is even simpler: if the health system and policymakers don't start to methodically address the root causes of our opioid epidemic, with individual patients and with our whole

society, the United States will continue to fail to stem the tide of drug-related harm. No amount of dealing with symptoms will be as effective as preventing the disease in the first place. Even the objection that changing social determinants will take too long fails when we consider that we have been throwing resources at symptoms for more than two decades without success.

Whole Person: legal responses to complicated people with multifaceted challenges

A whole person strategy for SUD recognizes that every person whose substance use threatens their health has their own set of intersecting risk factors, including their genes, their socioeconomic position, their race and gender expression, their state of overall mental health, and the conditions of the markets where they get their drugs. Health care providers, social workers, police, prosecutors, and judges all have the opportunity to engage, but unfortunately a whole person approach can be difficult to put into practice in our fractured health and social services system. Doctors don't normally provide housing. Judges don't have jobs to offer, nor police officers food stamps to distribute. From the W-G perspective, many simple steps like "prescribing" housing for SUD patients or providing safe injection spaces — are often not authorized or downright illegal. More broadly, the many systems and agencies that need to work together are not doing so; changing the law won't remove all the barriers, but it can help.

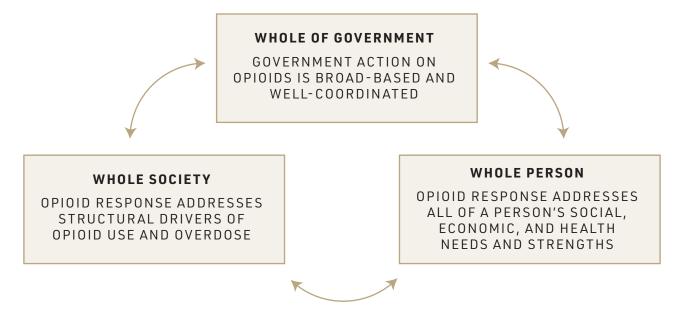


Figure 1: The Whole Picture

Other papers in this series have highlighted ways that reforms to improve W-G coordination can enhance the capacity of our health care system to address the whole person. These include, for example:

- Building a new Ryan White-like funding model that gives providers the resources they need to comprehensively treat all a patient's needs, including housing, nutritional supports, and other care coordination not traditionally provided through Medicaid.
- Removing regulatory restrictions that limit methadone treatment in all relevant care settings, including allowing licensed physicians to prescribe methadone and reforms to make a default "takehome" approach to methadone maintenance treatment.
- Make telehealth for medication for opioid use disorder (MOUD) a fully accepted mode of access.
- Removing legal barriers to comprehensive overdose prevention centers so that people not only have sterile equipment for drug use but also a safe place to consume their drugs.
- Amending laws and changing implementation practices to prevent child welfare laws related to drug use during pregnancy from being a barrier to prenatal or other treatment for drug users who are pregnant.
- Expanding Medicaid everywhere so people with or at risk of developing substance use disorders have access to behavioral health, pain care, and SUD treatment as needed.
- Change Medicaid enrollment rules and practices so that eligible people can get covered quickly (including people going in and out of incarceration) and stay covered without bureaucratic interruptions.

The US health care system is largely made up of private rather than government providers and institutions, a major cause of care fragmentation (Terry, 2020), particularly for people with dual diagnoses of mental illness and SUD (Anthony, Catterson, & Campanella, 2021) and a major hurdle for a Whole of Government approach to improving treatment. Although our health care institutions are largely private, a W-G lens can still help us see ways that law can improve the incentives for coordination and cooperation in health care, and not just with other providers but also social services. For example, Patient-Centered Medical Homes, encouraged by Section 2703 of the Affordable Care Act, have the potential to improve behavioral health integrated care (Kessler et al., 2014). Medicaid Section

1115 waivers that promote coordinated care between public carceral facilities and private Medicaid managed care providers have considerable potential (Centers for Medicare & Medicaid Services, 2023), as do a raft of other Section 1115 waivers that states can apply for to demonstrate the potential for improving care coordination and upstream determinants (Kaiser Family Foundation, 2023).

