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## TEALTH CAR

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## **Drug Company Faces Lawsuit for Not Releasing Safer Treatment**

#### By Dvorah Richman

ilead Sciences, Inc. is facing Charges of negligence in California because the company delayed the release of an allegedly safer HIV/AIDS drug than the one it was selling.

A California Court of Appeals affirmed a new, extraordinary negli-

gence liability theory on January 9, 2024, holding Gilead could be liable for negligence, not because its tenofovir disoproxil fumarate (TDF) was defective but because the company delayed commercializing tenofovir alafenamide

**Gymnast Mary Lou Retton** 

DRUG COMPANY, p. 6

BEAVER DAM, WI PERMIT NO. 412 NOITAZINAĐRO

PHOTO COURTESY ROBIN MARCHANT/GETTY IMAGES NEWS

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## Obamacare Enrollment Gets Big **Boost from Medicaid Dropouts**

#### By AnneMarie Schieber

fter the 2024 open enrollment peri-And for Obamacare ended, President Joe Biden boasted 21.3 million people signed up for health insurance on the government exchanges, an increase of 30 percent over 2023, and nine million since he took office.

"It's no accident," said Biden in a statement on January 24. "My actions to protect the Affordable Care Act and lower premiums continue to make a big difference. And the American people have made it clear: they don't want the Affordable Care Act weakened and repealedthey want it strengthened and protected."

#### **Nearly Half Covered Free**

Biden credited "lower premiums," not penalizing patients for preexisting conditions, and charging enrollees the same rates regardless of sex. Biden did not mention government subsidies for premiums, the tax credits offered to families whose income exceeds 400 percent of the federal poverty level (FPL), or the narrowing of access to doctors to control plans' costs.

"Many of the new enrollees are likely people who did not enroll when the premium was 2 to 4 percent of their income but do when coverage is given to them for free," said Theo Merkel, a senior research fellow at the Paragon Health Institute.

A graph in a post by Merkel shows nearly half of exchange enrollees live below 150 percent of the FPL. Those enrollees pay nothing for the benchmark plan. Premiums for an unsubsidized Obamacare plan can cost \$5,628 for a 40-year-old adult.

#### **Moving from Medicaid**

States are "unwinding" Medicaid enrollment after a pandemic-era moratorium on removing individuals from the program ended in 2023.

"Biden's real accomplishment was failing to return to Medicaid eligibility rules in an orderly fashion after the health 'emergency'—which stopped being a real emergency at least a year before the administration finally gave it up," said Joseph Antos, a senior fellow in health care at the American Enterprise Institute.

"On the one hand, Biden complains about states disenrolling millions of people from Medicaid," said Antos, "On the other hand, he crows about signing many of the same people for free Obamacare."

"The bump this year is a combination of Medicaid disenrollments and additional people moving to ACA coverage because it is essentially free—that is, zero premium, net of subsidy—for many of them."

JOSEPH ANTOS

SENIOR FELLOW, AMERICAN ENTERPRISE INSTITUTE

#### **Three-Year Trend**

Open enrollment counts jumped by about two million a year in 2022 and in 2023, after a period of steady enrollment numbers, Antos notes.

"The blip in exchange enrollment during the 2024 open enrollment period should be averaged over three years," said Antos. "Without keeping so many people on Medicaid despite no longer qualifying, there would be no surge in ACA enrollment."

The surge in enrollment began in 2022 when premium subsidies increased, says Antos.

"The bump this year is a combination of Medicaid disenrollments and additional people moving to ACA coverage because it is essentially free—

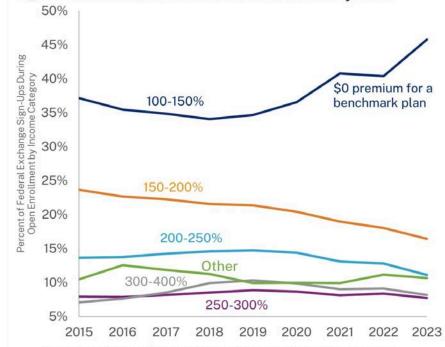
that is, zero premium, net of subsidyfor many of them," said Antos. "Next year's enrollment may increase somewhat because of the premium subsidy effect, although I think that effect will be low."

A change in the enrollment trend will provide an opportunity for political spin, says Antos.

"If a Republican wins [the presidencyl this year, Democrats will complain about the 'shocking' drop in additional ACA enrollment in the next open-enrollment period—the result of returning to normal patterns," said Antos.

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

#### Nearly Half of Exchange Enrollees Now Have Income Below 150% of the Federal Poverty Level



Source: Compiled from CMS Marketplace Open Enrollment Period Public Use Files Note: The lines represent percentages of the federal poverty level (FPL). The other category includes people with income below 100% FPL, above 400% FPL, and those with uncertain

COURTESY: PARAGON HEALTH INSTITUTE

#### **Continued from page 1**

Marketplace during the most recent annual enrollment period (see page 3).

On NBC's *Today* show, Retton attributed her lack of insurance coverage to 30 orthopedic surgeries, which count as preexisting conditions, plus the financial strains of a divorce.

"I couldn't afford it," Retton told host Hoda Kotb.

#### **Options for the Uninsured**

One of the selling points of the ACA was that it accepted uninsured people, even those with preexisting conditions, such as those Retton has. Under the ACA, insurers are also barred from charging higher premiums for people with preexisting conditions. Subsidies are based on household income.

Retton, a native of West Virginia who now resides in Texas, might have had difficulty qualifying for Medicaid in the Lone Star State because Texas has turned down the option to expand Medicaid (see related article, page 10). Retton, age 56, is too young and likely not disabled enough to qualify for Medicare

#### **Short-Term Insurance**

Another option for Retton and other cash-strapped Americans is short-term health insurance. Expanding access to short-term plans was a priority of the Trump administration, which said such plans would increase choices for people with limited means.

Under a Trump rule issued in August 2018, health insurers were allowed to sell short-term coverage good for up to 12 months, with a renewal option of up to three years. However, people with preexisting conditions can be excluded from coverage. Though cheaper than ACA plans, which have long-term guaranteed renewability, they are also less comprehensive.

According to the National Association

#### Obamacare Health Insurance Premium Estimate for Bronze Plan, No Subsidies



SOURCE: HEALTHCARE.GOV

of Insurance Commissioners, 235,775 people were covered under short-term policies in 2022. The number of enrollees might be higher because carriers are not required to report enrollment data.

In July 2023, the Biden administration proposed a rule limiting short-term health insurance policies to initial terms of no more than three months, with the option of an additional one-month renewal. The Biden rule would also bar a consumer from purchasing an additional short-term policy from the same insurer within 12 months.

Short-term plans are not available everywhere. Some states either ban them outright or make them so difficult to offer that insurers avoid them. Those jurisdictions include California, Colorado, the District of Columbia, Hawaii, Maine, Massachusetts, Minnesota, New Hampshire, New Jersey, New Mexico, New York, Rhode Island, Vermont, and Washington.

#### **Crowdsourcing Rescue**

Retton said on *Today* she now has health insurance. To help her pay outstanding medical bills, Retton's daughters set up a crowdfunding site that reported raising \$459,234 in

donations.

Kansas state Sen. Beverly Gossage, a licensed health insurance agent, says the options in the Obamacare marketplace are out of reach for many.

"We all sympathize with Mary Lou Retton's health scare," said Gossage. "We can assume she tried to find affordable rates before she developed pneumonia. Unfortunately, because of the ACA, the lowest-priced premium for her home state of West Virginia for a middle-income, 56-year-old woman would be over \$14,650 annually, with an \$8,000 out-of-pocket charge."

#### **Marketplace in Decline**

Retton would have few choices in the ACA Marketplace because it is inaccessible except for the open enrollment period and unsubsidized coverage is increasingly unaffordable, says Gossage.

"She had a narrow, six-week window to purchase this insurance," said Gossage. "Over the past 10 years, the ACA forced out most of the carriers, and rates are very high for all but those in the lower-income bracket.

"A few have found relief in the shortterm plan market, paying 70 percent lower rates than in the ACA market, but not everyone could qualify," said Gossage. "It's time to give Americans private, personalized, portable options from a truly competitive marketplace, without the federal government's thumb on the scale."

HOTO COURTESY ROBIN MARCHANT/GETTY IMAGES NEWS

#### 'Attacking the Victim'

Jeff Stier, a senior fellow at the Consumer Choice Center, echoed Gossage's sentiments.

"Sadly, some of Obamacare's most strident defenders are now insinuating Retton's appeal for help was somehow inappropriate," said Stier. "They refuse to accept that even someone who once achieved great success could face a series of challenges that could make Obamacare unaffordable.

"Rather than acknowledging that the market for health insurance is so fundamentally distorted by Obamacare that it barely resembles a truly operating market, some have resorted to attacking the victim," said Stier.

A February 2 article in *The Mercury News*, headlined "Mary Lou Retton got \$2 million in divorce but couldn't 'afford' health insurance," is an example of the attacks on Retton.

#### 'Coverage Does Not Equal Care'

Robert Henneke, executive director of the Texas Public Policy Foundation, says Retton's case is not an isolated one and shows the ACA's unfulfilled promises.

"Sadly, this type of tragedy has become all too common in the decadeplus since Obamacare became law," said Henneke. "Coverage does not equal care, and the high cost and the loss of provider options under the ACA have left most Americans worse off than before."

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

## Diabetes-Related Amputations on the Rise

#### **Bv Kevin Stone**

Diabetes-related amputations are on the rise, reversing a decadelong trend, according to the American Diabetes Association (ADA).

ADA's Amputation Prevention Alliance reports 154,000 diabetes sufferers per year now undergo amputations, and up to 80 percent of all nontraumatic lower-limb amputations are the result of uncontrolled diabetes.

Limb amputations due to diabetes occur every three minutes and 30 seconds in the United States, the report notes. Amputations are more prevalent among patients of color. More than half of patients with diabetes-related amputations die within five years.

#### **Downward Trend Reversed**

A study published by the ADA in 2019 of all nontraumatic lower-extremity amputations among young and middle-aged people in all demographic groups found a 43 percent decrease from 2000 to 2009 was followed by a rebound of 50 percent from 2009 to 2015.

Another study on diabetes-related amputations, led by Jessica Harding, Ph.D., found amputations per thousand diabetes patients fell by half from 2000 to 2009, dropping from 8.5 to 4.4 percent, and the rate ticked back upward after 2009, to 4.8 percent.

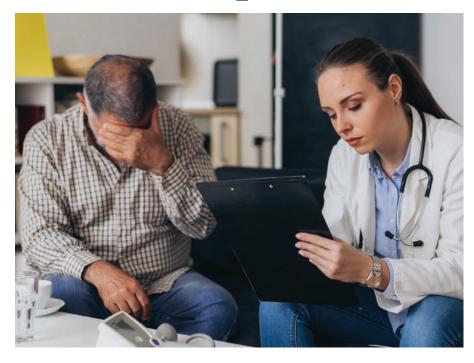
A paper by Bruce A. Perkins, M.D. reported a decline from 2005 to 2010, followed by an increase from 2010 to 2016.

The ADA noted the trend varied by state, with a handful of states leading the increase while others maintained lower rates.

#### **Ethnic Disparity**

A January 16, 2024 article in *The New York Times*, titled "Diabetes Is Fueling an Amputation Crisis for Men in San Antonio," focused on the explosion of diabetes-related amputations in the heavily Hispanic-populated Texas city. It cited the existence in Latino and Native American populations of genes that predispose the pancreas to make insufficient insulin, and other genes that cause tissues to become insulin-resistant.

