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HEALTH CARE NEWS

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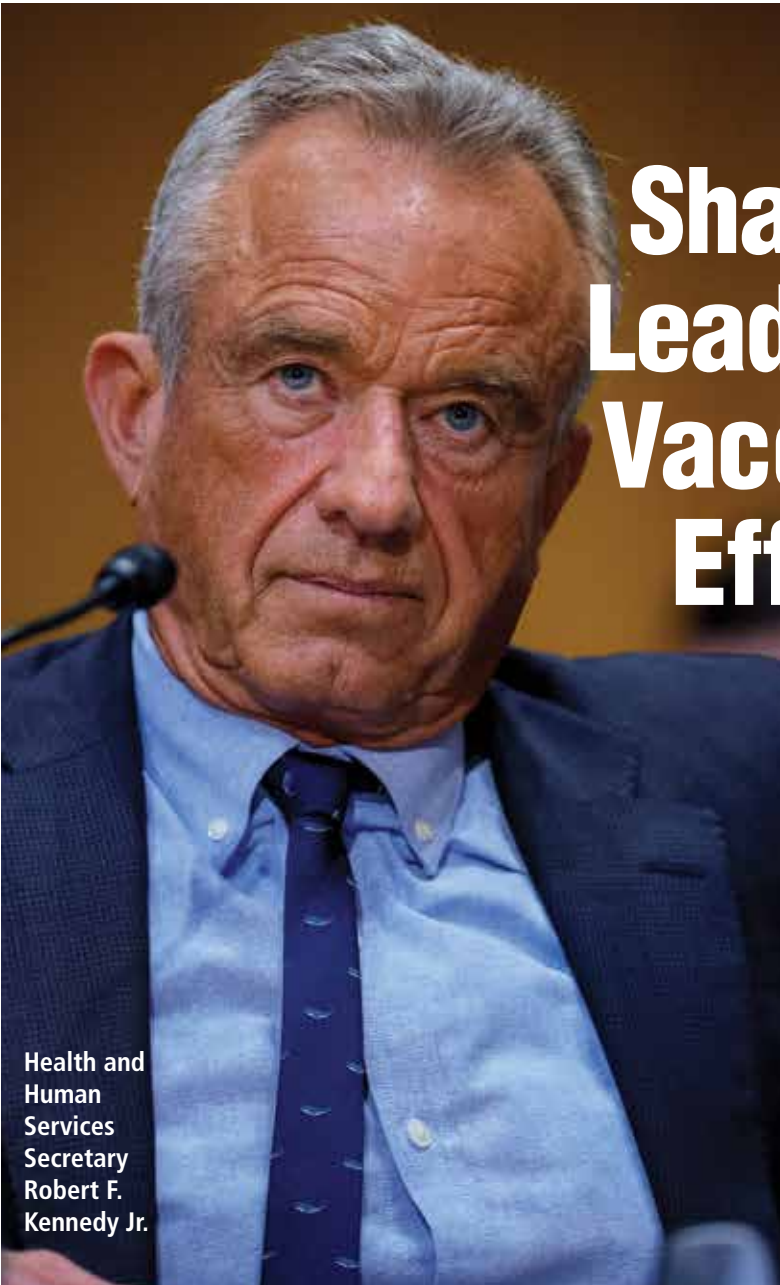
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Kennedy Shakes Up CDC Leadership Over Vaccine Safety, Efficacy Proof

By Kevin Stone

Major changes are underway at the Centers for Disease Control and Prevention (CDC) following the dismissal of director Susan Monarez and the subsequent resignations of four senior officials in protest over the removal of Monarez.

Health and Human Services (HHS) Secretary Robert Kennedy Jr. dismissed Monarez on August 27.

Resigning were the chief medical officer and deputy director for programs and science, Debra Houry; director of the National Center for Immunization and Respiratory Diseases, Demetre Daskalakis; director of the National Center

CDC SHAKEUP, p. 4

Health and Human Services Secretary Robert F. Kennedy Jr.

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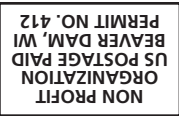
FDA Halts, Then Resumes Gene Therapy After Three Deaths

By Kevin Stone

After the deaths of three patients, the maker of an investigational gene therapy stopped shipments of the drug after refusing a request from the U.S. Food and Drug Administration (FDA) to pull the drug from the market.

Elevidys, made by Sarepta Therapeutics, is the first gene therapy treatment for Duchenne muscular dystrophy (DMD). The patients who died after taking the drug suffered

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they own and control

1

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again

2

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the retirement age
without losing retirement
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3

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4

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Won't Enforce Short-Term Plan Restrictions, Trump Administration Says

By AnneMarie Schieber

Under the Department of Government Efficiency (DOGE) deregulatory initiative, the Departments of Labor, Health and Human Services (HHS), and Treasury are reviewing rules imposed by the Biden administration that restricted short-term, limited-duration insurance (STLDI) plans to four-month terms with no option to renew.

The departments will undertake the notice-and-comment rulemaking process to consider changes to STLDI, which takes at least 60 days.

"Until future rulemaking is issued and applicable, the Departments do not intend to prioritize enforcement actions for violations related to failing to meet the definition of 'short-term, limited-duration insurance' in the 2024 final rules, including the notice provision," a statement by the departments said.

Stranded Policyholders

The Biden rules hamstrung policyholders because if they got sick toward the end of the four months, a new policy would not cover the now-preexisting condition. Such policyholders would have to wait until November to purchase an Obamacare plan.

Because STLDI plans are exempt from coverage requirements under the Public Health Service and the Affordable Care Act, premiums cost on average \$151 a month. Consumers can purchase the plans in minutes.

During his first term, President Donald Trump issued an executive order allowing states to offer the plans for up to one year with an option to renew without underwriting for three years. In 2020, a U.S. Court of Appeals upheld Trump's rule change.

Plans That Work

Consumers purchase short-term plans for a multitude of reasons, says Kansas state Sen. Beverly Gossage (R-District 9), an independent health insurance consultant and agent.

"My clients who choose STLDI are typically middle-income, leaving an employer with coverage to be self-employed or to an employer with no health plan, a spouse of a Medicare beneficiary needing temporary coverage until they are eligible themselves, leaving a parent plan, or waiting for open enrollment of an ACA plan," said Gossage. "Usually, these folks need



"The impact of this announcement will be almost nothing," said Cannon. "No insurer is going to invest in better products, with more consumer protections, until the federal government formally changes the rules."

MICHAEL CANNON
DIRECTOR OF HEALTH POLICY STUDIES
CATO INSTITUTE

three months to three years of affordable coverage."

The Trump administration's decision not to prioritize enforcement of the Biden rules will come in handy for people who benefited from the STLDI rules during Trump's first term, says Gossage.

"They have the peace of mind in knowing even if they develop a costly health condition, they can stay on the plan without a premium increase and their plan will cover them since they are not subject to re-underwriting for up to 24 months," said Gossage. "And the policies save them 30 to 40 percent in premium, and sometimes a lower out-of-pocket than an ACA plan."

Confused Market

Although the announcement is encouraging, consumers should not expect a flood of short-term plan options right away, says Michael Cannon, director of health policy studies at the Cato Institute.

"The impact of this announcement will be almost nothing," said Cannon. "No insurer is going to invest in better products, with more consumer protections, until the federal government formally changes the rules."

Now may be a golden opportunity for STLDI reform, says Cannon,

"The Trump administration should go further than it did in its 2018 rule," said Cannon. "We learned from that [Biden] rule that the industry needs more assurance of regulatory certainty if it is going to invest in long-term health insurance with greater consumer protections. Really, the only way to provide them that certainty is to have Congress change federal statute."

States have the authority to regulate their health insurance markets. When Trump made changes to STLDI plans in 2018, only 15 states took advantage of the new Trump rules, according to the Manhattan Institute.

Pushing Obamacare

The reason previous administrations restricted STLDI was to push more Americans into Obamacare plans, says Brian Blase, president of the Paragon Health Institute.

"Unfortunately, the past two Democratic administrations punished Americans who found this coverage valuable—restricting the amount of permissible contract periods to only a few months," wrote Blase in a blog post for the Paragon Health Institute.

When Trump "restored the historical contract period of 364 days, permitting renewals up to three years" in 2018, writes Blase, "states that fully permitted short-term plans had much better trends—in terms of premiums, enrollment, and insurer participation—in their ACA individual market than states that restricted short-term plans."

AnneMarie Schieber (amschieber@heartland.org) is the managing editor of *Health Care News*.

Kennedy Shakes Up CDC Leadership Over Vaccine Safety, Efficacy Proof

Health and
Human
Services
Secretary
Robert F.
Kennedy Jr.

PHOTO COURTESY ANDREW HARNIK/GETTY IMAGES

Continued from page 1

for Emerging and Zoonotic Infectious Diseases, Daniel Jernigan; and director of the Office of Public Health, Data Science, and Technology, Jennifer Layden.

President Donald Trump weighed in with a September 1 post on social media.

"It is very important that the Drug Companies justify the success of their various Covid Drugs," wrote Trump. "Many people think they are a miracle that saved Millions of lives. Others disagree! With CDC being ripped apart over this question, I want the answer, and I want it NOW."

'Knew the Gig Was Up'

Robert Malone, a Trump appointee to the Advisory Committee on Immunization Practices (ACIP), took to X to approve the shakeup.

"The real reason for the recent CDC resignations is that the ACIP Subcommittee on COVID 19 vaccines got approval to investigate the safety and efficacy of COVID vaccines, and they knew the gig was up, the truth was about to come out, and they would have to account for their actions," Malone wrote. "All you need to do is read the recently approved 'terms of reference' for that subcommittee and it all becomes clear."

'Lot of Gaslighting'

ACIP member Retsef Levi confirmed that claim in an interview with journalist Maryanne Demasi.

"It was their unwillingness to examine the issue of vaccine injuries," said Levi. "To me, recognizing vaccine injuries and vaccine-injured people is a foundational component of any successful vaccine program. You need

"The real reason for the recent CDC resignations is that the ACIP Subcommittee on COVID 19 vaccines got approval to investigate the safety and efficacy of COVID vaccines, and they knew the gig was up, the truth was about to come out, and they would have to account for their actions."

ROBERT MALONE, ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

to care for the people that trusted your system and were unfortunately injured as a result. We have seen a lot of gaslighting and leaving the vaccine-injured out to dry."

Levi also said the CDC leadership, especially Daskalakis, had been locked in an intense turf war with ACIP, attempting to populate the group with CDC loyalists and strictly limit its review authority.

'Agency Is in Trouble'

The White House tapped HHS Deputy Secretary Jim O'Neill to lead the CDC until Trump appoints a permanent director. O'Neill can serve for 210 days before needing to be confirmed by the Senate, under the CDC Leadership Accountability Act enacted during the Biden administration.

The CDC needs new direction, Kennedy told *Fox and Friends*.

"I cannot comment on personnel issues, but the agency is in trouble, and we need to fix it—and we are fixing it—and it may be that some people should not be working there anymore," said Kennedy. "So, we need to look at the priorities of the agency, if there's really a deeply, deeply embedded, I would say, malaise at the agency, and we need strong leadership that will go in there, and that will be able to execute on

President Trump's broad ambitions."

'Preserve Incentives'

With vaccines being an essential element of U.S. health care, government agencies cannot dismiss safety and efficacy concerns, says Sally Pipes, president, CEO, and Thomas W. Smith Fellow in health care policy at the Pacific Research Institute.

"Vaccines are among the greatest achievements in medical history," said Pipes. "They've saved millions of lives. According to the CDC, ACIP considers many factors before recommending any vaccine, including safety and effectiveness. I can't speak to the motivations of the CDC officials who resigned. What matters is that vaccines remain overwhelmingly safe, effective, and indispensable for keeping Americans healthy."

"It's crucial that public policy preserve incentives for investors and researchers to fund the research and development of new vaccines," said Pipes.

'Coverups Are Criminal'

A critical look at CDC's leadership team is long overdue, says Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons.

"It seems as though the CDC has

lost all claim to scientific objectivity and is bought and paid for by financial interests," said Orient. "Public agencies' refusal to acknowledge severe adverse [vaccine] effects and its coverups are criminal."

The CDC leadership was attacking ACIP's review authority, says Orient.

"If the ACIP is not supposed to look into safety and efficacy, what is it for?" said Orient. "I think Levi and Malone are right."

'Deeply Embedded Interests'

Malone is right to bring attention to the CDC leadership's resistance to objective review of vaccine safety, says John Droz, a physicist and author of the Media Balance newsletter.

"Dr. Malone is usually on target," Droz told *Health Care News*. "The stridency of the vaccine advocates, and especially those [promoting] the mRNA vaccines, indicates deeply embedded interests in the regulatory agencies. The reality is that mRNA is not really a vaccine in the classic sense, but should be viewed as a different technology."

Such a new technology requires especially thorough scrutiny, says Droz.

