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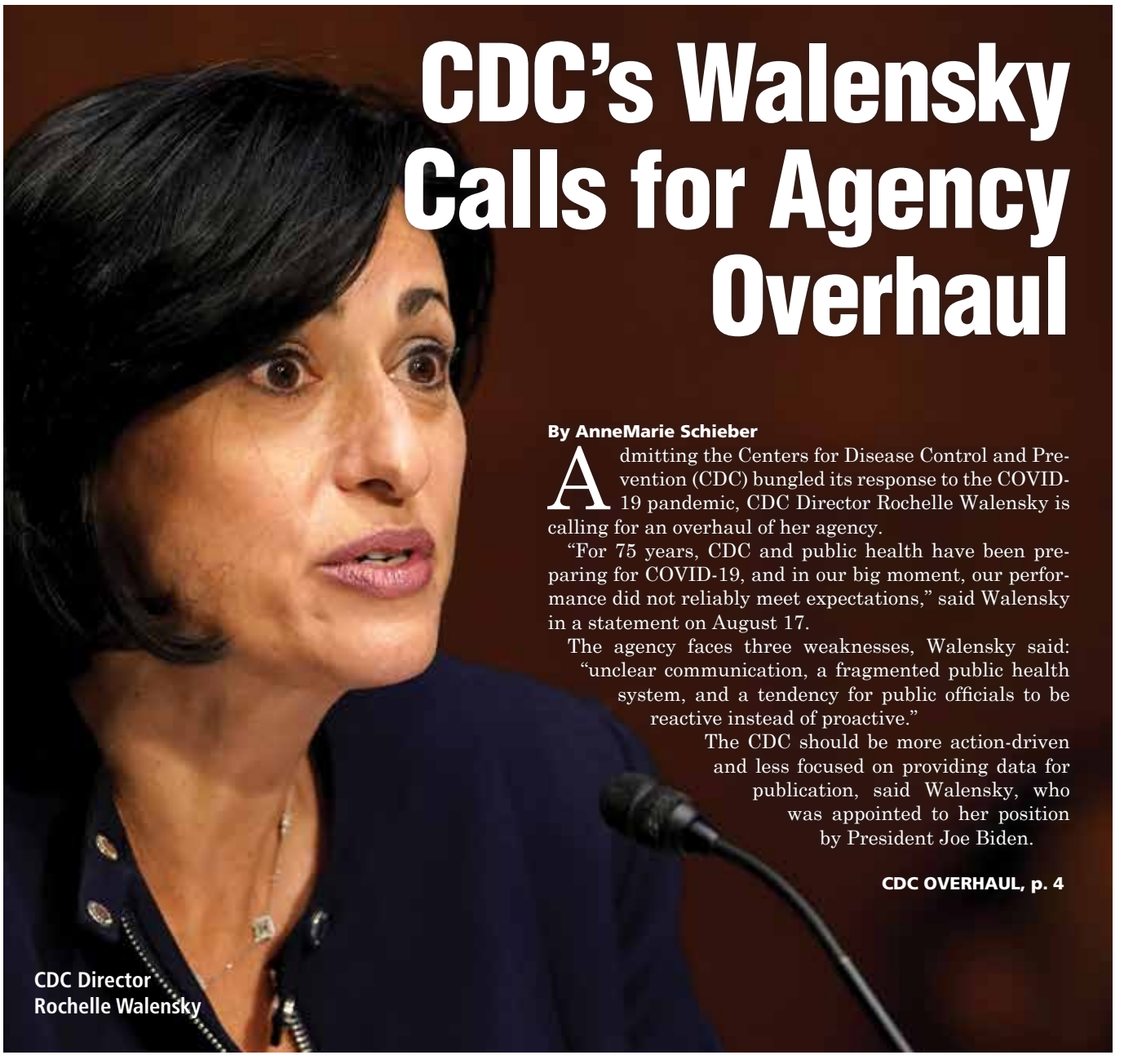
The Pulse

CDC's Walensky Calls for Agency Overhaul



CDC Director Rochelle Walensky

PHOTO COURTESY POOL/POOL/GETTYIMAGES

By AnneMarie Schieber

Admitting the Centers for Disease Control and Prevention (CDC) bungled its response to the COVID-19 pandemic, CDC Director Rochelle Walensky is calling for an overhaul of her agency.

"For 75 years, CDC and public health have been preparing for COVID-19, and in our big moment, our performance did not reliably meet expectations," said Walensky in a statement on August 17.

The agency faces three weaknesses, Walensky said: "unclear communication, a fragmented public health system, and a tendency for public officials to be reactive instead of proactive."

The CDC should be more action-driven and less focused on providing data for publication, said Walensky, who was appointed to her position by President Joe Biden.

CDC OVERHAUL, p. 4

Medicare Prescription Drug Price Controls Come with Strings Attached

By Bonner Russell Cohen

The Schumer-Manchin Inflation Reduction Act (IRA) includes provisions that will change the market for Medicare prescription drugs and boost the federal government's role in setting prices for pharmaceuticals.

The IRA's supporters point to out-of-pocket savings to seniors resulting from the new law's Medicare provisions, but many of them won't take effect for years, and they will come with undesirable tradeoffs.

People enrolled in Medicare Part D

PRICE CONTROLS, p. 6

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COMMENTARY

Finally, FDA Allows Over-the-Counter Hearing Aids

By Devon Herrick

The U.S. Food and Drug Administration (FDA) finally cleared the way for over-the-counter (OTC) hearing aids. Yes, this is a "no-brainer," and the most obvious question is: Why did it take so long? The law directing the FDA to approve OTC hearing aids was passed five years ago, in August 2017.

Under the new FDA rule announced on August 16, people with mild to moderate hearing loss should be able to buy hearing aids online and in retail stores as soon as October, without being required to see a doctor for an exam to get a prescription.

Hearing aids are not covered by traditional Medicare, and many people simply choose to do without them because of the cost. Hearing aids that require a prescription cost anywhere from $1,400 at Costco to a multiple of that elsewhere. I recall a relative saying she was quoted $8,000 for a pair, and she was assured they were better than the cheaper ones.

Officials anticipate OTC hearing aids will save an average of $2,800 off the cost seniors currently pay for audiology testing and legacy devices. The move is not without critics, especially those who benefit from the status quo.

Audiologists Unhappy

The move has rankled some audiologists, the professionals who guide people through the process of choosing the best hearing aid, adjusting the settings, and achieving the right fit. The new rule eliminates the longstanding requirement that consumers start with them in getting a hearing aid.

The legislation authorizing this was initially sponsored by Senators Chuck Grassley (R-IA) and Elizabeth Warren (D-MA). They issued a joint report in June 2022 alleging the legacy hearing aid manufacturers were engaged in AstroTurf lobbying and otherwise trying to obstruct competition from cheaper OTC hearing aids.

Warren and Grassley identified 19 industry-driven form letters that were submitted in 400 comments to the FDA. That represents 40 percent of the comments received in response to the proposal. The industry clearly did not want $250 OTC hearing aids to be of the same quality as those costing $1,400 to $8,000 and thus an obviously attractive alternative.

Stuck for Five Years

It's been nearly five years since President Donald Trump signed into law the Over-the-Counter Hearing Aid Act. The bipartisan bill, introduced by Grassley and Warren, was intended to make hearing amplification devices much cheaper and more readily accessible.

The Act gave the U.S. Food and Drug Administration (FDA) three years to formulate a guidance proposal and an extra six months to collect comments and issue final guidance. Then COVID got in the way. Or was it bureaucratic inertia?

Deadlines Missed

In April of this year, Grassley and Warren introduced a bill to force the FDA to issue its Final Rule within 30 days of the new law taking effect. The Final Rule would clarify the steps and parameters manufacturers must follow for OTC hearing aids to become widespread. The FDA had already missed its original three-year deadline in 2020.

President Joe Biden issued an Executive Order in July 2021 ordering the FDA to complete the rule. The FDA eventually proposed a rule in October 2021, but it didn't issue the Final Rule until August 2022. That's the second deadline the FDA missed.

You may recall similar delays occurred a few years ago with the Sunscreen Innovation Act of 2014. That law was designed to force the FDA to approve more sunscreen ingredients, most of which had been used safely in Europe for years.

After the bill became law, eight ingredients used in European sunscreens were submitted to the FDA for approval. The FDA rejected all of them, stating it wanted the industry to conduct extensive, detailed studies before it would approve these ingredients. The industry refused to perform these expensive studies because of the cost.

More Than a Money-Saver

The FDA says about 30 million Americans experience hearing loss and only one in five seek treatment. Recent studies have identified untreated hearing loss as a contributing factor to dementia, isolation, and depression in seniors.

The new rule will take effect in 60 days (mid-October). There are already rudimentary hearing amplification devices on the market (Apple AirPod Pro earbuds can amplify sound in addition to playing music), and the rule will encourage more electronics manufacturers to enter the market and improve the quality.

Devon Herrick, Ph.D. (**devonherrick@sbcglobal.net**) *is a health economist.* *A version of this article was published on the Goodman Institute's health care blog on August 17. Reprinted with permission.*

CDC's Walensky Calls for Agency Overhaul

CDC Director Rochelle Walensky

PHOTO COURTESY POOL/POOL/GETTYIMAGES

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Abundant Blunders

In its 66-year history, the CDC has handled several pandemics, such as the Hong Kong flu in 1968, SARS-CoV-1 in 2002, swine flu in 2009, and MERS in 2015. Unlike those instances, the agency's response to COVID-19 widely infuriated the public and failed to stop the virus.

Among other failures, the CDC missed entry of the virus into the United States by at least one month. After it acknowledged a case on January 8, 2020, the CDC blocked private labs from deploying a diagnostic test for the virus, and when it took over the effort, the agency delayed getting a working test out the door by as much as six weeks.

The CDC has continuously changed its guidance on masking, social distancing, and lockdowns. It withheld critical information about the virus, kept changing guidance on whether the virus was spread by droplets or aerosols, and was caught conferring with a teachers union on a federal government policy toward reopening schools.

The CDC banned rental evictions and ordered the use of masks on airplanes and public transportation. Federal courts put an end to those actions.

The agency has also been criticized for going beyond its scope of "disease control and prevention" by diving into ideological issues such as obesity shaming, "health equity," climate change, and gender confusion among teens (see article, page 18).

'Walk It Back'

The CDC has plenty of problems to fix, though becoming less "fragmented" and producing data more "proactively" are not among them, says Marilyn Singleton, M.D., J.D., author of "COVID-19: A Weapon to Fundamentally Transform America," a policy paper published by the *Journal of American Physicians and Surgeons*.

> **"States have police power; CDC does not. To complain about a 'fragmented public health system' is to miss that point entirely. State and local agencies are not subservient to the CDC. Rather, the federal agency exists to serve state and local agencies by providing them with accurate and actionable data and recommendations that they use to inform their policy decisions."**
>
> **DOUG BADGER, THE HERITAGE FOUNDATION**

"First, it needs an independent, external review to see how the public health agency should actually work," said Singleton on *The Heartland Daily Podcast* on August 22. "When you look at the CDC's history, when it started in 1946 it was a center for communicable diseases, and that might be the first step. Walk it back to communicable diseases—period, end of story."