A whole person approach doesn't just require change in the health system; it requires changes in attitudes, too. One cannot treat the whole person until one sees — and accepts — the whole person. There is room for innovation in health care, such as deploying tools like the medical vulnerability assessment questionnaire (Bourgois et al., 2017) to help clinicians and social service providers recognize broader vulnerabilities and manage the biases that lead to racial and other disparities in care. But law has played an important role in perpetuating negative, stigmaridden visions of people who use drugs.

Criminalization of drug use and the stigma, moralizing and blame it embodies certainly has influenced the way health and social service providers see and interact with drug users (Muncan, Walters, Ezell, & Ompad, 2020; van Boekel, Brouwers, van Weeghel, & Garretsen, 2013). As NIDA Director Nora Volkow has written, "Punitive policies around drugs mark people who use them as criminals, and so contribute to the overwhelming stigma against people contending with an often-debilitating and sometimes fatal disorder..." (Volkow, 2021).

Decisively rejecting criminalization would be a giant step toward better treatment of people who use drugs (Dasgupta, 2023; Gottschalk, 2023). It can start with de facto decriminalization through decisions not to make arrests or prosecute cases for minor drug possession offenses (Del Pozo et al., 2021; Stevens, Hughes, Hulme, & Cassidy, 2022), and reforming child welfare laws and enforcement so that pregnant drug users are not afraid to seek prenatal and other care (McCourt et al., 2022).

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Signaling a step back from arrest is also important to remove barriers to accessing services like syringe exchange, and to create sufficient social space to allow the founding and operation of drug user-led organizations like the Vancouver Area Network of Drug Users and Vocal NY User's Union.

Laws that remove barriers to government benefits and services can give willing providers tools to help the whole person and can remove the barriers that make holistic treatment difficult or impossible. Removing restrictions on services like housing for people with a record of drug law violations would make it that much easier for care providers to help meet those needs. Federal regulations for public housing still mandate denial of housing for current drug users, without any finding that the drug use is causing harm to others or the premises; the same rules bar people who have been evicted for drug use in the past three years, regardless of whether they were causing problems in the first place or have recovered from a substance use disorder (24 CFR §982.553). These regulations are broadly written, for example not defining the time limits of "current" drug use, and leave considerable discretion for local housing agencies to make stricter rules (Purtle et al., 2020). The Department of Housing and Urban Development has stated denying housing purely on the basis of a criminal record violates the Fair Housing Act (McCain, 2022), but many local public housing agencies have a long way to go to implement this guidance (Muñoz-Jones & Widra, 2023).

Pardon or expungement of past drug law convictions is another way to help, since a criminal record can be a disqualifier for various jobs and licenses, including, ironically, a license to run a commercial cannabis business (Yang, Berg, & Burris, 2023). In 2022, President Biden issued a blanket pardon of federal convictions for simple cannabis possession (The White House, 2022). That was an important gesture, but most such convictions arise under state law, and more than half the states have yet to do the same. Even in the states that have, the ease of the process (and so impact) vary. For maximum impact, the process should be universal, automatic, and not require any action or request from the person being cleared. New York's cannabis decriminalization law included automatic expungement for convictions arising from possessing up to 16 ounces or selling up to 25 grams of cannabis (N.Y. Crim. Pro. § 160.50 (McKinney 2021)) and a process to through which individuals can seek to havee other convictions vacated or dismissed (N.Y. C.P.L Law § 440.46(a) (McKinney 2021)).

There is no overstating the moral and practical imperative to help individuals deal with their full range of problems, but in the larger perspective this will never be a substitute for creating communities where people have fewer problems in the first place. That's why we conclude with an exploration of the relationship among social determinants of health, structural factors, W-G approaches, and the law.