"It's unconscionable that many corners appear to have been cut under the emergency use authorization," said Droz. "Given that the scientific footing behind experimental mRNA vaccines was less secure, more respect should have been given to objections to vaccine requirements."

"Manufacturers and regulatory agencies should have been more honest with the public, rather than claiming safety and efficacy that were, in fact poorly understood," said Droz.

Kevin Stone (kevin.s.stone@gmail.com) writes from Arlington, Texas.

Kennedy Cancels \$500 million in mRNA Contracts

By Kevin Stone

The Biomedical Advanced Research and Development Authority (BARDA) is canceling \$500 million of contracts to develop mRNA vaccines for flu and COVID-19, Health and Human Services (HHS) Secretary Robert F. Kennedy Jr. announced.

"We reviewed the science, listened to the experts," said Kennedy in announcing the decision.

"BARDA is terminating 22 mRNA vaccine development investments because the data show these vaccines fail to protect effectively against upper respiratory infections like COVID and flu," Kennedy said in an August 5 news release.

In May, HHS canceled \$590 million of contracts to develop mRNA shots against avian flu. In its recent release, HHS said it will let mRNA contracts in their final stages (Arcturus and Amplitude) run their course and allow "de-scoping of mRNA related work" (Luminary Labs, ModeX, and Seqirus) and other uses of mRNA technology.

As for respiratory viruses, HHS said it will shift funding toward "safer, broader vaccine platforms that remain effective even as viruses mutate."

'Stupid' Decision

The decision unleashed a storm of reaction. Alastair Thomson, chief data officer at the Advanced Research Projects Agency for Health (ARPA-H), announced his resignation in response to the move. Thomson called the cancellations "stupid," biotech news platform *Fierce* reported.

In an article for the news site *BioSpace*, Jonathan Kagan, Ph.D., a distinguished scientist at Corner Therapeutics, said the removal of funding was "the latest effort to undermine this promising technology at the federal level" and that mRNA technology provides essential "tools to program our cells with instructions to fight cancer and infectious diseases."

Biodefense Angle

Former BARDA Director Rick Bright says the decision puts national security at risk.

"BARDA invested in mRNA technology precisely because it could deliver safe, scalable vaccines in record time, a capability proven during COVID," Bright posted on X. "By dismantling that platform, we're crippling our front-line defense, just ahead of unknown biological threats."

Sen. Bill Cassidy (R-LA), a medical doctor, also cited biological warfare in



criticizing the contract cancellations.

"National defense today includes not only aircraft carriers and missile shields but also defenses against biological, chemical, and radiological weapons to protect both our military and everyday Americans," wrote Cassidy in the *Washington Examiner*. "The only question is whether we will abandon the herculean effort made by [President Donald] Trump in his first term to develop and deploy mRNA vaccines when they are now an essential tool in our national defense. If we do abandon them, our enemies will be watching."

'Completely Necessary & Appropriate'

Terminating the contracts is good because it allows the U.S. government to explore other options, says Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons.

"I think that cancelling this funding was completely necessary and appropriate," said Orient. "This technology has shown itself to be extremely dangerous and of dubious and, at best, limited effectiveness."

"Alternatives include better air purification and environmental sanitation, such as UV-C; immune system protection, as with adequate vitamin D levels; and repurposed drugs," said Orient. "Given that mRNA vaccines may promote cancer by various means, [mRNA experimentation] is a very risky approach, certainly unproven."

Urges Caution

The government should move carefully when conducting mRNA research, says Twila Brase, cofounder and president of the Citizens' Council for Health Freedom.

"Cancelling the contracts allows Secretary Kennedy to do a complete reevaluation of the vaccine program before spending \$500 million in taxpayer money," said Brase. "During COVID, we learned how little research has been done on current vaccines, and we learned the dangers of mRNA vaccines. A reevaluation of the entire pro-

gram is essential and prudent."

Messenger RNA research backfired when it led to collaboration between U.S. agencies and the Wuhan Institute of Virology in communist China to create the COVID-19 pathogen, writes author John Leake.

"It's hard for me to believe that Sen. Cassidy has remained ignorant of the mountains of evidence that the scheme he describes was, in fact, perpetrated by American and Chinese collaborators," wrote Leake, on his *Focal Points* Substack. "Given that he regards the Chinese Communist Party and military as adversaries of the United

"I think that cancelling this funding was completely necessary and appropriate. This technology has shown itself to be extremely dangerous and of dubious and, at best, limited effectiveness."

JANE ORIENT, M.D.
EXECUTIVE DIRECTOR
ASSOCIATION OF AMERICAN
PHYSICIANS AND SURGEONS

States, why did the U.S. NIH approve sharing cutting-edge American biotechnology with the Wuhan Institute of Virology between the years 2014 and 2020?"

Kevin Stone (kevin.s.stone@gmail.com) writes from Arlington, Texas.

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FDA Halts, Then Resumes Gene Therapy After Three Deaths



Continued from page 1

acute liver failure.

In a July 18 press release, Vinay Prasad, M.D., M.P.H., director of the FDA's Center for Biologics Evaluation and Research and the agency's top regulator, said the FDA's hold was ordered to avert harm to patients.

"Protecting patient safety is our highest priority, and the FDA will not allow products whose harms are greater than benefits," stated Prasad in the release.

The FDA put the drug on a "clinical hold" and revoked the company's platform technology designation.

Quick Change

In an unexpected reversal 10 days later, on July 28, the FDA announced it would allow Sarepta to resume some shipments of the treatment. The revised hold allowed shipment for ambulatory DMD patients, with the ban remaining in effect for non-ambulatory patients.

The death of an eight-year-old boy, which prompted the hold, was unrelated to the gene therapy itself, the FDA's press statement said.

Elevidys costs \$3.2 million for a one-time, single dose, according to drugs.com. DMD is a degenerative disease affecting males starting in childhood and is the most common form of muscular dystrophy.

Leadership Confusion

Confusion over the on-again, off-again hold was exacerbated by the resignation and reinstatement of Prasad, who had been critical of the therapy and its risks prior to the decision to implement the hold.

Prasad submitted his resignation on July 29, after a fiery exposé posted by political activist and Trump supporter Laura Loomer on July 21 attacked

"The FDA withheld the drug because Dr. Vinay Prasad was not convinced that the data proved it was effective. In light of a few reports on serious adverse reactions, he did not believe the risks outweighed the benefits based on his review of the efficacy trials."

JEFFREY SINGER, M.D.,
SENIOR FELLOW
CATO INSTITUTE

Prasad as a "progressive leftist saboteur" who has praised Sen. Bernie Sanders (I-VT). Prasad resigned just one day after the FDA loosened the Elevidys hold.

Two weeks later, Prasad was quietly reinstated to the agency, with critics of the Trump administration and leadership at the Department of Health and Human Services (HHS) suggesting the episode signaled an internal conflict over regulatory policy.

HHS spokesperson Andrew Nixon said the reinstatement was "at the FDA's request." Martin Makary leads the FDA, which is overseen by HHS Secretary Robert F. Kennedy.

Patients Overruled

Prasad did what he thought was right, but the government should not make these decisions, says Jeffrey Singer, M.D., a senior fellow at the Cato Institute.

"The FDA withheld the drug because Dr. Vinay Prasad was not convinced that the data proved it was effective," said Singer. "In light of a few reports on serious adverse reactions, he did not believe the risks outweighed the benefits based on his review of the efficacy trials. However, these patients were desperate, and the risk-benefit assessment should be theirs to make—not a government bureaucrat."

Singer says he has great respect for Prasad.

"He is committed to rigorous, evidence-based medicine, and that commitment was why he was a critic of the COVID-19 pandemic policy," said Singer. "Dr. Prasad practices clinical oncology in addition to his work in epidemiology and medical research. If I were one of his patients, I would very seriously consider his opinion on the efficacy of a drug."

Complex Calculation

Desperate patients often have to make tradeoffs, and those decisions can be complicated, says Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons.

"Treatment for people who have a terrible disease is vastly different from a product, such as a vaccine, to be given to millions for a hypothetical benefit," said Orient.

"People paralyzed by neuromuscular disease might be willing to take the risk of acute liver failure, but they need to understand the tradeoff: possibly a miserable death vs. possible future benefit, not cure, which might be transient and not very great," said Orient. "Would they be willing to trade everything they own for the chance, or are they demanding that others pay?"

Transparency would help patients

and physicians make informed decisions about the drug.

"I think the FDA was right to put a hold on the drug," said Orient. "If released because of popular pressure, it must be accompanied by full disclosure and be designated as experimental and therefore not covered by insurance."

"The company should pay the costs of their experiment, from which they hope to profit even if a lot of patients don't," said Orient.

New Framework

The science behind cellular and gene therapies is new, and it will take time for researchers to figure out how well each one works, says Gregg Girvan, a resident fellow at the Foundation for Research on Equal Opportunity. "It is therefore understandable that the regulatory environment around these therapies is continually evolving," said Girvan.

Sarepta should have been more transparent about the drug's safety data, says Girvan.

"Not releasing the data before media outlets reported on it made it look like Sarepta was engaging in a cover-up," said Girvan. "Sarepta left the FDA no choice but to order the company to suspend shipments of Elevidys while it investigated."

Girvan says cost should be a factor in whether a drug gets regulatory approval.

"Is it fair to expect society to help pay for the treatment through higher insurance premiums and taxpayer dollars?" said Girvan. "I think a price tag of \$3.2 million for a treatment that provides marginal benefit answers the question clearly: absolutely not."

Kevin Stone (kevin.s.stone@gmail.com) writes from Arlington, Texas.

Texas Attorney General Accuses Drug Company of Kickbacks

By Kevin Stone

Texas Attorney General Ken Paxton filed a civil lawsuit against pharmaceutical giant Eli Lilly, alleging the company illegally induced medical providers to prescribe some of its most profitable drugs, including high-demand GLP-1 weight-loss drugs Mounjaro and Zepbound.

The suit alleges violations of the Texas Health Care Program Fraud Prevention Act.

The law sets forth 13 unlawful acts. Sec. 36.002 (5) makes it illegal to knowingly to pay, charge, solicit, accept, or receive, in addition to an amount paid under the program, a gift, money, donation, or other consideration as a condition for providing a service or product paid for in whole or in part under the program.

Joining Texas in the lawsuit is Health Choice Alliance LLC, a research organization.

Back in Court

The suit builds on a previous lawsuit Paxton brought against Eli Lilly and other drug companies for artificially raising the price of insulin and then paying a significant, undisclosed kickback to pharmacy benefit managers for preferential treatment. The case is the latest in a series of actions by Paxton at the state and federal levels to rein in medical kickbacks and other improper financial arrangements.

Eli Lilly strongly denied the allegations, promised a robust defense, and said prior rulings had found the accusations lacked factual and legal merit. The case, *Texas v. Eli Lilly & Co.*, was filed on August 12.

Multiple Laws Violated

The alleged scheme is inherently unlawful on multiple levels, perhaps criminal, and the past rulings have no bearing on the current case, says John Dunn, M.D., J.D., a board-certified emergency medicine and legal medicine physician.

"The Texas Health Care Program Fraud Prevention Act identifies the elements of the criminal conduct behind the case and provides the legal basis that prohibits such conduct," said Dunn.

"Beyond that, fraud, bribery, and corruption are violations of the common law of torts," said Dunn. "So, the question is whether the actions were



violations of general fraud criminal statutes. The fact that they also potentially violate a law specifically concerning business practices involving Medicaid-billable medical products, services, sales, and distribution is secondary."

Middleman Temptation

The third-party payer system, an insurance health care plan, or a government program like Medicaid is partly to blame for the proliferation of incentives that can run afoul of the law, says Roger Stark, M.D., an author and health care policy analyst for the Washington Policy Center.

"The third-party payer system works both ways," said Stark. "It encourages the use of higher-costing drugs, while at the same time often denying patients the use of newer or off-label drugs. In a perfect world, drug manufacturers would be able to set their prices and patients would pay the company directly, without third-party interference. Then what are now considered corrupt kickbacks would simply be replaced by consumer discounts."

Aggressive Enforcement

Texas has recently been at the forefront of prosecuting medical kickback schemes. In February, the U.S. Department of Justice's Eastern District of Texas announced settlements with 18 doctors for almost \$3 million under the federal Anti-Kickback Statute and the Stark Law, for accepting kickbacks from medical testing laboratories.

In 2024, Paxton successfully prosecuted a rehabilitation facility owner, who was sentenced to 84 months in federal prison and ordered to pay \$8,680,380 in restitution to government health care programs for orchestrating a \$15 million fraud and kickback scheme.

In 2023, Paxton's Civil Medicaid Fraud Division recovered \$42.7 million from a group of pharmaceutical manufacturers, secured a 16-year sentence against an ambulance company owner for running a Medicaid fraud scheme, and sentenced the owner of a Frisco, Texas-based durable medical equipment company to 49 months and more than \$5 million in restitution in a case of orthopedic supplies fraud.