Power Grabs

Walensky overlooks two of her agency's most serious flaws: setting policies without first collecting evidence of their benefits and risks, and exceeding its statutory authority, says Doug Badger of The Heritage Foundation.

"The CDC backed extended school closures despite the infinitesimal risk of severe illness to children and the obvious harm the policy inflicted on them," said Badger. "It was the only public health agency in the world that recommended—and still recommends—masking two-year-olds."

The CDC has not followed the science, says Badger.

"It continues to advocate for school mask mandates in counties with high levels of community infection, despite the evidence that they do not reduce pediatric transmission," said Badger. "The CDC never did randomized, controlled trials to determine the effectiveness of any of its nonpharmaceutical interventions, from distancing to masking to vaccine mandates to public transportation mask mandates."

The CDC also suffers from overstepping its authority as it did with the eviction moratorium and public transportation mask mandates, says Badger.

"CDC has only the power that Congress grants it in statute," said Badger. "The agency must learn its legal boundaries and dedicate itself to operating inside them."

Reverse Federalism

The constitutional distinction between state and federal powers is also an important problem with the CDC, says Badger, who coauthored a policy paper titled "COVID-19 and Federalism: Public Officials' Accountability and Comparative Performance," published by Heritage in 2021.

"States have police power; CDC does not," Badger told *Health Care News*. "There is no centralized federal public health agency with the authority to dictate policy nationally.

"To complain about a 'fragmented public health system' is to miss that point entirely," said Badger. "State and local agencies are not subservient to the CDC. Rather, the federal agency exists to serve state and local agencies by providing them with accurate and actionable data and recommendations that they use to inform their policy decisions."

'Deeply Flawed' Plan

Unclear communication is also a problem at the CDC, as Walensky stated, but that results more from politics than from procedural flaws, says Badger.

"Examples are the influence teachers' unions exerted on agency guidance about extended school closures, and the issuing of pronouncements in the name of science without doing the hard work of determining their scientific validity," said Badger. "Walensky is right to criticize her agency, but her diagnosis and treatment plan are deeply flawed."

It is evident the pandemic was a political football, as indicated by then-senator Kamala Harris saying she didn't trust the COVID-19 shots when Donald Trump was president but went all-in for them when she and President Joe Biden took office, says Singleton.

"It was not as though Trump was in a lab coat, making the vaccine, so you can see the whole thing became political, to be used in an election," said Singleton.

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

CDC Recognizes Acquired Immunity to SARS-CoV-2

By Bonner Russell Cohen

The Centers for Disease Control and Prevention (CDC) now recognizes the role of acquired immunity for COVID-19.

In a revised "guidance for minimizing the impact of COVID-19," published on August 19, the CDC says the risk of infection with COVID-19 "is considerably reduced by immunity derived from vaccination, previous infection or both," and "persons that have had COVID-19 but who are not vaccinated have some degree of protection against serious illness from their previous infection."

From the beginning of the pandemic two and one-half years ago, the CDC has at various times touted social distancing, quarantines, masks, and vaccinations exclusively as protection against the virus.

Citing the high level of immunity in the U.S. population—from vaccination, previous illness, or both—the CDC rolled back its quarantine recommendations regardless of vaccination status.

"It is quite apparent that the COVID injections are not preventing infection or transmission, and thus there is no public health justification for discriminating against unvaccinated persons."

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

Some Mandates Remain

As of late August, New York University required students to be "fully vaccinated against COVID-19 and boosted, as soon as they are eligible, unless they have been granted a medical or religious exemption."

Other high-profile universities with vaccine and/or mask mandates for the fall term include Georgetown, Columbia, Johns Hopkins, Rice, and American University in Washington, D.C.

The Washington, D.C. public schools announced children were required to show proof of vaccination this fall or would not be allowed to attend classes in person and would not have a remote-learning option. According to the city's "Vaccine Data" website, 47 percent of black children ages 12-15 in the district had not completed the primary vaccination series required for in-person schooling.

After *The Daily Signal* reported the proof-of-vaccination requirement would keep many black children from attending school this fall, the D.C. government abruptly changed course and postponed the vaccine mandate until January 3, 2023.

FDA Clears Boosters

Meanwhile, the Food and Drug Administration (FDA) issued an emergency use authorization for new boosters developed by Pfizer and Moderna targeting the now-prevalent BA.4 and BA.5 omicron subvariants, on August 30. The boosters have not undergone human trials.

The COVID-19 shots serve no public health purpose, says Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons and a policy advisor to The Heartland Institute, which co-publishes *Health Care News*.

"It is quite apparent that the COVID injections are not preventing infection or transmission, and thus there is no public health justification for discriminating against unvaccinated persons," said Orient. "It is asserted that the shot will protect you against hospitalization and death, but that is looking increasingly dubious. The number of severe adverse reactions, including death, reported in close association with the shot, is unprecedented. More and more physicians are urging regulatory authorities to 'stop the shot.'"

Bonner Russell Cohen, Ph.D. (**bcohen@nationalcenter.org**) *is a senior fellow at the National Center for Public Policy Research.*

CDC's New Guidance Boosts Legal Challenges to Mandates

By AnneMarie Schieber

The Centers for Disease Control and Prevention's (CDC) newly adopted formal recognition of the existence of natural immunity to COVID-19 undermines a key argument for vaccine mandates.

So says Mark Chenoweth, president and general counsel at the New Civil Liberties Alliance.

"So long as federal guidance backed these mandates, other public entities could argue to a court that they had a rational basis for following federal guidance, even if the federal science was flawed," said Chenoweth. "That rational-basis argument will no longer be available to them."

The CDC's new guidance on protection against COVID-19, released on August 11, no longer states shots are the best and only way to keep people safe.

"CDC's COVID-19 prevention recommendations no longer differentiate based on a person's vaccination status because breakthrough infections occur, though they are generally mild, and persons who have had COVID-19 but are not vaccinated have some degree of protection against severe illness from their previous infection," states the agency's website.

'Will Make Lawsuits Easier'

Despite the new guidance, organizations such as New York University and Google still require vaccinations for employees and students as a condition of entering facilities or for employment.

The CDC guidance will help individuals in suing organizations that impose mandates, says Chenoweth.

"This will make lawsuits easier and possibly more plentiful against entities that insist on continuing with vaccine mandates," said Chenoweth. "We are following several situations and looking for the best opportunity to file a lawsuit against such an employer or school and against the officials responsible for the mandate."

Legal Actions Taken

When institutions first required COVID-19 shots, many denied medical or religious exemptions. Legal action has forced them to modify their mandates.

Among these cases, a federal judge in Ohio blocked the Air Force, Space Force, and Air National Guard from denying a religious exemption to their mandate, on July 27.

The first settlement in a class-action lawsuit was reached when NorthShore University Health System in Illinois agreed to pay $10.3 million to settle workers' claims for unlawfully denying religious exemptions to a policy that required COVID-19 shots as a condition of employment, on August 1.

The NorthShore settlement will not directly affect other cases involving the denial of religious exemptions working their way through the courts, says Doug Seaton, an attorney at the Upper Midwest Law Center, who is representing employees in a similar case.

"We would like to get some ringing appellate court decisions that are citable precedent for other cases," said Seaton on The Heartland Daily Podcast on August 11.

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

Medicare Prescription Drug Price Controls Come with Strings Attached

Continued from page 1

prescription drug plans, for example, will see their share of prescription drug costs capped at $2,000 per year starting in 2025. The new law also ends the 5 percent coinsurance payment requirement for Medicare Part D recipients with catastrophic prescription drug costs, in 2024.

Not Many Helped

Kansas state Rep. Beverly Gossage (R), president of HSA Benefits Consulting and a health policy fellow with Physicians for Reform, says eliminating the 5 percent coinsurance payment will benefit fewer patients than it might first appear.

"A senior does not pay that 5 percent of medication costs until his out-of-pocket expenses for prescription drugs reach $7,050 that year," said Gossage. "I can't see anyone doing handsprings over that."

The new law also allows the U.S. Department of Health and Human Services (HHS) to "negotiate" prices for high-cost drugs with manufacturers, with price controls on the first 10 drugs under Medicare Part D going into effect in 2026, and on drugs covered under Medicare Part B, which are administered by a physician, in 2028.

By 2029, a total of 60 drugs will be subject to price negotiation, a fraction of the thousands of drugs Medicare covers.

'Produces Negative Results'

The new Medicare prescription drug approach will increase taxpayer costs, says Doug Badger, a senior fellow for health care policy at The Heritage Foundation.

"The goal of restructuring the Part D benefit is to shift the costs in the catastrophic tier from taxpayers, who now bear 80 percent, to plans and manufacturers," said Badger. "Under the current system, neither manufacturers nor plans have strong incentives to negotiate aggressively over prices for the most expensive products. Done correctly, restructuring the benefit will reorder those incentives. Specifically, the government share would drop to 20 percent, with manufacturers and plans picking up 80 percent. That should save taxpayers money."

Unlike the IRA drug provisions, when the Congressional Budget Office (CBO) analyzed the Prescription Drug Pricing Reduction Act of 2019 it projected $35 billion in reduced federal spending over 10 years, says Badger.

"Unfortunately, CBO estimates the restructuring of Part D in the Inflation Reduction Act will increase federal spending by $25 billion over 10 years," said Badger. "Thus, even one of the most promising provisions of the IRA produces negative results."

Boon for Higher-Income Households

The IRA will not provide real savings to Medicare but will lower premiums for people with high incomes, says John C. Goodman, president of the Goodman Institute for Public Policy Research and co-publisher of *Health Care News*.

"Medicare is already spending more than it is receiving in the form of payroll taxes," said Goodman. "So, anything that reduces Medicare spending doesn't 'save' Medicare dollars. It just reduces the amount of deficit spending that is already going on."

The IRA uses this accounting trick to "pay for" the subsidized premiums of people who purchase Obamacare plans, says Goodman.

"Where does the new spending go?" Goodman said. "It goes to insurance companies so they can lower premiums for high-income buyers. Meanwhile, several million low-income households with no health insurance get no help under the bill."

Bonner Russell Cohen, Ph.D. (**bcohen@nationalcenter.org**) *is a senior fellow at the National Center for Public Policy Research.*

Congress Caps Medicare Patients' Insulin, Drug Costs

By Kevin Stone

The out-of-pocket cost of insulin for Medicare patients is about to be limited under a provision of the Inflation Reduction Act (IRA).

Under the IRA, the monthly cost for insulin will be capped at $35 for Medicare recipients. The law does not limit costs for patients using private insurance or for the uninsured.

The law also allows Medicare to negotiate prices for prescription drugs and limits out-of-pocket spending for enrollees in Medicare Part D to $2,000 a year.

Though Medicaid enrollees will welcome these provisions, price controls have been shown to discourage innovation, create shortages, and increase government spending.

"If Congress and/or federal bureaucrats really wanted to expand access to insulin, they could do so tomorrow. But it would require them to give up some of their power. The fact that congressional Democrats and the rest of the federal government will not give up even a little bit of their power in order to help diabetics tells you where their hearts really lie."