A fact sheet from the Amputee Coalition similarly cites a one-and-a-half times greater likelihood of Latino Americans suffering amputation of any kind compared with other ethnicities in the United States, and a 30 percent greater risk of diabetes-related amputation compared to "white Americans," suggesting that changing demographics may be a factor in the recent upward trend in amputations.



"Most of the complications of diabetes can be avoided or at least dramatically delayed by timely care, including close monitoring of diet and glucose levels by professionals, and drugs, when necessary, with close follow-up. That is precisely what they don't get with government insurance. Look up the section on Joel Brenner in my book, *Curing the Cancer in U.S. Healthcare*, to see what good care—that is, timely care—can do for diabetics. As the regulatory burden increases and payments to providers decrease, provider shortages get worse, further extending the wait times so there is more death by queue."

DEANE WALDMAN, M.D.
PROFESSOR EMERITUS OF PEDIATRICS, PATHOLOGY, AND DECISION SCIENCE
UNIVERSITY OF NEW MEXICO

#### **Risk-Reducing Care**

John Abramson, M.D., a family physician and author of *Sickening: How Big Pharma Broke American Health Care and How We Can Repair It*, says the rise is not just a matter of ethnicity, but results from societal factors as well.

"Preventing amputations among Americans with type 2 diabetes will require a multipronged approach," said Abramson. "First, participation in healthy lifestyle modification programs can reduce the risk of developing diabetes by more than 50 percent.

"Second, good medical care of lower leg and foot ulcers can prevent amputations," said Abramson. "This is especially true in the higher-risk populations: black and non-black Hispanic patients as well as those with less education. The risks of amputation are primarily socially determined. The most effective prevention will address the upstream causes."

#### 'Care When They Need It'

Beyond ethnicity, some experts see the increasing role of government insurance plans, including Medicare-Medicaid and plans under the Affordable Care Act, as reducing access and followthrough.

Deane Waldman, M.D., a professor emeritus of Pediatrics, Pathology, and Decision Science at the University of New Mexico, says disincentives for timely care under government health plans are a contributing factor. "The fundamental problem is a see-saw effect," said Waldman. "As government-insured patients—Medicaid and Tricare—go up, access to care goes down. So, as more diabetics enroll in Medicaid, especially—though Medicare will soon face the same problem when [system] bankruptcy stops Medicare paying for hospital care—they simply don't get care when they need it.

"This is well-documented in our veterans," said Waldman. "Patients wait longer and longer for care, and diabetes progresses to the point where amputation cannot be avoided."

#### 'More Death by Queue'

As more Americans enroll in government health care programs, access to care decreases, says Waldman.

"Most of the complications of diabetes can be avoided or at least dramatically delayed by timely care, including close monitoring of diet and glucose levels by professionals, and drugs, when necessary, with close followup," said Waldman. "That is precisely what they don't get with government insurance. Look up the section on Joel Brenner in my book, Curing the Cancer in U.S. Healthcare, to see what good care—that is, timely care—can do for diabetics.

"As the regulatory burden increases and payments to providers decrease, provider shortages get worse, further extending the wait times so there is more death by queue," said Waldman.

#### **High Copays and Medicaid**

High copays—up to 20 percent of treatment and medication costs under Medicaid for higher-income enrollees—may provide a disincentive for patients to seek timely care.

Robert Koshnick, M.D., a family medicine specialist and author of *Patient-Directed NIMBLE Healthcare: Reduce Health and Financial Disparities in the U.S. with Tax Credits for Direct Primary Care and HSAs*, says the lack of incentive to seek direct primary care increases the risk of diabetes complications for people in some demographics.

"People need to have incremental care by a primary care physician to address obesity issues and treat diabetes appropriately," said Koshnick. "One solution to ensure primary care access would be for the government to give a tax rebate to people for the cost of establishing a direct primary care relationship."

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



#### **Continued from page 1**

fumarate (TAF), an HIV drug that allegedly has fewer side effects.

TDF was approved by the Food and Drug Administration (FDA) in 2001. Gilead and the FDA knew the drug had potential side effects, including skeletal and kidney damage. Gilead began developing TAF in 2002, stopped, and then resumed its work on the drug. The FDA approved it in 2015.

TDF- and TAF-containing drugs are FDA-approved as "safe and effective" and are still marketed to treat and prevent HIV.

#### **Summary Judgment Denied**

In the original case, about 24,000 AIDS patients claimed Gilead's TDF drug caused injuries to them.

The plaintiffs did not contend the TDF drug was defective or lacked adequate warnings. Instead, they argued Gilead owes damages for not marketing a different, allegedly safer drug.

The plaintiffs made two other claims, including that Gilead fraudulently concealed its development of TAF from TDF users.

The Superior Court that tried the case denied Gilead's motion for summary judgment and said plaintiffs could seek a negligence claim based on Gilead's delay in developing TAF. Gilead appealed that decision.

#### **Financial Considerations?**

On appeal, the plaintiffs in the original case claimed TAF is safer than TDF and Gilead knew this but unreasonably paused TAF's development for financial reasons, thus depriving them of a drug that could have prevented their injuries.

The plaintiffs also argued the patent system incentivizes drug manufacturers "to try to extend their monopolies for as long as possible, with deleterious "To be clear, the Court did not decide that Gilead was required to bring TAF to market earlier than it did. Rather, it did not feel the present record was adequate at this stage to dismiss it and left open the possibility for Gilead to establish on a more developed record that there is no merit to Plaintiffs' claim."

GILEAD SPOKESPERSON

effects on innovation and competition." Gregg Girvan, a health care pol-

Gregg Girvan, a health care policy specialist at the Foundation for Research on Equal Opportunity, says the regulatory system is flawed.

"Government policy allows drug companies to manipulate patents and [FDA] exclusivities to have monopolies on branded drugs for long periods," Girvan said.

Girvan says patent reforms are possible through legislation or regulation, though congressional action "is preferable since regulations can be swept away by a future administration and are more vulnerable to litigation," particularly now, considering the Supreme Court's upcoming decision regarding the Chevron doctrine.

#### No Recognized 'Duty'

Gilead noted no court has recognized a duty to develop a product more quickly and product liability law already protects consumers. Additionally, the plaintiffs' negligence claims are preempted by federal law and don't state a claim under state tort law because there is no proven product defect, the defense argued.

Several groups filed amicus briefs in the case, including the Washington Legal Foundation (WLF) and the Product Liability Advisory Council. In conjunction with the U.S. Chamber of Commerce, California Chamber of Commerce, and the Alliance for Automotive Innovation, the WLF argued "as a matter of law and policy" the court should reject the plaintiffs' "dangerous" and "unsupported" theory that would authorize negligence liability "whenever a business fails to expeditiously release a new product."

The Court heard policy arguments from both sides, including impacts on public health and health care spending.

#### **Plaintiffs Prevail for Now**

The Appeals Court dismissed two of the plaintiffs' claims, including "fraudulent concealment," leaving only the negligence claim. By allowing that claim to proceed, the court "upended established California law," a Gilead spokesperson told *Health Care News*.

The appeals court's opinion in *Gilead Sciences, Inc. v. Superior Court* characterized the plaintiffs' negligence claim as "Gilead breached its duty of reasonable care by postponing, solely to maximize profit, its effort to commercialize TAF as a treatment for HIV/AIDs while continuing to market a medication with serious side effects that it knew TAF would have enabled patients to avoid."

Based on analysis of case law, in conjunction with certain assumptions—including that Gilead knew TAF was safer than TDF, knowingly and intentionally withheld TAF, FDA approval of

TAF would not be difficult, and physicians would prefer prescribing TAF—the appeals court held "the legal duty of a manufacturer to exercise reasonable care can, in appropriate circumstances, extend beyond the duty not to market a defective product."

"To be clear, the Court did not decide that Gilead was required to bring TAF to market earlier than it did," said Gilead's spokesperson. "Rather, it did not feel the present record was adequate at this stage to dismiss it and left open the possibility for Gilead to establish on a more developed record that there is no merit to Plaintiffs' claim."

#### **Could Impede Drug Development**

The appeals court said its opinion does not create a "duty to innovate" or "pursue ever-better new products."

If the decision holds, however, companies will be in a Catch-22, Girvan says: facing product liability suits arguing alleged defects were caused by overly rapid development, or where no defect exists, negligence suits for delaying or failing to market an allegedly better product.

"This could actually make the situation for patients worse, in that companies would not introduce a new and improved product at all," said Girvan.

Gilead's spokesperson says the company will continue to defend itself and is evaluating its appellate options. But "if the opinion is not overturned, the court's decision will have widespread, negative consequences across all fields of innovation and manufacturing, undermining the development of new products and discouraging improvement of existing products."

Dvorah Richman, J.D. (dvorahrichman@gmail.com) writes from Fairfax, Virginia.

# Families File Lawsuit over Hospitals' COVID-19 Treatments

#### **By Harry Painter**

Two women whose husbands died after they were given remdesivir while receiving care for COVID-19 filed a wrongful death lawsuit against HealthPartners, Inc. and Regions Hospital in St. Paul, Minnesota, where their spouses were treated.

One plaintiff was dismissed from the lawsuit without prejudice, meaning she may file suit again. The remaining complainant, Nicole Riggs, says her request that her father receive zinc, vitamin D, vitamin C, ivermectin, and hydroxychloroquine when he was admitted to Regions with COVID-19 was denied, according to an article published by *Alpha News* on December 29.

"Instead, Riggs claims her father was given over 50 medications and eventually put on a ventilator," *Alpha News* reported. Riggs' father died after he was eventually transferred to another hospital

The suit was filed in Ramsey County District Court in Minnesota.

#### 'Profits for the Wrongdoers'

The two women are part of a weekly support group for families who lost loved ones to COVID-19. Their attorney, Andrew Barnhart, was an emergency medical technician during the pandemic and started the organization Medical Justice MN, to work for people claimed to be injured or killed by the COVID-19 treatment protocol.

The group argues some pandemic protocols "violate the Minnesota Health Care Bill of Rights and generate profits for the wrongdoers."

Federal courts have allowed wrongful death suits over COVID treatments to go forward in other states, such as Louisiana. The family of actor Bill Paxton settled a wrongful death suit in California in 2022. Litigation over a death allegedly caused by remdesivir is ongoing in California.

#### **'Lack of Informed Consent'**

Officially recommended treatments such as the antiviral drug remdesivir harmed and killed patients, says Barnhart.

"We hope that as these financially incentivized harmful practices are brought to light, public awareness of this mistreatment will cause hospitals to change their ways," Barnhart said.

Barnhart says there are commonalities among many of the stories he has



heard about lackluster COVID care.

"Some of the most egregious are intense and prolonged isolation of the patient from family members and other advocates and for COVID-19 protocol treatments," said Barnhart.

#### 'Hospitals Failed'

One roadblock to getting justice for victims is the Public Readiness and Emergency Preparedness (PREP) Act, says Barnhart.

"The PREP Act is a serious hurdle because it purports to give immunity to hospitals for administering COVID-19 countermeasures," said Barnhart. "However, we are finding that in some of these cases, the hospitals failed to detect and treat non-COVID-19-related illnesses, we think partly due to their hyperfocus on financially incentivized COVID-19 protocol treatments.

"Such failures should not be covered by the PREP Act immunities," said Barnhart.

#### **Early Treatments Suppressed**

It was widely reported during the pandemic that therapeutic remedies such as hydroxychloroquine and ivermectin were ignored or suppressed in favor of officially recommended drugs such as Gilead Sciences' remdesivir.