"The question is whether the actions were violations of general fraud criminal statutes. The fact that they also potentially violate a law specifically concerning business practices involving Medicaid-billable medical products, services, sales, and distribution is secondary."

**JOHN DALE DUNN, M.D., J.D.
PHYSICIAN**

In 2022, Paxton secured the indictment of the manager and operator of a Houston dental clinic for fraudulent billing of nearly \$6.9 million to Medicaid.

Kevin Stone (kevin.s.stone@gmail.com) writes from Arlington, Texas.

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Congress Aims to ‘Bust Up the PBM Monopoly’

By Bonner Russell Cohen

Congress is considering a bill that would protect patients and pharmacies from pharmacy benefit managers (PBMs), middlemen who administer drug plans and negotiate prices between pharmacies and insurance providers.

On July 10, 11 members introduced the bipartisan PBM Reform Act, which is now in the hands of the House Committee on Energy and Commerce.

PBMs have bred resentment as patients, physicians, pharmacists, and elected officials struggle with rising medical costs.

“It’s time to bust up the PBM monopoly, which has been stealing hope and health from patients for decades,” said Rep. Earl “Buddy” Carter (R-GA), in a news release. “As a pharmacist, I’ve seen how PBMs abuse patients firsthand, and believe the cure to this infectious disease is transparency, competition, and accountability, which is exactly what our bipartisan package provides.”

“For too long, pharmacy benefit managers have been allowed to operate unchecked, raising prices and preventing patients from getting the medications they depend on,” said Rep. Debbie Dingell (D-MI) in a statement. “Their harmful, aggressive tactics are only getting worse, and we must take action now to protect pharmacies and lower patient costs.”

Ban on ‘Spread Pricing’

The bill would ban “spread pricing” in Medicaid by mandating a transparent system that allows pharmacies to review Medicaid reimbursements. New requirements under Medicare Part D would “delink PBM compensation from the cost of medications and increase transparency,” the release states.

The Centers for Medicare and Medicaid Services would have to “define and enforce ‘reasonable and relevant’ contract terms in Medicare Part D pharmacy contracts and enforce oversight on reported violations,” the release states.

For employer-based health insurance plans, the bill would require more transparent and semiannual reporting on drug spending, rebates, and formulary determinations.

Provisions addressing PBMs were included in the 2024 federal budget package and versions of the reconciliation bill but were ultimately dropped from both pieces of legislation.



“It’s time to bust up the PBM monopoly, which has been stealing hope and health from patients for decades. As a pharmacist, I’ve seen how PBMs abuse patients firsthand, and believe the cure to this infectious disease is transparency, competition, and accountability, which is exactly what our bipartisan package provides.”

REP. EARL “BUDDY” CARTER (R-GA)

Cozy Relationships

Conflicts of interest and lack of transparency are at the heart of the PBM issue, says Jeff Stier, a senior fellow at the Consumer Choice Center.

“For nearly a decade, the debate around PBMs centered on whether, as the companies claim, they actually negotiate on behalf of insurance companies to contain medical costs for patients, or instead, because of their inherent conflict of interest by being almost entirely owned by insurance companies themselves, whether they use the power given to them by their parent insurance companies to steer patients to higher-cost drugs to earn higher rebates that go to the company,” said Stier.

“To this day, we don’t have a clear answer,” said Stier. “To know, we’ll

need more transparency throughout the entire supply chain. Although there’s no magic bullet that would make prescription drug prices significantly more affordable for patients, increased transparency, followed by scrutiny, is a necessary step to shine a light on the all-too-shrouded world of drug pricing.”

Reforms vs. Price Controls

Although PBM reform has merit, lawmakers should not try to control prices, says William S. Smith, Ph.D., a senior fellow at the Boston-based Pioneer Institute.

“Without significant PBM reform that eliminates rebate contracting, the Biden and Trump price controls will cause seniors to pay more for their drugs out-of-pocket,” said Smith.

Micromanaging the Managers

Congress should not micromanage PBMs, says Jeremy Nighohosian of the Competitive Enterprise Institute (CEI). Spread pricing, for example, “is essentially just a markup: the difference between what a consumer pays and the price the seller paid,” Nighohosian wrote in a blog post for CEI.

Banning spread pricing would be a relatively minor reform in dollar terms, says Nighohosian.

“CBO estimates that banning spread pricing in Medicaid would save less than \$250 million over ten years, while Medicaid is expected to grow by more than a trillion dollars over the same period,” wrote Nighohosian. “This provision would save 0.02 percent from Medicaid’s expected growth.”

Government should leave free markets alone, says Nighohosian.

“Congress shouldn’t insert itself into complex and functioning markets,” wrote Nighohosian. “The existence of a profit margin is not evidence that a market is not working. Most would scoff at the idea that Congress should ban markups in electronics or groceries, and that rationale should also apply to pharmaceuticals as well.”

Dozens of State Reforms

While Congress continues to grapple with PBMs, Iowa and Louisiana recently joined 30 other states that had already enacted PBM legislation.

In Louisiana, Gov. Jeff Landry signed a measure regulating PBM transparency and competition practices, HB 264, on June 20. House Bill 358, which would have banned ownership of a pharmacy and a PBM by the same company, failed in the Senate.

Iowa Gov. Kim Reynolds signed a bill into law in June requiring PBMs to reimburse pharmacies based on average state or national drug prices instead of negotiated rates and prohibiting PBMs from favoring a specific pharmacy for filling a prescription.

“In enacting this bill into law, Iowa joins Texas, Georgia, Indiana, and Montana that this year passed similar legislation to address this important issue, along with several other states that have done this previously, bringing the total to 32 states,” Reynolds said in a statement.

Bonner Russell Cohen, Ph.D., (bonnercohen@comcast.net) is a senior policy analyst with the Committee for a Constructive Tomorrow.

Trump Takes Steps to Protect Security of U.S. Drug Market

By Bonner Russell Cohen

To ensure a “resilient domestic supply chain for essential medicines,” President Trump issued an executive order (EO) directing the Department of Health and Human Services “to develop a list of approximately 26 drugs critical to national health and security.”

The August 13 EO also calls for the development of a “repository to receive and maintain the Active Pharmaceutical Ingredients (APIs) used to make these critical drugs.” Only 10 percent of APIs for the U.S. drug market are made in the United States, the EO says.

“Overreliance on foreign, sometimes adversarial, nations for Key Starting Materials (the materials used to make APIs) and APIs risks shortages of essential medicines,” the EO states. “Stockpiling APIs, which are lower cost and have longer shelf lives, strengthens the Nation’s ability to ensure access to critical drugs during emergencies.”

Role of Tariffs

Pharmaceuticals were not included in the 39 percent tariffs the United States imposed on Swiss imports in early August, but Reuters reports that could change pending a review in Washington expected to be concluded in early fall. Tariffs would apply to global pharmaceutical giants Roche and Novartis, which are headquartered in Switzerland.

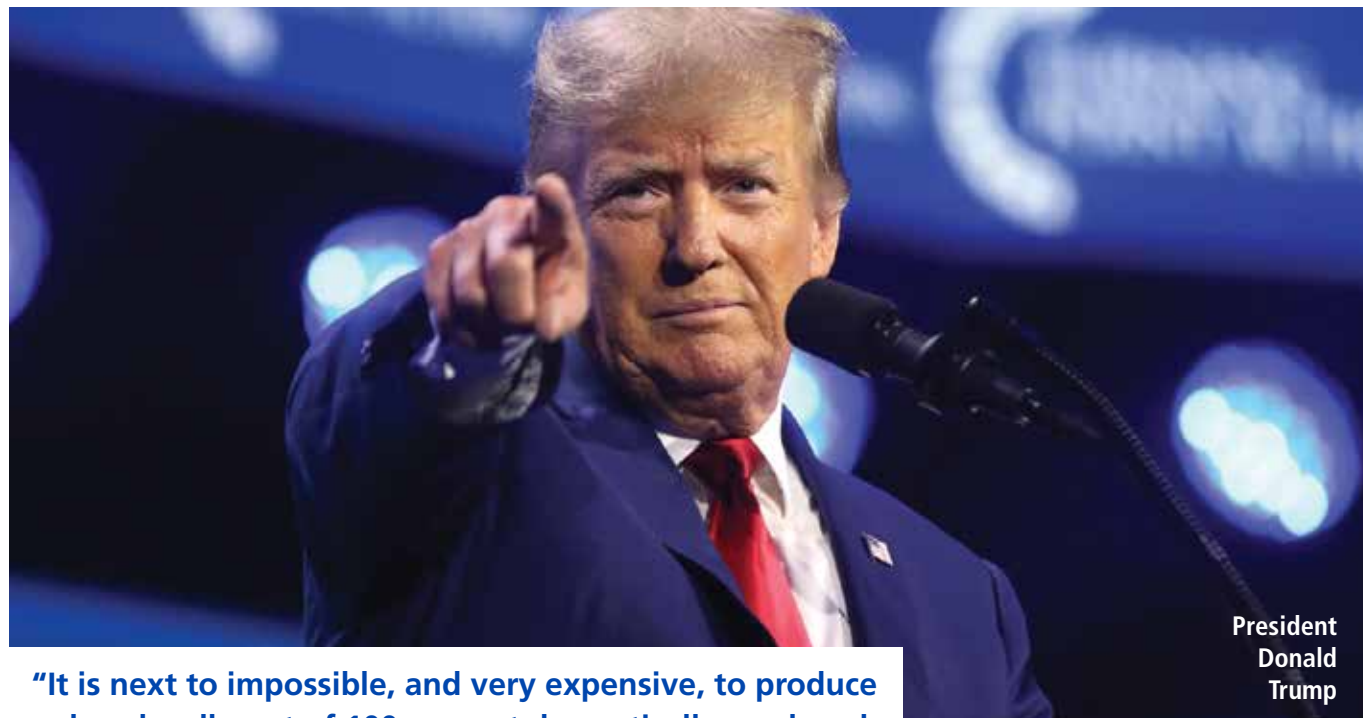
India poses its own unique set of problems. Trump has proposed tariffs on the country’s drug exports ranging up to 250 percent, *India Today* reported on August 7. India is the fifth-largest supplier of pharmaceuticals to the United States, behind Ireland, Switzerland, Germany, and Singapore.

India supplies nearly 40 percent of America’s generic drugs, reports DataVerse E Inc. The United States has a robust market for affordable generics, with “some of the lowest generic prices among developed countries,” states a new study by the Committee to Unleash Prosperity (CTUP).

Cost to Consumers

Tariffs are not invisible to consumers, says Wayne Winegarden, director of the Center for Medical Economics and Innovation at the Pacific Research Institute.

“Tariffs are taxes on the products U.S. households consume,” said Winegarden. “And the historical record clearly shows that, if imposed, these taxes will increase costs on Americans. Applied to pharmaceutical products



President
Donald
Trump

PHOTO COURTESY GAGE SKIDMORE/FICKR.COM

“It is next to impossible, and very expensive, to produce a drug locally out of 100 percent domestically produced material. Generic drugs are especially subject to supply-chain disruptions due to slim margins. Plus, drug companies are located all over the world.”

DEVON HERRICK, PH.D.
GOODMAN INSTITUTE HEALTH BLOG

and ingredients, tariffs will raise the cost of drugs.”

Tariffs could have a ripple effect on the broader U.S. drug market, says Winegarden.

“The tariffs will have a larger deleterious impact on low-cost generic medicines that account for about 90 percent of all generic medicines in the United States,” said Winegarden. “These lower-cost alternatives promote drug affordability and are part of the solution to drug affordability.”

Generic drug makers depend on volume to stay in business, says Michael Gaino, senior director of pharmacy and quality at the American Society of Health-System Pharmacists.

“A lot of these products have very slim profit margins,” Gaino told *Becker’s Hospital Review* in an August 12 interview. “We’re talking older drugs that are 20 to 30 years old.”

Pressure on Drug Makers

While moving to beef up the domestic market with tariffs on drug imports, the White House is taking measures to reduce drug prices.

On July 31, President Trump sent letters to 17 pharmaceutical manufacturers “outlining the steps they must

take to bring down the prices of prescription drugs in the United States to match the lowest price offered in other developed nations (known as the most-favored nation, or MFN price),” states a White House fact sheet.

Steps include more direct drug sales to patients, “Most Favored Nation” pricing in Medicaid, a promise by U.S. drug makers they will not offer better prices in other developed countries than in the United States, and government trade support to drug makers attempting to charge higher prices in other countries as long as the extra revenue is used to decrease drug prices in the United States.

The letters informed manufacturers that if they “refuse to step up,” the federal government “will deploy every tool in our arsenal to protect American families from continued abusive drug pricing practices.”

End of Business as Usual

Within the administration’s multipronged approach, one effort is already underway: direct-to-consumer (DTC) sales of drugs.

