Health Care News *is sent to every national and state elected official and thousands of opinion leaders.*

THE HEARTLAND INSTITUTE
IS ONE OF THE WORLD'S LEADING FREE-MARKET THINK TANKS. IT IS A NATIONAL NONPROFIT RESEARCH AND EDUCATION ORGANIZATION.

THE GOODMAN INSTITUTE
WORKS WITH THE BEST SCHOLARS FROM AROUND THE COUNTRY ON THE NATION'S MOST DIFFICULT PUBLIC POLICY PROBLEMS.

HEALTH CARE NEWS

Vol. 24 No. 10 November 2023 HealthCareNewsOnline.com

The Pulse

New COVID Shots Have Little Chance of Reducing Hospitalization

By Bonner Russell Cohen

As the virus that causes COVID-19 continues to mutate, the Food and Drug Administration (FDA) approved the use of two mRNA vaccines targeting the omicron variant (XBB.1.5) of SARS-CoV-2 on September 11, and the following day the Centers for Disease Control and Prevention (CDC) recommended universal vaccination of people ages six months and older.

CDC Director Mandy Cohen welcomed the 13 to 1 vote by a CDC panel of advisers to greenlight the rollout of the booster.

NEW COVID SHOTS, p.4

Florida, Physicians Push Back on COVID Shots

By Dvorah Richman

Growing concerns about the federal government's COVID-19 shot approvals, policies, and pressure tactics have led Florida Gov. Ron DeSantis and state lawmakers to push back with legislation and recommendations for the public.

The U.S. Food and Drug Administration (FDA) approved new versions and dosing of Moderna's Spikevax and Pfizer's Comirnaty COVID shots for people

SHOTS PUSH BACK, p. 6

NON PROFIT
ORGANIZATION
US POSTAGE PAID
BEAVER DAM, WI
PERMIT NO. 412

The Heartland Institute
3939 North Willke Road
Arlington Heights, IL 60004

Health Care News

The Heartland Institute
3939 North Wilke Road
Arlington Heights, IL 60004
312/377-4000 voice • 312/277-4122 fax

Goodman Institute
6335 W Northwest Hwy - #2111
Dallas, TX 75225

Health Care News is available on the internet. Point your web browser to **HeartlandDailyNews.com**

PUBLISHED BY
James Taylor, The Heartland Institute
John C. Goodman, Goodman Institute

EXECUTIVE EDITOR
S.T. Karnick

MANAGING EDITOR
AnneMarie Schieber

SENIOR EDITOR
Joe Barnett

ASSOCIATE PUBLISHER
Jim Lakely

DESIGN AND PRODUCTION
Donald Kendal

ADVERTISING MANAGER
Jim Lakely

CIRCULATION MANAGER
Keely Drukala

CONTRIBUTING EDITORS
Brian Blase, Dean Clancy
Twila Brase, R.N.
Matt Dean, John Goodman
Devon Herrick, Phil Kerpen
Jane Orient, M.D., Chad Savage, M.D.
Marilyn Singleton, M.D.

ADVERTISING: *Health Care News* accepts display advertising and advertising inserts. For an advertising kit with rate card, contact Associate Publisher Jim Lakely at 312/377-4000, e-mail **jlakely@heartland.org**.

Health Care News is published by The Heartland Institute and The Goodman Institute—nonprofit and nonpartisan public policy research organizations serving the nation's federal and state elected officials, journalists, and other opinion leaders. Their activities are tax-exempt under Section 501(c)(3) of the Internal Revenue Code.

Biden Plan to Limit Short-Term Insurance Draws Opposition, Support

By AnneMarie Schieber

The Biden administration's proposal to limit short-term, limited-duration health insurance (STLDI) to three months struck a nerve as 15,820 individuals and organizations submitted opinions during the 60-day comment period, which ended on September 11.

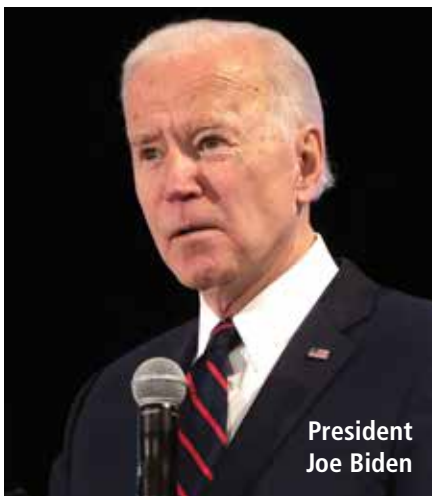
The proposed rule by the Departments of Health and Human Services, Labor, and Treasury is scheduled to take effect on January 1. The rule would restrict the plans to four months with no option to renew.

The new rule would restore limits put into place in 2014 by the Obama administration. President Donald Trump authorized states to allow plans of up to one year's duration, with the option to renew for up to two years.

Restricting short-term insurance could leave people who become sick without coverage, as their next option would be an Obamacare plan, which would not be available until the annual November enrollment period and could cost much more.

"The Biden administration is likely to finalize this rule even though doing so would hurt a lot of people, particularly people who get sick, and help virtually no one. They seem intent on taking coverage options away from people and promoting ACA plans at all costs."

BRIAN BLASE
FOUNDER AND PRESIDENT
PARAGON HEALTH INSTITUTE



President Joe Biden

PHOTO COURTESY GAGE SKIDMORE/FLICKR.COM

Forced into Government Plans

Many of the comments were submitted by people who would be harmed by the new rule, notes the Paragon Health Institute in a letter it submitted, which was signed by 40 individuals from market-oriented public policy organizations.

"The main beneficiaries [of the new rule] would be health insurance companies that want to restrict alternative options, forcing Americans to buy heavily government-subsidized products (government subsidies cover roughly 80 percent of the premium for the average exchange enrollee) from them and not their unsubsidized competitors," the letter states.

The letter says the proposal violates Americans' right to control their health care and a promise by President Joe Biden and will lead to higher premiums and subsidy costs for alternative private plans. The comment also points out the unemployed, who are the customers of such plans, are often out of work for more than four months, creating gaps in coverage that will leave health care providers with more uncompensated care.

In another comment, 29 Republican state legislators in 19 states urged the administration to reconsider the rule.

"State policymakers and regulators have a better understanding of what the people of their respective states need," the legislators wrote. "Continuing to recognize the preeminence of this type of regulation of insurance allows legislatures and departments of insurance to quickly adapt to market conditions and tailor responses appropriate to protect their citizenry."

Half-Million Lose Coverage

It is hard to describe how harmful the proposed limits on STLDI would be, wrote Michael Cannon, director of Health Policy Studies at the Cato Institute, in his multi-page public comment.

Cannon says 95 percent of STLDI plans offer "comprehensive major medical" coverage, often more comprehensive than those on the Obamacare exchanges. The Congressional Budget Office estimates 500,000 people will be left uninsured when STLDI plans end after four months, Cannon notes.

"Most amazing is the administration acknowledges how dangerous the change is in its own rule," wrote Cannon. "There is a label that will warn people about how dangerous the administration's own proposal is by stating 'when this policy ends, you might have to wait until an open enrollment period to get comprehensive health insurance.'"

Alternatives Cost More

Cannon included in his article a chart of the price differences between STLDI and Obamacare. In Phoenix, Arizona, for example, a bronze Obamacare plan will cost $680 a month, while the range for short-term plans is $161.57 to $1,281.67. Consumers pay more for higher coverage caps and lower out-of-pocket maximums.

"This proposal is not an attempt to protect consumers," wrote Cannon. "Quite the contrary: it would expose consumers to greater risk by reducing the consumer protections available in the STLDI market."