Doctors were sometimes penalized for choosing to treat patients with offlabel treatments such as hydroxychloroquine and ivermectin.

The Food and Drug Administration (FDA) issued an Emergency Use Authorization for remdesivir in May 2020, though it admitted there is "limited information known about the safety and effectiveness of using remdesi-

vir to treat people in the hospital with COVID-19."  $\,$ 

#### Remdesivir's Side Effects Ignored

The wrongful death lawsuit filed by Barnhart states remdesivir "poisons the kidneys, causes the lungs to fill with fluid, damages other organs, and published studies show a causal connection between remdesivir and the death of heart cells, heart attacks, hypotension, and bradycardia."

The plaintiffs allege the federal government incentivized hospitals to treat patients with remdesivir by allowing them to bill "a base amount of \$3,200 for each Remdesivir treatment administered despite the production cost of each vial of Remdesivir being \$9."

Hospitals could also bill as much as \$20,000 per patient receiving remdesivir, the lawsuit claims.

#### Legionnaires' Lessons Forgotten

Scott Jensen, M.D., a former Minnesota legislator and gubernatorial candidate who nearly had his medical license removed for promoting alternative views, contrasts the COVID protocols with what happened after the 1976 Philadelphia Legionnaires' disease outbreak.

Jensen said he and other doctors treating the respiratory infection were allowed to provide alternative medications to their patients.

"We gave them our best antibodies, and they weren't responding," said Jensen. "They continued to die at an alarming rate, and we didn't have the causative agent identified. Ultimately, the agent was identified as the bacteria Legionella pneumophila.



"You put in protections through your licensing boards in the various

50 states. We could put a shield of protection up for physicians and patients. Patients feel like they've been abandoned and betrayed by their physicians, their clinics, as well as the public health people."

SCOTT JENSEN, M.D.
FORMER MINNESOTA LEGISLATOR

"Doctors kept experimenting," said Jensen, until they "stumbled on the fact that erythromycin—an old-fashioned, longstanding generic cheap medication—stopped the pneumonia and helped people heal."

That lesson was forgotten in 2020, Jensen says.

"That didn't happen with COVID, because early on, ivermectin and hydroxychloroquine were given the kiss of death by a lot of policymakers," said Jensen.

#### **Doctors Unprotected**

"As a general rule, physicians have always been allowed to repurpose drugs or use them off-label to do what we thought might work as long as we had the informed consent of patients," said Jensen.

Today, most physicians would acknowledge the failures of the federal government during the pandemic, says Jensen

"When politicians dabble in how physicians should practice medicine, it's a very slippery slope," said Jenson.

Jensen calls for more protection for physicians by explicitly authorizing doctors to prescribe off-label treatments.

"You put in protections through your licensing boards in the various 50 states," Jensen said. "We could put a shield of protection up for physicians and patients. Patients feel like they've been abandoned and betrayed by their physicians, their clinics, as well as the public health people," said

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

## FDA Greenlights Florida's Canadian Drug Import Program

#### **By Ashley Bateman**

The U.S. Food and Drug Administration (FDA) authorized Florida's plan to import drugs from Canada, a first for the agency which could save patients millions of dollars.

The program limits access to individuals enrolled in certain state programs run by the Agency for Persons with Disabilities, the Department of Children and Families, the Department of Corrections, and the Department of Health, and it restricts the number of drugs they can get. Medicaid recipients will receive access later.

In the wake of the FDA approval issued on January 5, the Sunshine State faces some major hurdles in implementing its program. Requirements include a "pre-import request" for each imported drug, which must be approved by the FDA before ordering, and adherence to quality testing and labeling standards of any medications received through the program.

#### **FDA Delayed Approval**

The FDA approval came after a 2022 lawsuit Florida brought against the Biden administration for "slow-walking" the state's request. Explaining the reason for the lawsuit, Florida Gov. Ron DeSantis pointed to FDA delays in approving the import program.

"The lack of transparency by the Biden administration during the approval process, and failure to provide records on the importation proposal, is costing Floridians who are facing rising prices across the board due to inflation," said DeSantis at a press conference. "Florida is confident in our importation model, and we continue to look for more ways to lower drug costs for Floridians while the FDA delays approval of this importation approval."

#### **Resistance from Canada**

Gregg Girvan, a resident fellow of the Foundation for Research on Equal Opportunity (FREOPP), says he is skeptical the program will achieve its aims

"I am doubtful the anticipated savings will be realized right away, if ever," said Girvan. "Canadian officials have made it clear that they will not allow themselves to be the pharmacy of the United States and risk their drug supply. It is therefore unknown whether Florida will even be able to obtain the drug supply it needs. Lack



of availability of certain branded drugs in Canada and complex and expensive administration stateside could also serve as roadblocks."

Florida is one of a handful of states, including Colorado and Texas, that decided to purchase Canadian drugs after the Trump administration authorized importation through a rule in 2020. Texas approved an import program in 2023. Colorado submitted an importation application in 2022 and plans to submit a revised version this year.

A report from the Colorado legislature cited several "significant challenges" to the implementation of its plan, including medication availability, resistance from drug makers, and "regulatory ambiguity" at the federal level.

#### **More Roadblocks**

"The program is a waste of time and money, regardless of the bureaucracy," said Wayne Winegarden, director of the Pacific Research Institute's Center for Medical Economics and Innovation. "Drug importation won't work on a practical level. Canada does not have enough drugs to serve the U.S. market. ... It will not be possible to import from Canada on a practical basis."

The risk of non-Canadian imposter drugs entering states' programs is another efficacy and safety concern, says Winegarden.

U.S. drug vendors could be a further

deterrent to access. LifeScience Logistics, which is being paid more than \$39 million to manage Florida's plan, is chaired by former Health and Human Services Secretary Alex Azar. Azar's work as a U.S. pharmaceutical executive before his appointment has raised conflict of interest concerns.

"We don't know how the pharmaceutical industry is going to respond behind the scenes," said Girvan. "One could envision drug companies negotiating higher prices in the Canadian market with the anticipation that some of their products will end up in American patients' hands."

#### **Stateside Market Better**

Brand-name drugs are much cheaper in Canada, but most medicines prescribed in the United States are generics, which are less competitively priced in Canada because of manufacturing limits and price controls.

"The U.S. market for generics is much more efficient than in other countries, and 90 percent of all medicines prescribed [here] are generics," said Winegarden. "These medicines cost, on average, around \$20 per prescription, so they are generally affordable. There are also innovations in how generics are sold that demonstrate a better, promarket approach to promoting greater drug affordability."

Drug importation is fundamentally backward and could create the same "I am doubtful the anticipated savings will be realized right away, if ever. Canadian officials have made it clear that they will not allow themselves to be the pharmacy of the United States and risk their drug supply. It is therefore unknow whether Florida will ever be able to obtain the drug supply it needs."

GREGG GIRVAN
FOUNDATION FOR RESEARCH ON EQUAL
OPPORTUNITY

exploitive, antimarket effects as countries with price controls and ultimately harm consumers, says Winegarden.

"Canada and all of the other countries that impose price controls are expropriating revenues from U.S. pharmaceutical companies," said Winegarden. "The problem of U.S. consumers funding drug innovation for the world should be negotiated into trade agreements."

#### **Avoiding Price Controls**

"Part of the issue here is that Florida is trying to obtain access to bulk amounts of drugs from Canada," said Girvan. "This is different in scope than an individual purchasing a drug from a Canadian pharmacy and having it mailed to themselves; hence the program is far more complex."

A bill currently advancing in Florida's House may prove a better alternative to the state's "stutter step" importation program, says Girvan.

House Bill 1431, International Drug Reference Pricing, would implement a proposal resembling FREOPP's Market-Based International Index. This program ties the prices paid for drugs to a group of industrialized countries, with the important caveat that countries with single-payer health care systems are excluded, says Girvan.

"This proposal would align what Florida pays with countries that support drug innovation and would drive down the cost of brand-name drugs without the expensive overhead or supply-chain risks of the drug importation program," said Girvan.

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

## **Biden Administration Takes Steps to Reform 'Prior Authorization'**

#### By Kenneth Artz

The Biden administration finalized a new rule on how insurers can use prior authorization (PA), a practice aimed at reducing unnecessary treatment, which has been a headache for doctors and patients.

The new rule, announced on January 17, will apply to plans under the authority of the Centers for Medicare & Medicaid Services (CMS). It is meant to remove a barrier to health care, says Kaye Pestaina, director of the Program on Patient and Consumer Protections at KFF

"This could include delays in getting access to care due to prior authorization red tape or wrongful denials," said Pestaina. "The most significant changes in the final regulation are to automate the exchange of information needed in the prior authorization process. This could speed up review across the board, with new, expedited timeframes for making a PA decision for certain plans."

#### **Transparency Goal**

Insurers will be required to disclose on their websites certain aggregate statistics: claims approved, claims denied, and the services that require PA. The additional information is expected to help patients and providers plan for possible coverage delays.

The rules do not apply to authorization of prescription drugs, says Pestaina.

"CMS said that drug electronic-claim processing is operationally distinct from the process for medical claims," said Pestaina. "As a result, the agency would need to evaluate this separately."

The rule applies to insurers in programs that CMS has direct oversight over: Medicare Advantage, Medicaid, the Children's Health Insurance Program, and the federal health insurance marketplace. The Department of Labor regulates most private employer-sponsored health plans, so any regulatory changes that apply to them would have to come from that agency.

#### More Paperwork, Less Care

Prior authorization causes more problems than it solves, says Marilyn Singleton, M.D., J.D., a board-certified anesthesiologist and visiting fellow at the medical advocacy group Do No Harm.

"In theory, prior authorization of medical services by the patient's insurer was supposed to save money by reducing unnecessary utilization of such services," said Singleton. "Instead, prior authorization's busywork increased



"Doctors get paid for doing things. They get paid nothing if they do nothing. Some experts think that 30 percent of everything we do in health care is unnecessary. Medicare Advantage plans should be able to do something they are now not allowed to do: advertise how many prior authorizations get resolved, how quickly they are resolved, and estimate how much lower premiums are because some unnecessary care is avoided."

JOHN C. GOODMAN, PH.D.
PRESIDENT, THE GOODMAN INSTITUTE

physicians' administrative costs and contributed to burnout. Worse, not only did the process cut into physicians' time with patients, the delays in approval of medical services have cost patients timely diagnosis and treatment and, in some cases, their lives."

In response to physician and patient demand, Congress began giving more scrutiny to bureaucratic roadblocks to patients' access to medical care, says Singleton. Prior authorization was high on the list. Beginning in 2026, the new rules require insurers in government programs to process urgent prior authorization requests within 72 hours.

That's not good enough, says Singleton.

"Since when is three days an appropriate response to urgency?" said Singleton.

#### 'Eliminate It Entirely'

Under the new rule, nonurgent requests must be completed within seven calendar days—about half of the current wait. The reviewers must give clear, specific reasons for denials, and they must report the number of denials they issue to providers, patients, and other health plans.

The system requires providers to install an "application programming interface" to enable this shortened time frame, says Singleton.

"On the other side of the process, the government insurance programs likely will have to hire more personnel, increasing government costs," said Singleton.

The system was ineffective from the start, says Singleton.

"Prior authorization reform is a step

forward to improving access to medical care; it didn't save money, and it didn't save lives," said Singleton. "Prior authorization proved to be another way for the government and insurers to stick their noses between the doctor and the patient."

Singleton's recommendation?

"Eliminate it entirely," said Singleton.

#### 'Let the Market Work'

Insurers use prior authorization because so much that happens in medicine is not necessary, says John C. Goodman, president of the Goodman Institute and co-publisher of *Health Care News*.