“In recent years, Eli Lilly, Pfizer, Bristol Myers Squibb, and Novo Nordisk have all unveiled DTC programs for a

select handful of drugs,” wrote Sally Pipes, president of the Pacific Research Institute, in *Forbes*. “And President Trump recently urged every major pharmaceutical firm to follow suit. The result will be lower drug prices for American patients.”

The reason to promote DTC is simple, says Pipes.

“If DTC sales become the norm in the pharmaceutical industry, patients and employers could save tens of billions of dollars—by cutting out middlemen who currently profit from the convoluted and opaque drug supply chain at everyone’s else’s expense,” wrote Pipes.

‘Truly a Global Product’

The global supply chain will probably continue to affect the cost of drugs in the United States, says Devon Herrick, Ph.D., a health economist who writes for the *Goodman Institute Health Blog*.

“Drugs are truly a global product,” said Herrick. “It is next to impossible, and very expensive, to produce a drug locally out of 100 percent domestically produced material. Generic drugs are especially subject to supply-chain disruptions due to slim margins. Plus, drug companies are located all over the world.

“The most likely result of tariffs is higher prices, not more domestic production,” said Herrick.

Bonner Russell Cohen, Ph.D., (bonnercohen@comcast.net) is a senior policy analyst with the Committee for a Constructive Tomorrow.

HHS Reinstates Child Vaccine Task Force

By Ashley Bateman

The U.S. Department of Health and Human Services (HHS) reinstated a federal task force on pediatric vaccine safety after a hiatus of nearly 30 years.

National Institutes of Health (NIH) Director Jay Bhattacharya, M.D., will chair the reinstated task force alongside senior members of the NIH, the Food and Drug Administration, and the Centers for Disease Control and Prevention.

“By reinstating this Task Force, we are reaffirming our commitment to rigorous science, continuous improvement, and the trust of American families,” Bhattacharya stated in the August 14 press release. “NIH is proud to lead this effort to advance vaccine safety and support innovation that protects children without compromise.”

The task force will make recommendations on the “development, promotion, and refinement of childhood vaccines that result in fewer and less serious adverse reactions” than those on the market and “improvements in vaccine development, production, distribution, and adverse reaction reporting.”

The task force will also support research to improve vaccine safety. Reports will be submitted to Congress every two years beginning with the initial report, which is due within two years.

On February 13, President Donald Trump established the Make America Healthy Again Commission (MAHA) to investigate rising chronic childhood diseases and other issues.

Disrupted Safety Oversight

In response to the 1986 National Childhood Vaccine Injury Act, Congress created the Task Force on Safer Childhood Vaccines to provide oversight and increase the safety and quality of pediatric vaccines. The Task Force was supposed to report to Congress every two years.

The panel disbanded in 1998 after it issued its first report. That report criticized the lack of “interagency coordination on vaccine safety” and deferred the coordination of vaccine safety programs to the Vaccine Interagency Group, an organization within the Public Health Service that was formed in 1980.

A 2008 report found a “lack of coordination and oversight of vaccine-related activities” has impeded federal efforts. A 2010 publication determined “the absence of broader NIH participation in vaccine safety

“By reinstating this Task Force, we are reaffirming our commitment to rigorous science, continuous improvement, and the trust of American families. NIH is proud to lead this effort to advance vaccine safety and support innovation that protects children without compromise.”

JAY BHATTACHARYA, M.D.
DIRECTOR, NATIONAL INSTITUTES OF HEALTH

research” may have “slowed ... progress in vaccine safety.”

Growing Distrust

Rising rates of childhood diseases and a lack of complete data defining the safety of increased injections on the pediatric vaccine schedule contributed to a record number of exemption requests filed by concerned parents in 2024 and 2025.

HHS Secretary Robert F. Kennedy Jr. has spoken out regularly on vaccine safety and efficacy. Kennedy’s removal of all members of the Advisory Committee on Immunization Practices in June, the cancellation of nearly \$500 million in federal funding for mRNA vaccine development (see related article, page 5), and updated guidance on mRNA vaccines for healthy children have resulted in backlash from some major medical boards.

Former Allies’ Lawsuit

In May, Children’s Health Defense, a vaccine safety nonprofit Kennedy founded in 2007, sued Kennedy to force him to reestablish the task force.

“If the Secretary is not performing a nondiscretionary duty, then a citizen has a right to bring a suit against him to have the court force [the issue], provided there is a 60-day notice and some personal harm,” attorney Ray Flores told *Health Care News*.

Flores filed the notice and lawsuit. HHS asked for a two-week grace period to respond and explore a way to settle the case. The settlement included reinstatement of the task force.

Flores says he blames HHS for all the vaccine injuries that have occurred over the past 30 years.

“They never fulfilled their basic duty,” said Flores. “It’s not just about a MAHA task force or blanket safety task force. It’s about licensing, manufacturing,

testing, labeling, warning, storage, administration, field surveillance. ... If they already had an effective system in place, a lot fewer people would have died, but instead they allowed these second-rate, inaccurate under-reportings.

“They allowed these hot lots to stay in circulation, and they never did anything to make vaccines safer than when the 1986 Act went into effect,” said Flores.

MAHA Criticism

Flores says he has not been impressed with the MAHA Commission’s efforts.

“The commission can talk about other things, but this is set into motion, and this is what’s going to matter to save children and [decrease] suffering,” said Flores. “I think the [lawsuit] put this discussion back in the forefront.”

Ashley Bateman (bateman.ae@gmail.com) writes from Virginia.

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Pediatric Group Calls for Elimination of Nonmedical Vaccine Exemptions

By Ashley Bateman

The American Academy of Pediatrics (AAP) released a report recommending a nationwide ban on nonmedical exemptions from vaccines.

The report, published in the August 2025 issue of *Pediatrics*, argues the geographical clustering of unvaccinated children results in communities with vaccination rates “insufficient” for disease prevention, causing “greater likelihood of disease outbreaks.”

In states where vaccine requirements are less stringent, “nonmedical exemptions erode the safety of school environments,” the report states.

In addition, the “heterogeneous implementation of these policies across states and locales creates a confusing legal environment for children, parents, and pediatricians,” the report says.

AAP “advocates for the elimination of nonmedical exemptions from immunizations as contrary to optimal individual and public health,” the report states. The organization called for all 50 states, territories, and Washington, DC to impose bans.

Dueling Recommendations

In May, Health and Human Services (HHS) Secretary Robert F. Kennedy Jr. announced the federal government no longer recommends COVID-19 vaccines for pregnant women and healthy children. In response, the AAP released its own vaccination guidelines, calling for the continued use of COVID-19 vaccines for children.

In an August 19 news release, the AAP said it had to create its own guidelines because Kennedy fired all members of the federal Advisory Committee on Immunization Practices (ACIP) this spring and replaced them with “individuals who have a history of spreading vaccine misinformation,” as the AAP put it.

In addition to the guidelines and the call for eliminating nonmedical vaccine exemptions, AAP and multiple other major medical groups filed a federal lawsuit in July challenging the revised COVID-19 vaccine recommendations.

The first meeting of Kennedy’s newly appointed ACIP resulted in no major changes to the schedule for pediatric vaccines.

Medical Big Brother

The AAP report is “in apparent disregard to parent rights, religious rights, patient rights, and constitutional



rights,” said Twila Brase, president and co-founder of the Citizens’ Council for Health Freedom.

“This position views America’s children and parents as government subjects who must submit to injections, regardless of risk, personal choice, or religious convictions,” said Brase. “Government vaccination mandates are bad medicine and antithetical to individual freedom protected by the Constitution.”

AAP’s claim that its plan “constrains parental authority as little as possible while attempting to optimize the public health benefit” is disingenuous, says Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons.

“Eliminating all nonmedical exemptions means eliminating virtually all exemptions, because so few medical exemptions are officially recognized and doctors can lose their licenses for writing too many,” said Orient. “This is an outrageous violation of religious freedom. ... It is also a violation of human rights in general to force people to have their bodily integrity violated or to accept risks exceeding any benefit they might gain in order to hypothetically benefit someone else.”

‘Taking a Fresh Look’

The American College of Pediatricians says it considers vaccines a “successful mainstay of preventative healthcare” and the group is “committed to taking a fresh look at their safety and effectiveness based on the latest data,” said Jill Simons, M.D., the organization’s execu-

tive director.

“We also support the rights of parents to make truly informed decisions for themselves and their families, including the right to religious or moral exemptions from vaccines,” said Simons.

‘Arbitrary and Capricious’

Current litigation could stymie the AAP’s plan. Two pediatricians filed a federal lawsuit on August 15 challenging the U.S. Centers for Disease Control and Prevention’s (CDC) childhood vaccine schedule in its entirety.

The suit calls the framework “arbitrary and capricious” and a violation of the Administrative Procedure Act because it does not consider vaccine safety and imposes rules outside the rulemaking process.

The plaintiffs, Paul Thomas, M.D. and Kenneth Stoller, M.D., filed their case in the U.S. District Court for the District of Columbia, seeking declaratory and injunctive relief.

The federal schedule recommends more than 72 vaccines for children. The suit claims the CDC has failed to provide vaccine safety reports twice per year based on its own guidelines and says no high-quality studies are comparing fully vaccinated and unvaccinated children. The suit claims Thomas faced license suspension after he published a study critical of childhood vaccines, and a medical board revoked Stoller’s license to practice when he tried to use genetic markers to protect children from vaccines that could harm them.



“This is an outrageous violation of religious freedom.

... It is also

a violation of human rights in general to force people to have their bodily integrity violated or to accept risks exceeding any benefit they might gain in order to hypothetically benefit someone else.”

JANE ORIENT, M.D.
EXECUTIVE DIRECTOR
ASSOCIATION OF AMERICAN
PHYSICIANS AND SURGEONS.

“Unable to defend their position scientifically, the medical establishment now seeks total control,” the lawsuit states, specifically citing the AAP’s recent report on exemptions.

Vaccine Politics

While claiming to be apolitical, the AAP has taken positions on multiple hot-button issues in recent years, such as promoting gender transition medication and advocating gun control. The AAP’s position that children and parents must submit to injections regardless of risk, personal choice, or religious convictions may reflect the influence of government funding, says Brase.

“In 2018, AAP reported \$121.8 million in revenue, with \$20.5 million coming from government grants,” said Brase. “The AAP appears to be working hand-in-glove with the government and not for children or the parents who love them.”

Several vaccine mandates are difficult to justify, says Orient.

“Most of the vaccines in the sacred schedule are for conditions that are rare, mild, treatable, or not transmitted in a school setting,” said Orient. “There is no public-health justification for requiring them.”

“The AAP is selling out its responsibility for children,” said Orient. “They are in deep denial about the significant and mounting evidence of serious vaccine harms.”

Ashley Bateman (bateman.ae@gmail.com) writes from Virginia.

Homelessness, Untreated Mental Illness Put Public at Risk, Trump EO States

By Kenneth Artz

President Donald Trump issued an executive order (EO) urging local governments to clear homeless encampments from public areas, increase the use of involuntary commitment for psychiatric treatment, and reduce support for government programs such as Housing First and harm reduction, to mitigate problems caused by risky behavior.

The July EO also encourages states and cities to adopt or enforce tougher laws against camping, squatting, loitering, and public drug use, prioritizing federal grants for jurisdictions that comply.

The EO directs federal agencies to broaden the use of civil commitment, making it easier to institutionalize people, often without their consent, on the grounds of severe mental illness, substance abuse, or threats to public safety.

The framing of the issues as a matter of public safety amounts to a significant change in how the United States addresses mental illness, addiction, and housing.

"The Federal Government and the States have spent tens of billions of dollars on failed programs that address homelessness but not its root causes, leaving other citizens vulnerable to public safety threats," states the EO.

"Vagrancy is a crime, and the pathology of homelessness is multifactorial, but the phenomenon has to be stopped," said John Dale Dunn, M.D., a Texas physician, attorney, and policy advisor to The Heartland Institute, which co-publishes *Health Care News*. "A humane society does not allow it and ends it."

Mental Health First

The establishment approach, backed by progressives, is to get the mentally ill into housing first and then address substance abuse and violence, says Merrill Matthews, Ph.D., a health policy analyst and columnist for *The Hill*.

"I think the better approach, which is generally favored by conservatives, is to take on mental illness and substance issues first, and then housing if and when the patients are ready," Matthews said. "In other words, homelessness is a result of mental illness and substance abuse problems, not the other way around. That could mean controlled



and even forced institutionalization for some patients."

Staffing Shortages

States must ensure there are enough mental health professionals to deal with these patients, because there is a nationwide shortage of them, says Matthews.

"Two years ago, in my role as chair of the Texas Advisory Committee to the U.S. Commission on Civil Rights, we released a report on our findings related to the Texas Juvenile Justice System, especially as it related to kids with mental health issues," said Matthews.

"The system was unable to provide the mental health professionals to see these kids," said Matthews. "Staffing problems, in part because of low pay and pandemic-related challenges, left kids sitting in their cells for virtually the whole day, exacerbating their mental health troubles. The state needed more and better mental health care and decided to expand its efforts after our report appeared."