Law in a Whole Society Response

Drug use and its patterns of harm in America reflect the state of the society (Galea & Vlahov, 2002), and law has an important place in the whole society picture. Law is a key mechanism through which power, wealth, income, and education are allocated in society, and then law operates every day to sort people to different exposures and protections based on their social position (Burris, Kawachi, & Sarat, 2002). The growth of economic inequality in this country over the past half century has been caused in significant degree by legal changes: in the tax code, which became drastically less progressive and redistributive; in labor law, which has become far less enabling of union organizing and collective bargaining; and in election law, which has allowed the steady expansion of gerrymandered, "safe" districts that do not reflect the diversity of populations or political views (Peterson Institute for International Economics, 2020). There is increasing evidence of the broad impact of politics and policies on health and well-being — and vice versa. Egalitarian policies, more progressive health and social welfare systems, strong labor influence, and well-functioning democratic life all go together (Chung & Muntaner, 2006; Jennifer Karas Montez et al., 2020; J. K. Montez, Cheng, & Grumbach, 2023; Jennifer Karas Montez et al., 2022; Muntaner et al., 2011; Navarro et al., 2006; Raphael & Bryant, 2004; Wilkinson & Pickett, 2009; D. A. Wolf, Monnat, & Montez, 2021; D. A. Wolf, Montez, & Monnat, 2022).

Law visits harm on people both directly and by omission. Arrest and incarceration are characteristic traumas regularly visited on people who use drugs, but law also does harm by failing to take action to reduce vulnerability and forestall harmful behavior by others. Princeton University sociologist Matthew Desmond has recently made the case powerfully that one of the ongoing forces maintaining people in poverty is common, if not systematic, economic predation on the poor through conditions law can address, like exploitative rents, predatory lending, and relentless court fines and fees (Desmond, 2023).

Law operates actively to create vulnerabilities and sort people to differing exposures and outcomes based on their social position. Law constituted chattel slavery, and ever since has been consistently used in ways that re-subordinate or undermine economic and educational opportunity for Black people (Alexander, 2010; Blackmon, 2008; Rothstein, 2017). Race was behind the US decision to reject universal health care after World War II and one of the reasons that so many were excluded when Medicaid

was enacted into law. Ten states continue to reject Medicaid expansion for the same reason the Affordable Care Act of 2010 became politically toxic — most of the newly insured would be Black people (Grogan & Park, 2017; Lanford & Quadagno, 2016; Jennifer Karas Montez, 2020).

Drug laws apply to all users of controlled substances, and drug use is not dramatically skewed by race (Substance Abuse and Mental Health Services Administration, 2021), but race and class consistently shape who is subject to arrest and incarceration (Tiger, 2017). School discipline systems apply to all pupils, but for Black students discipline tends to be harsher — harsh enough to interfere with educational success and launch children into a "school to prison" pipeline (K. C. Wolf & Kupchik, 2016). Books like Richard Rothstein's "The Color of Law" powerfully depict the continuing intergenerational consequences of policies like mortgage red-lining and discrimination in housing in the form of lost chances for Black families to build intergenerational wealth that post-war federal lending programs seeded for white families only (Rothstein, 2017).

As these examples suggest, "social determinants of health" or structural factors" or "social position" — by whatever name — are not distant, abstract untouchable verities: they are vulnerabilities and exposures, and immunities and advantages – that happen to people every day. They have their effect on health and well-being in the day-to-day experiences that grind people down or lift them up. Laws and their enforcement are part of that web of experiences, and that means that policy change can lead to substantial and rapid improvement. We run through a set of examples here that make the case that legal action is a very practical way to act now to create healthier environments for humans.