'Help[s] Virtually No One'

Among the commenters supporting the rule were the American Academy of Family Physicians (AAFP) and the Planned Parenthood Federation of America.

"… STLD plans are not meant for long-term use and should be capped appropriately," wrote the AAFP.

"… STLDI plans frequently have blanket exclusions for basic health care services that women, nonbinary, and transgender people rely upon, such as birth control, maternity services, abortion, and gender transition-related services," wrote Planned Parenthood.

Supporters of the rule are likely to get their way, says Brian Blase, founder and president of the Paragon Health Institute.

"The Biden administration is likely to finalize this rule even though doing so would hurt a lot of people, particularly people who get sick, and help virtually no one," said Blase. "They seem intent on taking coverage options away from people and promoting ACA plans at all costs."

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

New COVID Shots Have Little Chance of Reducing Hospitalization

Continued from page 1

"We have more tools than ever to prevent the worst outcomes from COVID-19," Cohen said in a statement on the CDC website. "CDC is now recommending updated COVID-19 vaccination for everyone 6 months and older to better protect you and your loved ones."

Resistance Likely

The CDC's decision to recommend the shot for everyone, rather than narrowly targeting vulnerable older people, could easily become a mandate for schools, businesses, and government agencies.

The vaccine is likely to encounter stiffer resistance than the introduction of COVID-19 vaccines nearly three years ago. A Reuters-Ipsos poll found 30 percent of respondents were "very interested" in the new booster, 24 percent "somewhat interested," 17 percent "not very interested," and 30 percent "not interested at all."

One day before the CDC's action, the FDA approved vaccines from Moderna and Pfizer-BioNTech. The FDA is expected to give the go-ahead for a booster by Novavax shortly.

All three boosters are designed to combat XBB.1.5. Evidence from laboratory tests suggests another recent strain of the coronavirus, BA.2.86, does not pose an omicron-level threat and should not require its own booster to bolster antibodies, *The Washington Post* reported on September 17.

Boosters Chase Extinct Variants

Investigative journalist Alex Berenson, a vocal critic of the public-health bureaucracy's response to the coronavirus pandemic, wrote on Substack that the CDC's own statistics show the mRNA vaccine and boosters make no difference.

"They become ineffective against Omicron variants of COVID within months, possibly weeks," Berenson wrote. "'Updating' them—that is, changing the mRNA they contain, in an effort to keep current with the current variant—does not help. Why? Imprinting from the original jabs makes our immune systems produce antibodies tailored to fight the now-extinct original coronavirus variant, no matter the specifics of the mRNA in the booster."

"The CDC itself estimated yesterday that 1 million mRNA boosters in adolescents would prevent at most one death from COVID (and probably zero), as well as roughly 10 COVID intensive-care admissions. At the same time, giving teenagers a million mRNA doses will cause anywhere from 100,000 to 200,000 cases of severe short-term side effects, such as fevers and nausea. They will also cause anywhere between 50 and 300 cases of myocarditis severe enough to cause hospitalization."

ALEX BERENSON, INVESTIGATIVE JOURNALIST

The evidence the shots protect against hospitalization and severe illness is weaker than mRNA advocates claim, says Berenson.

"The CDC reported [on September 12] the jabs have roughly 0 to 25 percent effectiveness against hospitalization within three to four months," wrote Berenson. "Health authorities originally promised the COVID vaccines needed at least 50 percent effectiveness for approval. But the CDC's own data show booster effectiveness against Omicron is nowhere near that level."

'A Very Bad Bet'

The potential side effects of the shots outweigh the risks of the virus, particularly to healthy young people, says Berenson.

"[T]he mRNA vaccines have much more severe side effects than flu shots, the only vaccines that are comparable in terms of their (lack of) effectiveness," Berenson wrote. "This combination makes the mRNA vaccine a very bad bet—particularly for children, who are at miniscule risk of hospitalization or death from COVID."

A staggering number of cases with severe side effects are caused by mRNA vaccines, says Berenson.

"The CDC itself estimated yesterday that 1 million mRNA boosters in adolescents would prevent at most one death from COVID (and probably zero), as well as roughly 10 COVID intensive-care admissions." wrote Berenson. "At the same time, giving teenagers a million mRNA doses will cause anywhere from 100,000 to 200,000 cases of severe short-term side effects, such as fevers and nausea. They will also cause anywhere between 50 and 300 cases of myocarditis severe enough to cause hospitalization (depending on which estimates and what mix of Pfizer and Moderna shots are used).

"That math has prompted Japan, Germany, Britain, and Australia to stop recommending COVID boosters for children and teenagers, and the latter three countries no longer recommend the shots for the vast majority of people under 65," wrote Berenson.

CDC 'Failing in Its Responsibility'

The CDC has learned nothing from its poor performance during COVID-19, says Joel Zinberg, M.D., J.D., a senior fellow at the Competitive Enterprise Institute and director of the Public Health and American Well-Being Initiative at the Paragon Health Institute.

"As it did throughout the pandemic, the CDC is once again failing in its responsibility to clearly communicate with the public," said Zinberg. "Its recommendation that everyone six months or older be vaccinated fails to inform people that the benefits and risks of the new vaccines vary substantially among different age groups, leaving them without the information they need to make an informed consent."

'Shocking to See'

The CDC's and FDA's actions betray their basic mission, says Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons.

"The main job of our regulatory agencies is to ensure safety," said Orient. "As safety signals about COVID jabs are becoming too frequent for ordinary people to ignore, it is shocking to see this blanket recommendation with no effort to do the intensive investigations needed to confirm or refute the association of the jabs with heart damage, blood clots, paralysis, sudden death, infertility, or cancer.

"Maybe these associations are 'rare,' but how big a risk are you willing to take?" said Orient.

The CDC's recommendations lack a needed scientific context, says Orient.

"There have been no head-to-head studies of vaccines compared with nasal sprays, vitamin D, zinc, or prophylaxis with hydroxychloroquine or ivermectin," said Orient.

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

INTERVIEW

Company Fights FTC Penalties for Promoting Its COVID-19 Treatment

On October 28, 2021, the Federal Trade Commission (FTC) sued Xlear, a Utah-based company, for claiming its over-the-counter xylitol-based nasal sprays can help prevent and treat COVID-19. The FTC has sought to stop the company from making such claims, and it has imposed monetary penalties on the company. Xlear CEO Nathan Jones and attorney Rob Housman spoke with Harry Painter of Health Care News *about the lawsuit.*

Health Care News: The public health emergency ended this year in May, yet this lawsuit is still in the discovery phase. Why?

Jones: The FTC has no desire to move it forward, as they know there is no case. If it is ever made known that the FTC, through their warning letters and lawsuits, suppressed the best option we had in early 2020 for stopping the pandemic, they will have some serious egg on their face.

Health Care News: Briefly, what are the FTC's claims against Xlear?

Housman: The FTC claims that Xlear made false and misleading statements concerning the use of Xlear as an additional countermeasure to fight COVID-19. The FTC's allegations, however, are themselves misleading in that the FTC has produced no studies to rebut the studies Xlear has provided the government.

Xlear denies that we made false and misleading statements. We have provided the government with numerous studies showing Xlear and the ingredients that make up our products are an effective countermeasure to help prevent COVID-19 transmission and reduce the duration and severity of the illness for those already infected.

Health Care News: Specifically, how do Xlear nasal sprays mitigate the negative effects of the COVID-19 virus or other viruses and pathogens?