"Doctors get paid for doing things," said Goodman. "They get paid nothing if they do nothing. Some experts think that 30 percent of everything we do in health care is unnecessary."

The Biden administration's approach is bureaucratic, trying to tell health plans what to do, says Goodman. A better approach is to let the market work.

"Medicare Advantage plans should be able to do something they are now not allowed to do: advertise how many prior authorizations get resolved, how quickly they are resolved, and estimate how much lower premiums are because some unnecessary care is avoided," said Goodman.

#### **Could 'Ambush Patients'**

There is an upside to prior authorization, says Devon Herrick, a health economist who writes for the Health Blog of the Goodman Institute.

"On the one hand, patients need access to appropriate care recommended by their doctors," said Herrick. "The issue is not simple, however. Patients also need information about costs and any options they may have, something that prior authorization can provide.

"For instance, my wife was referred to a hospital outpatient clinic, where the hospital had to get prior authorization for a diagnostic procedure," said Herrick. "The request was approved, but in the process she learned her share of the cost was going to be \$2,700. She proceeded to find the service elsewhere for \$403.

"Prior authorization is all that saved her from spending \$2,300 unnecessarily," said Herrick." I worry about providers using Biden's new regulation to ambush patients with care that costs more than necessary."

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

## Kansas Debates Whether to Expand Medicaid

#### **By Kenneth Artz**

Kansas is heading for a conflict over whether to become the 42nd state to expand its Medicaid program.

Gov. Laura Kelly (D) proposed the Cutting Healthcare Costs for All Kansans Act on January 17. The Republican-led legislature is poised to reject her bill after party leadership in December gave expansion a thumbs-down.

In December, North Carolina became the most recent state to approve expansion, after much wrangling. It may provide a glimpse of what is in store in Kansas.

Individuals and families with incomes up to 138 percent of the Federal Poverty Level can qualify for Medicaid under expansion. For an individual or a family of four in 2024, those numbers are \$20,783 and \$44,382, respectively.

#### 'Doubt She Will Succeed'

Kelly has supported Medicaid expansion in Kansas for years, says Devon Herrick, a health economist who writes for the Health Bog of the Goodman Institute, which co-publishes *Health Care News*.

"Kelly claims her plan is 'middle-ofthe-road' for advocating work require"Despite the added federal funds, North Carolina must still pay the state portion, via a new tax on hospitals, called an 'assessment,' This state share is estimated to cost \$325 million and \$482 million in the first two years, respectively."

BRIAN BALFOUR
SENIOR VICE PRESIDENT, THE JOHN LOCKE FOUNDATION

ments, but that's a provision she has no authority to grant," said Herrick. "Moreover, the Biden administration opposes work requirements for welfare programs and will be unlikely to agree to them."

Kansas House Minority Leader Vic Miller introduced Kelly's bill in the House Appropriations Committee.

"Medicaid expansion is not only popular, but it saves lives, creates jobs, and saves our rural hospitals," said Miller in a news release. "Hardworking Kansans shouldn't die because of legislative inaction."

"While polls claim a majority of Kansans support Medicaid expansion, a desire to protect rural hospitals is not a primary concern for most people," said Herrick. "It is early, but most political experts in Kansas doubt she will succeed."

#### 'Already Stretched Thin'

North Carolina's expansion was the largest increase in government entitlements in the state's history, says Brian Balfour, senior vice president of research at The John Locke Foundation.

"North Carolina's Medicaid program had already added about one million people in the two decades preceding the decision to expand," said Balfour. "This occurred at a time when the number of doctors and hospitals serving Medicaid patients remained flat at best. Adding up to another 600,000 in a short period of time will further overwhelm a system already stretched thin.

"Who will Medicaid patients see

when they get sick?" said Balfour. "Coverage does not equal access to care."

If projections are correct, roughly one in three North Carolinians will be dependent on Medicaid for their health insurance coverage after expansion.

#### **NC Adds Hospital Tax**

Gov. Roy Cooper (D) of North Carolina made Medicaid expansion a top priority for several years, putting him at odds with the majority-Republican legislature. Expansion was a sticking point in budget negotiations for years, prompting Cooper to veto the legislature's budget submission in 2019.

"The clincher for the Republican-led General Assembly, though, was the federal government's sweetener of an added \$1.8 billion in federal funds over two years that came along with expansion," said Balfour.

"Despite the added federal funds, North Carolina must still pay the state portion, via a new tax on hospitals, called an 'assessment," said Balfour. "This state share is estimated to cost \$325 million and \$482 million in the first two years, respectively."

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

## **Congress Moves to Allow Inpatient Drug Addiction Care under Medicaid**

#### By Kenneth Artz

The U.S. House of Representatives passed a bill to allow states for the first time to provide inpatient care for drug addiction in mental hospitals for 30 days under Medicaid without seeking a waiver.

The House approved the Support for Patients and Communities Reauthorization Act (H.R. 4531) by 386 to 37 on December 12.

H.R. 4531 "makes permanent a requirement that Medicaid programs cover medication-assisted treatment for individuals with substance use disorders." States would be eligible for reimbursement for treating addiction in mental hospitals.

The Senate Finance Committee approved legislation with similar provisions in December, and the American Hospital Association has stated its support.

#### **Medicaid a Good Fit?**

Drug abuse and homelessness are so prevalent that hospitals are now turning into detox facilities and men-



tal health wards, says Linda Gorman, director of the Health Care Policy Center at the Independence Institute. The differences between the two conditions create complications for treatment, however, according to Gorman.

"The evidence suggests we know too little about drug and alcohol abuse treatment to make determinations about residential versus nonresidential programs," said Gorman. "The families of people who are mentally ill plead for hospitalization and residential treat-

ment, and there is a fairly large literature suggesting improved outcomes from residential care or supported housing. But the 'treatment' periods are far longer than a month."

Medicaid currently pays hospitals for care of acute illnesses and is better suited to that task, says Gorman.

"Severe mental health problems caused by brain-based diseases are more likely to be long-term chronic illnesses," said Gorman. "If one is going to do a program expansion, it might make

more sense to develop block-granted, separate state-run programs."

#### 'Bring on the Caregivers'

The reason for expanding inpatient treatment is unclear, but it will be a financial bonanza for the mental health industry, says John Dale Dunn, M.D., J.D., a physician and policy advisor to The Heartland Institute, which publishes *Health Care News*.

"I am not sure what the drive is to create a health care handout for mental health disorders, since access to Medicaid is already present and used to an incredible degree," said Dunn.

The legislation will be a boon for psychiatric professionals and treatment facilities, says Dunn.

"Sleep disturbance, dysphoria of any kind, unhappiness—bring on the caregivers with medications, counseling, or various therapies included in the payment categories for Medicaid," said Dunn

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

## **Undocumented Aliens Get Free Health Care in California**

#### **By Kenneth Artz**

California has set another milestone this year by becoming the first state to extend taxpayer-funded health insurance to all undocumented immigrants.

All aliens illegally in the Golden State now qualify for Medi-Cal, the state's version of the federal Medicaid program for American citizens with low incomes. That makes an additional 700,000 noncitizens, ages 26 to 49, eligible for full coverage in the state.

Until now, Medi-Cal covered undocumented aliens only over age 50.

#### 'Fiscally Irresponsible'

Medi-Cal is creating a disastrous situation for the state, says Sally C. Pipes, president and chief executive officer of the Pacific Research Institute.

"California is spending more taxpayer dollars on noncitizens—this is fiscally irresponsible," Pipes said.

Already, one in three Californians are enrolled in Medi-Cal, at an annual cost of \$152 billion, with state taxpayers covering \$37 billion of it, says Pipes. The state is facing a budget deficit of \$60 billion or more, based on projections by the state Legislative Analyst's Office. Expanding Medi-Cal to cover 700,000 noncitizens will cost California \$400 billion a year because the federal government does not share in the cost of covering undocumented aliens.

"There will be an added incentive now for illegals in other states to come to California, to take advantage of the new state-funded benefit," said Pipes. "And those who legitimately qualify for Medi-Cal will find it harder to find doctors to treat them. That is because doctor reimbursement rates are so much lower than what they receive for treating patients with private insurance."

#### 'Vicious Circle' of Tax Hikes

California taxpayers will face further increases in their very high tax burdens for the tremendous cost of covering all illegal immigrants, says Pipes.

"This decision is a major problem which will put additional pressure on the state and its budget deficit," said Pipes. "It will result in even more people and companies leaving for states with either lower taxes or no state income tax. Then, taxes will have to increase yet again. It is a vicious circle. Californians already face the highest state tax rates in the country. The federal government cannot fund illegal immigrants, nor can it subsidize coverage for the undocumented through the Obamacare exchanges."



#### **Coverage but Not Care**

As things stand, the Affordable Care Act is becoming a replica of the British health care system, with California ahead of the curve, says Linda Gorman, director of the Independence Institute's Health Care Policy Center.

"States have been building to this for decades," Gorman said. "The ACA moved the process along a lot faster. To see what is coming, look at the [Kaiser Family Foundation's] State-Funded Health Coverage for Immigrants policy brief. Note that the section this is filed under is racial equity and health."

"Covering all residents is the only logical endpoint when policy evaluation is primarily focused on whether or not everyone has coverage, and blames poor outcomes on 'barriers to access,' which include any payment at the point of service, and only pays lip service to the quality of the medical care people get," said Gorman.

#### 'Quality of Care Will Fall'

Although a single-payer system has been a goal of the political left since 1912, Medicaid does not fit the plan because its payments do not cover providers' total costs, says Gorman.

"Policymakers act as if expensive, sophisticated, medical staff and equipment will show up no matter what," said Gorman. "They legislate coverage wish lists and assume that brutalized suppliers will continue to supply topnotch medical care. They are wrong, and we will all suffer."

California already depends on com-

mercial insurers to subsidize "free" health care, says Gorman.

"A fair amount of [Medi-Cal's] deficit is shifted to private payers," said Gorman. "With fewer private payers, the private sector's ability to make up for payment shortfalls will be limited. Capital in the private health care system that wears out will not be replaced, innovation will halt, and providers will not be as well-trained. The quality of care will fall."

#### 'Tooth Fairy Model'

So much government intrusion makes hospitals increasingly dependent on supplemental payments from taxpayer money, and health care decisions are made by bureaucrats, not patients, says Gorman.

"This is the tooth fairy model of medicine," said Gorman. "As the number of people with government coverage grows, the main client of any health care provider will be the government. The 'system' will be unresponsive to patient needs, will be poorly equipped, and will not innovate. The wealthy and well-connected will get their care from the private sector."

Medicaid already covers emergency services for noncitizens, says Gorman.

"They are a relatively small fraction of its total spending," said Gorman. "Making illegal aliens eligible for standard Medicaid coverage does not increase the supply of doctors, hospitals, or medical equipment. Provider shortages already make it hard for California Medicaid patients to get the

"This decision is a major problem which will put additional pressure on the state and its budget deficit. It will result in even more people and companies leaving for states with either lower taxes or no state income tax. Then, taxes will have to increase yet again. It is a vicious circle. Californians already face the highest state tax rates in the country. The federal government cannot fund illegal immigrants, nor can it subsidize coverage for the undocumented through the Obamacare exchanges."

SALLY C. PIPES
PRESIDENT AND CHIEF EXECUTIVE
OFFICER
PACIFIC RESEARCH INSTITUTE

care they need. Expanding all Medi-Cal coverage to illegals will heighten the provider shortage while exacerbating California's already severe budget problems."