Money is an effective short-term treatment for poverty

Poverty is bad for health generally (Brady, Kohler, & Zheng, 2023), but there is compelling evidence that income support mechanisms that put more money into the pockets of lower income people make their lives and health better. Legal epidemiology research over the past five years has shown positive health effects for a variety of programs:

- Temporary Assistance for Needy Families (TANF) is associated with a reduction in child maltreatment (Spencer et al., 2021).
- Minimum wage increases reduce suicide rates (Kaufman, Salas-Hernández, Komro, & Livingston, 2020), STI incidence (Ibragimov et al., 2019), HIV cases (Cloud et al., 2019), heart disease (Van Dyke, Komro, Shah, Livingston, & Kramer, 2018), and infant mortality and low birthweight (Komro, Livingston, Markowitz, & Wagenaar, 2016).

- The earned income tax credit (EITC) improves birth outcomes, and more generous EITCs have a greater effect (Markowitz, Komro, Livingston, Lenhart, & Wagenaar, 2017).
- The expanded Child Tax Credit provided during the COVID-19 pandemic increased food sufficiency and improved mental health among adults with children, and the effect was strongest among the most marginalized groups (Batra, Jackson, & Hamad, 2023).

A recent experiment with a \$500/month guaranteed income in Stockton, California, explored how economic security improves quality of life: compared to the control group, people receiving the guaranteed income "reported lower rates of income volatility ..., lower mental distress, better energy and physical functioning, greater agency to explore new opportunities related to employment and caregiving, and better ability to weather pandemic-related financial volatility" (West & Castro, 2023). These are the typical stress-related phenomena that wear people down and drive deaths of despair (Geronimus, 2023) and health research illustrates what should be obvious: if economic distress causes a wide variety of harms, its absence should be associated with the absence of those harms.

The COVID-era expanded Child Tax Credit (CTC) provided a natural test of government's capacity to rapidly provide economic assistance at a large scale. The credit expanded eligibility to families with little or no income, benefitting the poorest families and making its distribution more racially equitable. It was unrolled rapidly, using 2019 and 2020 tax records to determine eligibility and directly deposit the credit on a monthly basis. In its first six months, nearly more than \$90 billion went to millions of households, lifting 5.3 million people out of poverty, including 2.9 million children (Burns & Fox, 2022). In politics, the effort to make this highly effective program permanent ran into dubious assertions that it would reduce the incentive for people to work and politicians who were shocked, shocked at the estimated \$12 billion cost of making the regular \$2,000 tax credit fully refundable to people with low or no incomes. As Desmond is the latest to make clear, however, the richest country in the world has the money to address poverty. For example, the home mortgage interest deduction still costs over \$20 billion and lifts no one out of poverty.

Law can protect the poor from economic exploitation

One of the reasons that it is better not to be poor is that being poor in America exposes people to near constant risk of some business or government agency taking away the little they have. Poorer people need credit as much or more than the better off, but face "predatory lending" — a variety of lending devices and practices, including making loans to borrowers that they probably cannot afford to repay; inducing a borrower to repeatedly refinance a loan in order to charge additional fees; and concealing the true nature or terms of a loan (Pew Charitable Trusts, 2023). Payday loans are a frequently used form of shortterm credit, with 12 million borrowers every year (Pew Charitable Trusts, 2013). Payday loans are expensive, so borrowers often end up spending more in interest and fees than they borrowed in principle. States can protect consumers from exaggerated interest rates and unfair terms, and some have (Pew Charitable Trusts, 2023). The same goes for bank overdraft fees as a routine resort for short-term credit, which tend to be even more expensive than payday loans (Zernik, 2018), but can be regulated by states (e.g., N.Y. COMP. CODES R. & REGS. tit. 3 §§ 32.1-32.2 (2019)).

Being poor, especially a poor person of color, means that too often financial deprivation comes in the form of an encounter with the police or other government authority. The imposition of legal financial obligations, which include fees, fines, and bail, in connection with criminal justice charges or civil offenses has become a widespread phenomenon in the United States (Martin, Sykes, Shannon, Edwards, & Harris, 2018). Municipal offenses like traffic and "quality of life" violations can have significant economic city operations. In 2015 the Justice Department found that in Ferguson, Missouri, "revenue generation is stressed heavily within the police department, and that

the message comes from City leadership" (United States Department of Justice & Civil Rights Division, 2015). Using poor people as municipal ATMs is unjust (and, it seems, fiscally unwise (Menendez, Crowley, Eisen, & Atchison, 2019)). States can stop these practices through legislation, and some have (Fines and Fees Justice Center, 2022).