Housman: Nasal hygiene interventions—sprays, washes, rinses—work by physically washing viruses and bacteria away, much like hand washing but more directly. Nasal washes also alleviate symptoms. In vitro studies indicate that Xlear blocks viral adhesion—the process by which the spikes of the COVID virus attach to the nasal tissue and inject the viral genetic material and infect a person. The xylitol in Xlear is the component that does the blocking, and the grapefruit seed extract (GSE) in Xlear destroys the virus' capsid (outer membrane).

One randomized, controlled trial (the gold standard clinical trial) done in India—using a saline and xylitol spray like Xlear—reduced the rate of transmission by 62 percent over the placebo. That is a huge reduction in the risk of infection and transmission, more than the current vaccines.

Jones: The placebo in this study was saline, which reduces transmission by about 13 percent. So, using a nasal spray that has ingredients that block viral adhesion, and destroys viruses, works significantly better.

This study was done with hospital workers in India during the Delta wave of COVID, arguably the deadliest wave at the deadliest place.

Health Care News: Do you think in any way the marketing was getting ahead of the science?

Housman: No. Rather, it seems the science is out in front of what public health officials and the U.S. government are telling the American people. There is a great deal of reliable, sound science behind nasal hygiene. The government doesn't want you to hear about [it because] it could undercut the vaccine strategy, which has failed. By the way, I'm vaccinated and boosted.

Jones: There is a long history of government and establishment health care organizations fighting hygiene solutions for health care problems. Dr. Semmelweis, who first proposed handwashing by physicians in 1848, was laughed at and mocked by the establishment. Dr. John Snow in London was mocked for suggesting that they put in a sewer system to end their cholera epidemics. The American Medical Association sent lawyers to Congress to try to put an end to Dr. Sara Jo Baker's handwashing and hygiene programs here in the United States.

These doctors all saw great results from things they did, and people in the bureaucracy that were not seeing patients were the ones fighting against them—very similar to what we are seeing today.

Health Care News: Why have there not been more clinical trials studying nasal sprays?

Housman: There is a large amount of clinical data behind nasal sprays—the public is just not seeing it, in large part because the government is censoring it. The FTC's suit against Xlear is part of that censorship. Many studies are published on the National Institutes of Health's website. We have produced these studies in our lawsuit.

Health Care News: How has the government tried to block Xlear products or other products, and why do you think they have done that?

"There is a great deal of reliable, sound science behind nasal hygiene. The government doesn't want you to hear about [it because] it could undercut the vaccine strategy, which has failed. By the way, I'm vaccinated and boosted."

ROB HOUSMAN
XLEAR ATTORNEY

Housman: The government's primary effort has been for the FTC to sue Xlear to prevent us from telling people about scientific studies. This lawsuit has had a significant chilling effect. You don't see the media covering the science.

We know from discovery that the FTC involved itself in Xlear's efforts to seek Emergency Use Approval from the FDA. The FTC has no role in FDA matters. So why were FTC lawyers talking to the FDA? We also know the government has taken steps to intimidate the doctors who conducted some of these trials.

Health Care News: How would the pandemic look had the government not tried to clamp down on alternative treatments?

Housman: If one looks at the India study finding a 62 percent reduction in transmission over placebo, and reasonably extrapolates, it seems logical that if the government had promoted the use of nasal hygiene as a countermeasure, the size and impact of the pandemic would have been greatly reduced.

INTERNET INFO

"*USA v. XLEAR et al.,*" July 14, 2022: **https://www.govinfo.gov/content/pkg/USCOURTS-utd-2_21-cv-00640/pdf/USCOURTS-utd-2_21-cv-00640-1.pdf**

Defendants' Amended Answer to the Government's Complaint, July 16, 2022: **https://xlear.com/wp-content/uploads/2022/08/Dkt.-45-Amended-Answer-with-Exhibits176006339.1.pdf**

Florida, Physicians Push Back on COVID Shots

Continued from page 1

aged 12 and older, and gave "Emergency Use Authorizations" (EUA) for children aged 6 months to 11 years, on September 11.

The FDA's approval was based on "manufacturing data and non-clinical immune response data." Moderna announced non-peer-reviewed clinical trial data for Spikevax "confirming" an increase in neutralizing antibodies against currently circulating COVID variants.

Florida became the first state to recommend against COVID-19 boosters for anyone under age 65, on September 13.

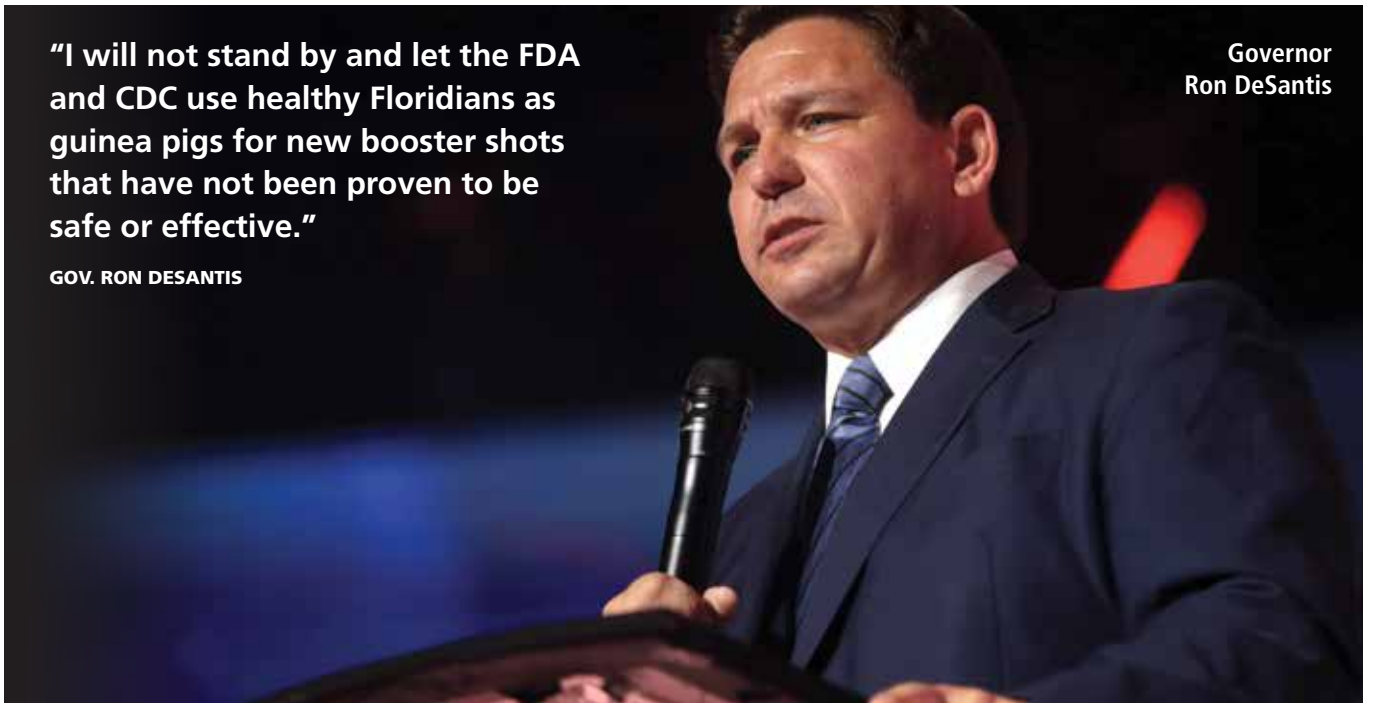


PHOTO COURTESY GAGE SKIDMORE/FLICKR.COM

Lingering Questions

Questions regarding Moderna's shot are "still looming," and Pfizer's version has "zero efficacy data," "has not been tested on humans at all," and has data only "about antibody protection from 10 mice," wrote Marty Makary, M.D., M.P.H. and Tracy Beth Høeg, M.D., Ph.D. in the *New York Post* on September 14.