MICHAEL CANNON
DIRECTOR OF HEALTH POLICY STUDIES
CATO INSTITUTE

Bias for Older Versions

Insulin products are complex biologics, of which there are different formulations and delivery systems that are not covered by a single price cap, says health economist Devon Herrick, Ph.D., a policy advisor to The Heartland Institute, which co-publishes *Health Care News*.

"There have always been sources of cheaper insulin, just not the latest insulins at generic prices," said Herrick. "The insulin diabetics inject today is far better than insulins from 30 years ago."

The price cap on insulin will reduce manufacturers' revenues, leaving them with less money to invest in development, says Herrick.

"Price controls may be popular with those who benefit from artificially low prices but will ensure diabetic patients decades from now will not benefit from new advancements in technology, because there will be no incentive to invest in newer insulins," said Herrick.

Drug Development Obstruction

Government-negotiated drug pricing has been tried in other countries, says Linda Gorman, director of the Health Care Policy Center for the Independence Institute.

"As government typically underpays in health care, the negotiated price will likely be less than full cost," said Gorman. "The result will inevitably be less money for research on new drugs. The destruction of drug research in the United Kingdom after negotiated pricing with a fixed profit rate is the real-world example."

Alternatively, capping the out-of-pocket cost to seniors in Part D plans could shift costs to taxpayers, says Gregg Girvan, a resident fellow in health care policy at the Foundation for Research on Equal Opportunity.

"The problem is that if we cap the cost, it allows the manufacturer to consistently raise the price of that drug because the consumer is going to pay the same price," said Girvan. "That can raise government spending in the Medicare program."

Girvan equates price caps to the discount cards drug manufacturers give out that remove co-pays for a product.

"Not only does it allow them to raise the price behind the curtain, but it also allows manufacturers to develop that brand loyalty to the point where the people stay on the product even when there is a cheaper generic or biosimilar available," said Girvan.

Better Cost-Saving Options

In Medicare and in private-sector health plans alike, it would be better for prescription drugs to be covered as medical treatments, says John C. Goodman, president and CEO of the Goodman Institute for Public Policy Research and co-publisher of *Health Care News*.

"Having two different health insurance plans—one for drug coverage, the other for medical coverage—creates perverse incentives," said Goodman. "If diabetics don't take their insulin, the drug company's expenses go down. But a resulting trip to an emergency room causes the medical insurer's expense to go up. What's good for one insurer is bad for the other, and bad for the patient as well."

This is not an uncommon occurrence, says Goodman.

"Patient noncompliance, especially with prescription drugs, is the biggest problem in care for diabetes and other chronic conditions," said Goodman. "That's why integrated health plans that cover both drugs and medical services typically make insulin free to the patient. These plans 'invest' in free insulin and the payoff is fewer emergency room visits and hospitalizations."

Regulatory Damage

Government intervention in health care can drive costs up instead of reducing them, says Michael Cannon, director of health policy studies at the Cato Institute.

"Insulin prices should be falling over time, yet they have more than doubled over the last 10 years," wrote Cannon in a blog post on August 8. "Many diabetics struggle with those rising prices, sometimes with deadly consequences. A humane health system would make insulin increasingly accessible to diabetics."

Federal regulators have made the U.S. health care sector inhumane toward diabetics, says Cannon. These harmful policies include exorbitant costs imposed by the approval process for new drugs and medical devices; requiring a prescription to purchase insulin; and strict limits on the amount of insulin an American traveling to a country such as Canada that does not require a prescription can bring back.

Government regulations also promote excessive health insurance coverage; insulate patients from the price of their health insurance; push drug costs higher; and discourage private insurers from structuring insulin cost-sharing to maximize diabetics' long-term health, says Cannon.

"If Congress and/or federal bureaucrats really wanted to expand access to insulin, they could do so tomorrow," wrote Cannon. "But it would require them to give up some of their power. The fact that congressional Democrats and the rest of the federal government will not give up even a little bit of their power in order to help diabetics tells you where their hearts really lie."

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

Traffic Deaths Rising: U.S. Transportation Department Has a Plan

By Bonner Russell Cohen

After decades of steady decline, the number of traffic deaths in the United States has rebounded in recent years, raising questions about the reversal of a trend that had indicated increased safety on the nation's roads and highways.

U.S. motor vehicle traffic fatalities in the first three months of 2022 were the most since 2002, the National Highway Traffic Safety Administration (NHTSA) stated on August 17.

The NHTSA puts the number of people who died in motor vehicle traffic crashes in 2021 at 42,915, a 10.5 percent increase from 38,824 fatalities in 2020.

"The projection is the highest number of fatalities since 2005 and the largest annual percentage increase in the Fatality Analysis Reporting System's history," NHTSA reported.

Transportation Secretary Pete Buttigieg called the sharp rise in deaths "a national crisis of fatalities and injuries on our roadways."

'Equity and Climate Goals'

Citing the rise in traffic deaths, the U.S. Department of Transportation (DOT) on January 27 announced its National Roadway Safety Strategy (NRSS).

The NRSS is based on "a five-pronged model to address safety: safer people, safer roads, safer vehicles, safer speeds, and post-crash care," and supports the Biden administration's larger agenda.

"The NRSS recognizes that roadway safety is inextricably linked with the Biden-Harris Administration's equity and climate goals," states the DOT. "Fatalities due to traffic crashes disproportionately affect communities of color, people living in rural areas, people with disabilities and older adults. Traffic deaths among people who walk, or bike are increasing more sharply than with people who drive."

Electric Vehicle Push

The Biden administration's push to address climate change is partly responsible for the decline in traffic safety and its outsized effect on the less-wealthy, says Sterling Burnett, director of The Heartland Institute's Arthur B. Robinson Center on Climate and Environmental Policy.

"Biden's DOT says it is working hard to reduce traffic deaths and create more equity on the roads," said Burnett. "But its policy of embracing more expensive electric vehicles (EVs) will keep lower-income people in older, less-safe cars."

New car prices rose by an average of 10.4 percent from July to August, making them less affordable, according to the Bureau of Labor Statistics' Consumer Price Index. People with lower incomes are disproportionately represented among traffic fatalities, especially blacks and Hispanics, according to *The New York Times*.

Drivers Misbehaving?

DOT's approach to traffic safety is flawed, says Marc Scribner, a senior transportation policy analyst with the Reason Foundation.

"While identifying and treating the root cause of these problems may be extremely challenging, the Biden administration's attempt to address these traffic safety problems leaves much to be desired," said Scribner. "For instance, the Biden DOT's flagship traffic safety program, Safe Streets and Roads for All, pointedly excludes from eligibility the roads where more than half of U.S. traffic fatalities occur and doubles down on high-cost, low-value treatments favored by many environmentalists and mass-transit activists.

"This problem, like the others, deserves careful analysis," said Scribner. "Unfortunately, it does not appear that thoughtful transportation safety policy will be forthcoming from this administration."

The increase in fatalities could be a result of the general increase in reckless and antisocial behavior, says Scribner.

"The troubling rise in traffic fatalities appears to be a symptom of a broader trend of public misbehavior," said Scribner. "Growing problems with crime and substance abuse have been well-documented, but less-discussed are more bizarre bad-behavior upticks in the pandemic era, including the 41 percent increase in dangerous laser strikes reported by pilots to the Federal Aviation Administration between 2020 and 2021."

Lower Speed Limits

Buttigieg's plan includes lowering speed limits and increasing enforcement with traffic cameras.

"Automated speed enforcement, if deployed equitably and applied appropriately to roads with the greatest risk of harm due to speeding, can provide significant safety benefits and save lives," states the NRSS.

Gary Biller, president of the National Motorists Association, opposes the push for more speed cameras.

"The widespread corruption that automated enforcement has instigated since coming to America has cut a wide swath of fraud, bribery, and convictions," wrote Biller in a blog post. "When profitability is a primary measure of success for devices that, with a slight tweaking of settings, can exponentially increase the number of tickets issued and fines levied, scandal is sure to follow."

Anti-Car Sentiment

Rising gas prices, lower speed limits, speed bumps, obstacles to buying affordable cars, expanding pedestrian and bike lanes, and expansion of mass transportation are all efforts to make driving less attractive, says Shelia Dunn, a spokesperson for the National Motorists Association.

"The majority of Americans that drive aren't aware of anti-car sentiment, because all traffic is local and if it's not affecting you as a driver, you're not going to be concerned about it," said Dunn. "But then, suddenly, one day you're driving and instead of taking 15 minutes to get to work, it's taking you 30 minutes because traffic has been restricted by new bike lanes. Then they take notice and it's too late."

The Biden administration's NRSS represents an unprecedented federal effort to regulate drivers, says Dunn.

"This is the first time nationally there has been a concentrated effort to get people out of their cars," said Dunn. "But we don't have the transit structure or the bike lane structure to make all that work. Engines still drive the economy."

Bonner Russell Cohen, Ph.D. (**bcohen@nationalcenter.org**) *is a senior fellow at the National Center for Public Policy Research.*

"While identifying and treating the root cause of these problems may be extremely challenging, the Biden administration's attempt to address these traffic safety problems leaves much to be desired. For instance, the Biden DOT's flagship traffic safety program, Safe Streets and Roads for All, pointedly excludes from eligibility the roads where more than half of U.S. traffic fatalities occur and doubles down on high-cost, low-value treatments favored by many environmentalists and mass-transit activists."

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Uncontrolled Borders Pose Health Threat If Title 42 Ends

By Kevin Stone

Infectious diseases could flow across U.S. borders unchecked if a current national health order expires.

A Trump administration pandemic-era order by the U.S. Surgeon General under Title 42 of federal law has allowed the expulsion of migrants at the border to slow the spread of COVID-19.

The Biden administration announced it was ending the order, and the attorneys general of Arizona, Louisiana, and Missouri brought a lawsuit joined by 21 other states. U.S. District Judge Robert Summerhays issued a nationwide injunction against lifting the health order while the issue is adjudicated. The Biden administration is appealing the judge's May 2022 ruling.

The National Emergency declaration is currently scheduled to end on October 13, which would halt enforcement of the Trump-era Title 42 order. President Joe Biden could extend the emergency declaration.

'Other Health Risks'

There are plenty of reasons to keep the Title 42 order in effect, says Ira Mehlman, media director at the Federation for American Immigration Reform (FAIR).

"COVID is still very much with us and is likely to remain so for the foreseeable future," said Mehlman. "There are also other health risks like monkeypox and a resurgence of polio."

Another health threat the U.S. Centers for Disease Control and Prevention (CDC) has acknowledged is crossing U.S. borders, says Mehlman.

"[That is] the national health crisis cited by CDC: the opioid crisis," said Mehlman. "Even if COVID were to magically disappear tomorrow, Title 42 would still be absolutely justified to combat the opioid epidemic that CDC has declared a public health emergency."

Opioid smugglers use the border traffic as a cover, says Mehlman.

"Deadly narcotics, most notably fentanyl, were responsible for more than 100,000 U.S. deaths last year," said Mehlman. "Much of the supply of these lethal drugs is moved across the southern border by the same criminal cartels that smuggle and traffic human beings. The cartels are taking advantage of the fact that some 90 percent of the Border Patrol's manpower is now devoted to processing the flood of migrants entering the country. In many cases, the cartels use the migrants as decoys to divert the attention of CBP (U.S. Customs and Border Patrol), while a few miles away they move drugs across the border."