A wide range of reforms can make judicial and administrative processes fairer and less harmful to lower income people. Some of these laws include provisions capping fine amounts (e.g., MO. ANN. STAT. § 479.353 (West, 2019)); prohibiting court costs for indigent defendants (CAL. PENAL CODE § 688.5 (West, 2019)); requiring the reinstatement of drivers' licenses that were suspended for failure to pay certain fees or fines (D.C. Code Ann. § 50-2302.08 (West, 2018); allowing waivers or reduced fees or costs for low-income individuals (WASH. REV. CODE ANN. § 10.01.160 (West, 2023)); allowing participation in community service as an alternative to paying fees or fines (TEX. CODE CRIM. PROC. ANN. art. 45.049 (West, 2019)); and allowing installment plans (TENN. CODE ANN. § 55-50-502 (d) (West, 2022)). Rhode Island eliminated costs, assessments, and fees for people serving 30 or more days in prison, along with waiving or reducing court costs based on indigency (12 R.I. Gen. Laws Ann. 18-1-3 (West, 2022). Although two cities experimented with the idea several decades ago, as far as we can determine no US jurisdictions have adopted the European model of "day fines," in which monetary penalties are set in terms of a number of days of the offender's annual income (Kantorowicz-Reznichenko, 2018).

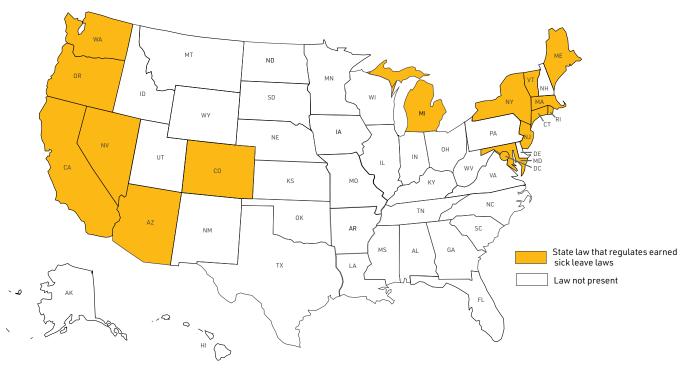


Figure 2: As of January 1, 2021, 16 jurisdictions have a state law that regulates earned sick leave (LawAtlas, 2021).

More progressive tax policies can fund the social investment we need to eliminate "deaths of despair" and promote the welfare of everyone

Tax policy is at the center of many of the factors that drive deaths of despair or make them harder to address. Local governments are strapped, which is why they are tempted to fund their operations with fines and fees. In many state governments, "fiscal hawks" committed to smaller government and lower taxes hold sway (Kemp, Grumbach, & Montez, 2022; Jennifer Karas Montez, 2020). Our health and social service system are coping with everlarger problems with smaller and smaller budgets. Proven mechanisms for reducing poverty and its many perils for people and communities can't be expanded because current revenue cannot support them. But the fact that money is not in agency budgets or legislative coffers does not mean that the United States is too poor to end poverty and severe financial hardship. On the contrary. The money is there, and a renewed willingness to raise the revenue needed to solve problems is the main barrier to action.