Despite the lack of clinical evidence, the FDA and Centers for Disease Control and Prevention (CDC) are vigorously promoting the new mRNA shots, say Makary and Høeg.

"The push is so hard that former White House COVID coordinator Dr. Ashish Jha and CDC head Mandy Cohen are making unsupported claims the new vaccine reduces hospitalizations, long COVID and the likelihood you will spread COVID. None of those claims has a shred of scientific support," Makary and Høeg wrote.

Scant Safety Record

Scott Jensen, M.D., a physician, author, and former Minnesota state senator and gubernatorial candidate who has been critical of government pandemic policies, said it is "mindboggling" that the FDA claims "the public can be assured that these updated vaccines have met the agency's rigorous scientific standards for safety, effectiveness, and manufacturing quality."

Contrary to the experience during the COVID-19 pandemic, the FDA assumes the mRNA vaccines have a safety profile like that of seasonal flu shots, says Jensen.

"The flu vaccine approval process, which doesn't require clinical trials, shouldn't be used for COVID shots," said Jensen. "Flu vaccines have a long safety record, but COVID shots don't. They have higher complication rates, including severe and life-threatening adverse events."

Safety, Efficacy Concerns

The FDA stated in its EUA announcement it is "confident in the safety and effectiveness of the updated vaccines."

COVID shots have been associated with a serious adverse event rate of one in 5,000 doses, and serious events have been estimated to be as high as one in 556 recipients, according to studies cited by Makary and Høeg. The incidence of myocarditis for younger people is six to 28 times higher after the vaccine than after infection. There are also concerns about how multiple boosters affect the immune system.

Drug safety advisors and scholars recently petitioned the FDA to amend COVID-19 shot labeling to reflect associated adverse events. The FDA denied virtually all the petitioners' requests.

Research from 17 southern hemisphere countries and equatorial regions found "a definite causal link" between "many peaks in all-cause mortality and rapid vaccine rollouts" and fatal toxicity risk per injection that is "exceedingly large in the most elderly," states an article published by *CORRELATION Research in the Public Interest* on September 17. The authors recommend elderly people not be prioritized for COVID-19 shots.

As for efficacy, Makary and Høeg say follow-up studies of COVID vaccines in general reveal mild efficacy against infection is transient, "lasting just a few months."

Lack of Clinical Trials

In advising against the shots for individuals age 65 and under, Florida Surgeon General Joseph Lapado, M.D., Ph.D. noted the insufficient safety and effectiveness data and lack of any "meaningful booster-specific clinical trial data performed in humans."

Lapado urged those over age 65 to discuss the booster with a health care provider. Specifically, Lapado mentioned concerns about the ineffectiveness of the shots after four to six months, the increased risk of infections, the risk of myocarditis and other heart conditions, and elevated levels of spike proteins from the shots for indefinite periods of time.

"I will not stand by and let the FDA and CDC use healthy Floridians as guinea pigs for new booster shots that have not been proven to be safe or effective," said DeSantis regarding Lapado's announcement.

Legislative Backlash

Despite evidence that masks are ineffective against COVID-19 and potentially harmful, a growing number of universities, businesses, and hospitals are reinstituting mask mandates and other restrictions.

Florida enacted legislation banning various COVID mandates, empowering doctors, and prohibiting gain-of-function research. Other states and cities have also banned various COVID-19-related restrictions. At the federal level, "Freedom to Breathe" legislation prohibiting mask mandates in various settings has been introduced in the U.S. Senate and House of Representatives.

Doctors report it has become harder to distinguish COVID from allergies or the common cold.

John Salop, a patient of the Virginia-based Inova Hospital System, said he received poor advice from his Inova physicians.

"Particularly considering treatment for my blood disorder, I need nuanced answers," said Salop. "Instead, I've only been told, 'We follow CDC guidance.'"

Media Attacks

Media outlets attacked DeSantis for his policy moves, calling them political and intended to distinguish his presidential campaign from Donald Trump's.

Paragon Health Institute Senior Policy Analyst Drew Keyes disagreed, saying, "It should come as no surprise that state leaders are stepping into the void that federal missteps have opened."

Those who say the backlash against federal COVID-19 policies is all about politics are "dead wrong," says Jensen.

"We're dealing with serious, complicated, and difficult issues," said Jensen. "Collectively, we must have the courage, even in this charged environment, to stand up and counter government presumptions with facts and concrete arguments."

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

California Does U-Turn on Doctor Censorship

By Harry Painter

Free speech and medical freedom advocates scored a win when California legislators quietly reversed a controversial law censoring doctors who challenged official COVID-19 narratives.

On September 30, Gov. Gavin Newsom signed into law a bill repealing AB 2098. The repeal (of Section 2270 of the Business and Professions Code) is part of a broader package that reforms the Medical Board of California. In effect since early 2023, AB 2098 punished doctors for disseminating what government authorities designate as "misinformation or disinformation" about COVID-19.

The law resulted in four lawsuits and opposition from the right and left alike, with the ACLU of Northern California and independent presidential aspirant Robert Kennedy Jr. criticizing it for vague language and violation of people's rights.

"Legislatures shouldn't succumb to public hysteria, especially hysteria of a tiny but vocal segment of the population. Ultimately, as shown by the legislative history, this bill's main proponents were several extremists who made no secret of the fact they wanted to silence doctors who disagreed with them on various aspects of COVID policy."

JENIN YOUNES
ATTORNEY, NEW CIVIL LIBERTIES ALLIANCE

Under Pressure

"I believe two lawsuits put significant pressure on the legislature," said Jenin Younes, an attorney for the New Civil Liberties Alliance who represented five doctors suing the state in *Høeg v. Newsom*.

"Our motion for summary judgment was due October 2nd," said Younes. "Meanwhile, the Ninth Circuit Court of Appeals heard *McDonald v. Lawson* in July. Two of the three judges on the panel indicated they had serious problems with the law's constitutionality."

Even though AB 2098 stayed in force after that hearing, the judges' published decision may have been enough to cause the legislature to reconsider the law, says Younes.

"Given the obvious misgivings about the law voiced by several federal judges, the legislature may have decided to voluntarily repeal the law rather than suffer another humiliation in court," Younes said.

Still in Danger

Despite the win for freedom advocates, California still has ways to punish doctors who do not conform to the health establishment, says Younes.

"There is still danger," said Younes. "One of our arguments is that the law punishes First Amendment-protected speech because California already requires doctors to abide by certain standards, which cover malpractice, negligence, and that sort of thing.

"This indicates that the law is designed to punish and chill speech that is First Amendment protected," said Younes. "Unfortunately, those legal doctrines can be wielded unfairly against doctors who simply depart from the [Centers for Disease Control and Prevention] or state orthodoxy."

False, or Just Debatable?

Younes notes a doctor was disciplined by the Medical Board of California in 2021, before AB 2098 was enacted, for disseminating "false" information to a patient.

"The problem is that two of the allegedly false statements are at least up for debate: that masks don't do much or anything to stop the spread of COVID and that ivermectin can be an effective means of treating COVID-19," said Younes.

"Still, AB 2098 would have been another tool to utilize against doctors who dissent from the state, and it was clearly designed to intimidate doctors into silence, so it is ultimately beneficial that it has fallen," said Younes.

Dr. Marilyn Singleton, a board-certified anesthesiologist with professional experience in California, agrees the government can still control dissenting physicians.