Facility Needs

In 2024, Texas Gov. Greg Abbott said the state would spend \$2.5 billion building or expanding seven psychiatric hospitals, including one for youth and a new facility in Lubbock. An increasing number of prisoners in the state require psychiatric care.

"In 2023, 60 percent of those treated in the state's psychiatric hospitals came from county jails or the prison system," said Matthews.

Texas is taking the right approach, says Matthews.

"If states are going to address mental

illness and addiction first, and then try to get stabilized patients into housing, they will likely need to spend more on facilities," said Matthews. "But it's important to try and ensure there are enough facilities for families to visit their loved ones to provide that emotional support. That may mean a larger number of smaller facilities."

Emergency Failures

Too many advocates on the issue don't know the value of "tough love" in dealing with mental illness and substance abuse, says Dunn.

"I practiced emergency medicine for 50 years, and the emergency department is where mentally distressed, drug- and alcohol-impaired people get treated," said Dunn.

"I involuntarily committed hundreds of people in my career, and every state I practiced in had mental institutions where interventions and definitive treatment were imposed on those suffering from a crisis that resulted in their arrest, apprehension, or having friends or family take them in for evaluation and treatment. I worked with local mental health services people to address homeless, drug- and alcohol-addicted, and mentally disabled persons. I never saw a psychiatrist in the emergency department—they were always in mental institutions or mental health clinics."

Deinstitutionalization Legacy

Taking severely mentally disabled, drug-addicted, homeless people out of institutions and putting them on the street simply disrupts neighborhoods and creates disorder and disturbance of the peace, says Dunn.

"Most of the homeless use drugs of abuse; it's self-treatment in many cases. Mentally ill individuals are inclined to abuse drugs to reduce their discomfort and mental stressors. Criminal behavior follows mental illness and substance abuse, and it ranges from behavior problems to violence, along with criminal activities to enable drug abuse."

JOHN DALE DUNN, M.D.
TEXAS PHYSICIAN

"Particularly in cities, the welfare of the citizens is compromised," said Dunn.

The deinstitutionalization project developed in the 1950s and matured in the 1960s because people didn't like institutions for the insane and severely disabled, says Dunn.

"I watched it happen, and deinstitutionalization increased the problem of public behavior that was disruptive and disturbing, all the way to violent," said Dunn.

Drug abuse rises with street chaos and homelessness, says Dunn.

"Most of the homeless use drugs of abuse; it's self-treatment in many cases," said Dunn. "Mentally ill individuals are inclined to abuse drugs to reduce their discomfort and mental stressors. Criminal behavior follows mental illness and substance abuse, and it ranges from behavior problems to violence, along with criminal activities to enable drug abuse."

Kenneth Artz (KApublishing@gmx.com) writes from Tyler, Texas.

INTERNET INFO

Merrill Matthews et al., "Mental Healthcare in the Texas Juvenile Justice System," Texas Advisory Committee to the U.S. Commission on Civil Rights, May 2023: <https://www.usccr.gov/files/2023-05/texas-interim-report-mental-healthcare-in-tjjd.pdf>

HHS Investigates Drug History of Child Killers

By Harry Painter

The Department of Health and Human Services (HHS) is investigating the possible link between certain drugs and mass shootings, says Secretary Robert F. Kennedy Jr.

After the Annunciation Catholic School shooting in Minneapolis, Minnesota on August 27, Kennedy told “Fox & Friends” his department is “launching studies” into the contribution of drugs to school shootings. Kennedy was asked about the topic against the backdrop of recent shooters such as Robin Westman and Audrey Hale, both of whom identified as transgender.

Westman, identified as the shooter in the Minnesota case, worked at a medical-cannabis dispensary until the month of the shooting, reports *Time*. Investigative reporter Alex Berenson has documented connections between cannabis and psychosis-induced violence in his book *Tell Your Children: The Truth About Marijuana, Mental Illness, and Violence*.

SSRI Review

Kennedy said his department is studying selective serotonin reuptake inhibitors (SSRIs), which are commonly used to treat depression, as potential contributors to violence. Many SSRIs have black-box warnings saying they may lead to suicidal and homicidal ideation.

House Majority Whip Tom Emmer (R-MN) expressed doubt that no one saw warning signs in Westman.

“Somebody had to know,” Emmer told the *New York Post*.

Dangers of THC Use

“Intoxicants like THC [an ingredient in cannabis] can enable an exaggerated response, just like alcohol increases a tendency to behavior that is exaggerated,” said John Dale Dunn, M.D., J.D., an emergency physician for 50 years who has treated many patients with psychological illnesses.

“Do you think there is any doubt [Westman] was a regular user?” said Dunn. “THC of the more recent variety is much more intoxicating and affecting. THC can aggravate criminal and sociopathic tendencies in some individuals. It depends on their underlying mental state.”

Dunn said Westman’s actions indicate narcissism.

“He was angry and agitated with his condition, his situation, he seems to have had a narcissistic personality disorder, and he was prone to what



“There has been some research pointing to an increased risk of depression for males with high levels of estrogen. So, if Westman was taking cross-sex hormones, it’s possible they could have worsened his mental state beyond the distress he was already feeling.”

PAUL DUPONT
POLICY DIRECTOR
AMERICAN PRINCIPLES PROJECT

is called narcissistic rage: impulsive, anger-generated acts striking out at the world,” said Dunn.

A 2018 article in *Psychology Today* defines narcissistic rage as “intense anger, aggression, or passive-aggression when a narcissist experiences a setback or disappointment, which shatters his (or her) illusions of grandiosity, entitlement, and superiority, and triggers inner inadequacy, shame, and vulnerability.”

Connection With Treatments

It is reasonable to question whether drug and hormone treatments can cause transgendered individuals to become violent, says Dunn.

“SSRIs are mood changers and stimulants, so they have pharmacological effects that are excitatory,” said Dunn. “Estrogen and progesterone, female hormones for a male who is ‘tranny,’ would not increase aggressive tendencies, but if they are given to someone with intact male sex organs secreting testosterone, there is no predicting the result of the interaction.”

Physicians and others involved in transitioning children are committing malpractice and violating “international

and domestic law on medical practice and human experimentation,” says Dunn.

“Encouraging gender-confused individuals with gender-affirming practices, hormone manipulation, and surgical mutilation is criminal behavior,” said Dunn. “Liberal, neurotic” mothers in the home and teachers and groomers outside the home are responsible for the outcomes, says Dunn.

‘An Unhealthy Coping Mechanism’

Whether someone has physically transitioned or not, “the mere attempt to live as the opposite sex is an unhealthy coping mechanism,” says Paul Dupont, policy director for the American Principles Project. (See related article, page 14.)

Studies suggest transgender individuals on cross-sex hormones might be more prone to mental illness, says Dupont.

“There has been some research pointing to an increased risk of depression for males with high levels of estrogen,” said Dupont. “So, if Westman was taking cross-sex hormones, it’s possible they could have worsened his mental state beyond the distress he was already feeling.”

Westman underwent a name change as a minor.

“Ending the practice of giving minors transgender drugs and surgeries should be a no-brainer,” said Dupont. “Much of the transgender industry is built upon government subsidy, and cutting off that flow of support would make a significant difference.”

Mental Health Crisis

The U.S. sex reassignment surgery industry was valued at \$2.1 billion in 2022. The Trump administration is

in the process of defunding hospitals that engage in chemical and surgical alteration of children and ignore their real problems.

“We have become afraid as a society to speak about the crisis of persons who manifest delusions, far removed from reality, and are dealing with temptations and inner torments,” wrote Bishop Michael Burbidge of Arlington, Virginia in a commentary after the Minneapolis attack. “We must acknowledge and respond to the crisis of mental health in our country.”

‘Therapy Bans’

State governments have turned a mental health problem into a social crisis, says Dupont.

“Over 20 states currently have so-called ‘conversion therapy bans’ which actually mandate that a therapist reinforce a person’s gender dysphoria rather than treating it,” said Dupont.

“These laws are a significant intrusion into mental health care by politicians and have had a damaging impact,” said Dupont. Congressional Democrats have tried unsuccessfully to pass them at the federal level, Dupont says.

“Fortunately, they are being challenged in many places, and the Supreme Court will soon rule on whether or not they infringe on the First Amendment rights of therapists, in the upcoming *Chiles v. Salazar* case,” said Dupont.

Other states are taking positive steps, with 27 having passed bans on gender-affirming care, states a *KFF* policy tracker dated August 12, 2025.

Harry Painter (harry@harrypainter.com) writes from Oklahoma.

INTERNET INFO

“U.S. Sex Reassignment Surgery Market Size, Share & Trends Analysis Report by Gender Transition (Female-to-male, Male-to-female), by Procedure (Mastectomy, Vaginoplasty, Scrotoplasty, Hysterectomy, Phalloplasty), and Segment Forecasts, 2023-2030,” Grand View Research, September 6, 2025: <https://www.grandviewresearch.com/industry-analysis/us-sex-reassignment-surgery-market>

Report Calls for Gender Industry Accountability

By Ashley Bateman

Describing the accounts of several people who underwent transgender medical treatments and later regretted it, a new report argues for holding the transgender industry accountable for harms and abuses it imposed on vulnerable individuals.

The American Principles Project (APP) published the report in July because “transgenderism was pushed into the national spotlight during the 2024 presidential election as never before” and “as poll after poll confirms, a growing supermajority of Americans rejects the radical claims and practices of radical gender ideology, and demands political accountability,” the study states.

The report, “Transgender Accountability: Holding an Industry Responsible for Its Harms,” summarizes the recent history of pediatric medical transition and the role politics has played in the growth of the industry. It provides an analysis of two case studies of patients who underwent gender treatments and the physical and emotional harms they suffered. Both individuals are now trying to reverse the effects of those treatments.

Doing Harm

Providers have failed to abide by the Hippocratic Oath of “do no harm,” states the report.

“To neglect the mental health care needs of members of an already vulnerable population of youth with complex psychiatric, neurodevelopmental, and psycho-social challenges is to deny them a benefit to which they are entitled, and to expose them to medically unnecessary risk of harm is to impose a burden unduly,” states the report.

“In almost any other circumstance, what these individuals underwent would result in serious professional or legal consequences for the responsible parties,” the report notes.

Trade Investigation

The report calls for the Federal Trade Commission (FTC) to launch a “multifront campaign” to investigate deceptive or unfair practices in pediatric medical transition.

In public remarks on July 9, FTC Chairman Andrew Ferguson said federal law requires the FTC to defend Americans from businesses and individuals making “claims about their health products and services that [are] not backed by scientific evidence.”



The report outlines ways the FTC can take action by seeking restrictive court orders, freezing assets, and imposing fines.

The federal government may also investigate whether manufacturers and distributors misrepresented drugs used for transition treatment under the Food, Drug, and Cosmetic Act and probe pharmaceutical companies for “their advocacy for liberalizing access to treatments” that may include their products, and any financial incentives they may offer physicians to prescribe their products.

“The government is on our side for once,” said APP President Terry Schilling. “You have a government to secure your rights from [malicious] practices.”

Informed Consent

One of the most critical areas to address is informed consent, says Al Oliva, M.D., a board-certified plastic and reconstructive surgeon and long-time opponent of gender transition treatment.

“A physician explains to the patients the perceived benefit of going through this procedure and the risks,” said Oliva. “A patient can then make the decision whether they want to undergo the risk to achieve the benefits.”

Young people are not capable of giving informed consent, says Oliva.

“An adolescent cannot fully perceive

risk,” said Oliva. “They cannot make these decisions. They have an undeveloped prefrontal cortex.”

False information is another big problem, as studies are often conducted by biased organizations and based on self-reporting by hand-selected participants, says Schilling.

“The datasets and research they conduct are inadequate,” said Schilling. “They lose track of people, and participants stop responding. Unfortunately, a lot of people who underwent transitioning have committed suicide or de-transitioned.”

Lawsuit Power

Lawsuits by people who regret having undergone these procedures will ultimately discourage physicians from performing these treatments, says Oliva.

“Malpractice claims by de-transitioners will be a wake-up call to physicians, and practices will eventually shut down,” said Oliva. “The claims that these interventions are reversible is completely false, as these de-transitioners are truly injured, and injured for life,” said Oliva.

Although lawsuits are effective in gaining redress, they can be slow and cannot reverse the physical and mental damage to the patients, says Schilling.

“We need laws that prevent this type of harm being done to our children,” said Schilling. “The institutions responsible

for safeguarding Americans from these types of atrocities are safeguarding those who perpetrate them. Sexual changes on minors are the most basic thing that any society should ban. We want to use the full force of the federal government to protect the people.”

The obstacles plaintiffs face in litigation are formidable, the report states.

“They have neither the means nor the time and energy to prosecute campaigns against some of the most powerful corporate and medical entities in the world,” states the report. “Accountability requires the state to intervene in their defense.”