Tuberculosis 'Worst Problem'

All border-crossers should be tested for communicable diseases, says Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons.

"Allowing thousands of illegals to pour unscreened into the country is very dangerous with or without COVID-19," said Orient. "Multidrug-resistant tuberculosis (TB) is likely the worst problem. You can catch it on the bus. It may remain latent for years. With COVID-19, you are only contagious for a week or so. TB is a lifelong threat."

In addition, people from far-flung countries can harbor exotic diseases, and many people are doubly victimized in transit, says Orient.

"Undocumented immigrants also present many parasitic diseases with which American doctors are unfamiliar, such as Chagas, with devastating, untreatable long-term consequences," said Orient. "Many have lice or scabies. Sexually transmitted infections are also very likely, given the high incidence of rape."

'It Is Nonsensical'

U.S. Sen. James Lankford (R-OK) proposed an amendment to the Inflation Reduction Act to keep Title 42 in place for 120 days after the broader COVID-19 public health emergency expires. His amendment failed in a tied vote of the U.S. Senate on August 7.

An amendment by Sen. Jon Tester (D-MT) requiring the Biden administration to put a comprehensive plan in place to control the border before lifting Title 42 received 56 votes, including all Republicans and six Democrats running for reelection, falling short of the 60 votes required under Senate rules.

Biden has extended the national health emergency order several times, showing the need for continuation of the Title 42 order, said Lankford in a statement.

"The Biden Administration continues to declare that we are in a public health emergency because of COVID-19," said Lankford. "This public health emergency first declared in January 2020 has been renewed 10 times. Title 42 is the health authority specifically designed to prevent people from coming into the country during a pandemic. It is nonsensical to say that we have a COVID health emergency everywhere but on our southern border."

The Title 42 health order will remain in place until there is a final court decision. Biden has the authority to extend the national emergency order, currently due to expire on October 13.

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

"The Biden Administration continues to declare that we are in a public health emergency because of COVID-19. This public health emergency first declared in January 2020 has been renewed 10 times. Title 42 is the health authority specifically designed to prevent people from coming into the country during a pandemic. It is nonsensical to say that we have a COVID health emergency everywhere but on our southern border."

U.S. SEN. JAMES LANKFORD (R-OK)

Polio Is Back, New York Health Officials Say

By AnneMarie Schieber

The discovery of polio virus in wastewater after a case of paralysis indicates transmission of the disease in the United States, health officials say.

Rockland County and New York state health officials reported a case of polio transmission in the United States on July 21 after an unvaccinated man was hospitalized with weakness in his legs. Testing by the Centers for Disease Control and Prevention found the virus in wastewater in Rockland, Orange, and Sullivan counties and in New York City, indicating community spread of the virus, the New York State Department of Health (NYSDH) announced in a press release on August 26.

Health officials are conducting a vaccination campaign. About 40 percent of the eligible population in the Hudson Valley counties is not vaccinated, the NYSDH said.

"It is claimed that the vaccine virtually eradicated polio in the United States, but we still have acute flaccid paralysis, which clinically looks a lot like polio. New, different disease? Or change of definition?"

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

'A Vaccine-Preventable Disease'

Polio was thought to be eliminated in the United States, and in 1994 the Americas became the first region of the world to be certified free of polio, according to the Pan American Health Organization.

A series of polio vaccinations is still recommended for childhood immunization, and compliance has decreased. Over the decades, a few U.S. cases of polio were reported, all thought to be imported from overseas.

Polio outbreaks are preventable, Irina Gelman, Orange County, New York commissioner of health, told National Public Radio on August 24.

"It's just disappointing at this point that we are still here," said Gelman. "This is a vaccine-preventable disease. And had everyone just been up to date on their vaccination, we would have continued to report it as being eradicated."

Phasing Out Oral Vaccine

The Gates Foundation and other groups are trying to eradicate polio globally through vaccination programs in less-developed countries that have generally used the oral polio vaccine instead of the inactivated virus Americans receive, says Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons.

"Bill Gates and others have the ambition to eradicate polio altogether—regardless of cost, it appears—although this is probably impossible," said Orient. "U.S. children get the killed vaccine. Third-World children get the live vaccine because the killed vaccine is held to be insufficiently effective. Vaccinated children can transmit the virus to others, and the [live] vaccine strain has paralyzed thousands. Babies are likely to be asymptomatic but can transmit the virus through fecal-oral contact with older children and adults. Thus, there is much popular resistance to the program."

The use of oral polio vaccines should be phased out, states an article in *Expert Review of Vaccines* published in 2015.

It is possible polio was never eliminated in the United States, says Orient.

"It is claimed that the vaccine virtually eradicated polio in the United States, but we still have acute flaccid paralysis, which clinically looks a lot like polio," said Orient. "New, different disease? Or change of definition?"

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

COMMENTARY

Europe Is Light Years Ahead of America in Biosimilar Adoption

By Gregg Girvan

European Union drug pricing policies are often criticized in the United States, but the EU is light years ahead of us in adopting biosimilar biologics.

There are several reasons for this.

Anticompetitive Patent Practices

First, the EU has a rigorous patent opposition system in which trivial patents can be challenged.

In contrast, drug companies in the United States engage in various practices to ward off competition that would not occur in Europe. These practices include patent "evergreening"—seeking approval of additional disease indications to extend market exclusivity—and patent "thickets," or filing a web of numerous patents on various aspects of a drug's composition, manufacturing processes, and method of administration to forestall approval of competing products.

The drug maker Abbvie is famous for building a patent thicket around its blockbuster drug Humira, which will remain exclusive in the United States until 2023 (20 years after it was first approved) even though the drug has had biosimilar competition in Europe since 2018.

In addition, the European Medicines Agency is forward-thinking in approving biosimilar applications in a timely manner.

Longer Patent Protection

Second, U.S. law affords biologics longer market exclusivity granted by the U.S. Food and Drug Administration (FDA) than for small-molecule drugs, which are usually delivered in tablet or capsule form.

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, is responsible for the robust generics market we have today.

Among other things, Hatch-Waxman sets the FDA exclusivity for small-molecule drugs at five years, requires drug makers to publish their patents so generic manufacturers know which ones to avoid, and allows generic drug manufacturers simply to show their active pharmaceutical ingredients are substantially similar, without having to conduct costly clinical trials.

In contrast, the Biologics Price Competition and Innovation Act of 2009 (BPCI), passed as part of the Affordable Care Act, regulates the biologics market. The BPCI arbitrarily set the exclusivity for biological products at 12 years instead of five. In addition, the BPCI requires manufacturers of biosimilars to conduct lengthy trials to demonstrate efficacy and safety, driving up development costs and risk.

A critical reform would be to align the BPCI with Hatch-Waxman, with the same five-year exclusivity and FDA approval requirements. This would inject greater competition into the biologics market and drive down costs for patients and taxpayers.

Harsher Pharmacy Restrictions

In addition to many other needed reforms, one that is absolutely critical to greater biosimilar use is making biosimilar products interchangeable with brand-name biologics.

This means a pharmacist could automatically substitute a biosimilar for the reference product without permission from the doctor. This has been a critical component driving greater generic drug use since the passage of Hatch-Waxman.

The Biosimilars Council appears to be trying to address the lack of automatic substitution in the biologics market by encouraging consultations between pharmacists and patients about the benefit of biosimilars. This could help around the margins, but several states have laws preventing automatic substitution without prior prescriber approval. Unless automatic substitution is permitted in every state, biosimilars will struggle to gain sufficient market share to make such medicines more affordable.

In short, we need to reform our patent laws, align biologics laws with those for small-molecule drugs, and allow automatic substitution at the pharmacy level. These and other reforms will drive greater biosimilar adoption, saving patients and taxpayers billions of dollars.

Gregg Girvan (***ggirvan@freopp.org***) *is a resident fellow in health care policy at the Foundation for Research on Equal Opportunity.*

"In short, we need to reform our patent laws, align biologics laws with those for small-molecule drugs, and allow automatic substitution at the pharmacy level. These and other reforms will drive greater biosimilar adoption, saving patients and taxpayers billions of dollars."

GREGG GIRVAN
RESIDENT FELLOW
FOUNDATION FOR RESEARCH ON EQUAL OPPORTUNITY

Government, Big Tech Run 'Censorship Enterprise': State Attorneys General

By AnneMarie Schieber

Missouri Attorney General Eric Schmitt says documents he and Louisiana Attorney General Jeff Landry received from the U.S. Department of Justice (DOJ) show a vast "Censorship Enterprise" between federal agencies and social media platforms.

"We have already received a number of documents that clearly prove that the federal government has an incestuous relationship with social media companies and clearly coordinate to censor freedom of speech, but we're not done," said Schmidt in a news release on September 1.

The DOJ was required to send the documents as evidence in a lawsuit against the agency. The department is still withholding documents in the case, says Schmidt.

"The Department of Justice is cowering behind executive privilege and has refused to turn over communications between the highest-ranking Biden administration officials and social media companies," said Schmidt. "That's why, yesterday, we asked the Court to compel the Department of Justice to produce those records. We're just getting started—stay tuned."

Biden: 'They're Killing People'

Although evidence of a "Censorship Enterprise" is mounting (see article, page 15), it is important to understand the amount of pressure the Biden administration has put on Big Tech, says Matt Dean, a senior fellow for health care policy outreach at The Heartland Institute, which co-publishes *Health Care News*.

"President Biden publicly rebuked Big Tech for not doing enough to shut down posts which were critical of his pandemic response," said Dean.

Biden blamed social media companies for carrying what he said was misinformation that caused COVID-19 deaths in 2021.

"Look, the only pandemic we have is among the unvaccinated, and they're killing people," said Biden at the time.

'Our Teams Met'

After Biden's statement, a Meta (Facebook) executive contacted U.S. Surgeon General Vivek Murthy, M.D., in an email chain uncovered by the AGs' lawsuit.

"I know our teams met today to better understand the scope of what the White House expects from us on misinformation going forward," wrote the Meta official.

Dean says the exchange shows the vast power the government is wielding.

"Why should a private company need to know what the president expects from them in what is essentially a censorship campaign?" said Dean.

Other former guardians of truth are also under the government's thumb, says Dean.

"Academic journals should be calling this out but are now completely in the tank, in large part due to the enormous influence by Biden's COVID advisor, Anthony Fauci," said Dean.

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

Lower-Cost Biologics Face Obstacles, Says Industry Group

By Ashley Bateman and Joe Barnett

Manufacturers of generic drugs and biosimilars opposed to the drug-price provisions of the Inflation Reduction Act (IRA) continue to push for cost-saving reforms.

The IRA takes government regulation of the drug market in the wrong direction, the Biosimilars Council and its parent trade organization, the Association for Accessible Medicines (AAM), stated upon passage of the bill by the U.S. Senate.

"The Senate has chosen to replace competition—the only proven way to provide patients relief from high brand-drug prices—with a flawed framework for government price-setting that will chill the development of, and reduce patient access to, lower-cost generic and biosimilar medicines," said the AAM in a press release on August 7.