"There are plenty of ways, in the definition of unprofessional conduct, to make life difficult for medical gadflies," said Singleton.

Patients to the Rescue

Patients can protect doctors from government harassment, says Singleton.

"Patients want information," said Singleton. "They spoke out. When you get patients on your side it certainly helps the fight against government overreach."

Instead of criminalizing speech, governments and other institutions should "combat erroneous information with more information backed with facts," says Singleton.

The repeal of AB 2098 will probably have an impact on other states, says Younes.

"I think this will show other states that such laws will be a huge headache for them, at the very least, and most likely will end in embarrassment," said Younes.

"If this law couldn't survive in California, which has some of the most totalitarian, oppressive COVID policies in the country, I don't know where it would survive," said Younes. "This is an important victory for free speech and due process."

Lawmakers Bowing to Hysteria

The passage of such an overtly anti-freedom law shows legislatures are exceeding their proper role in society, Younes says.

"Legislatures shouldn't succumb to public hysteria, especially hysteria of a tiny but vocal segment of the population," said Younes. "Ultimately, as shown by the legislative history, this bill's main proponents were several extremists who made no secret of the fact they wanted to silence doctors who disagreed with them on various aspects of COVID policy."

The California legislature and the governor both refused to consider the constitutionality of the bill before passing it, says Younes.

"The legislature has a duty to contemplate the constitutionality of its laws, and had the state done its job, it would have realized this bill didn't pass muster," said Younes. "Likewise, the governor should have followed his gut—misgivings articulated in his signing statement—and declined to sign this obviously unconstitutional bill into law."

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

INTERNET INFO

California Legislative Information: "SB-815 Healing Arts. (2023-2024)," September 19, 2023: **https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202320240SB815**

"Memorandum and Order Re: Plantiffs' Motions for Preliminary Injunction," U.S. District Court, Eastern District of California, January 25, 2023: **https://childrenshealthdefense.org/wp-content/uploads/CA-AB2098-Inj-Granted-1.25.23.pdf**

"Høeg v. Newsom, Complaint for Declaratory and Injunctive Relief," U.S. District Court for the Eastern District of California, November 1, 2022: **https://nclalegal.org/wp-content/uploads/2022/11/Complaint_Hoeg-v.-Newsom-final-complaint.pdf**

Autopsies Raise Questions about COVID-19 Shots

By Kenneth Artz

Spike protein from the COVID-19 shots has been identified in lymph nodes and in some cases the heart in the bodies of people who died within 30 days of inoculation, a scientific study states.

The finding was published on September 27, 2023, in the scientific journal *Nature*.

The study raises concerns about the long-term effects of COVID-19 shots BNT162b2 (Pfizer) and mRNA-1273 (Moderna), and it casts doubt on the wisdom of the U.S. government's quick approval of the vaccines, says Jane M. Orient, M.D., executive director of the Association of American Physicians and Surgeons, president of Doctors for Disaster Preparedness, and chairman of the Public Health Committee of the Pima County (Arizona) Medical Society.

"Why are we finding out only now, from autopsy studies, after billions of doses have been given, that vaccine mRNA persists in many tissues, including the heart?" said Orient.

"The authors find that the vaccine may persist for up to four months, but it could persist much longer," said Orient. "Proper biodistribution and pathologic studies should have been conducted before authorization."

Mixed Success, Real Risks

During the early stages of the COVID-19 pandemic, scientists developed two vaccines—BNT162b2 and mRNA-1273—to fight the disease. Both produced the full-length SARS-CoV-2 spike protein to help the body fight the virus. The shots had mixed success, failing to stop transmission or prevent infection, government agencies later admitted.

Members of the public have expressed worry about adverse effects from the shots. Epidemiological data from the U.S. military showed a large uptick in a variety of illnesses after members of the armed forces were ordered to take the injections.

The *Nature* report shows a possible damaging effect of the vaccines, says Orient.

"These findings are very concerning, yet the first paragraph claims that the vaccines are 'estimated'—by computer modeling—to have prevented 20 million deaths," said Orient. "The article makes no attempt to estimate how many died from vaccine effects, but it does show pathologic evidence of cardiac damage," said Orient.

Kenneth Artz (**KApublishing@gmx.com**) w*rites from Tyler, Texas.*

Why Does the Census Bureau Need Children's Health Information?

By Ashley Bateman and AnneMarie Schieber

The U.S. Census Bureau is gathering information from select households to "improve the health of children and families throughout the United States."

According to a letter from the Census sent to a household in Kansas on June 23, the information requested is part of the National Survey of Children's Health (NSCH) conducted on behalf of the U.S. Department of Health and Human Services (HHS). The letter includes a $5 bill for participation, a paper survey, and a link and ID to participate digitally. The study takes 40 minutes to complete. The letter states the Census Bureau is required by law to protect the information.

The NSCH survey topics include child and family characteristics; physical and mental health status, including current conditions and functional difficulties; health insurance status, type, and adequacy; access and use of health care services; medical, dental, and specialty care needed and received; family health and activities; the impact of children's health on the family; and neighborhood characteristics.

The survey asks participants whether their child has ever been "treated or judged unfairly because of their sexual orientation or gender identity."

Health or Equity?

Kansas state Sen. Beverly Gossage (R-Johnson County), who is a health insurance agent and received the mailed survey, says the questions are invasive.

"The survey asked for names, sex, race, ages of children, their health conditions, and what medications they were taking," said Gossage. "Why does a government survey need to know such private health information?"

Gossage says the government could also be probing to push for more spending in the name of social determinants of health.

"There is a push now to expand the use of Medicaid dollars to pay for non-health-care services such as housing and food," said Gossage.

Data Collection Costly

An NSCH survey conducted in 2021 by the Health Resources and Services Administration (HRSA), an agency within HHS that administers 90 programs for care to low-income Americans, reached out to 300,000 households, and after screening, 50,892 surveys were completed, according to the Census Bureau.

Data gathered from the NSCH contributes to decisions on Title V money for Maternal and Child Health block grants to the states. The HRSA requested $13.3 billion in 2023 Fiscal Year funding for its activities.

The cost of this data collection is a concern, says Gossage.

"My survey included a $5 bill, not to mention the mailing costs for each survey packet," Gossage said. "How much and what benefit do we get out of this research other than to increase government spending?"

Privacy Concerns

Data collected by the U.S. Census Bureau is often used to push policy agendas, says Twila Brase, president and cofounder of the Citizens Council for Health Freedom (CCHF), a watchdog organization.

> **"The power of government is police power. Data on individuals and groups can be used to harm Americans economically and personally. As I like to say, 'He who holds the data makes the rules.' Refusing to divulge details about your family and your home protects your freedom and your constitutional rights in a free society."**
>
> **TWILA BRASE**
> **PRESIDENT AND COFOUNDER**
> **CITIZENS COUNCIL FOR HEALTH FREEDOM**

"The Census Bureau is a tool for government surveillance, not only to monitor the public but to use the data gathered from so-called community surveys to drive policy and funding in whatever direction the sponsoring agency wants it to go," said Brase. "This can be in the opposite direction of where taxpayers and freedom-loving citizens want to go. As the Census has moved far beyond the simple 10-year census, the government is pushing to violate Americans' Fourth Amendment rights."

The CCHF recommends people not participate in this kind of data collection, says Brase.

"The power of government is police power," said Brase. "Data on individuals and groups can be used to harm Americans economically and personally. As I like to say, 'He who holds the data makes the rules.' Refusing to divulge details about your family and your home protects your freedom and your constitutional rights in a free society."