Federal Action

On May 1, the U.S. Department of Health and Human Services (HHS) released “Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices,” in response to “growing international concern about pediatric medical transition,” the report states. The HHS report is strong and authoritative, says Schilling.

“It provides a legal basis for pushing back,” said Schilling.

Before the HHS report was released, U.S. Attorney General Pam Bondi published a plan of action to stop pediatric medical transition. Bondi’s plan directs her department to investigate violations under the Food, Drug, and Cosmetic Act and push for the termination of any U.S. alliance with the World Professional Association for Transgender Health and other organizations promoting medical pediatric gender transition.

The document also calls for federal legislation to create a “private right of action” for parents and children, with a “long statute of limitations and retroactive liability.”

Ashley Bateman (bateman.ae@gmail.com) writes from Virginia.

INTERNET INFO

“Transgender Accountability: Holding an Industry Responsible for Its Harms,” American Principles Project, July 8, 2025: https://americanprinciplesproject.org/wp-content/uploads/2025/07/2025-fraud-trans-report_final_digital-2-1.pdf

Alcohol Use Down, Cannabis Use Up

By Harry Painter

Self-reported alcohol consumption among American adults is at its lowest point in at least 90 years, a Gallup poll finds.

The poll found 54 percent of U.S. adults reported consuming alcohol, the lowest level in Gallup's nearly 90 years of tracking the trend. The second-lowest rate, 55 percent, was recorded in 1958.

The annual Consumption Habits survey, conducted July 7 to July 21, also found 53 percent of Americans say drinking in moderation is bad for one's health. That marks the first time a majority saw moderate drinking as having negative health effects since Gallup began asking in 2001.

Recorded alcohol consumption in the United States reached its zenith in the mid-1970s, hovering between 68 and 71 percent.

'A Positive Development'

The Gallup results are a good sign, says Chad Savage, M.D., founder of YourChoice Direct Care and a policy advisor to The Heartland Institute, which co-publishes *Health Care News*.

"The overall trend toward reduced alcohol consumption is a positive development," said Savage. "This is especially true given recent research that overturns the early 2000s belief that low levels of alcohol consumption might be protective."

The science has improved since then, says Savage.

"That earlier conclusion was based on lower-quality epidemiological studies, which were confounded by the inclusion of very ill individuals—who couldn't drink—alongside those who simply chose not to," said Savage.

Removing this confounding factor led to researchers finding "there is essentially no level of alcohol consumption that can be considered 'safe,'" said Savage. Negative effects rise with higher levels of consumption, says Savage.

"Alcohol is generally associated with higher levels of acute toxicity risk, but marijuana research is not as robust, potentially skewing a direct comparison. Thus, a true apple-to-apple comparison is challenging. Better to avoid both substances due to their toxicity rather than determine which one will kill you less quickly."

CHAD SAVAGE, M.D.

FOUNDER, YOURCHOICE DIRECT CARE

Switching to Alternatives?

While cannabis use has been steady over the past year, it has risen over the past decade as more states have legalized its use.

"Alcohol is generally associated with higher levels of acute toxicity risk, but marijuana research is not as robust, potentially skewing a direct comparison," said Savage. "Thus, a true apple-to-apple comparison is challenging. Better to avoid both substances due to their toxicity rather than determine which one will kill you less quickly."

In June, researchers at New York University found record numbers of senior citizens are using cannabis, with 7 percent of adults aged 65 and older reporting use in the past month.

An Age Thing

The results of the Gallup survey have multiple causes, says Jeffrey A. Singer, M.D., a senior fellow at the Cato Institute.

"Younger generations, especially Gen Z, have been drinking less alcohol, using less marijuana, and smoking fewer cigarettes for some time, but this trend has increased," said Singer. "Much of it might be due to changes in socialization and social norms among young people, along with a focus on wellness. Older generations are more accustomed to using alcohol in social settings and are slower to stop this practice."

Access to substances can also be a factor, says Patrick T. Brown, a fellow at the Ethics and Public Policy Center.

"It's hard to know exactly whether drugs and alcohol are substitutes or complements, but it's safe to assume that making weed more accessible will cause usage to go up, as we have seen in states that have legalized it," said Brown.

Open Door Policy

In an August *City Journal* article, Brown says President Trump's plan would place cannabis on par with anabolic steroids and ketamine and "open the door for Big Weed to go mainstream" despite what Brown says are oversold health benefits and understated harms.

"Businesses now operating in a legal grey area could licitly deduct business expenses, access capital, and advertise openly," Brown wrote.

Rescheduling cannabis to Schedule III, as President Trump is considering doing, would greatly reduce federal restrictions on its medical and recreational uses and "would massively expand the ability for firms to market it, and build up a larger consumer base," Brown told *Health Care News*.

Drugs do not have the same market effects as other products, says Brown.

"Drugs are not something that many free-market thinkers have

seen as fitting a classical economics framework," said Brown. "It's hard to talk rationally about supply and demand when you have the potential for abuse and addiction for a given consumer product, which is why we recognize the need for government intervention on either the supply side or the individual treatment side."

Autonomy and Safety

Singer argues market processes apply to drugs. In his book *Your Body, Your Health Care*, Singer says government "should not infringe on their right to use any substance or participate in any activity, as long as they do not violate the rights of others."

Laws against use in public and while driving are acceptable, says Singer.

A common refrain of cannabis advocates is "marijuana is safer than alcohol." Singer agrees.

"Generally speaking, weed is safer than alcohol," said Singer. "One cannot fatally overdose on cannabis, whereas if one consumes too much alcohol at once, they can stop breathing and die."

In addition, "there is no evidence that cannabis directly causes organ damage, whereas alcohol can cause cirrhosis, cancer, cardiomyopathy, and encephalopathy, including dementia," said Singer.

Marijuana and Psychosis

Singer acknowledges cannabis use can lead to psychosis, which investigative journalist and cannabis opponent Alex Berenson argues may be linked to mass shootings such as the NYC office shooting and the Annunciation Catholic School shooting. (See related article, page 13.)

"But drug-induced psychosis is not unique to cannabis," said Singer. "For example, alcohol, steroids, stimulants, antihistamines, and even some antibiotics can induce psychosis."

Harry Painter (harry@harrypainter.com) writes from Oklahoma.

COMMENTARY

Public Grows Weary of ‘Harm Reduction’

By Devon Herrick

Blue cities are moving away from so-called harm reduction strategies in combating overdose deaths from use of hard drugs.

Harm reduction aims to decrease the negative consequences of risky behavior and is a hodgepodge of different initiatives such as needle exchanges, providing safer drug paraphernalia, Narcan stockpiling, and decriminalization of drug use in a few West Coast cities. Other examples include the provision of pre-exposure drugs to prevent AIDS infections via unprotected, risky sexual behavior, the promotion of marijuana as a “safe” alternative to alcohol, and encouraging the use of vape pens instead of cigarettes.

In the past few years, many civic leaders have decided drug use is inevitable. They then conclude that a better strategy than interdiction is



to adopt policies to reduce the harm caused by drugs rather than try to reduce drug use.

Opinions differ about the success or failure of these policies. Harm reduction appears to reduce death rates, though critics say the policy encourages drug use.

Fentanyl Dipsticks

New York Times writer Jan Hoffman, on August 25, described some harm-reduction efforts.

“To prevent life-threatening infections, more states authorized needle exchanges, where drug users could get sterile syringes as well as alcohol wipes, rubber ties and cookers,” the *Times* reported. “Dipsticks that test drugs for fentanyl were distributed to college campuses and music festivals. Millions of overdose reversal nasal sprays went to homeless encampments, schools, libraries, and businesses. And in 2021, for the first time, the federal government dedicated funds to many of the tactics, collectively known as harm reduction.”

Numbers Game

Overdose deaths peaked in 2023 at 110,000 and fell to around 80,000 last year. It is easy to extrapolate and say harm reduction saved 30,000 lives, possibly more, with the growth trajectory of hard drug use experienced over the past dozen years. However, that estimate is likely naïve.

Overdose deaths are a function of drug use, which critics suspect rose in response to harm reduction campaigns. In July, President Trump echoed what many others believe when he said harm reduction strategies “only facilitate illegal drug use and its attendant harm.”

The *Times* article says sentiment against harm reduction strategies has been building in liberal cities. For example, San Francisco’s new mayor, Daniel Lurie, ended city-funded distribution of “safe-use smoking supplies such as pipes and foil” in the city’s parks. Philadelphia is no longer funding syringe service programs

“In city after city the public has grown weary of open-air drug sales, drug use in public, drug users in a stupor laying on the sidewalk and drug syringes and needles strewn about public space. The disenchantment with harm reduction probably has as much to do with the public growing tired of negative externalities of permissive drug laws where their kids once played.”

JAN HOFFMAN
NEW YORK TIMES WRITER

despite the ringing endorsement of the Centers for Disease Control and Prevention.

Normie-Shaming

Harm-reduction supporters reject the notion that protecting people from the worst consequences of drugs encourages drug use.

In city after city the public has grown weary of open-air drug sales, drug use in public, drug users in a stupor laying on the sidewalk and drug syringes and needles strewn about public space. The disenchantment with harm reduction probably has as much to do with the public growing tired of negative externalities of permissive drug laws where their kids once played.

Facts can speak louder than theories. Not everyone is an expert on addiction, but there can be wisdom in the collective voice of nonexperts who are free to express their opinions and cast votes.

Devon Herrick (devonherrick@sbcglobal.net) is a health-care economist and policy advisor to *The Heartland Institute*. A version of this article appeared on the Goodman Institute Health Blog. Reprinted with permission.

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COMMENTARY

Massive Fraud Found in Minnesota Medicaid Housing Assistance Program

By Devon Herrick

“Nonmedical social determinants of health” is a fancy way of saying external conditions can affect people’s well-being. Being homeless is not conducive to good health, and the stress of not having access to affordable housing can worsen an individual’s mental health. Under that premise, several states have diverted Medicaid funding to housing assistance.

In 2024, 19 states funneled Medicaid funds into various housing programs. I asked whether this was a delusional quest that would fail to improve health care or was a worthy discussion to have if Medicaid is to remain an entitlement for the poor.

Minnesota Cost Explosion

The case of Minnesota, one of those 19 states, is illuminating. Minnesota was the first state to seek approval to use Medicaid funds for housing under a program called Housing Stabilization Services (HSS). Minnesota has a long history of maximizing federal funding for Medicaid while expanding the program as much as

“Earlier this month, the FBI raided five Minnesota businesses that have received millions in Medicaid money for services they didn’t provide, according to unsealed search warrants.”

J. PATRICK COOLICAN
MINNESOTA REFORMER

possible.

Starting in 2020, HSS had an anticipated budget of \$2.5 million. By 2021 the cost was already nearly 10 times the original budget. Four years later it is costing Minnesota (and federal) taxpayers \$107 million annually. The reason for the surge in spending is not homelessness; it is massive fraud.

On July 25, Minnesota shut down its \$107 million housing stabilization

program, the *Minnesota Reformer* reports.

Massive Corruption

The program was riddled with corruption, the publication found.

“Earlier this month, the FBI raided five Minnesota businesses that have received millions in Medicaid money for services they didn’t provide, according to unsealed search warrants,” wrote J. Patrick Coolican. “The Housing Stabilization Services program is intended to help older adults and people with disabilities find and maintain housing.”

Tellingly, the Minnesota legislature had to pass a law authorizing the Minnesota Department of Human Services to freeze payments to the 50 HSS providers. Perhaps that is the problem. The department that administers housing assistance is not even allowed to police it without asking permission.

Not Just a Few Bad Apples

The fraud in the HSS program could exceed \$1 billion, acting U.S. Attorney

Joe Thompson told KSTP.

This is not just a few bad apples ruining it for everyone else. It is the vast majority of vendors. Many of the people whose names were used to apply for funds claimed they had not received any services. The people had never even heard of the companies billing on their behalf.

Around 700 different companies are billing HSS for housing services, most of which were never provided. Some of the companies used the same business address as others.

Maybe there is some merit to the idea that external conditions affect health, but the public may never know the truth when there are no guardrails to protect against rampant corruption and fraud in a government program attempting to find out.

Devon Herrick (devonherrick@sbcglobal.net) is a health care economist and policy advisor to The Heartland Institute. A version of this article appeared on the Goodman Institute Health Blog. Reprinted with permission.

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COMMENTARY

Expanding Medicaid Hasn't Improved Health Care

By John C. Goodman

The media are clamoring over the Congressional Budget Office's (CBO) estimate that 16 million people will lose health insurance by 2034 because of Trump administration policies—10.9 million due to the One Big Beautiful Bill Act alone.

Most of the news coverage misses three important details. While it's true that many people will lose insurance, that doesn't mean a significant loss of health care.

Not a Crisis

First, most of those who will lose coverage are almost certain to be healthy and not in need of medical care. The bulk of the loss from the One Big Beautiful Bill (7.8 million) will be a reduction in Medicaid enrollment. Nearly five million of these are able-bodied people without dependents, who the CBO predicts will balk at the requirement to work 20 hours a week or go to school or engage in community service.