Similar, Not Identical

Biologics are produced in living organisms, can be costly to develop and manufacture, and cannot be replicated as "generics" like small-molecule drugs that are usually taken orally.

Biologics include hormones, vaccines, insulin, monoclonal antibodies (mAb), and certain cancer therapies. Biologics are mostly administered by injection or infusion, instead of being swallowed like tablets or capsules.

A biosimilar is an FDA-approved biologic product that is functionally or clinically equivalent to the original reference biologic. Biologics are more complex than chemical drugs, and biosimilars are not molecularly identical to the originals.

'More-Competitive Markets'

In 2007, Congress passed the Biologics Price Competition and Innovation Act allowing the licensure of biosimilars based on approved biologics.

Today, biologics account for almost half the market for medicines, comprising 46 percent of net U.S. pharmaceutical sales in 2018, according to the Foundation for Research on Equal Opportunity (FREOPP). Currently, more than 20 biosimilars are on the market, at costs averaging 50 percent less than their reference biologics.

These products are decreasing treatment costs, says Allen Goldberg, senior vice president of communications at the AAM.

"Biosimilars are helping to create more-competitive markets, which in turn are leading to lower prices for these brand biologics as well," said Goldberg.

"Through this market competition, biosimilars successfully contributed to $7.9 billion in savings in 2020 and more than $12.6 billion in savings over the last 10 years," said Goldberg. "In just the past three years, we've seen biosimilars cut the growth of spending on oncology medicines in half."

Consumer Skepticism

Acceptance of biosimilars has been a marketing challenge, says Goldberg.

"The single greatest obstacle to greater biosimilar adoption among patients has been the misconceptions surrounding their efficacy and safety," said Goldberg. "Many patients have signaled these concerns with biosimilars and are choosing to purchase brand-name [reference] biologics at higher prices. Because biosimilars are not identical to their reference products, many may believe that these medicines are not up to the same standards."

The rigorous approval pathway at the U.S. Food and Drug Administration (FDA) ensures biosimilars "have no clinically meaningful differences from the reference product," said Goldberg.

Biosimilars have been used in Europe safely and successfully for more than a decade, says Goldberg.

Struggles with PBMs

The AAM and the Biosimilars Council are fighting for a level playing field, and one obstacle to that has been pharmacy benefit managers (PBMs), says Goldberg.

"PBMs continue to restrict patient access to lower-cost biosimilar alternatives and instead steer them toward brand biologics," Goldberg said. "By doing this, PBMs are able to take in greater profits from more-expensive medicines under the current rebate structure."

Despite the challenges, the market for biosimilars is growing, says Goldberg.

"As more biosimilars continue to reach the market, going forward we expect savings to increase," said Goldberg.

Biosimilars now account for more than 30 percent of the total market for biologics and are projected to provide $133 billion in savings by 2025, according to data compiled by IQVIA, a market research firm.

Patient Education

The Biosimilars Council has launched a "Biosimilars Patient Resource Center," a website that explains the FDA approval process and provides patient testimonials. The website suggests patients meet with a pharmacist before a doctor visit, to learn about biosimilar options.

Such consultations can significantly increase the number of patients who opt for biosimilars, a study published in *Joint Bone Spine* in May found.

"Despite several studies proving the efficacy and safety of biosimilars compared with original drugs, switching to a biosimilar remains challenging when the decision is at the discretion of physicians with mandatory consent from patients," write the study authors. "Educating patients about biosimilars seems important to increase the prescription rate of biosimilars."

Substitution Proposal

Bipartisan legislation introduced in the U.S. Senate by Maggie Hassan (D-NH), Tim Kaine (D-VA), and Susan Collins (R-ME) would allow for interchangeability between biologics and some biosimilars in the FDA review process and require makers of biologics to share information about market releases.

Although the bill and the efforts of the Biosimilars Council are a step in the right direction, more reform is needed, says Gregg Girvan, a resident fellow at FREOPP.

"These are rather modest proposals that probably won't move the needle much in driving greater biosimilar adoption in the United States," said Girvan. "Part of this is because patients are shielded from the true cost of drugs through third-party payment of health benefits."

Intellectual property protection for new biologics is more extensive than for brand-name drugs facing generic competition, which limits cost savings, says Girvan.

"Laws in the United States afford biologics a longer exclusivity period granted by the FDA than small-molecule drugs," said Girvan. "In short, we need to reform our patent laws, align biologics laws with those for small molecules, and allow automatic substitution at the pharmacy level." (See related commentary, page 12.)

Ashley Bateman (**bateman.ae@googlemail.com**) *writes from Virginia. Joe Barnett* (**jbarnett@heartland.org**) *is a senior editor at The Heartland Institute.*

Examples of Biologic and Small Molecule Drugs

BIOLOGIC DRUGS	SMALL MOLECULE DRUGS
Avastin	Abrocitinib
Botox	Aripiprazole
Enbrel	Aspirin
Herceptin	Atorvastatin
Humira	Esomeprazole
Insulin	Ezetimibe
Lantus	Fexinidazole
Lucentis	Fluticasone
Remicade	Rosuvastatin
Rituxan	Voclosporin

Sources: GoodRx.com, verywellhealth.com

Study: Regular Use of Ivermectin Prevented COVID-19 Deaths

New evidence from a study of 223,123 people in Brazil shows ivermectin protected people from death by COVID-19.

"Non-use of ivermectin was associated with a 12.5-fold increase in mortality rate and a seven-fold increased risk of dying from COVID-19 compared to the regular use of ivermectin," state the authors.

The study, "Regular Use of Ivermectin as Prophylaxis for COVID-19 Led Up to a 92% Reduction in COVID-19 Mortality Rate in a Dose-Response Manner: Results of a Prospective Observational Study of a Strictly Controlled Population of 88,012 Subjects," was published on August 31 in *Cureus*.

One of the authors of the study is Pierre Kory, M.D., cofounder of the Front Line COVID-19 Critical Care Alliance. Kory testified before a U.S. Senate panel on December 8, 2020.

The August study builds on an earlier study published in January, which found ivermectin used as a prophylaxis for COVID-19 reduced infection, hospitalization, and mortality from the disease, even if not used as regularly as in the current study.

The new study zeroed in on subjects who regularly used the drug: 8,325 people in total. The subjects were part of a group of 223,128 residents of the Brazilian city of Itajaí who were offered a chance to participate in a voluntary program to use ivermectin prophylactically between July and December of 2020. Among regular users, mortality rates were 92 percent lower in the group of regular users than for non-users and 84 percent lower than for those who used the drug irregularly.

In the United States, the National Institutes of Health (NIH) recommends against the use of ivermectin for COVID-19, except in clinical trials. The most recent update to the NIH's webpage on the subject was on April 29, 2022.

After the January study, Joel Hirschhorn, author of the *Pandemic Blunder Newsletter* on Substack, wrote, "The P values (level of marginal significance) of this study are extraordinary and cannot be discounted easily by mainstream media. But clearly, the leftist mainstream media are not making these results major news stories. Use your critical thinking to make personal decisions to protect your health."

—Staff reports

Fauci to Leave NIH but 'Not Retiring'

Dr. Anthony Fauci

By AnneMarie Schieber

Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases (NIAID) and President Biden's chief medical advisor, announced he will step down from those positions in December.

"While I am moving on from my current positions, I am not retiring," said Fauci in a statement on August 22. "After more than 50 years of government service, I plan to pursue the next phase of my career while I still have so much energy and passion for my field.

"I want to use what I have learned as NIAID Director to continue to advance science and public health and to inspire and mentor the next generation of scientific leaders as they help prepare the world to face future infectious disease threats," said Fauci.

Fauci, 81, has worked in the federal government for nearly his entire career. Fauci joined the National Institutes of Health (NIH) in 1968 after finishing his medical residency and went on to lead NIAID in 1984, where he remains today. Fauci became a public figure during the advent of AIDS, ebola, Zeka, and anthrax, and his fame soared during the COVID-19 pandemic.

On the Hotseat

Fauci hinted at retirement in the spring when questions about his handling of the pandemic began to multiply. Fauci has been criticized for suppressing evidence of the origins of the COVID-19 virus, discrediting scientists and doctors who questioned the lockdowns, using tax dollars to support gain-of-function research in China, making hundreds of media appearances during a pandemic, and most recently, not being forthcoming about royalty payments from private companies to NIH scientists under his wing.

In an interview on August 22, Sen. Rand Paul (R-KY) said Congress might subpoena Fauci even if he retires.

"And I say absolutely we should," said Paul on the *Clay Travis and Buck Sexton Show*.

Concerns About Royalties

Asked what accountability would look like, Paul said he wants more transparency about royalty payments.

"Through FOIA, Freedom of Information, outside organizations have found out that 1,800 doctors that are on the payroll of the NIH also received $193 million in royalties from the pharmaceutical companies," Paul told the interviewers.

"We should be told—without question, we should be told—whether or not any of these people sit on the vaccine committees," said Paul on the show. "Did any of them receive royalties from the companies that made the vaccines? When I asked Dr. Fauci this question, he got all up in arms, started rattling on."

Watchdogs Investigating

The government watchdog organization Open the Books has been working with the government accountability group Judicial Watch to look into the royalty payments.

"OpenTheBooks.com has relentlessly investigated these private royalty payments because we've seen the drastic impact public health guidance can have on Americans' lives and well-being," Adam Andrzejewski, CEO and founder of Open the Books, told *Health Care News*. "The public needs to know precisely how these decisions get made and why, including whether there are financial or other stakes involved.

The royalties raise serious doubts about the NIH's integrity, says Andrzejewski.

"Dr. Fauci and NIH Acting Director [Lawrence A.] Tabak have already begun facing some criticism over royalty payments, from Republicans in the House and Senate," said Andrzejewski. "But the fact of the matter is, if politicians want to restore confidence in public health agencies, then this should be a bipartisan concern. Sen. Paul has consistently led the way, but lawmakers from both sides of the aisle need to get involved and take these investigations seriously.

"We're grateful that Sen. Paul remains committed to getting transparency for the public when it comes to how the NIH operates and whether leadership have inappropriate stakes in the decision-making process," said Andrzejewski. "Whether or not Dr. Fauci is there, whether or not it's run by Dr. Collins or Tabak, these issues remain and demand answers."

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

INTERNET INFO

"NIH Acting Director Admits Royalty Payments Have Appearance of Conflict-Of-Interest," Open the Books, May 14, 2022: **https://www.openthebooks.com/nih-acting-director-admits-royalty-payments-have-appearance-of-conflict-of-interest/**

U.S. Senate Committee on Homeland Security and Governmental Affairs, letter to NIH, June 1, 2022: **https://www.paul.senate.gov/news/dr-rand-paul-and-hsgac-republicans-send-letter-acting-director-nih-requesting-informatio**

REPORT

Government, Big Tech Colluded to Block Health Information

By Kevin Stone

A legal advocacy group is asking the U.S. Department of Health and Human Services Inspector General to investigate Centers for Disease Control and Prevention (CDC) collusion with social media companies to push Biden administration COVID-19 talking points covertly and illegally.