#### 'California Has Gone Commie'

What we're witnessing in California is what two sociologists described in 1966, called the Cloward-Piven strategy, says John Dale Dunn, M.D., J.D., a physician and policy advisor to The Heartland Institute, which publishes *Health Care News*.

"If the Left pushes the welfare state and overwhelms the economy and society with unlimited migration from Third World hellholes, the Cloward-Piven strategy predicts the resulting failures of state institutions like Medi-Cal will usher in a revolution, and also, commies hope, their rise to power," said Dunn. "California has gone commie."

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

# Bodies of Alabama Prisoners Missing Organs, Say Families

#### **By Kevin Stone**

The Alabama Department of Corrections is under fire after families alleged the bodies of prison inmates Brandon Clay Dotson and Charles Edward Singleton were returned with their organs removed.

A lawsuit filed by Dotson's family alleges a pattern, citing the Singleton case and complaints by University of Alabama medical students alarmed by what they claim are lax ethics in obtaining organs from prisoners for education and research.

#### **Families Became Suspicious**

Suspecting foul play in the November 2023 death of Dotson, the family hired a pathologist to conduct a second autopsy. The autopsy revealed Dotson's heart had been removed, prompting the lawsuit. The family also alleges the body was improperly stored and was in a state of decomposition, necessitating a closed coffin funeral.

Singleton's daughter, Charlene Drake, told Lauren Faraino, the attorney in the Dotson case, that Drake had been informed by the funeral home her father's body had been returned with no internal organs. Drake said funeral home staff told her that organs removed during an autopsy are normally returned in a bag placed in the body cavity.

Singleton's family was also notified the body was returned in a state of decomposition characterized by "advanced skin slippage." The brain was also missing. Singleton died while incarcerated in November 2021.

#### 'Organs Are Not Returned'

Cynthia Gould, a reporter from Birmingham TV station WBMA, who was investigating the Dotson and Singleton cases, obtained a statement from the University of Alabama at Birmingham (UAB) Department of Pathology, which conducted the original autopsy, regarding its policy on disposition of removed

"We are now learning that the horrors do not end at death. Institutions that society should be able to trust are abusing the corpses of those who die in prison custody. The families of these individuals are being disrespected and taken advantage of during their time of deepest grief. Such outrageous conduct by state leaders must not be tolerated by any civilized society."

**LAUREN FARAINO, ATTORNEY** 

organs.

"In an autopsy, organs and tissues are removed to best determine the cause of death," the department stated. "Autopsy consent includes consent for final disposition of the organs and tissues; unless specifically requested, organs are not returned to the body.

"UAB is among providers that—consistent with Alabama law—conduct autopsies of incarcerated persons at the direction of the State of Alabama," the department stated. "A panel of medical ethicists reviewed and endorsed our protocols regarding autopsies conducted for incarcerated persons."

#### 'Warden Provides Consent'

Faraino says exhibits in the case show a group of UAB Medical School students in 2018 noticed a disproportionate number of the specimens they encountered in their lab studies were from people incarcerated at the time of death.

These students raised ethical concerns with the administration and met with the UAB Ethics Committee. The exhibits Faraino gave *Health Care News* appear to demonstrate UAB was aware of the lack of donor consent for the retention or donation of organs obtained from prisoners.

Exhibit B, a summary of a meeting between concerned students and UAB doctors identified as Reilly and Litovsky, states the "Consent process involving specimens in the lab

DOES NOT involve the patients or their families. The prison warden provides consent and always signs for 'no restrictions' on what specimens can be used for, which includes their use for research and teaching purposes."

The students went on to state the doctors did not appear to have concerns that the practices were unethical. A document identified as Exhibit C characterizes a November 26, 2018, meeting between concerned students and UAB administrators as "unproductive" and cites concerns the students were accused of being "inflammatory."

#### **'Explicitly Refuse to Donate'**

Heidi Klessig, M.D., a retired anesthesiologist and authority on clinical death, is a harsh critic of so-called "optout" laws that assume de facto consent absent an overt refusal by the subject to waive rights or refuse consent. Klessig says those laws turn the concept of informed consent on its ear.

"The 2006 update to the Uniform Anatomical Gift Act (UAGA) now mandates that people must explicitly refuse to donate tissues or organs," said Klessig. "This case highlights the problems with an 'opt-out' system, one that takes organs unless the individual or family specifically refuses.

"Such a system has great potential for abuse, and not just for Alabama prisoners," said Klessig. "The UAGA empowers the coroner, medical examiner, or even the hospital administrator to make an anatomical gift of the decedent's body or part if the person has no documented refusal to donate and their family or surrogate cannot be located within 12 hours."

#### 'Trafficking Body Parts'

Other abuses have come to light, such as the September 2023 scandal in which workers at the Harvard Medical School morgue were caught allegedly stealing human remains and selling them to "oddity" traffickers, Klessig says.

"It is possible these Alabama cases represent another example of trafficking body parts to oddities dealers," said Klessig. "I recommend that everyone protect themselves by documenting their refusal to be an organ or tissue donor by adding a refusal to donate to your advanced directive and electronic medical record, and by carrying a wallet card stating your refusal."

#### 'Horrors Do Not End at Death'

"Alabama's prison system is characterized by cruelty," said Faraino. "From the moment a person enters the Alabama Department of Corrections, they are thrown into a lawless world of beatings, rapes, drugs, and extortion. No other prison in the United States comes close to Alabama's in terms of violence, suicides, and overdoses."

The abuses and indignities continue after a prisoner's demise, says Faraino.

"We are now learning that the horrors do not end at death," said Faraino. "Institutions that society should be able to trust are abusing the corpses of those who die in prison custody. The families of these individuals are being disrespected and taken advantage of during their time of deepest grief. Such outrageous conduct by state leaders must not be tolerated by any civilized society."

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

#### **BOOK REVIEW**

## Stop—Don't Take My Organs!

Review of The Brain Death Fallacy, Heidi Klessig, M.D. (Good Samaritan Books, 2023), 178 pages, ISBN 9798863485003 (Paperback)

#### By AnneMarie Schieber

Crash victim Daniel Gonzalez received a "hero's walk" while "his body was transported from the hospital where he was declared dead" in December, a news report stated.

Daniel's "body" was about to be airlifted to a surgical suite in nearby Madison, Wisconsin, where his vital organs would be removed for transplantation.

A key fact, however, is that Daniel was alive, as most people would define it—with a beating heart, circulation, and respiration. The only way hospitals can remove vital organs while they are viable is to keep the donor alive. Daniel was likely deemed "brain-dead," and his condition "irreversible," for the hospital to declare him legally dead.

How do doctors determine whether someone's brain damage is "irreversible"? How can a patient trust such a decision when organ transplantation has become a multimillion-dollar enterprise?

Heidi Klessig, M.D.'s book *The Brain Death Fallacy* provides insight.

#### Organ-Harvesting 'Vultures'

Klessig, a retired anesthesiologist, became intrigued by organ transplantation in medical school when she noticed her medical professors fell into two camps: those who embraced a more liberalized definition of "brain death" and those who did not.

"No longer was the physician-patient relationship paramount for many medical doctors," writes Klessig. "Now there were organ donations to be considered."

Klessig describes her encounter with a transplant team barreling down the hall and a nurse muttering to herself, "vultures."

When a patient becomes unresponsive after brain trauma, families can be told there is no hope and organ donation could turn a tragic situation into a better one. Patients may unwittingly consent to this when they check the organ donation box on their driver's license.

If permission is unclear and no family members are present, hospitals now have wide latitude to make the donation decision on a patient's behalf—permission granted by government.



#### **Death Redefined**

How and when hospitals began to wield so much power goes back to 1968, when an Ad Hoc Committee at Harvard Medical School moved the point of death to "irreversible" unconsciousness. Not coincidentally, in 1967, Christiaan Barnard, M.D., made global headlines after performing the world's first heart transplant.

The Harvard committee's acceptance of "brain death" eventually became the basis for model legislation, the Uniform Determination of Death Act (UDDA), used in all states today.

#### **Transplant Factor**

Klessig quotes Alan Shewmon, M.D., emeritus professor of pediatrics and neurology at the University of California, Los Angeles, the author of a 2009 report published by the Hastings Center, a bioethics research institute.

"Brain death as death began as a utilitarian legislative decree and has remained a conclusion in search of a justification ever since: a conclusion clung to at all costs for the sake of the transplantation enterprise that quickly came to depend on it," wrote Shewmon.

Cell growth defines life, and decay is death, says Klessig, a process that begins rapidly the moment the body's "systemic integration" ends. Patients with "brain death" are not in a state of decay, nor are their brains, as autopsies have shown. Even if they are on a ventilator, the patients' hearts are beating, the lungs are functioning, and there are other signs of life.

An irreversible coma is determined when an electroencephalogram cannot detect electrical activity in the brain.

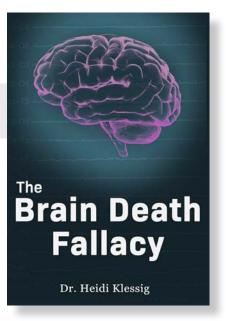
#### **Brain-Death Recovery**

Klessig's book describes several cases where "brain-dead" patients showed signs of brain function or recovered outright.

Joseph, a premature infant, showed no brain electrical activity after two tests, but thanks to the persistence of his parents and neonatologist Paul Byrne, M.D., Joseph survived, grew up, got married, and had a family.

Jahi McMath was a 13-year-old California girl who never woke up from a botched tonsillectomy. There was so much resistance to continuing her care that the family raised money and flew her to New Jersey, where she would have more legal protection. Jahi survived five years, and while she was in a minimally conscious state, she began to menstruate, which requires the hypothalamus, a part of the brain, to function.

In 2015, 20-year-old Aden Hailu had a heart attack during abdominal sur-



gery and did not wake up. Because of the "brain death" determination, Hailu's father had difficulty convincing the hospital to try other treatments. Aden died in 2016 from cardiac arrest, not brain death.

#### **Third-Party Interests**

Organ harvesting is not the only reason governments and medical associations have broadened the definition of death. Third-party payers may not want to cover the bills for long-term care and treatment. California refused to cover Jahi's medical expenses after her braindeath determination.

A more liberal definition of death can give hospitals legal cover in wrongful-death lawsuits. Nonresponsive patients may be viewed as taking up beds and using up limited medical resources.

Klessig's book can help inform families and patients before the emotional crush of a crisis. Legislators might appreciate the legal chronology of the brain-death determination and how it has evolved with advances in treatment and new knowledge about how the brain functions.

#### **Moral Quandaries**

As the public learns more about the ethical dilemmas surrounding organ transplantation, they might demand the development of better technologies and medicines to treat failed organs.

Last summer, the Uniform Law Commission considered revising the UDDA to give doctors and hospitals even more latitude in declaring death. The revision was tabled.

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

## **Clinicians Demand Gender Care Textbook Be Withdrawn**

#### By Bonner Russell Cohen

More than 6,000 clinicians, scientists, and researchers signed an open letter calling on the American Psychiatric Association (APA) to withdraw its new textbook on gender care.

The signers expressed "grave concerns" about the claims made in the book

The textbook, *Gender-Affirming Psychiatric Care* (GAPC), edited by Teddy G. Goetz, M.D., M.S., and Alex S. Keuroghlian, M.D., was released in November. According to the APA's publishing house, the book "is the first textbook in the field to provide an affirming, intersectional, and evidence-informed approach to caring for transgender, non-binary, and/or gender-expansive (TNG) people."