Ashley Bateman (**bateman.ae@googlemail.com**) *writes from Virginia. AnneMarie Schieber* (**amschieber@heartland.org**) *is the managing editor of* Health Care News.

FDA Wants to Fix Outdated Recall System

By Dvorah Richman

The U.S. Food and Drug Administration (FDA) recently announced a public "listening session" about "modernizing" its product recall system.

The FDA has the authority to recall drugs, medical devices, and foods for human or animal use, and cosmetics, biologics, and tobacco products. Considering the FDA's enforcement powers, which include criminal sanctions, most companies conduct voluntary recalls. The FDA can also request or mandate recalls.

FDA-regulated companies remove or correct marketed products that violate FDA rules and present a risk of injury, involve gross deception, or are otherwise defective according to standards in the Code of Federal Regulations.

Critics say the recall process is outdated, inefficient, and dangerously slow.

"It can take weeks or months for recall notices to get to the right people in a health care system, and notices may never arrive. There can be products in hospital inventory for up to two years after the product was recalled."

GUILLERMO RAMAS
CEO AND FOUNDER, NOTISPHERE

Drug and Medical Device Recalls

The first quarter of 2023 brought the most pharmaceutical recalls in a single quarter in the past 18 years, with 144 events, according to a Sedgwick's Recall Index report.

"The number of units impacted increased 1,071.8 [percent] to 49.5 million after an unusually low number of units were recalled in Q4 2022," states Sedgwick's news release on the report.

Deviation from good manufacturing practices was the most common reason for pharmaceutical recalls in 2022, Sedgwick states.

Medical device recalls increased by 4.6 percent in the first quarter of the year to 252 events. Sedgwick says manufacturing defects account for the greatest proportion of medical device recalls, and "quality concerns were the leading cause in terms of units impacted, with 68.5 million or 82.3% of all recalled devices."

One reason for the increases may be backlogs during the pandemic.

'A Time-Consuming Mess'

Significant medical device recalls associated with deaths and serious injuries include Allergan's breast implant products (2019), Medtronic's HeartWare ventricular assist device (2021), and Ethicon's power morcellators (2014; updated in 2023).

Drug recalls include Lupin Pharmaceutical's oral contraceptive Tydemy for insufficient amounts of vitamin C, which "may have reduced effectiveness" and "could result in unexpected pregnancy."

Diabetes drug Metformin has a history of recalls due to the presence of potential carcinogen N-nitrosodimethylamine. Metformin was recalled in 2023 by Teva Pharmaceuticals for the same reason.

"Recalls are a time-consuming mess," said Denise Armellini, M.D., an endocrinologist.

Armellini says she has never received a recall notice from generic Metformin manufacturers. To keep current, Armellini reviews medical websites for recalls, but "frantic patients" sometimes let her know first. After checking the FDA website, where the number of companies and batches can be daunting, she refers patients to their pharmacy for further help.

The FDA posts various recall databases, such as "recalls, market withdrawals, and safety alerts," enforcement reports, MedWatch, recalls and withdrawals of pet food and products, withdrawals of biologics, medical device safety, and recalls and alerts regarding cosmetics.

'Companies Should Not Wait'

Product recalls are generally complex, time-consuming, and expensive.

The FDA published Recall Guidance in 2022 to provide the industry with information about recall steps, including the identification of and response to product problems, recall communications, and the FDA's role in recalls.

Although it is somewhat helpful, the guidance doesn't address several critical issues, says Hans Beinke, an industry consultant and former vice president of Siemens Healthcare.

"Companies should not wait for the FDA to assess health hazards and risks but should perform their own such assessments in determining whether and how to conduct a recall," said Beinke.

'Extremely Inefficient and Slow'

Though problems have plagued the recall system for many years, the last 10 years have been much worse, says Guillermo Ramas, CEO and founder of NotiSphere, a software company that facilitates FDA-regulated recalls.

"The recall system employs practices from the 1970s, doesn't take advantage of modern technologies, and is extremely inefficient and slow," said Ramos. "This puts patients at great risk, costs recalling companies millions of dollars, and consumes thousands of hours of hospital time."

Problems have included lack of standardization, poor communication, reliance on mailed paper notifications, disorganized databases, difficulty identifying products and tracking them down, confusion about responsibilities, and users' failure to respond to recall notifications.

"Medical providers expend enormous effort reviewing thousands of alerts while 95 percent aren't relevant," said Ramas. "Multiple databases, notices, press releases, and safety alerts for the same recall add to the confusion."

Recalled Products Still in Use

Delays in communicating with customers and patients are common, says Ramas.

"It can take weeks or months for recall notices to get to the right people in a health care system, and notices may never arrive," said Ramas. "There can be products in hospital inventory for up to two years after the product was recalled."

The confusion directly impacts patients when recalled products continue to be used although they have been recalled. One ongoing recall nightmare is Philips Respironics' recall of 5.5 million sleep apnea and ventilator devices manufactured between 2009 and 2021.

Almost a year after Philips publicly initiated the recall, the FDA required Philips to notify all its customers, including patients and health care providers. The FDA said customers were unaware of the recall and the health risks of continuing to use the device, and the company's previous efforts were "inadequate."

Listening Session

The FDA said its listening session will provide "an opportunity for stakeholders to share information and feedback about topics related to recall modernization, for FDA-regulated products."

Discussion topics include general recall preparations and contingency planning; creating successful recall strategies; methods to reach underserved communities; initiating a recall; strategies for public warning, press releases, social media, and other communication tools; increasing the efficiency and effectiveness of recall information exchange; ensuring effective recalls; terminating a recall; and strategies for reducing recall recurrence for similar situations.

The FDA says its listening session will raise awareness and jump-start fixes that will benefit patients, medical providers, and industry.

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

Primary Care Practice Sues Michigan to Avoid Woke Statute

By AnneMarie Schieber

A direct primary care practice has filed an appeal in a federal lawsuit against Michigan Attorney General Dana Nessel over a new state law that forces the organization to use preferred pronouns and hire people who disagree with its religious mission.

Christian Healthcare Centers (CHC) opened in 2018 in Grand Rapids, Michigan as an alternative to traditional primary care, offering a direct-pay model that also addresses patients' spiritual needs.

The Alliance Defending Freedom (ADF) is representing CHC in the case, along with Sacred Heart of Jesus Parish in Grand Rapids, Michigan, which operates a Catholic school.

The ADF filed the notice of appeal for both cases in the U.S. Court of Appeals for the Sixth Circuit on August 23. A federal district court dismissed the original lawsuit on March 30.

Michigan's civil rights law was expanded this year to include "sexual orientation and gender identity." The law forces organizations to use preferred pronouns and, in CHC's case, prescribe cross-sex hormones. CHC says it treats all patients regardless of sexual preference and identity, but employees must share the organization's religious point of view and sign a statement to that effect.

'It's Unconstitutional'

"Christian Healthcare Centers serves everybody with compassionate care and respect, including patients who identify as the opposite of their biological sex, providing them with the same high-quality care it provides to all of its patients," said ADF Senior Counsel Hal Frampton in a press release. "Yet this lawsuit is necessary to protect Christian Healthcare Centers' constitutional rights and to ensure other religious organizations can freely operate according to the dictates of their faith."

"It's unconstitutional for the state to require that this Christian ministry abandon its faith principles in order to continue serving those in need," said John Bursch, vice president of appellate advocacy at the ADF.

The lawsuit is necessary to ensure the state does not take action against CHC or Sacred Heart, says Frampton.

"Christian Healthcare Centers is vulnerable to being punished under the new law in Michigan, which would keep the organization from helping clients and operating according to their religious beliefs. The threat they face is great and could result in significant criminal or civil penalties."