Matthew Desmond offers a concise but telling list of how tax reform could bring an actual end to poverty in America (Desmond, 2023). He starts with the cost, which he puts loosely at \$177 billion per year. Then he lays out what we would get, which would include more generous funding for the sort of income transfer programs we already know work, but also real progress toward ending homelessness and eviction, schools that were not preoccupied with caring for traumatized and needy children, and more stable and safe neighborhoods. And finally, the question of where to find the money. Nearly \$200 billion sounds like a lot, but he notes that the "IRS now estimates that the United States now loses more than \$1 trillion a year in unpaid taxes, most of it owing to tax avoidance by multinational corporations and wealthy families." Over the past 60 years, the progressivity of our income tax has narrowed dramatically, and as it has done so the tax rates paid by the poor have gone up and the taxes paid by the rich have gone down. Just uncapping the amount of income liable to the Social Security tax would produce \$64 billion. Imagine if we treated capital gains just like ordinary income? We've already noted the \$25 billion that could come from ending the home mortgage interest deduction. Another useful comparator is the sort of tax breaks for corporations regularly on the agenda in Congress, which the Center on Budget and Policy Priorities has costed out at \$15 billion/ year (R & D breaks), \$33 billion/year (full expensing of equipment), \$20 billion/year (greater deductibility of interest payments) (Cox, Marr, Calame, & Hingtgen, 2023).

Before the reader writes this off as hopelessly idealistic and unrealistic, just recall the expanded Child Tax Credit, which effectively spent more than \$90 billion in less than a year and made an immediate difference in millions of people's lives. It can be done, and it makes everyone — even those who pay higher taxes — better off.

Across all policies, prefer the humane, equitable, and supportive over the punitive and deregulatory

Along with the strong evidence that inequality is bad for health (Wilkinson & Pickett, 2009), we have seen a growing body of research suggesting that policies focused on broadly supporting social welfare seem to be associated with higher levels of generalized social welfare (Chung & Muntaner, 2006; Muntaner et al., 2011; Navarro et al., 2006). In the United States, new research has brought strong support to a rather simple and obvious idea: if you want your community to thrive, then use law and policy to protect residents from unhealthy exposures, support them in times of trouble, and smooth the path to education, work, and stable housing in communities equipped with parks, transportation, shops, and the other basic amenities of comfortable life. (Oh, and democracy also matters; places that look like this also tend to be places where people feel they have a real say in the workings of government (J. K. Montez et al., 2023).) We've already reviewed the evidence of how specific income support programs improve health, but a recent series of studies led by Jennifer Karas Montez has shown the drastic differences in health between the places that follow this approach and the places that veered toward passive government and commercial deregulation (Jennifer Karas Montez, 2017; Jennifer Karas Montez et al., 2020; Jennifer Karas Montez, Hayward, & Wolf, 2017; Jennifer Karas Montez, Hayward, & Zajacova, 2019; Jennifer Karas Montez et al., 2022; Jennifer Karas Montez, Zajacova, et al., 2019; D. A. Wolf et al., 2021; D. A. Wolf et al., 2022). The dramatic declines in life expectancy in the United States are not the result of a nationwide decline: states with more supportive social policies have continued to see their life expectancies increase; declining "national" life expectancy is concentrated in places that are tougher to live in. Since 1984, the gap between the best and worst states for life expectancy has increased from less than five years to seven years (in 2017). And there's a pattern: generally speaking, states that have become more conservative across a wide range of policies have seen life expectancy stagnate or decline; those that have moved or remained on the more progressive side have seen their life expectancies improve. Take for one example the difference between Connecticut and Oklahoma, which had the same life expectancy in 1959 (71.1 years), but by 2017 were five years apart (80.7 in Connecticut versus 75.8 in Oklahoma) (Jennifer Karas Montez et al., 2020).

The list of policies included in the analysis is long and ranges broadly, including abortion, criminal justice, gun control, "health and welfare" (such as CHIP access and Medicaid expansion), education spending and school choice, public and private labor laws (e.g., paid leave, minimum wage, right to work), civil rights protections, environment (including state NEPAs and solar tax credits), tax laws (progressivity and credits), housing and transportation, and a miscellany of protective measures like smoking controls and motorcycle helmet requirements. Across the board being more protective or supportive is tied to longer lives. People are healthier when it is harder to get guns, easier to get an abortion, taxes are more steeply progressive, tobacco controls are more protective, workers have more rights, and people are better protected against discrimination based on race, sexual orientation, or other traits.