"The book's claims of being evidenceinformed are untenable," states the letter, posted in January by the New York City-based Foundation Against Intolerance & Racism (FAIR). "GAPC omits any in-depth analysis of evidence to date, dismisses 'scientific neutrality' as 'a fallacy,' and chooses authors with the correct 'lived experiences' and 'com"After conducting careful systematic reviews of the evidence, Finland, Sweden, and the United Kingdom are drastically retrenching from their earlier affirmation model for treating gender dysphoria in minors."

**OPEN LETTER SIGNED BY MORE THAN 6,000 CLINICIANS** 

munity impact of prior work over academic titles."

#### 'Out of Date'

The letter says the authors failed to consider the latest thinking on psychiatric care for young children and adolescents confused about their biological sex.

"After conducting careful systematic reviews of the evidence, Finland, Sweden, and the United Kingdom are drastically retrenching from their earlier affirmation model for treating gender dysphoria in minors," states the letter. "In Norway, the Netherlands, Denmark, France, Australia, and New Zealand we see either critical reviews by public health agencies or pushback by professional societies and in mainstream medical journals.

Having omitted these international developments and heated debates, GAPC was out of date before its publication."

The letter says the book's authors are "disturbingly nonchalant" about concurrent behavioral problems in young people struggling with gender dysphoria, and they neglect to recognize those who regret the surgeries and cross-sex hormone treatments.

"Such detransitioned individuals are now suing surgeons, endocrinologists, and psychiatrists for damages, claiming their doctors encouraged them to follow measures that are not backed by rigorous science and did not address their co-morbid conditions."

#### 'Affirming a Delusion'

Jane Orient, M.D., executive director of the American Association of Physicians and Surgeons and a signer of the FAIR letter, deplores what she describes as the textbook's shoddy science and its potential to do irreversible harm to children.

"The problem with the book starts with the title," said Orient. "A psychiatric textbook about affirming a delusion, instead of trying to treat the patient's illness and helping the person connect with reality, is a dangerous aberration. It's a simple biological fact that there are two sexes, determined immutably at conception.

"One can interfere with a patient's normal maturation, resulting in lifelong dependence on medical treatment for the adverse effects, but cannot change the person's sex," said Orient. "For APA to advocate sterilizing and mutilating children is an outrageous breach of ethics and has no scientific justification."

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

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#### **COMMENTARY**

## Would I Accept an Organ Transplant?

#### By Heidi Klessig, M.D.

Would I ever accept a transplant? I have often addressed this question in my lectures and videos on the ethics of organ harvesting and transplantation. Like most questions, the answer to this question is, "It depends!"

There are many types of transplants, some of which are ethical and some which are not. And since ethical questions require a moral framework, my answers are based on the moral laws in the Ten Commandments against murder, lying, and theft.

#### **Tissue Transplants, Yes**

Would I receive a tissue transplant? Absolutely! Tissues are things like skin, bone, heart valves, and corneas. Tissues are simple structures and are very tolerant of a lack of blood flow. Tissue can be harvested from a corpse (a donor who is biologically dead and whose spirit has departed) and is completely ethical.

There is one ethical caveat to tissue donation, however. A Los Angeles Times article revealed organ procurement organizations are harvesting tissues from the corpses of registered organ donors before the medical examiner has determined the cause of death.

The article shared the devastating sorrow of families denied closure because their loved ones had unselfishly signed a donor card. Unfortunately, at autopsy the bodies of these victims are so mangled by tissue harvesting that crime lab pathologists are sometimes unable to determine whether injuries related to domestic violence resulted in murder.

Thus, I recommend that no one be a registered organ or tissue donor. If you desire to donate your tissues, simply notify your family that they may release your corpse for tissue donation after all their questions regarding your death have been answered.

#### Living Organ Transplants, Yes

Organs (things like livers, kidneys, hearts, and lungs) can only be harvested from a biologically living donor. Internal organs are complex structures that very quickly begin to break down and decompose when circulation stops, making them unsuitable for transplant.

Living organ donation, in which both donor and recipient remain alive after the procedure, is a wonderful and ethi-



cal form of transplant, one that every altruistic person should consider. I would certainly consider donating one of my paired organs (such as a kidney) or a lobe of my liver to help another

One of our friends donated a kidney to her young daughter, allowing her daughter to live for over 20 years more. Living donations are some of the most successful transplants and are in the best tradition of selfless service to a person in need.

#### Coercion or Brain Death, No

I would never condone travel to Communist China to receive an organ from a political prisoner executed by forced organ harvesting. And I deplore the exploitation of the poor by organ trafficking of kidneys on the black market. Both of these are human rights abuses and deserve to be condemned.

What about organs harvested from a "brain dead" organ donor? Brain death is a legal fiction, a term that was coined in 1968 when a group of doctors at Harvard Medical School decided that people in an irreversible coma could be declared dead for use as organ donors. People in a coma are still biologically alive, with beating hearts, and their spirits are still incorporated within their bodies.

The fact that people have survived a diagnosis of brain death and have gone on to live normal lives bears this out. These people are alive when brought to the operating room and respond to surgery like any other patient, as I saw firsthand during my anesthesiology training.

Calling these people dead is a lie, and even though removing their beating hearts is legal under the Uniform Determination of Death Act, it is morally wrong. Knowing these facts, I could not ethically receive an organ from a "brain dead" person without being complicit in their murder.

#### **Circulatory Death, No**

Lastly, would I accept an organ from a 'circulatory death" organ donor? These donors are not brain-dead but are not expected to survive. Again, the devil is in the details.

Because organs begin to disintegrate so quickly without circulation, doctors begin harvest surgery in these cases within 75 seconds to five minutes after the heart stops beating. Every medical

consequences of organ transplantation in an attempt to justify the lack of transparency, if not outright obfuscation on which the transplantation enterprise rests, is not a very compelling argument."

MICHAEL NAIR-COLLINS, PH.D.

professional knows that people are routinely resuscitated after such a short period of cardiac arrest.

Even worse is the newer technique of normothermic regional perfusion with controlled donation after circulatory death (NRP-cDCD), in which doctors clamp off the circulation to the brain to make the donor brain-dead on purpose before resuscitating to keep the remaining organs viable for harvesting.

#### **Hiding the Truth**

Emotional appeals about organ donation ignore what is really going on behind the operating room doors. Catchy slogans like "Give the gift of life" sound good, but they gloss over critical details everyone who signs a donor card has a right to know.

The public is being misled while doctors, lawyers, and ethicists continue to debate whether people should be told the truth. Even Robert Truog, M.D., a transplant proponent, states in his book Death, Dying, and Organ Transplantation, "brain dead' donors remain alive and donors declared dead according to circulatory-respiratory criteria are not known to be dead at the time that their organs are procured."

I agree with ethicist Michael Nair-Collins, Ph.D., who writes, "Appealing to the good consequences of organ transplantation in an attempt to justify the lack of transparency, if not outright obfuscation on which the transplantation enterprise rests, is not a very compelling argument."

Heidi Klessig, M.D. (heidi@respectforhumanlife.com) is a retired anesthesiologist and pain management specialist, and author of The Brain Death Fallacy. A version of this article appeared in American Thinker on April 22, 2023. Reprinted with permission.



#### **By Ashley Bateman**

Prominent physicians told members of Congress the COVID-19 shots are dangerous, at a hearing on injuries associated with the shots over the past three years.

Sen. Ron Johnson (R-WI) and Reps. Andy Biggs (R-AZ), Warren Davidson (R-OH), and Marjorie Taylor Greene (R-GA) discussed the systems, agencies, and individuals responsible for the flawed national response to COVID-19 and subsequent rollout of high-risk emergency use inoculations.

Testifying at the two-hour session on January 12 were internist and cardiologist Peter McCullough, M.D.; clinical pathologist Ryan Cole, M.D.; and pediatric cardiologist Kirk Milhoan, M.D.

The expert witnesses called for immediate removal of the COVID-19 shots from the market, citing dozens of studies, clinical experience, and international scientific papers showing the danger and longevity of bioengineered mRNA in the human body.

#### **FDA Suppressed Data**

Three COVID-19 inoculations came on the market in 2021, though the Janssen (Johnson & Johnson) vaccine was later discontinued because of a dangerous clotting response. The mRNA shots manufactured by Pfizer/BioNTech and Moderna are still being sold.

Scientists and health professionals requested more data on the mRNA vaccines from the Food and Drug Administration (FDA) in 2021 through a Freedom of Information Act (FOIA) filing, citing concerns over a lack of transparency regarding the new biotechnology. The FDA requested the Pfizer data not be disclosed for 75 years. A lawsuit forced compliance with the FOIA request in 2022, months after the vaccines were widely administered.

At the hearing, Biggs read from the now-public list of more than 1,000 known side effects of the Pfizer shot, including acute kidney injury, brain stem embolism, brain stem thrombosis, cardiac arrest, cardiac failure, central

"I began seeing vaccine injuries early on in the rollout. Paralysis, heart attacks, strokes, blood clots, GI bleeds, all in populations we weren't used to seeing them in. We started to see a rise in infections—RSV [respiratory syncytial virus] in adults was unheard of prior to 2021. I had never seen so many cases of adult appendicitis and strep throat. The mRNA injections are seemingly destroying immune systems."

KIMBERLY OVERTON, B.S.N., R.N. FOUNDER, NURSE FREEDOM NETWORK

nervous system vasculitis, encephalitis of the brain stem, encephalitis hemorrhagic, frontal lobe epilepsy, epileptic psychosis, fetal distress syndrome, liver injury, low birth weight, myocarditis, pancreatitis, pneumonia, and stillbirth.

Major federal agencies continue to market and pay for the shots, citing "millions of lives saved." The U.S. government invested at least \$31.9 billion of taxpayer money in the shots.

#### Big Pharma Sold Disease, Cure

In her opening remarks, Greene criticized members of Congress who shun the topic of shot injuries for fear of generating "vaccine hesitancy."

"Given the overwhelming data, people should be hesitant about injecting unproven vaccines," said Greene.

"Even though I'm not a doctor, I know that it's unscientific to ignore the data," said Greene. "Some members of Congress are afraid to upset their friends in Big Pharma who sell the disease and then sell the cure. ... They don't care how many Americans get hurt. They don't care how many taxpayer dollars are spent. They just exploit, exploit, exploit."

Administering a potentially lethal spike protein devised in a Chinese biosecurity lab to Americans is the most "dangerous proposition our government agencies could have ever put forward to our country," McCullough testified.

"I never supported these vaccines,"

said McCullough. "I never told a single patient that it was safe to take a vaccine. I didn't take a COVID-19 vaccine myself, because it wasn't safe."

#### **Physicians May Fear Reprisals**

Patients need more physicians like McCullough, says Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons.

"I do not know why more physicians are not raising the alarm but are even pushing the vaccine," said Orient. "One possibility is that they have been thoroughly indoctrinated about the vaccination miracle. Or they are terrified of losing their job, their board certification, or even their license if they deviate from the official narrative. Or both."

#### 'These Are Contaminated Products'

Cole testified the current situation is unprecedented.

"It used to be that we were a nation of the people, for the people, by the people," said Cole. "Now we're of the corporation, for the corporation, by the corporation. Countless Americans have been harmed because people have believed biased media, people have believed corrupt pharmaceutical narratives. Countless people in this nation are hurting and being ignored."

E. coli contamination, found in every tested vial of the mRNA vaccines, is reason enough to halt its use, Cole testified.

"These are contaminated products. ...

Every attorney general in this nation, if they have one ounce of honesty, one iota of responsibility to their citizens, should impound whatever is on the shelf of a pharmacy, send it to independent laboratories, have it tested, and it should be removed from the market post-haste," said Cole.