The remaining losses are mainly due to paperwork: more frequent eligibility verification, the need for proof of citizenship or legal immigration status, and changes in processing of applications and renewals.

Second, if people who lose coverage later get seriously sick, they can easily re-enroll and get Medicaid to pay their bills retroactively. Currently, there's a three-month look-back period for coverage. Beginning in 2027, retrospective payment will be limited to one month for Medicaid expansion enrollees and two months for traditional enrollees. This should be more than enough time for a patient to get the coverage they need. If a hospital or nursing home can't manage to enroll a patient in 30 days, it needs new management.

Not Worth the Hassle

It's a similar story with the other largest portion of insurance loss. The CBO estimates 7.3 million people on the Obamacare exchanges will soon be without coverage for two reasons: a Biden-era expansion of enhanced tax credits will expire at the end of the year, and the One Big Beautiful Bill increases administrative barriers to enrollment.

Those who end up without insurance because of this will almost all be healthy, because they are the most likely to give up in the face of more



"After two years, researchers compared the medical conditions of those on Medicaid and those not on it. Those who had enrolled had less financial stress and were less likely to be depressed, but there was no significant improvement in their physical health."

JOHN C. GOODMAN, PH.D.

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paperwork. One of the reasons health insurers are announcing an 18 percent increase in premiums in next year's exchanges is that they expect healthy people to leave, making the remaining pool sicker and more costly.

If someone who drops out of Obamacare gets sick, it isn't difficult to get back on. Theoretically, they are supposed to wait until the next open enrollment period (November 1 through January 15). But they can receive immediate enrollment if there is a "qualifying event" such as getting married, having a baby, or moving to a new ZIP Code. Native Americans and Alaskan Natives have access to continuous open enrollment.

Third, having health insurance isn't the same as having health care. Although Obamacare (including the Medicaid expansion) has helped cut the number of uninsured people in the United States nearly in half, all that spending has resulted in very little benefit, including for enrollees.

Twenty Cents on the Dollar

Medicaid enrollees place a low value on enrollment. Low-income adults value their Medicaid coverage at about 20

to 50 cents on the dollar of what their plans cost the taxpayers.

Medicaid also doesn't seem to make much difference to enrollees' health. The most rigorous study of the matter was the Oregon Health Insurance Experiment, a one-of-a-kind randomized controlled trial. Researchers selected Medicaid enrollees by lottery.

After two years, researchers compared the medical conditions of those on Medicaid and those not on the program. Those who had enrolled had less financial stress and were less likely to be depressed, but there was no significant improvement in their physical health.

'Implicit Insurance'

As one of the Oregon investigators, MIT economist Amy Finkelstein, explained in a recent interview, people without health insurance still get about 80 percent of the health care that Medicaid enrollees do. When they're confronted with high medical bills, they usually pay only a small portion of the total amount.

Sometimes this means taking on debt, but as Finkelstein said in MIT

News on December 15, 2018, "the nominally uninsured have a fair amount of implicit insurance." This can include help from nonprofit hospitals or government-funded health clinics.

In other words, Medicaid has little marginal value. Among the lottery winners who were offered enrollment in the Oregon study, more than half turned it down.

Fake Access

Likewise, Obamacare has done little to improve access to health care. A study in the *American Journal of Public Health* found that after the introduction of Obamacare in 2010, there was a small increase in the number of low-income patients who had at least one doctor's office visit.

However, that was offset by "small, nonsignificant reductions" among the rest of the population. There was no change for the population as a whole.

The United States has spent almost \$200 billion a year on Obamacare subsidies. If the One Big Beautiful Bill can reduce some of this waste, it will cause little harm while saving taxpayers a lot of money.

John C. Goodman, Ph.D., (johngoodman@goodmaninstitute.org) is co-publisher of Health Care News and president and founder of the Goodman Institute for Public Policy Research. A version of this article was published in The Wall Street Journal. Reprinted with permission.

Judge Blocks Use of Medicaid Data for Immigration Enforcement

By AnneMarie Schieber

A federal judge has ordered the U.S. Department of Health and Human Services (HHS) to stop sharing Medicaid data with Immigration and Customs Enforcement (ICE).

HHS began sharing Medicaid data in June 2025. On July 4, President Donald Trump signed the One Big Beautiful Bill Act, which stops federal funds intended for law-abiding Americans from being used to pay for non-emergency Medicaid benefits for people illegally in the country.

In June, a coalition of 20 states filed a lawsuit to prevent HHS from sharing Medicaid data, arguing it is a violation of the Health Insurance Portability and Accountability Act (HIPAA).

The preliminary injunction, issued August 12 by U.S. District Judge Vince Chhabria of the Northern District of California, remains in effect until HHS and DHS perform a process that complies with the Administrative Procedures Act.

Established Practice

Chhabria's decision states there is nothing unlawful about the data sharing, but the practice reverses policies of previous administrations.

"Given these policies, and given that the various players in the Medicaid system have relied on them, it was incumbent upon the agencies to carry out a reasoned decisionmaking [sic] process before changing them," wrote Chhabria in his ruling. "The record in this case strongly suggests that no such process occurred."

'Unchecked Eligibility'

"The states are prioritizing the interests of noncitizens over American taxpayers who foot the bill for a bloated welfare system already strained by unchecked eligibility," said Gary Alexander, director of the Medicaid and Health Safety Net Initiative at the Paragon Health Institute.

Alexander has served as Secretary of Human Services and Medicaid director for both Pennsylvania and Rhode Island and launched programs to eliminate waste, fraud, and abuse.

"During my tenures in Rhode Island and Pennsylvania, I wrote numerous letters to the Centers for Medicare and Medicaid Services and [the Department of Agriculture's] Food and Nutrition Services about these data-sharing



issues," said Alexander. "They all fell on deaf ears. Also, critics claim that it will deter immigrants from health care, but that's a red herring: emergency care remains available, and the real issue is preventing fraud that drains billions from hardworking Americans and takes benefits away from the truly vulnerable."

'It's Been a Joke'

Since 1996, illegal immigrants have been able to receive emergency care under the Emergency Medical Treatment and Active Labor Act (EMTALA). Federal law prohibits hospitals from releasing patients without a treatment plan, so illegal immigrants without financial resources may stay longer than necessary.

Loopholes and lax enforcement have made keeping immigrants from receiving non-emergency care an uphill battle, says Alexander.

"It's been a joke, allowing billions in improper payments and fraud that conservatives have railed against for decades," said Alexander. "In essence, it's unrealistic to think we can fully prevent this without stronger tools like data sharing."

'Applicants Game the System'

Verification failures and "bureaucratic ineptitude" extend Medicaid to people who are ineligible, says Alexander.

"States use the Federal Data Services Hub to check status, but self-attestation lets applicants game the system with provisional approvals that often go unverified," said Alexander. "Mismatched from faulty databases or missing docs mean ineligible folks slip through, especially in mixed-status

families where citizen kids qualify but parents shouldn't.

"This isn't rocket science; it's basic accountability that big-government types ignore to inflate rolls," said Alexander.

'Audits Reveal Sloppy Reporting'

Another problem is that blue states such as California and New York supposedly use their own money to cover illegal immigrant adults for non-emergency Medicaid services while blurring the line between state and federal funds.

"Audits reveal sloppy reporting, with federal funds subsidizing nonemergency care for ineligible," said Alexander. "The COVID-era pause on verifications supercharged this mess, and even post-unwinding error rates are high because oversight is under-resourced and politicized."

Long ago, the federal government long ago abdicated its responsibility to monitor spending, says Alexander.

"For too long, Washington has prioritized Obama-era expansions over enforcement, leading to GAO reports exposing massive waste," said Alexander.

"The feds' poor job of checking states stems from a lack of will—until now, with Trump's team pushing audits and penalties," said Alexander. "It's about time we demand real accountability."

'Transparency Trumps Secrecy'

Enrollees forfeit their privacy by accepting taxpayer money, says Alexander.

"When taxpayers are paying, transparency trumps secrecy," said Alexander. "Enrollees consent to data sharing



"It's been a joke, allowing billions in improper payments

and fraud that conservatives have railed against for decades," said Alexander. "In essence, it's unrealistic to think we can fully prevent this without stronger tools like data sharing."

**GARY ALEXANDER
DIRECTOR OF THE MEDICAID AND
HEALTH SAFETY NET INITIATIVE
PARAGON HEALTH INSTITUTE**

for eligibility checks, including with DHS. It's right there in the fine print."

Sharing data between government agencies to root out fraud is smart government, says Alexander.

"In a free-market world, we'd minimize government involvement altogether, letting private charity and insurance handle care without this mess," said Alexander. "But as long as Medicaid exists, privacy isn't absolute; it's balanced against preventing abuse."

Buying Time for Lawbreakers?

Restricting data sharing is a tactic for protecting illegal activities, says John Dunn, M.D., J.D., an emergency medicine physician in Texas and policy advisor to The Heartland Institute, which co-publishes *Health Care News*.

"Illegal aliens are not supposed to be eligible for welfare programs, and the judge wants them to be able to get their benefits," said Dunn.

"Medicaid information going to ICE would help ICE track and identify illegals who are not easy to track because they are off the grid and their only contact with the government might be as Medicaid recipients," said Dunn. "The info about where they receive their checks and benefits and under what name would allow ICE to identify them so they can be apprehended. The judge wants to impair the ability of ICE to find and identify illegals."

AnneMarie Schieber (amschieber@heartland.org) is the managing editor of *Health Care News*.

Urban Hospitals Pose as Rural for Federal Money, Study Finds

By Bonner Russell Cohen

A growing number of urban hospitals are reclassifying themselves as both urban and rural to reap financial benefits Congress intended for rural hospitals only, a new study has found.

"In 2016, in response to two federal court decisions, the Centers for Medicare and Medicaid Services began allowing geographically urban hospitals to be dually classified as urban and rural simultaneously," states the study published in *Health Affairs*. "This dual classification enables hospitals to use urban wage indexes for calculating Medicare reimbursements, while also benefiting from Medicare policies solely intended to support rural health."

The study said cases of dual classification rose from three in 2017 to 425 in 2023. More than 75 percent were non-profit institutions in large metropolitan areas, including many large academic centers. Prevalence varied by state.

Congressional Attention

It did not take long for the results of



the study, "Sharp Rise in Urban Hospitals with Rural Status in Medicare, 2017-2023," to draw attention on Capitol Hill.

"The dual classification scheme imposes damaging costs on American taxpayers as well as our rural communities who are at risk of seeing critical

resources like affordable doctors and medicines being funneled away to feed the bottom line of urban hospitals," said Rep. Jason Smith (R-MO), chairman of the House Ways and Means Committee, in an August 19 statement.

"As the committee with jurisdiction over Medicare hospital payments, we must restore integrity, common sense, and balance to the system," said Smith.

Rural Hospital Closures

The findings come at a time when the Centers for Medicare and Medicaid Services reports Medicare spending grew 8.1 percent to more than \$1 trillion in 2023, or 21 percent of all health care spending, and 193 rural hospitals closed over the past 20 years.

"Truly rural hospitals continue to struggle, while large urban academic medical centers see record profits," states a House Ways and Means Committee news release. "According to data from the Sheps Center for Health Services Research, 112 rural hospitals have completely closed in the past 20 years. At the same time, the top 20 hospitals abusing the dual classification process, many of them nonprofits and large, academic medical centers, are exceeding a combined \$80 million in net patient revenue in one year alone."

The *Health Affairs* study lists some of the benefits urban hospitals can reap while using dual classification, such as certain Medicare benefits intended for rural hospitals and "potential eligibility for sole community hospital, rural referral center, and Medicare-dependent small rural hospital status; lower eligibility standards for participation in the 340B Drug Discount Program; and increased graduate medical education slots."

Drug Discounts

The dual-classification arrangement has led to misuse of the federal 340B Drug Discount Program, which requires drug makers to sell drugs at reduced prices to struggling hospitals, often in rural areas, the study says.

"Concerningly, dual classified hospitals now have easier participation in the 340B program through needing to meet the rural disproportionate share hospital adjustment percentage of 8 percent compared with an 11.75 percent threshold for urban hospitals, effectively meaning that these hospitals can serve a lower number of low-income patients to qualify," the study states.

The use of the 340B program by urban hospitals due to the dual classification arrangement has brought renewed attention to the troubled drug program for low-income people, states an August 6 analysis by the Commonwealth Fund.

"[S]ome believe the 340B program's growth has contributed to consolidation in the health care industry, with more and more hospitals acquiring provider practices and specialty pharmacies," states the analysis. "The program has also been criticized for worsening generic drug shortages and for incentivizing hospitals to shift care from underserved areas to wealthier communities in a bid to raise revenue."