The letter by the America First Legal Foundation (AFL) is based on information disclosed in response to a Freedom of Information Act (FOIA) request made by AFL after the White House admitted the Biden administration colluded with corporate allies to censor what it deemed COVID-19 "misinformation" and "disinformation," on July 15, 2021.

The administration initially refused to respond to the FOIA request, triggering a lawsuit by AFL demanding the production of the public records. The CDC complied on July 17, 2021, turning over 286 pages of documents.

"These records are damning," the AFL stated in a press release on August 3, 2022. "They prove that the Biden Administration and Big Tech knowingly and intentionally combined to mislead the public about the origin of COVID-19 information on social media; censor social media users who dissented from the government's approved talking points; and conceal the government's role in writing and publishing masking and vaccination talking points."

Willing Accomplices

The CDC records show Twitter, Facebook, and Google regularly colluded with the CDC to stifle information contrary to the CDC's official positions regarding such topics as treatment, vaccine safety, and vaccine "shedding," the tendency of new contagions to arise in and spread from vaccine recipients to other persons.

A document AFL obtained includes a letter to the CDC from Facebook offering the agency $15 million in advertising credits.

"This gift will be used by CDC's COVID-19 response to support the agency's messages on Facebook, and extend the reach of COVID-19-related Facebook content, including messages on vaccines, social distancing, travel, and other priority communication messages," states the letter.

The AFL says this may violate limits on gifts in the federal Antideficiency Act.

"Much of what the government and Big Tech claimed to be fake news turned out to be true. Meanwhile, the public was relatively less informed, and government had a freer hand than it otherwise would have had. This is precisely why we have a First Amendment: to prevent that from happening."

JEFFREY A. TUCKER
FOUNDER AND PRESIDENT, BROWNSTONE INSTITUTE

Doing Government's Bidding

An email exchange between a CDC official who spoke at Google's 2020 "Trusted Media Summit" and one of Google's conference organizers shows the CDC is sensitive to public image concerns: the official turned down a request to post her comments on YouTube, saying she was not authorized to speak publicly on the topic.

The same email chain reveals a Google staffer proposing to a senior CDC official that the search engine giant promote a World Health Organization initiative "addressing the COVID-19 infodemic and strengthen community resilience against misinformation," and offering to introduce the CDC official to a Google colleague who was "working on programs to counter immunization misinfo."

Twitter appears to be even more aggressive. Records show CDC officials provided Twitter with a list of 13 tweets it deemed to be "misinfo." The accounts of seven of the Twitter users were suspended. The involvement of the CDC in the decision was not revealed previously.

'Profoundly Disturbing'

The documents show big social media corporations colluded with big government to stifle speech, says Jeffrey A. Tucker, founder and president of the Brownstone Institute.

"The FOIA request revealed deep cooperation between Big Tech and the government, to the point that it is impossible to know which is the hand and which is the glove," said Tucker. "This is profoundly disturbing. The government claims it is the one source of truth. No such claims are admissible in a free society.

"The current practice pretends as if the First Amendment does not exist," said Tucker. "This is an attack on our founding principles. I see no solution here but to disable the administrative state. Any technical solution limiting interactions seems destined to fail with too many loopholes."

The danger is not just control of information by the government but the health risks of denying citizens the right to make informed medical decisions during a health crisis, says Tucker.

"Much of what the government and Big Tech claimed to be fake news turned out to be true," said Tucker. "Meanwhile, the public was relatively less informed, and government had a freer hand than it otherwise would have had. This is precisely why we have a First Amendment: to prevent that from happening."

Some of the information flagged as misinformation turned out to be accurate. Deborah Birx, M.D., the COVID-19 response coordinator under former President Donald Trump, has admitted she knew the COVID-19 shots would not prevent infection. Now there is evidence mRNA from the vaccines can be incorporated into the DNA of recipients via reverse transcription.

'Paid Off for Both'

The Biden administration needs to come clean on its collusion with private industry to censor information, says Matt Dean, a senior fellow for health care policy outreach at The Heartland Institute, which co-publishes *Health Care News*.

"Very clearly, Big Tech had good reason to want to please the administration by shutting down any opposition to the Biden COVID-19 response," said Dean. "Both Biden and Big Tech had a lot at risk. If they inappropriately colluded, it paid off for both in the short term.

"Tech companies experienced record growth during the pandemic, and President Biden's party consolidated power over both houses of Congress while muting opposition through censorship," said Dean. (See related article, page 12.)

Censorship is a way of pushing propaganda, says Mark Crispin Miller, a professor of media, culture, and communication at New York University, in a webcast sponsored by the Vaccine Safety Research Foundation on August 25, 2022.

"We naturally believe something if it is the only thing we hear," said Miller.

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

INTERNET INFO

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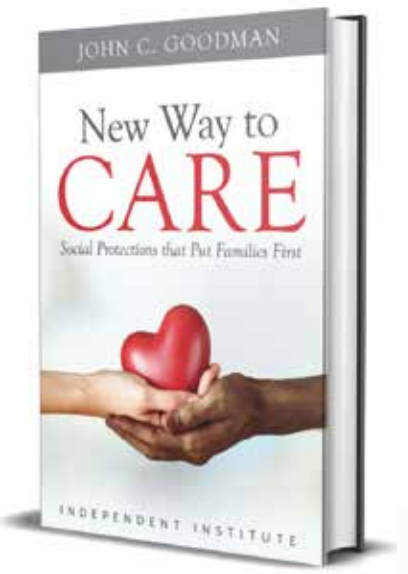
New Way to Care!



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John C. Goodman is Senior Fellow at the Independent Institute, President of the Goodman Institute, and author of the acclaimed, Independent books, *A Better Choice: Healthcare Solutions for America,* and the award-winning, *Priceless: Curing the Healthcare Crisis*. *The Wall Street Journal* has called him the "Father of Health Savings Accounts."

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New Studies Raise Questions About Drug Treatments for Depression

By Harry Painter

Two new scientific studies are raising questions about the use of antidepressants in treating clinical depression.

A study published on August 2 in *BMJ*, a journal for health care professionals, found about 15 percent of people receive a large benefit from antidepressants, whereas the pills are no better than a placebo for 85 percent of those who take them.

A July study in *Molecular Psychiatry* found low serotonin levels do not cause depression. Researchers at University College London (UCL) found no link between serotonin levels and depression, through a "systematic umbrella review" of evidence about the association. The scientists reached their conclusions through an analysis of 17 studies on the topic.

The study calls into question the prescription drug Prozac and other selective serotonin reuptake inhibitors (SSRIs) that have been sold for decades. SSRIs are designed to boost levels of serotonin by inhibiting reuptake by nerve cells. The UCL study found no evidence of any mechanism linking the drugs and depression outcomes.

"Our study shows that [the serotonin theory of depression] is not supported by scientific evidence. It also calls into question the basis for the use of antidepressants," the authors write in an article describing their conclusions.

Theory vs. Practice

Critics of the study say scientists have long known the serotonin theory, popularly referred to as a "chemical imbalance," was simplistic and drugs can still work even if we don't know how they do so.

"I have never once in my career, when I prescribed an antidepressant, told my patient that the drug corrects a serotonin deficiency," said Robert Emmons, M.D., a psychiatrist and clinical ethics advocate who is a policy advisor to The Heartland Institute, which publishes *Health Care News*.

"I don't say much to my patients about the mechanism of action of any drug, because not enough is known to tell that story in a responsible way," Emmons said. "The brain is incredibly complex, so any story about a mechanism of action for any given drug is, by necessity, overly simplistic."

Drugs vs. Therapy

Emmons says monetary incentives can lead doctors to treat depression with drugs instead of therapy.

"The American Psychiatric Association (APA) receives a lot of funding from the pharmaceutical industry, which creates an incentive for APA educational programs to emphasize pharmacotherapy over psychotherapy," said Emmons. "Third-party payers tend to pay psychiatrists higher fees for brief, medication-focused visits, compared to the fees for psychotherapy sessions. Psychiatrists, like anyone else, tend to follow the money."

The studies are getting particular attention because the use of antidepressants soared during the COVID-19 pandemic. About 13 percent of American adults were taking a prescribed antidepressant before the pandemic, and the number of prescriptions increased by 6 percent during the pandemic. A Boston University study found reported depression rates tripled during the first year of the pandemic. The global antidepressant market reached $26.25 billion in 2020.

Universal vs. Particular

Even when drugs are shown to be useful, the findings may be less applicable than most people realize, says Emmons.

"Randomized, placebo-controlled clinical trials can demonstrate the efficacy of drugs in highly selected, relatively small pools of subjects," said Emmons. "There exist very strong financial incentives for investigators to puff up relatively weak findings of efficacy.

"Demonstrating the efficacy of a drug in a clinical trial says relatively little about its precise neurochemical mechanism of action," said Emmons.

Trusting Scientific Process

Doctors and scientists need more information about the drugs' effectiveness, says Jeffrey Singer, M.D., a surgeon and a senior fellow at the Cato Institute who has spoken out about the challenges of proving a drug's efficacy.

"I don't prescribe antidepressants," said Singer. "However, many psychiatrists and internists I know tell me they definitely work. The *BMJ* study is just one study. I would not jump to any conclusion based upon one study. And I am not sure how good the study's methodology is.

"It is not unusual for medical science to have accepted one explanation for why a specific drug works, only to learn, upon further research, that the explanation was incorrect and there is a different explanation, as is the case in the *Molecular Psychiatry* article," said Singer. "That's how science works."

Clinical trials are the gold standard in answering these questions, says Singer.

"Clinical trials are the best we have to work with when it comes to medical science," said Singer. "What works in a test tube may not work in a living human. Clinical trials provide empirical data as to whether a drug works and how safe and effective it is."

'Enforcing Social Hierarchy'

Just as drugs don't work the same way on all patients, depression affects individuals differently, says Emmons.

"'Depression' is a popular name that encompasses a complex, heterogeneous set of disorders that involve interactions between individual minds, individual lifestyles, genetics, environmental toxins, and social systems," said Emmons. "The upside of all this complexity is that there are a lot of different avenues open for effective intervention."

Sometimes health professionals feel pressured to follow consensus views, says Emmons.

"Individuals who do not comply with the demands of social hierarchy often get ignored or punished," said Emmons. "As we have seen with COVID over the past two years, most public discourse about any medical topic is more about enforcing social hierarchy than it is about rigorous application of the scientific method.

"Enforcing consensus, formally or informally, is not at all part of the scientific method. Enforcing consensus is expressly anti-scientific," said Emmons.

"Randomized, placebo-controlled clinical trials can demonstrate the efficacy of drugs in highly selected, relatively small pools of subjects. There exist very strong financial incentives for investigators to puff up relatively weak findings of efficacy. Demonstrating the efficacy of a drug in a clinical trial says relatively little about its precise neurochemical mechanism of action."

ROBERT EMMONS, M.D.
PSYCHIATRIST

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

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CDC's LGBT Youth Resources Promote 'Q Chat Space'

By Ashley Bateman

The Centers for Disease Control and Prevention (CDC) has set up an "LGBT Youth Resources" webpage that promotes a live group chat site for teens to learn more about changing their biological sex, transgender activism, and sexual relationships.