HAL FRAMPTON
SENIOR COUNSEL
ALLIANCE DEFENDING FREEDOM

"Christian Healthcare Centers is vulnerable to being punished under the new law in Michigan, which would keep the organization from helping clients and operating according to their religious beliefs," Frampton told *Health Care News*. "The threat they face is great and could result in significant criminal or civil penalties. No one should have to wait to be punished by the government to challenge an unconstitutional law."

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

INTERNET INFO

Christian Healthcare Centers, Inc. v. *Dana Nessel* et. al., U.S. District Court for the Western District of Michigan Southern Division, August 29, 2023: **https://adfmedialegalfiles.blob.core.windows.net/files/ChristianHealthcareCentersComplaint.pdf**

Michigan Considers Single-Payer Health Care System

By AnneMarie Schieber

Michigan lawmakers are attempting to set up a single-payer health care system that would provide medical, dental, and mental health care benefits without deductibles, copays, or premiums and promises to reimburse providers 25 percent more than current Medicare rates.

State Rep. Carrie Rheingans (D-Ann Arbor) introduced House Bill 4893 with 22 cosponsors. The big question under debate is who would pay for it.

Rheingans envisions a trust with funding from a variety of sources, including federal funds and state bonds, according to an article on the *State of Reform* website.

"We're hoping the federal administration will approve a Medicaid waiver to allow Medicaid funding to be used," said Rheingans.

For the first time in 40 years, Michigan Democrats have full control of both chambers and the governor's office. In 2018, during her first gubernatorial campaign, Gov. Gretchen Whitmer said single-payer health care is "unrealistic" but she supported the idea "in concept," news media reported at the time.

> **"Most of these proposals involve a payroll tax of about 10 percent, and what they find, repeatedly, is 10 percent is not enough. Not for what they want to do, which is often a Cadillac health plan at bargain basement prices."**
>
> **DEVON HERRICK**
> **HEALTH CARE ECONOMIST**

Money Problems

Between 2010 and 2019, 66 single-payer bills were proposed by legislators in 21 states, according to an article in the *University of Pennsylvania Law Review*.

Over the past two years, Washington and Oregon have been looking for ways to fund the implementation of their single-payer systems. Officials are still working on the problem.

Vermont pulled the plug on its single-payer plan in 2014 because it would have required an 11.5 percent increase in payroll taxes and a 9 percent increase in state income taxes.

Unrealistic Assumptions

If Obamacare were doing what it was promised to do—provide affordable access to health insurance regardless of preexisting conditions—states would have no need to push for single-payer systems, says Devon Herrick, a health care economist and policy advisor to The Heartland Institute, which publishes *Health Care News*.

"Progressives are lulled into this idea that they can do it better if only we had the power of government," said Herrick on *The Heartland Daily Podcast* on September 7. "Now they blame the insurance companies."

Herrick says the states typically go to the federal government first and ask to have full control of all the money the state receives for Medicare and Medicaid. States then approach employers asking for the same thing.

"And then they say, we'll decide what they'll get back," said Herrick. "Most of these proposals involve a payroll tax of about 10 percent, and what they find, repeatedly, is 10 percent is not enough. Not for what they want to do, which is often a Cadillac health plan at bargain basement prices."

Vermont dropped its single-payer system when tax rates had to be doubled. Colorado eventually voted down its single-payer proposal. In California, "it seemed like it was quietly dropped when it was discovered the health budget would have been triple the size of the entire state budget," said Herrick.

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

Dallas-Area Hospital Files for Bankruptcy Two Years After Opening

By Kenneth Artz

Trinity Regional Hospital Sachse (Texas) filed for bankruptcy just two years after opening.

The hospital, located about 26 miles northeast of Dallas, defaulted on $70 million of municipal bonds issued in 2020. Trinity Regional's owner listed assets of $50 million to $100 million and liabilities of $100 million to $500 million on its bankruptcy petition filed in late August.

The nonprofit, 32-bed hospital with surgical services, an emergency department, and both inpatient and outpatient care is the most recent to file for bankruptcy, joining five other hospitals around the country that filed earlier this year.

Looking to Sell

Trinity Regional is still open and operating with the same quality of care as when it started and aims to find a buyer, says Jon Nash, chief restructuring officer for the hospital.

"There is nothing bad or wrong about this hospital," said Nash. "It's a beautiful facility with state-of-the-art equipment throughout. It's in a bedroom community with a population that is growing quickly. It just started without an appropriate amount of start-up capital and a good strategy."

Problems with the COVID-19 lockdowns, construction costs, and hospital personnel working remotely contributed to the financial difficulties leading to the bankruptcy, says Nash.

"We have filed a motion for the sale to proceed," said Nash. "Anyone is welcome to make an offer—we're selling all the assets free and clear of any liens and encumbrances."

Rural Hospitals Closing

Many hospitals will never be able to recover from their pandemic financial losses, and that will cause a big spike in hospital bankruptcies, says Natalie Schibell, M.P.H., vice president of product marketing at Zyter|TruCare and a former vice president and research director at Forrester Research.

In a Forrester Research report, Schibell states more than 30 percent of all rural hospitals are at immediate risk of shutting down because of low financial reserves and reliance on government aid.

Schibell told MedCityNews there is a lot of risk in rural areas, where closures accelerated in the 2000s.

"[S]ince 2013, we've seen 100 rural hospital closures," Schibell said. "There's just low patient volume in those areas. And people are now traveling further to hospitals, because many of them have closed down."

'Difficult to Thrive'

Though the COVID-19 pandemic has ended, smaller hospitals are still at risk, and larger independent hospitals in urban areas face challenges of their own, says Nash.

"Larger systems will continue to grow because they have the funds to weather any storms," said Nash.

Nash says these hospitals' financial troubles result from a bevy of problems outside their purview.

"Health care is becoming an ever-increasing portion of [gross domestic product], and our Byzantine regulations that create impenetrable layers of bureaucracy make it difficult to thrive in any part of the health care system," said Nash. "The problems are so complex; I really don't see a solution."

'Investors Making Bad Decisions'

It is widely reported and agreed that the management of Trinity Regional Hospital made several missteps in the hospital's development and opening, says Merrill Matthews, Ph.D., a resident scholar at the Institute for Policy Innovation.

"Among its challenges, pandemic-related construction costs exploded and supply-chain snarls also hindered its completion, but also [it] initially failed to meet some hospital-related building codes," said Matthews. "With Sachse being so close to Dallas and its major suburbs, it was difficult to recruit physicians who would bring in the needed patients, even as labor and borrowing costs were rising."

In addition to the normal obstacles to provision of health care in rural areas, Trinity Regional had difficulties of its own making, says Matthews.

"While rural hospitals are facing a number of challenges, including low Medicare and Medicaid reimbursements and numerous federal mandates increasing costs—such as requiring a fully equipped emergency room that may see very few patients—Trinity's failure may be more of a case of investors making bad decisions and paying a financial price for it," said Matthews.

Plans Went Awry

Trinity Regional's bankruptcy was a perfect storm of bad timing and poor planning, says Devon Herrick, a health economist and policy advisor to The Heartland Institute, which publishes *Health Care News*.

"The project was initiated in 2020 during COVID, a pandemic tsunami that pushed many hospitals into the red," said Herrick. "After COVID let up and the hospital opened, it faced the problems of inflation, supply chain bottlenecks, and higher labor costs. It also had trouble recruiting doctors. … Trinity had planned to expand the campus with medical office buildings at a later date, which is where physicians would have [had] their offices."