#### **Long-Term Impact Unknown**

Another concern is the messenger RNA technology used in the shots to deliver the spike protein. Long-term effects are simply not known, the experts testified.

"The human body, to our knowledge, has no way of breaking down the messenger RNA, and in my view, the COVID-19 vaccine program has complicated this because people have taken unprecedented numbers of shots," said McCullough. "If one was to follow the U.S. government program right now, taking a shot every six months, with the primary series, they'd be approaching ten shots."

Cole noted a two- to threefold increase in certain types of cancer since the vaccines were first administered, including some very aggressive melanomas in the cells of very young patients.

#### **Saw Rise in Infections**

Kimberly Overton, B.S.N., R.N., who founded the Nurse Freedom Network after she left her position for refusing to push the shots on children, says the hearing confirmed her experience.

"I began seeing vaccine injuries early on in the rollout," Overton said. "Paralysis, heart attacks, strokes, blood clots, GI bleeds, all in populations we weren't used to seeing them in. We started to see a rise in infections—RSV [respiratory syncytial virus] in adults was unheard of prior to 2021. I had never seen so many cases of adult appendicitis and strep throat," said Overton.

"The mRNA injections are seemingly destroying immune systems," said Overton.

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

## World Health Organization Preps for 'Disease X'

#### By Bonner Russell Cohen

World Health Organization (WHO) Director-General Tedros Ghebreyesus, M.D., is pressuring countries around the globe to agree to a new pandemic treaty, warning the next pandemic could be deadlier than COVID-19.

Ghebreyesus rang the alarm at a meeting of the World Economic Forum (WEF) in Davos, Switzerland in January, during a panel discussion on "Preparing for Disease X," an as-yet unspecified illness.

"There are things that are unknown and that may happen, and anything happening is a when, not if, so we need to have a placeholder for that, for the diseases we don't know," said Ghebreyesus.

#### 'All-of-Society Approach'

The "placeholder" Ghebreyesus referred to is a WHO-sponsored, legally binding pandemic treaty which delegates from the U.N. health agency's 194 member countries have been negotiating since March 2021.

"The pandemic agreement can bring all the experience, all the challenges we have faced, and all the solutions into one," said Ghebreyesus. "That agreement could help us prepare for the future in a better way."

The idea of a global pandemic treaty was first launched by the European Union in 2021, when two-dozen heads of state outlined their vision of an allencompassing document.

"The main goal of this treaty would be to foster an all-of-government and all-of-society approach, strengthening national, regional, and global capacities and resilience to future pandemics," the statement said

#### 'A Common Global Interest'

Ghebreyesus, the only panelist who mentioned the pandemic treaty, said COVID-19 was the first Disease X. in a way. Such diseases are a "common enemy requiring a united response," said Ghebreyesus, adding "this is a common global interest" and "very narrow national interests should not come in the way."

Panel member Preetha Reddy, a vice chair of Apollo Hospitals, one of India's largest health care providers, cited the role "lockdowns and early vaccinations" played as her country dealt with the pandemic. Panelist Nisia Lima, a social scientist who has served as Brazil's minister of health since 2023, pointed to the necessity of "surveillance" to monitor the spread of a pandemic and



corrupted by financial conflicts of interest and political agendas. In particular, we should have learned from the perils of mass injections of a minimally tested genetically engineered product with serious adverse effects and long-term impacts that cannot be known for years."

JANE ORIENT, M.D.

**EXECUTIVE DIRECTOR, ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS** 

called for greater "equity" between developed and developing countries in confronting future pandemics.

Journalist Larry Taunton, in an interview on The Dinesh D'Souza Podcast on January 18, noted that in WEF discussions of pandemic-related matters, "vaccines were always mentioned in a positive way. That they could do harm to certain people never came up."

#### 'Largest Sinkhole for Money'

Peter McCullough, M.D., a Texas-based physician board-certified in internal medicine, cardiovascular diseases, and clinical lipidology, was an early critic of the public health response to COVID-19. In a January 17 blog post, he recommended a change of policies.

"In the future, we should always prioritize early treatment and carefully record the acquisition of natural immunity," wrote McCullough. "Massive efforts to 'escape' the index occurrence of a highly infectious respiratory virus are futile. We should all have expected to contract SARS-CoV-2. managed it, and moved on in life. The massive waste of government interventions driven by the Bio-Pharmaceutical Complex will go down as the largest sinkhole for money and public health efforts in history."

#### 'Lab Leak Will Happen Again'

Notably absent from the discussion in

Davos over how to confront a future pandemic was any mention of the role a future lab leak might play in unleashing a deadly disease.

In an address at Hillsdale College's Kirby Center in Washington, D.C. on November 1, Sen. Rand Paul (R-KY), a physician, noted the extraordinary efforts U.S. health officials, led by Anthony Fauci, undertook to discredit the possibility COVID-19 might have resulted from a lab leak at China's Wuhan Institute of Virology.

"A growing number of virologists and other scientists worry that a lab leak will happen again, and with even more serious consequences," said Paul. "With COVID, the mortality rate was far less than 1 percent. Experiments are now being carried out with viruses that have the potential for mortality rates between 15 and 50 percent."

#### 'Worse Disaster Than the Disease'

Jane Orient, M.D., executive director of the American Association of Physicians and Surgeons, says the public-health establishment's response to COVID-19 is a good reason to shun a grandiose global approach to confronting future pandemics.

"One thing we should have learned from COVID-19 is that the governmental response was a worse disaster than the disease," Orient said. "Those jurisdictions that adopted early treatment

with repurposed drugs or had public health policy that led to natural immunity rather than a crippled economy, fared far better.

Tedros Ghebreyesus, M.D.

"Nations should have learned from each other rather than imposing a centralized policy devised by 'experts' corrupted by financial conflicts of interest and political agendas," Orient said. "In particular, we should have learned from the perils of mass injections of a minimally tested genetically engineered product with serious adverse effects and long-term impacts that cannot be known for years."

#### Donors' 'Undue Influence'

Marilyn M. Singleton, M.D., J.D., a senior fellow with the health care advocacy group Do No Harm, says the real danger is an enhanced bureaucratic approach to public health.

"In what universe does adding more top-down bureaucracy [increase] efficiency, transparency, and accountability?" said Singleton.

"WHO continues to tout itself as a public health leader but kowtowed to China by failing to challenge it on the origins of the new coronavirus, now known as SARS-CoV-2," said Singleton. "Moreover, WHO relies on donations to fulfill its mission. This leaves the organization vulnerable to private entities—like its largest donor, the Bill and Melinda Gates Foundation-having an undue influence on policies," said Singleton.

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

PHOTO COURTESY AV UN GENEVA/GETTY IMAGES NEWS

## Candidates Should Tell the Truth About Entitlements, Reform Group Says

Voters need to be told the truth about the fiscal sustainability of Medicare and Social Security, say the authors of Plan for America, a proposal for private accounts to pay for retirement and health care, and to address the debt of the national and state governments.

"Plan for America is a tremendous opportunity for a presidential candidate to seize on and run with," said Eric Nager, one of the authors of the proposed reforms.

"Both leading major-party candidates have said [they support] no changes to entitlements, which is an unsustainable position," said Nager. "Combined with the fact that 70 percent of Americans do not want to see a rematch of the 2020 election, Plan for America creates an opening for candidates to differentiate themselves. There is hope: our crushing national debt problem can be solved!"

#### **Private Lifetime Accounts**

The Plan for America would replace Medicare and Social Security and government health care with private savings accounts managed by a clearly defined trust.

The authors have made presentations around the country, most recently during the Freedom Seminar at Northwood University in Midland, Michigan, on February 7, which can be viewed online at the Plan for America website. Health Care News and economists, including Stephen Moore of the Committee to Unleash Prosperity, participated in a three-day panel discussion in 2023 at Principia College

As Health Care News reported in May 2023, the Plan for America, which is detailed in a book, would be a voluntary alternative to Medicare and Social Security, allowing participants to direct payroll taxes into a savings account held by a trust that would invest in companies domiciled in the United States. The growth of

"Both leading majorparty candidates have said [they support] no changes to entitlements, which is an unsustainable position," said Nager. "Combined with the fact that 70 percent of Americans do not want to see a rematch of the 2020 election, Plan For America creates an opening for candidates to differentiate themselves. There is hope: our crushing national debt problem can be solved!"

ERIC NAGER
AUTHOR, PLAN FOR AMERICA

the trust would allow the plan to guarantee lifetime health coverage and retirement income equal to what someone paying into traditional entitlement programs would receive.

#### **Universal Option**

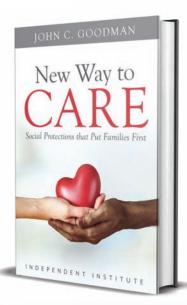
Even Americans who move in and out of the workforce could participate. Unlike Social Security, unused portions of the savings account could be passed on to surviving family members upon an individual's death.

The plan incorporates many of the very same principles as The Heartland Institute's American Health Care Plan.

—Staff reports

## New Way to Care!

With the COVID-19 pandemic and shutdowns, federal debt has reached \$22.8 trillion with a 2020 deficit of \$3.3 trillion, more than triple the deficit for 2019. Not including Obamacare, the unfunded liability in Social Security and Medicare alone is \$120 trillion, 6 times the entire U.S. economy. If such spending continues, average people will be paying two-thirds of their income to the federal government by mid-century, destroying families, businesses, and communities. And with entitlements the largest component of federal spending, politicians have failed at



reining in one of the most troubling issues facing Americans.

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  —Scott W. Atlas, M.D., Member,
  White House Coronavirus Task Force
- "In *New Way to Care*, John Goodman is consistently ahead of his time. What he writes today will be policy in the coming years."

  —Bill Cassidy, M.D., U. S. Senator

**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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#### **COMMENTARY**

## Corporate Medicine, Physician Licensure a Bad Deal for Patients

#### **By Devon Herrick**

Physician licensure has created a cartel—there, I said it out loud.

The right to practice medicine has high barriers to entry, both in terms of high standards and high costs. It takes seven to 11 years beyond college to train a new physician, but the process begins long before medical school.

A successful application requires not only excellent grades but also excellent grades in the right classes. Going back to the 1970s and possibly before, medical school acceptance also requires extracurricular activities, such as internships and volunteering at hospitals, clinics, social organizations, or churches. The competitiveness to get into medical school has gotten worse over time.

Another barrier to entry for practicing physicians is graduate medical education residency programs, required to practice medicine in all 50 states. The shortest residency is three years, with some lasting up to seven years.

#### **Artificial Residency Shortage**

There is a shortage of residency training slots. It varies, but in some years there are more than 10,000 medical school graduates who apply for a residency program but are turned away. Most residency programs are funded by Medicare, and there has been a restrictive cap on the number of new residencies since 1997.

Congress capped the number of new Medicare-funded residencies after lobbying by the American Medical Association (AMA), which argued there would soon be a glut of physicians. Strange, isn't it? The trade association whose members stood to gain the most from a physician shortage lobbied for a cap, and Congress believed them.

Another regulation contributing to the cartel power of physician licensure is the Durham-Humphrey Amendment of 1951. It ostensibly only required habit-forming drugs to be dispensed by prescription, but it led the way for a drug class where all newly approved drugs are available only by prescription. That is unfortunate because the Durham-Humphrey Amendment resulted in much higher prices for drugs than would otherwise be the case.



#### **Corporate Ownership Banned**

Physicians are the gatekeepers of the U.S. health care system, rendering their licenses very valuable.