The chatroom, "Q Chat Space," is directed at teens ages 13 to 19 and features adult moderators who are not necessarily licensed mental health professionals.

"Find and give support, have fun, connect around shared interests and get good information," states the Q Chat Space home page. "Chat with like-minded peers in live chats designed for you & by you, facilitated by folks who care."

The CDC website displays a disclaimer before a visitor is directed to the chatroom, stating the agency does not endorse the website and cannot attest to its accuracy, privacy protection, or compliance with federal laws.

Teens are encouraged to gain status on the site by becoming "Q Chatters" who commit to participate in at least one chat each week for a year.

"These ideologues dismiss the physical body, and the value of physical evidence, in favor of a purely subjective and internal sense of 'gender identity.' How many kids will have to suffer lifelong bodily and psychological damage before our federal institutions rethink their enthusiasm for gender ideology?"

JAY P. GREENE
SENIOR FELLOW, THE HERITAGE FOUNDATION

'Will Do Terrible Damage'

A review of the interviews and encounters with children on Q Chat Space shows only a handful of cases of children confused by their sex, says clinical psychologist Gabriela Eyal, Ph.D., who has worked with her state's Child Protective Services (CPS) and has evaluated more than 1,000 children enrolled in Head Start, a federal school readiness program for low-income children.

"I've seen so many children in terrible situations, and now the state is doing this to children," said Eyal. "It's terrible. When you've worked with CPS, you feel so strongly for the children."

Gender confusion is typically associated with unsafe homes, rather than occurring naturally, and encouraging it will cause significant mental health problems for these youth in the future, says Eyal.

"[Children] get confused and stay confused until they are in their twenties, and then they will fall apart," said Eyal. "In 10-to-15-year-olds, it will do terrible damage. People need to have a cohesive sense of self."

'Rethink Their Enthusiasm'

President Joe Biden issued an executive order banning "discrimination on the basis of gender identity or sexual orientation" on the day he took office.

Biden's order states, "Children should be able to learn without worrying about whether they will be denied access to the restroom, the locker room, or school sports."

Biden also appointed Rachel Levine, a transgender woman who was born a male, as assistant secretary for Health and Human Services.

Gender ideologues have captured federal government agencies, says Jay P. Greene, a senior fellow at The Heritage Foundation's Center for Education Policy.

"These ideologues dismiss the physical body, and the value of physical evidence, in favor of a purely subjective and internal sense of 'gender identity,'" said Greene. "How many kids will have to suffer lifelong bodily and psychological damage before our federal institutions rethink their enthusiasm for gender ideology?"

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

Federal Legislators, Physicians Push Back Against Youth Sex Treatment

By Harry Painter

A bill before Congress would make it a federal felony to perform gender-changing surgery and give puberty blockers to minors.

The Protect Children's Innocence Act (H.R. 8731) was introduced by Rep. Marjorie Taylor Greene (R-GA) on August 19 and has five cosponsors.

"I'm introducing a bill, creating a law, causing it to be a Class C felony for any person involved in so-called gender-affirming care—that means gender mutilation surgery, hormones, puberty blockers, anything involving youth under the age of 18—because they're too young to make these awful decisions that will affect them and will be permanent for the rest of their lives," said Greene in a statement.

"We are gaslighting [psychologically abusing], diseasing, mutilating, and sterilizing our children. We are destroying the mental and physical health of the next generation under the direction of Malthusian billionaire elites."

MICHELLE CRETELLA, M.D., PEDIATRICIAN

Hospital Clinics in Spotlight

At least privately, pediatricians are pushing back against medical authorities such as the American Academy of Pediatrics that spread radical gender ideology, the *Daily Wire* reports.

Michelle Cretella, M.D., a pediatrician who speaks out on transgender ideology, says at least 80 of 215 hospitals with pediatric training programs offer sex-change interventions for minors.

One example is the Boston Children's Hospital Center for Gender Surgery, which drew national attention in August for providing double mastectomies and sterilizing surgery to teenagers, among other controversies.

The Boston Children's Hospital "is not at all unique," said Cretella.

'Malthusian Billionaire Elites'

Cretella cites Christopher Rufo, an activist opposed to radical gender ideology, for exposing the fact Lurie Children's Hospital in Chicago was encouraging schools to provide sexually explicit gender training material to children as young as 11.

"We are gaslighting [psychologically abusing], diseasing, mutilating, and sterilizing our children," said Cretella. "We are destroying the mental and physical health of the next generation under the direction of Malthusian billionaire elites."

Real care for transgendered patients would do the opposite of affirming their self-identified gender with radical medical treatments, says Cretella.

"Doctors, those in any helping profession, and parents should do what we all used to do: recognize that proclaiming a trans identity is proclaiming a false belief and that [the identity concern] is a cry for help, a sign that there is a mental or emotional problem that needs to be explored and addressed with individual and family psychotherapy," said Cretella.

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

Federal Appeals Court Rejects Rule Forcing Doctors to Perform Abortions

By Harry Painter

In a win for religious liberty and personal medical autonomy, the U.S. Fifth Circuit Court of Appeals ruled against an attempt by the Biden administration to force physicians to perform abortions and gender reassignment surgery, on August 26.

Health and Human Services (HHS) Secretary Xavier Becerra proposed a rule that would have compelled doctors and hospitals to provide abortion and "gender transition" services against their religious or moral objections.

A coalition of Christian and religious liberty groups and nearly 20,000 doctors successfully sued the government over the proposed regulation, just as it had challenged a similar Obama administration rule.

Religious Objections

A bill signed into law by President Bill Clinton in 1993 forbids the federal government from putting "undue burdens" on the exercise of religious convictions, and the appeals court followed the law, says Joe Davis, an attorney with the Becket Fund for Religious Liberty.

"The Religious Freedom Restoration Act (RFRA) offers very broad protection for religious liberty," said Davis. "I think it was a straightforward case."

Davis argued the case, *Franciscan Alliance v. Becerra*, on behalf of Christian medical and dental associations, Specialty Physicians of Illinois, and the Franciscan Alliance, a Catholic hospital system.

The HHS rule had less to do with access to certain procedures than with forcing doctors to comply, says Davis.

"You're attempting to elevate ideology over medicine," said Davis. "If you want to go ahead with abortion and gender reassignment surgery, you don't need to violate freedom of conscience rights to do that."

Trans Ideology

The transgender movement is based on the idea that we can change our human nature by transforming our bodies, says Michelle Cretella, M.D., a pediatrician and member of the Catholic Medical Association.

"The Biden administration, along with every other leader of the Western world, is forcing transgender ideology onto every man, woman, and child to usher in the Fourth Industrial Revolution—that is, transhumanism," said Cretella. "In fact, transgenderism itself is transhumanism."

Transhumanism is an ideology that envisions using science, biotechnology, and artificial intelligence to make humans more than human.

Obama Pushed Rule

The effort to require insurers to cover and physicians to perform gender transitions and abortions under the Affordable Care Act (ACA) was started by the Obama administration when Joe Biden was vice president. Becerra has resumed the push during the Biden administration.

"They want to weigh in on this very hot debate that's going on about gender transitions, and they want to resolve it in one direction through force of nondiscrimination law," said Davis. "We ordinarily let the medical profession come to conclusions about this and leave it up to the judgment of doctors, whereas the HHS rule runs against a very long tradition, [including] the Hippocratic Oath."

In 2016, the Obama administration proposed a federal regulation under Section 1557 of the ACA regarding sex discrimination, which would have forced doctors to help "transition" patients by altering their sex organs, even if the doctor had medical or conscientious objections to doing so. The rule required medical facilities that offer women medically necessary procedures, such as hysterectomies, to provide the same procedures for transgender men.

Physicians and health care providers could not decline for religious reasons, and the government could fine them if they disobeyed.

The Becket Fund responded quickly, charging the government with violating the Administrative Procedure Act and the RFRA. A federal district court issued a preliminary injunction preventing the rule from going into effect. Subsequent court rulings in 2019 and 2021 also sided with Becket, and the rule became moot.

Becerra Tries Again

The Biden administration claims the fact the 2016 rule is no longer in effect means the court order protecting the Franciscan Alliance's religious liberty is contestable.

Davis disagrees, saying the federal district court's permanent injunction in *Franciscan Alliance v. Becerra* provides broad protection for Franciscan Alliance's religious liberties and protects religious organizations against lawsuits brought by private individuals.

"We won the case on our merits," said Davis. "I think it's critically important that people in health care continue to follow their judgment on these issues and recognize that there are protections that will be there for them if and when they do."

The federal government can still appeal the ruling in the Fifth Circuit or even the U.S. Supreme Court, says Davis.

"We don't know if they're going to do that or not," said Davis. "We feel very confident in our arguments. I think that they are very ideologically committed to these procedures, and they want to change the norms of the medical profession."

The Becket Fund argued another case in December 2021 regarding the same ACA provision, *Religious Sisters of Mercy vs. Becerra*, before the Eighth Circuit Court of Appeals, which could be decided soon, says Davis.

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

"We won the case on our merits. I think it's critically important that people in health care continue to follow their judgment on these issues and recognize that there are protections that will be there for them if and when they do. We don't know if they're going to do that or not. We feel very confident in our arguments. I think that they are very ideologically committed to these procedures, and they want to change the norms of the medical profession."

JOE DAVIS
ATTORNEY
BECKET FUND FOR RELIGIOUS LIBERTY

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COMMENTARY

The Pharmacy Benefit Manager Scam

By Katy Talento

When I served as a White House health adviser, I invited a group of large employers to describe the challenges company health plans faced. The top complaint? An obscure type of middleman who is part of every health plan: the Pharmacy Benefit Manager (PBM).

Three Companies Dominate

The PBM industry, with only three giant companies controlling almost 80 percent of the market, offers a seemingly simple value proposition: if you are an employer or an insurance carrier serving individuals or businesses, hire the PBM to help you get volume discounts from prescription drug makers. Sounds great!

But what if these middlemen pocket much of the savings instead of passing them on to employers? What if they allow patients access only to products that deliver the biggest kickback to the PBM, instead of cheaper and equally effective drugs? What if they merge with insurers administering employer plans, instead of having to compete for their business? What if the newly merged PBM/insurer refuses to allow employers to hire a different PBM or specialty or mail-order pharmacy other than the one the insurer owns? What if PBMs sue the federal government to block a regulation that would require them to disclose to employers the size of their kickbacks?

In a July 12, 2022 opinion piece in *The Wall Street Journal*, my former White House colleagues Joe Grogan and Casey Mulligan (now consultants for PBMs) expressed bewilderment about bipartisan opposition to these corrupt business practices. Perhaps opposition arises because if giant companies need White House help in beating back PBM predations that drive up health care costs, what possible chance do smaller employers have, struggling to meet payroll in our inflationary economy?

Washington health policy "experts" rarely have experience building health plans out in the real world, and they too often make decisions based on which industry group drafts the most compelling talking points.

Independent Advisers Help

Outside the Washington Beltway, there is an insurgency of fed-up employers fighting back against the health care industry's plunder of Main Street. They are partnering with independent advisers who help vet PBMs and negotiate PBM contracts.