Double Injury

Dual classification hides the true magnitude of rural hospitals' struggles, says Merrill Mathews, Ph.D., a columnist on health care and other issues for *The Hill*.

"According to a Kaiser Family Foundation report, 193 rural hospitals closed between 2005 and 2024, raising concerns about access to care for millions of rural Americans," said Mathews. "When urban hospitals seek dual classification, as both urban and rural, it can skew the perception, making it appear that rural-hospital decline is not as severe as it is, which can affect how policymakers respond."

Use of workarounds to take advantage of government programs is widespread, says Matthews.

"Many hospital systems have become masters at how to maximize revenue by gaming Medicare's and Medicaid's system of regulations and price controls," said Matthews.

Bonner Russell Cohen, Ph.D., (bonner-cohen@comcast.net) is a senior policy analyst with the Committee for a Constructive Tomorrow.



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Mandatory Charity Care Is Unconstitutional Taking of Property, Hospitals Say

By AnneMarie Schieber

Several hospital systems are considering an appeal to the U.S. Supreme Court after the New Jersey Supreme Court rejected their claim that inadequate compensation for charity care is an unconstitutional taking of private property without just compensation.

New Jersey's charity care program prohibits hospitals from billing patients who qualify for charity care, which the state defines. The state compensates hospitals for the care with annual payments from its Health Care Subsidy Fund. The hospitals say the program fails to cover the basic cost of care and does not compensate them for the use of their facilities, staff, supplies, and treatment services.

Regulated Care

On July 16, the New Jersey Supreme Court ruled against the providers.

"Under the facts as presented in this case, we hold that charity care is not an unconstitutional 'per se' physical taking of private property without just compensation," the majority opinion states. "It does not grant an affirmative right of access to occupy hospitals; it does not give away or physically set aside hospital property for the government or a third party; and it does not deprive hospitals of all economically beneficial use of their property."

"We also hold that charity care is not an unconstitutional 'regulatory' taking of private property without just compensation," the court ruled. "That is due to the highly regulated nature of the hospital industry and the legislatively declared paramount public interest that the charity care program serves."

Compensation Concern

The hospitals, eight for-profit and nonprofit general acute-care facilities operating throughout the state, argued the inadequate compensation was their main complaint, not the requirement to provide charity care. The state's

"By passing [the Emergency Medical Treatment and Active Labor Act], Congress required hospitals to provide free services to patients with 'emergent' conditions. In cases of serious illness or injury to illegal aliens or people who simply refuse to pay, this can cost hospitals millions of dollars. When hospitals are privately owned, this effectively expropriates funds from private investors."

LINDA GORMAN

DIRECTOR OF HEALTH CARE POLICY, INDEPENDENCE INSTITUTE

Supreme Court said the financial issue is best resolved in the state legislature.

John Zen Jackson, the attorney representing the hospitals, told *NJ Advance Media*, the court's analysis is "flawed" and "contrary to the trend of United States Supreme Court decisions in the last decade finding wrongful physical takings occurring in regulated industries and activities."

Charity care subsidies are not a dollar-for-dollar reimbursement, the court's opinion acknowledged. The state apportions reimbursements based on what the legislature funds, which cannot be less than 75 percent of what hospitals provide per year in charity care.

The state reimburses hospitals "by dividing the amount of hospital-specific gross revenue for charity care patients by the hospital's total gross revenue for all patients," says the opinion. The cost of care is based on Medicaid rates, which are far below market value.

The tradition of mandated charity care goes back 178 years, codified by the state "to protect the general health and welfare of its citizens," the court's opinion states. New Jersey's Certificate of Need laws also require facilities to provide charity care, as does the federal Emergency Medical Treatment Active Labor Act (EMTALA).

Long Tradition

Hospitals are "legally required to offer

financial assistance—but the systems in place are broken," states the website of "Dollar For," an organization calling for an improved application process for charity care, better ways to identify patients who need financial assistance, and "debt collection protections to prevent aggressive billing."

Eli Rushbanks, the organization's general counsel, says the court decided the case correctly.

"The 'takings clause' was an interesting argument the hospitals put forward," said Rushbanks. "At the federal level, nonprofit hospitals receive a tax exemption, so that is compensation to them. We see a lot of financial-assistance denials because the hospitals require people to apply for Medicaid before they can receive financial assistance, and that takes time."

Most hospitals today are far from poor, says Rushbanks.

"We have the Ascensions, and the Mayo Clinics, and the Providences, some of the most well-off financial organizations in the country," said Rushbanks. "They have lots of cash, massive investments, and foundation funds. Little revenue comes from actual patient services."

Costly Mandates

State and federal laws that require hospitals to provide charity care have forced many to close departments with high charity volume, says Linda

Gorman, director of health care policy at the Independence Institute.

"EMTALA has proven to be so costly that some hospitals closed their emergency departments," said Gorman. "Others shut down their obstetrics units. Both generated substantial amounts of uncompensated care."

States on the southern border, where the costs of treating illegals have historically been concentrated, are hit especially hard by the federal mandate, says Gorman.

"Some hospitals have had to defer elective surgeries, as the costs of treating people who do not pay have made them unable to pay for adequate staffing," said Gorman.

"While Medicaid expansion has reduced uncompensated care, losses from Medicaid underpayment have likely exceeded the uncompensated care gains," said Gorman.

Takings Clause Confusion

Mandatory charity care that is not fully compensated requires people to give away their time, services, and capital investments, says Gorman.

"By passing EMTALA, Congress required hospitals to provide free services to patients with 'emergent' conditions," said Gorman. "In cases of serious illness or injury to illegal aliens or people who simply refuse to pay, this can cost hospitals millions of dollars. When hospitals are privately owned, this effectively expropriates funds from private investors."

The New Jersey Supreme Court suggests there is a difference between taking real estate without payment and appropriating services without compensation, says Gorman.

"Real estate is constitutionally protected," said Gorman. "The money people earn to purchase the real estate? Not so much. Economically, there isn't really a difference—but with law, who knows?"

AnneMarie Schieber (amschieber@heartland.org) is the managing editor of Health Care News.

Minnesota Lawmakers Approve Medicaid Payment for Home Births

By Bonner Russell Cohen

Minnesota lawmakers approved legislation requiring Medicaid to pay for home births, including paying nurses and midwives the same rate as doctors.

The legislation requires payment for Medicaid home births under certain conditions. Mothers must be “low-risk” patients and have a home birth and transfer plan to a hospital if needed. Coverage would include prenatal, labor, birth, and postpartum care.

The bill, sponsored by a state senator who gave a political speech in 2022 while in labor, was passed as part of a special session agreement with Gov. Tim Walz in June.

“SF 1113 aims to codify Medical Assistance coverage of birth services provided at home,” wrote Minnesota state Sen. Erin Maye Quade (D-District 56) on Facebook. “In rural communities with limited or inconsistent access to perinatal care, home birth providers offer critical care to fill the gaps. This bill will allow home birth providers to serve more Medicaid clients who choose to give birth in their homes and improve reimbursement rates for those providing these services.”

Physician Rates for Nonphysicians

Minnesota’s expansion of Medicaid to include home births is part of a growing trend since the pandemic. A report by KFF in 2022 found 25 out of 42 state programs provided some level of home birth coverage, though many require a physician’s presence.

Minnesota’s new law will pay professional providers such as midwives, doulas, and nurses 100 percent of the physician rate and does not require a medical doctor to be present.

“It seems that Minnesota is devaluing the services of the most highly trained practitioners in caring for a high-risk population,” said Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons. “A group that has a higher mortality rate is more likely to need services not available at home, such as transfusions or surgical interventions for hemorrhage.”

The state’s Medicaid program will also pay mothers a “facility services fee” at 70 percent of the statewide average hospital rate for an uncomplicated non-caesarean delivery at home.



“If a patient is transported to the hospital before delivery, the facility service payment will be reduced to 15% of the average hospital rate,” a summary of the law notes.

Equity over Safety

Although the new law is intended to provide more equitable treatment to low-income people, it could endanger the health of mothers and newborns, says Matt Dean, a policy fellow at the Center of the American Experiment.

“A 2022 Minnesota study found that black women were 2.3 times more likely to die from a childbirth-related event than white women,” Dean wrote. “Given that 72.9 percent of all pregnant black women in Minnesota are served by Medicaid, this population is at a significantly higher risk for complication and possible death during childbirth. Keeping them out of the hospital will make that worse, not better.”

Classifying home births as no different from hospital deliveries sends a false message, says Dean.

“Significantly, pregnant women of color are being told that hospitals are inherently unsafe,” wrote Dean. “The number of black women who delivered at home tripled from 2016 to 2023. While there are challenges to care for marginalized populations, scaring them away from hospitals is just plain dangerous.”

Flight from Safety

The characterization of hospitals as

unsafe puts mothers and children in greater danger of poor treatment outcomes, Dean told *Health Care News*.

“The trope of the ‘racist hospital’ is driving moms toward care that is unquestionably less safe for them and their babies,” said Dean.

“Paying Medicaid patients to give birth at home will hurt African-American women and their babies because once again our woke ‘betters’ got it backwards,” said Dean. “The infant and maternal mortality rates will go up, not down, if women are paid to stay away from the hospitals for a patient population with less access to prenatal care and higher likelihood of needing lifesaving interventions unavailable at home.”

Ideology Against Quality

Legislators should emphasize quality of care, not ideology, says Donna Jackson, a senior policy analyst with the Committee for a Constructive Tomorrow (CFACT) and a black mother of five children.

“Equity always seems to come with lowering the quality of care and services for minority communities while pretending to show compassion,” said Jackson.

“Having access to high-quality health-care services is absolutely critical for minority birth mothers, who tend to suffer from several high-risk health conditions such as high blood pressure, diabetes, and so on that put their pregnancies at risk,” said Jackson. “This move to push pregnant minority

“Now, with pricey doulas and midwife services available to wealthier patients, advocates are demanding Medicaid moms have access to home delivery. While some studies show planned home births have comparable outcomes when conditions are perfect and predictable, the factors that make things perfect are far less predictable for the poor as compared to the rich. Many advocates are the highly educated, wealthy folks who, for their own care, demand and receive concierge-level services often paid for in cash.”

MATT DEAN
POLICY FELLOW
CENTER OF THE AMERICAN
EXPERIMENT

mothers toward home deliveries shows the real focus is on ideology instead of access to high-quality health care.”

Status over Substance

Although home birth has grown in popularity over the years and has become more sophisticated, it is still a niche market, says Dean.

“Now, with pricey doulas and midwife services available to wealthier patients, advocates are demanding Medicaid moms have access to home delivery,” wrote Dean. “While some studies show planned home births have comparable outcomes when conditions are perfect and predictable, the factors that make things perfect are far less predictable for the poor as compared to the rich. Many advocates are the highly educated, wealthy folks who, for their own care, demand and receive concierge-level services often paid for in cash.”

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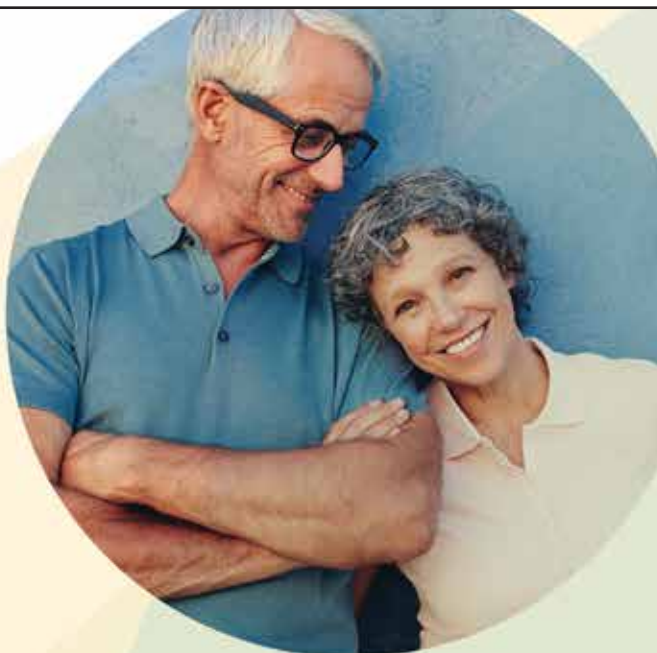
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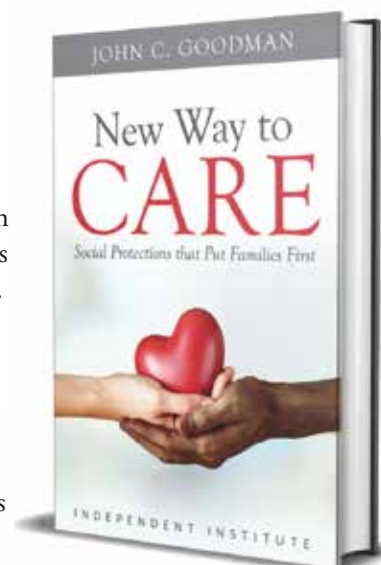
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