There is an old joke of sorts in health policy. Question: what is the most expensive medical device? Answer: the physician's pen. A licensed physician must sign off on all drug prescriptions, all hospital admissions, all surgeries, all therapies, and all diagnostic services. That makes the cost of physicians' pens collectively about \$4 trillion. In years past, hospitals would attempt to curry favor with doctors because only doctors could refer patients to them.

There were also laws in many states prohibiting doctors from working for hospitals or practicing medicine on behalf of corporate entities. In other words, nonphysicians could not practice medicine by hiring physicians to do so on their behalf. Going back decades, laws in about one-third of the states prohibited the corporate practice of medicine, while about one-third of states allowed it under some conditions and the remaining one-third were vague on the concept.

#### **Physicians Have Become Employees**

Today, the prohibition on the corporate employment of physicians is rarely enforced. Meanwhile, hospitals and investors get around prohibitions on the corporate practice of medicine by placing physicians as the nominal head, with no real power, over corporate-owned medical practices.

Various state medical societies are starting to take notice. This includes Michigan, about which I told Health Care News earlier this year: "The problem with allowing the corporate practice of medicine is that doctors are no longer advocates for their patients. When physicians are employed by hospitals, private equity, health plans, or corporations, they answer to their employers rather than to their patients. That can result in unnecessary care and unnecessarily expensive care."

Physician groups in California are among those taking notice and are suing to enforce the state's prohibition on the corporate practice of medicine. Numerous corporate entities are employing physicians for the use of their licenses. In the past, doctors maintained they controlled their licenses, and they would not put their employers' interests above those of their patients.

#### **Salaried Doctors Under Pressure**

Over the objections of medical groups, hospital employment of physicians has skyrocketed in the past two decades.



"M.D. employment has gotten so pervasive, and the use of

noncompete agreements so widespread, that most employed physicians do not have the leverage to push back against abusive corporate practices. In addition, physician compensation is often tied to revenue targets, making it even harder for physicians to put the needs of their patients first."

**DEVON HERRICK, PH.D. HEALTH CARE ECONOMIST** 

Nearly three-fourths of doctors work for a hospital, an investor-owned group practice, a health plan, or some other

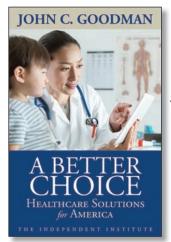
M.D. employment has gotten so pervasive, and the use of noncompete agreements so widespread, that most employed physicians do not have the leverage to push back against abusive corporate practices. In addition, physician compensation is often tied to revenue targets, making it even harder for physicians to put the needs of their patients first.

Devon Herrick, Ph.D. (devonherrick@ sbcglobal.net) is a health care economist. An earlier version of this article  $was \, published \, on \, the \, Goodman \, Institute$ Health Blog. Reprinted with permission.

#### INTERNET INFO

Mitchell Li, M.D., Sailesh Konda, M.D., Robert McNamara, M.D., "The Corporate Practice of Medicine: A Call to Action to Take the Profession Back from Corporate Interests." Take Medicine Back, October 2023: https://grco.de/beUEJm

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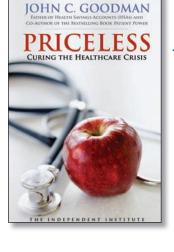
John C. Goodman

John Goodman understands the real life effects of the Affordable Care Act and the proposed alternatives. John also writes extremely well, making complicated concepts clear. All this makes *A Better Choice* a highly recommended read for those who wish to understand the current health policy debate."

—Bill Cassidy, M.D., U.S. Senator

Polls show that by a large margin Americans remain opposed to Obamacare and seek to "repeal and replace" it. However, the question is: Replace it with what? In *A Better Choice*, John C. Goodman clearly and concisely provides the compelling answer. For anyone who wants to learn about some of the boldest prescriptions designed to remedy our healthcare system, Goodman's book is a must-read.

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Curing the Healthcare Crisis **John C. Goodman** 

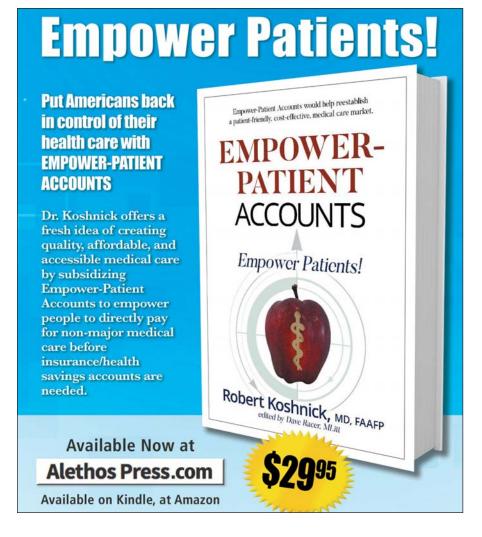
"There's no question that today's healthcare system is littered with distorted incentives and what John Goodman calls dysfunctionality. *Priceless* is a call to arms to do something about it. . . . You should read this book if you want to be an informed participant in the debate over the future of healthcare in this country."

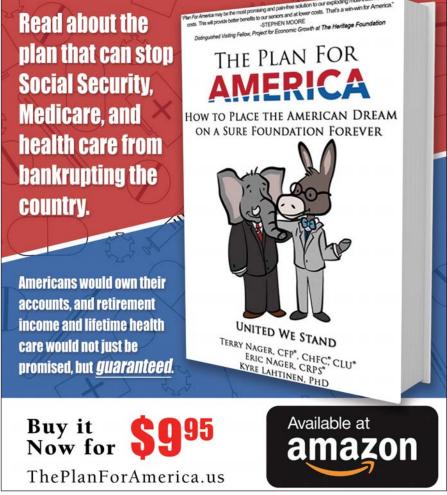
—Peter R. Orszag, former Director, Congressional Budget Office

Americans are trapped in a dysfunctional healthcare system fraught with perverse incentives that raise costs, reduce quality, and make care less accessible. Now *Priceless* cuts through the politics and proposes dozens of bold reforms to free patients and caregivers to be empowered to chart their own lives with low-cost, high-quality healthcare.



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#### **COMMENTARY**

## Health Insurance Does Not Mean Health Care

#### By John C. Goodman

One reason the United States spends more on health care than other countries is that we are obsessed with health insurance instead of health care.

When the British National Health Service or the Canadian Medicare system spends additional money, they spend it employing doctors, building hospitals, or buying medical equipment. When the U.S. government spends more money, we give it to insurance companies.

Take Obamacare. We are currently spending \$214 billion a year insuring people through Medicaid (which is mostly contracted out to private insurers) and the Obamacare exchanges. At \$1,731 for every household in America, that's a great deal of money being transferred from taxpayers to insurance companies every year.

What are we getting for all that spending? Are people getting more health care? If they are, what difference is that making?

Few people find these questions interesting. In a Google search on "Obamacare," every article I encountered discussed health insurance, but not health care. Even at the Obama Foundation website, the focus is entirely on insurance, not care.

#### **Doctor Visits Have Fallen**

Nonetheless, one scholarly study finds there has been no overall increase in health care in the United States since the enactment of Obamacare. The number of doctor visits per capita actually fell over the last decade. That's surprising, because our population has been aging, and older people require more health care.

Unfortunately, there is nothing particularly new here. When Obamacare was enacted, it was expected to cost close to \$1 trillion over the next 10 years. But there was no serious discussion of what we were going to buy with all that spending—not in Congress, not in the mainstream media, or even in the health policy community.

To have more health care, we must have more doctors, more nurses, more hospital beds, and so on. Without any increase in supply, for one group of people to get more care, some other group must get less.

We saw a vivid illustration of that during the COVID pandemic. To tend to the needs of a sudden surge in COVID



"Under Obamacare, the number of people without health insurance fell from 15.5 percent of the population in 2010 to 7.9 percent by 2022. Yet [an MIT study] found health care utilization across all of society did not increase at all. There was some shifting, as low-income patients got more care, but that care was offset by reductions elsewhere in the system."

JOHN C. GOODMAN, PH.D.
PRESIDENT AND FOUNDER. THE GOODMAN INSTITUTE

patients, health care providers had to delay care for the non-COVID patients.

#### **Throwing Money at the Problem**

Our experience with Obamacare is like our experience with every major health program Congress has passed or even considered. We begin with a claim of unmet needs; we decide on a large sum of money to throw at the problem; but we never ask how the money can meet the unmet need if nothing is done on the supply side.

Medicare for the elderly and Medicaid for the poor were huge programs, even when they started in 1965. In a short period, the number of people who lacked health insurance dropped from nearly 25 percent to under 15 percent of the population.

As a result, physician visits by low-

income people increased 6.2 percent and surgical procedures among the elderly increased 14.7 percent. However, since there was no increase in the ability of the system to supply medical services, these increases were offset by a decrease in care delivered to the non-poor and the non-elderly. A study in the *American Journal of Public Health* found that "society-wide utilization of medical care remained unchanged."

Even though there was an increase in health care services for seniors, Massachusetts Institute of Technology Professor Amy Finkelstein discovered the passage of Medicare had no effect on the health of the elderly—at least as measured by mortality. The additional spending set off a bout of health care inflation, however, for all patients.

#### No Increase in Utilization

Under Obamacare, the number of people without health insurance fell from 15.5 percent of the population in 2010 to 7.9 percent by 2022. Yet the study cited above found health care utilization across all of society did not increase at all.

There was some shifting, as low-income patients got more care, but that care was offset by reductions elsewhere in the system. In particular, "a 3.5-percentage-point increase in the proportion of persons earning less than or equal to 138 percent of the federal poverty level with at least one office visit was offset by small, nonsignificant reductions among the rest of the population."

#### **Taxpayers Foot Drug Bills**

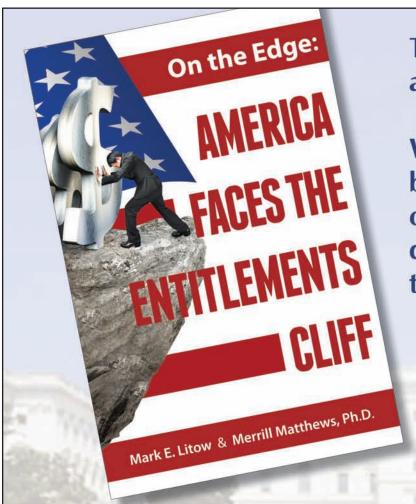
You might think prescription drugs are different. If Congress expands government insurance for drugs, the drug companies can supply as much as patients demand. But here again, there appears to be no limit to Congress' ability to waste taxpayer money.

When Congress created Medicare Part D to pay for drugs in 2003, it created a \$15.6 trillion unfunded liability for the federal government, looking indefinitely into the future. That was more than the unfunded liability in Social Security.

Yet, economist Andrew Rettenmaier discovered only 7 percent of the benefits bought new drugs for seniors. The other 93 percent simply transferred to the government (and therefore to taxpayers) the bill for drugs the elderly or their insurers were already buying. Only \$1 in every \$13 represented a new drug purchase.

Interestingly, the help given to the small number of people who were not otherwise getting medications reduced Medicare spending, as drugs were substituted for more expensive doctor and hospital therapies. But this profit on the truly needy was overwhelmed by the cost of giving the benefit to those who didn't need it—a cost that has created an enormous obligation for current and future taxpayers.

John C. Goodman, Ph.D. (johngoodman@goodmaninstitute.org) is copublisher of Health Care News and president and founder of the Goodman Institute for Public Policy Research. An earlier version of this article appeared in Forbes. Reprinted with permission.



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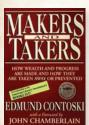




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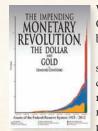
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