Of course, the story is not quite as simple as "red states bad, blue states good." There are important stories about education policy and NIMBYism in these data, too. More educated people do better regardless of state, and so big metropolitan areas with lots of highly educated residents do well even when their state overall is going down — and individuals' education advantages give them what Montez called "a personal firewall" against contextual factors like state policy (Jennifer Karas Montez, Hayward, & Zajacova, 2021). Less educated people lack this protection, and so are more powerfully affected by the policy conditions of the places they live. In states red, blue, and purple, educated, well-off people use their political and economic resources to block efforts to build affordable housing and transportation systems that would benefit those with fewer resources.

The bottom line is the same as the top line: as a general matter, legislators at any government level looking to improve overall health in the community should aim to use law and policy to protect residents from unhealthy exposures, support them in times of trouble, and smooth the path to education, work and stable housing in communities equipped with parks, transportation, shops and the other basic amenities of comfortable life.

Finally, pursue equity and racial justice

Law has been a persistent mechanism of discrimination, producing severe and chronic health disparities and inequities. And yet for decades now, American law has forbidden the sort of de jure discrimination exemplified by policies like Jim Crow and red lining. Yet, notwithstanding the Supreme Court's insistence on a "colorblind" Constitution ("Students for Fair Admissions, Inc. v. President and Fellow of Harvard College," 2023), facially "neutral" laws continue to be applied in ways that discriminate based on race, sexual orientation, and other aspects of people's identity.

The pervasive and continuing inequitable application of law, whether intentional or inadvertent, requires explicit, self-conscious action by both advocates and policymakers. Along with considering the evidence about how law causes harm and how changing law can create healthier conditions, one must also systematically explore how both problems and solutions may be operating inequitably. A guide for changemakers developed by ChangeLab Solutions succinctly sets out some "best practices" (2019). These include recognizing fundamental drivers of health inequity (structural discrimination, income inequality and poverty, disparities in opportunity, disparities in political power and governance that limits meaningful participation), learning from the past and using that broad focus to guide all action for change.

Law can be deployed in ways that address all the drivers of inequity. Law is a basic way to make large scale change in social conditions, and to sustain those changes over time. It can stand as an important expression of a community's rejection of bias, injustice and unfairness. It can help us direct our attention to structural factors and not blame individuals or leave them to sink or swim on their own. It can be used, as we have detailed above, to change the distribution and use of money, opportunity and power. It can actively undo the harms policy has helped do in the past (ChangeLab Solutions, 2019; Coates, 2014), as Evanston, Illinois, has done with its reparations policy (City of Evanston, 2023). Desmond makes a powerful point when he argues that in the case of eliminating poverty, what's lacking is not the way, but the will.

Conclusion

The millions of people caught up in unhealthy drug use need effective government help now, and most of our project reports have gone into detail about how laws can be changed to remove barriers and increase concerted action across government lines today. But the United States has had a severe opioids problem for more than two decades, and it was not the first instance of widespread drug-related harm, so it has to be obvious that there are no quick fixes. Care and support for individuals will be more effective if they embrace the whole person, both their needs and capacities, but responding to immediate needs is not stemming the flow of new people into trouble. Root causes must be addressed - but defining the root causes of the problem as drug trafficking and drug use has also failed. If the nation wants things to change with substance abuse, things that make people vulnerable to the harm will have to change. The United States has work to do to become a place where everyone not only has no reason to use drugs dangerously. but also many good reasons not to. There is much that legal change can do to start this process of national reinvestment in the needs and welfare of all its people. •

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ABOUT THE AUTHORS

Scott Burris, JD is a professor at the Temple University Beasley School of Law and College of Public Health and director of the Center for Public Health Law Research.

Nicolas Terry, LLM is the Hall Render Professor of Law at the Indiana University Robert H. McKinney School of Law and executive director of the Hall Center for Law and Health.

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