One story close to my heart is that of a group of Catholic nuns who faced double-digit rate hikes on their insurance plan every year for a decade, largely driven by a few high-cost medications. Their insurance company, of course, partnered exclusively with one of the big three PBMs. After the group of nuns switched to a transparent PBM that does not take kickbacks from drug makers, the sisters saved 32 percent on their health costs while reducing their $4,000 annual deductibles to zero.

Matheny Motors, a chain of auto dealerships in the Rust Belt, fired their insurance carrier and Big Three PBM, and saved 37 percent in two years with the help of independent benefits adviser Bryce Heinbaugh.

According to Rachel Means, the San Antonio Independent School District she advises fired its Big Three PBM and has saved $2.5 million each year, with teachers and their families paying zero out of pocket for medications.

Caterpillar, Inc. fired its PBM years ago, directly contracting with pharmacies, and saved 25 percent annually—tens of millions of dollars.

These examples are not outliers. Similar results occur every time an employer gets out from under the crooked alliance of PBMs and insurance carriers. This reality belies the industry talking point that although PBMs or carriers pocket the rebates, they are used only benevolently to drive down premiums.

Cites Market Distortion

Some would suggest these stories are evidence the free market is working and regulation is not needed. However, the fact that even large companies, with the most negotiating leverage, are being taken to the cleaners by these tactics points to a market distortion worthy of policymakers' attention.

Most companies rely on their insurance broker to recommend a PBM, not realizing that PBMs are wholly entangled with insurance companies, which are equally entangled with brokerage houses, creating little incentive to slow down the gravy train. Even worse, most Americans are insured by a policy that doesn't allow them or their employer to choose their PBM. If they pick Aetna, they get CVS Caremark as their PBM. If they pick United, they get Optum, period.

That is why even free-marketeers are now railing against the arrangement PBMs (and drug-makers, insurers, and brokers) have built and enjoyed for so long.

Washington usually proposes whack-a-mole "solutions" that merely shift costs to different parts of the system without ever actually lowering overall costs. Despite the caterwauling from the Health Care Swamp, *the only way to pay less for health care is to pay less for health care*. There is no better starting point than government policies that restore transparency in drug pricing once and for all.

Katy Talento **(katy@allbetter.health)** *is the CEO of AllBetter Health, an employer benefits advisory firm, and is an epidemiologist, and former special assistant to the president for domestic policy.*

"Washington usually proposes whack-a-mole 'solutions' that merely shift costs to different parts of the system without ever actually lowering overall costs. Despite the caterwauling from the Health Care Swamp, *the only way to pay less for health care is to pay less for health care*. There is no better starting point than government policies that restore transparency in drug pricing once and for all."

KATY TALENTO
CEO, ALLBETTER HEALTH

COMMENTARY

Are America's Best Health Plans Being Attacked Unfairly?

By John C. Goodman

Medicare Advantage (MA) is the unique program under which the elderly and the disabled can enroll in private health plans, like the plans many of them were in as employees.

MA plans have enrolled nearly half of all eligible people and have satisfaction rates of 90 percent or higher. MA is the only place in the entire health care system where health plans specialize in various chronic conditions and advertise to attract those patients.

In MA, a doctor who discovers a change in a patient's medical condition can get a higher premium payment from the government for that patient. Thus it is in the financial interest of MA plans to discover medical problems and solve them. And that is why MA is the only place in the system where health plans aggressively compete to solve the problems of people who are sick.

"The MA program is not perfect. Reforms are needed, including making enrollment continuous. Enrollees should be able to get into the right plan as soon as their health condition changes, instead of waiting 12 months for an open enrollment period. But this and other reforms would only make a good program better."

JOHN C. GOODMAN
PRESIDENT, GOODMAN INSTITUTE FOR PUBLIC POLICY RESEARCH

Are Cost, Quality Better?

Studies show MA plans, overall, provide higher-quality care at a lower cost than fee-for-service Medicare. One study found MA plans cost $1,704 less per enrollee per year, all else being equal.

Seniors usually enroll in an MA plan for no more than the cost of Part B (outpatient) and Part D (drugs) premiums. They avoid almost $2,000 a year other beneficiaries spend on Medigap policies to meet deductibles and copays in regular Medicare. They also receive extra benefits—such as hearing, vision, and dental care—not available in regular Medicare.

Interestingly, the highest-rated plans are doctor-run, and they are not necessarily HMOs. IntegraNet Health in Houston is an example of a doctor-run plan that achieves very high scores on quality and pays its physicians on a fee-for-service basis.

Are Patients Denied Care?

MA plans are now under attack after the U.S. Department of Health and Human Services' Office of Inspector General (OIG) reported instances where doctors' requests for prior authorization of a drug or procedure (consistent with Medicare's general rules) were denied by MA plans.

The OIG's March report did not find any patients were denied needed care but raised the specter of that possibility. However, the OIG only looked at a handful of prior authorization requests—247 out of a population of 28 million enrollees. Of these, 95 percent of the requests were approved, and of the ones not approved, only 13 percent (33 cases) were questionable.

Prior authorization is used to avoid procedures that are wasteful and even unsafe. A majority of doctors say 15 percent to 30 percent of health care is unnecessary, and almost everyone agrees our system provides too much low-valued care and too little high-valued care. MA was created in part to address that issue.

If MA plans do what they are supposed to, we would expect them to provide fewer of some types of services and more of others. An accurate evaluation would compare MA plans with traditional Medicare, but the OIG report did not do so.

Do Plans Overcharge Taxpayers?

Critics of MA also point to a report by the Medicare Payment Advisory Commission (MedPAC), an independent body that advises Congress, which found patients' "risk scores" for medical problems are higher in MA plans than in traditional Medicare, leading to higher premium payments.

This is to be expected. MA plans get paid more if enrollees have more health problems, so they have a financial incentive to find and document medical conditions. By contrast, a typical fee-for-service doctor doesn't have such incentives and therefore may be less careful in maintaining patient records.

To the extent high risk scores are a problem, part of the answer is conducting audits and fining health plans with excessive patient coding errors.

More drastic action should be taken if actual fraud is involved. An estimated $60 billion a year in Medicare spending is lost to fraud, and almost all of it is in regular Medicare, not MA plans.

Are Plans Overpriced?

A MedPAC study concluded Medicare pays 4 percent more than it would if the MA enrollees were in regular Medicare, whereas an insurance industry study concluded just the opposite: that Medicare spends 9 percent less.

George Halvorson, former CEO of Kaiser Permanente, calls the MedPAC study "shoddy" and notes MA plans have 35 percent fewer emergency room days, 40 percent fewer hospital days, and many more virtual visits than traditional Medicare.

Even MedPAC says MA plans are more cost-effective.

Do Critically Ill Patients Leave?

Critics also point to a report by the General Accounting Office (GAO) that found patients in MA plans are more likely to disenroll and return to regular Medicare in their last year of life. Presumably, this is the point at which patients are the sickest, requiring the costliest care.

However, the disenrollment rate among this group was only 4.6 percent, versus 1.7 percent for other enrollees. More than 95 percent of patients in the last year of life stayed in MA plans.

Moreover, there are good reasons why terminally ill patients might disenroll, having nothing to do with the quality of their care. They may choose to enter a hospice, for example, or move to be closer to family.

The MA program is not perfect. Reforms are needed, including making enrollment continuous. Enrollees should be able to get into the right plan as soon as their health condition changes, instead of waiting 12 months for an open enrollment period. But this and other reforms would only make a good program better.

John C. Goodman (**johngoodman@johngoodmaninstitute.org**) *is president of the Goodman Institute for Public Policy Research and co-publisher of* Health Care News. *An earlier version of this article appeared in* Forbes *on July 13, 2022. Reprinted with permission.*

SATIRE

CDC Warns of New 'Stealth' COVID Variant Where You Test Negative and Get No Symptoms

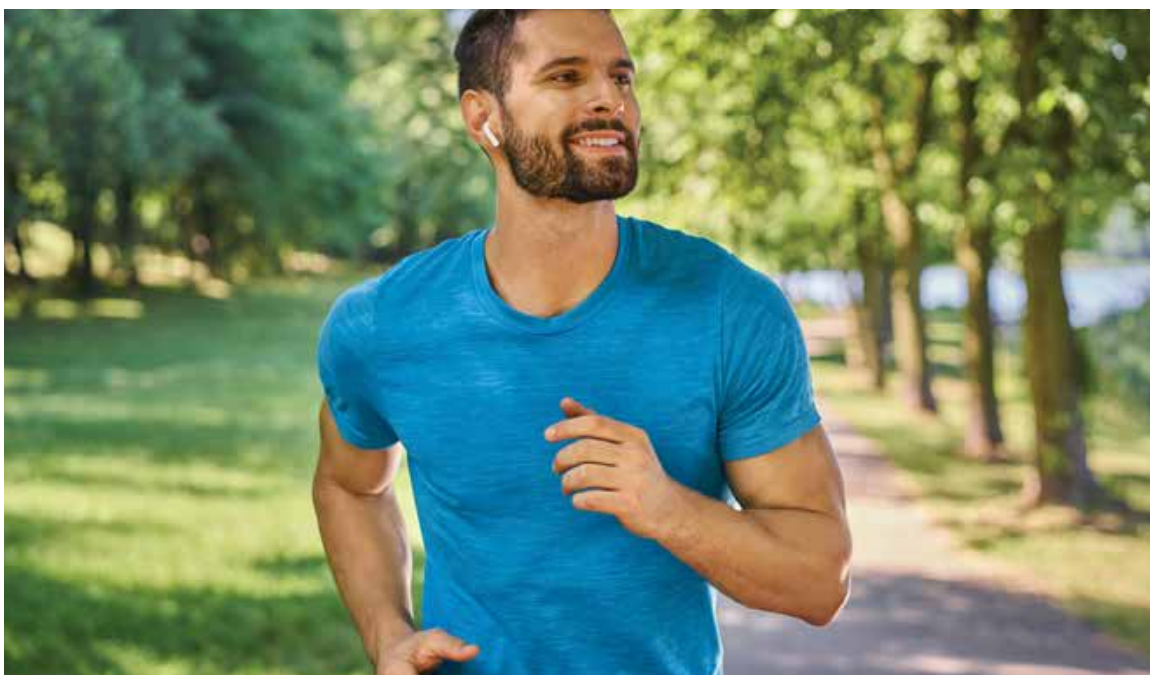
The Babylon Bee

ATLANTA, GA—CDC Director Dr. Rochelle Walensky held a press conference to warn the public about a deadly new "stealth" COVID-19 variant that causes negative test results and causes no symptoms.

"This deadly variant has bypassed our most sophisticated tests by ingeniously becoming harmless to the human body," said Director Walensky, "It is estimated that eight billion people have caught this variant. We must prevent it from spreading further by closing schools and locking up kindergarten children."

The CDC director's guidance to close schools and stem the tide of this "stealth" variant is backed by data that has been thoroughly and rigorously altered, proving that public school teachers are the most susceptible, testing negative a whopping 100 percent of the time and often succumbing to the worst symptom-free symptoms.

At publishing time, Pfizer had announced early development of a new, 103 percent effective vaccine, followed 3.8 seconds later by approval from the FDA.



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