The hospital faced a litany of other problems, including high interest rates on the bonds it used to finance the facility and the high cost of leasing the land underneath (purportedly $2 million a year), says Herrick.

"It was also rather small for a hospital—only 32 beds," said Herrick.

Doomed by Poor Start

Trinity Regional also had construction delays and some licensure problems that prevented it from treating those covered by Medicare and Medicaid when it first opened. Also, its intensive care unit was not operational initially and had to be reconfigured and renovated later, losing months of valuable time, says Herrick.

"The restructuring officer, whose job it is to get the facility ready for sale, claimed its launch was poorly planned and lacked a coherent operational and startup strategy," said Herrick. "Trinity had positioned itself in a fast-growing region northeast of the Dallas metro area. While [that is] a good long-term strategy, it didn't help keep it afloat in the short term."

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

"The restructuring officer, whose job it is to get the facility ready for sale, claimed its launch was poorly planned and lacked a coherent operational and startup strategy. Trinity had positioned itself in a fast-growing region northeast of the Dallas metro area. While [that is] a good long-term strategy, it didn't help keep it afloat in the short term."

DEVON HERRICK
HEALTH CARE ECONOMIST

Slowdown in Medicare Spending—Real or Imagined?

By Kevin Stone

Medicare spending since 2011 has fallen below Congressional Budget Office (CBO) estimates, sparking debate over what it means for future costs.

The New York Times (NYT) ran articles on September 4 and 9 suggesting Obamacare (ACA), Medicare Part D drug coverage, enrollment of younger baby boomers, COVID-19, and the decline in cigarette smoking as reasons for the decrease.

Eugene Steuerle, an economist at the Urban Institute, says the explanation is simple: the CBO estimates were wrong.

"The type of measure used by most government and academic researchers suggests that if health costs stay at [the same] share of [gross domestic product] … there is no 'excess' cost growth because health costs now are growing no faster than GDP," Steuerle wrote in a September 20 article on his website, *The Government We Deserve*. "That's wacky!"

'Competition Works'

John C. Goodman, president and CEO of the Goodman Institute for Public Policy Research and co-publisher of *Health Care News*, leans heavily toward the emergence of Medicare Advantage (MA) plans as the primary causative factor.

"It appears that the Medicare Advantage program, where seniors enroll in plans that look like garden-variety employer plans, controls costs much better than traditional Medicare," said Goodman. "The fact that half of all seniors are now enrolled in Medicare Advantage plans may explain why there has been a slowdown in Medicare costs over the past decade."

David Cutler, an economics professor at Harvard University, says the competition introduced by reforms has improved the quality and reduced the cost of Medicare.

"The private plans have expanded case management care coordination and a strong emphasis on preventive care," said Cutler. "Not only has care quality increased, but the private plans have demonstrated repeatedly an ability to provide standard Medicare benefits well below the cost of traditional Medicare. Competition works."

'Nobody Knows What Will Happen'

Cutler says Medicare spending will probably continue to grow but at a slower rate of increase.

"We should always be worried about stuff we don't fully understand or control," said Cutler. "But I think the old era of very rapid cost increases relative to the economy may not apply any longer. We are better at targeting cost savings than we used to be. That's good; it represents economic and medical progress.

"CBO assumes the older growth rate will reassert itself," said Cutler. "My guess is that they are too high in their cost forecast, but I stress the word 'guess.' Nobody knows what will happen in the future, so there is no way to say for sure that any single forecast will be off."

"The current projections include a major acceleration of Medicare enrollment, especially over the next 10 years, accompanied by a doubling of Medicare spending from roughly $1 trillion to nearly $2 trillion, imposing higher financial burdens on beneficiaries and taxpayers alike, while aggravating record federal deficits and dangerous debt. By 2040, Medicare spending will consume nearly 27 percent of all federal business and income taxes. So, any notion that Medicare's financial issues are a thing of the past is akin to breaking diplomatic relations with reality."

ROBERT E. MOFFIT
SENIOR RESEARCH FELLOW, THE HERITAGE FOUNDATION

'A Doubling of Medicare Spending'

Focusing on past projections may be unwise, says Robert E. Moffit, a senior research fellow at the Center for Health and Welfare Policy at The Heritage Foundation and coeditor of a book titled *Modernizing Medicare*.

"As your financial advisor warns, past performance is no guarantee of future results," said Moffit. "To their credit, CBO analysts routinely warn that their health care projections are highly uncertain, given the dynamism of the health sector of the economy. Today's policymakers, however, should not be focused on previous projections, but rather current projections of the CBO and especially the Medicare trustees."

The CBO's current projections of future Medicare spending are alarming, says Moffit.

"The current projections include a major acceleration of Medicare enrollment, especially over the next 10 years, accompanied by a doubling of Medicare spending from roughly $1 trillion to nearly $2 trillion, imposing higher financial burdens on beneficiaries and taxpayers alike, while aggravating record federal deficits and dangerous debt," said Moffit.

"By 2040, Medicare spending will consume nearly 27 percent of all federal business and income taxes," said Moffit. "So, any notion that Medicare's financial issues are a thing of the past is akin to breaking diplomatic relations with reality."

'Unacceptable Loss of Access'

The Medicare actuaries' reports show reasons to be concerned about the future trajectory of Medicare spending, says Joseph Antos, a senior fellow in health care policy at the American Enterprise Institute.

"Twelve years of reports from the Medicare actuaries point out that current policy is not sustainable," said Antos.

Thus far the government's plan to reduce Medicare spending is to cut the pay of doctors and health care systems, which will cause even more providers to stop accepting Medicare patients, says Antos.

"Automatic payment cuts under current law will lead to [an] unacceptable loss of access to care," said Antos. "Congress has been deferring some of those cuts already, and there's pressure from providers to provide more funds. That won't lead to a more efficient delivery system, just more spending.

"Medicare Advantage can lead to efficiencies, but [what] we pay [MA providers is] tied to traditional Medicare, so the savings to the taxpayer are reduced," said Antos.

'Unsustainable Fiscal Path'

As for the reasons cited in the *Times* article, Antos says Medicare spending did fall during the COVID lockdown and seniors are healthier than in years past, helped by reduced smoking rates, but that doesn't mean they will consume less health care in the coming years.

"Rather than dying relatively young from lung cancer, more people will live longer and incur other medical expenses," said Antos. "[Also], we do too many diagnostic tests, which can lead to unnecessary treatments.

"We're still spending a greater share of GDP on health care than any other country," said Antos. "The recent lull should not be an excuse to add more benefits to Medicare, which is on an unsustainable fiscal path."

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

Dove Soap Celebrates Obesity

By Ashley Bateman

Dove Soap, a brand Unilever markets as a "real life version of beauty," has launched a fat liberation campaign and is teaming up with a 22-year-old woman who amply fits the bill.

Zyahna Bryant, a woman who defends living in a "fat body" and is known for her Black Lives Matter activism, announced the endeavor with Dove on her Instagram page.

New Dove Soap brand ambassador Zyahna Bryant (on right), talked to the people in attendance on August 8, 2020 in Charlottesville, Virginia.

PHOTO COURTESY EZE AMOS/STRINGER/GETTYIMAGES

Big Problem

The news comes as more reports affirm obesity is a growing problem in the United States, particularly among certain racial, ethnic, and geographic groups. Obesity is defined as having a body-mass index (BMI) number exceeding 30.

According to a report from the Centers for Disease Control and Prevention (CDC), all U.S. states and territories have obesity prevalences higher than 20 percent (one in five adults). Black adults with BMIs over 35 were prevalent in 38 states, the highest number for all racial groups.

An article published on September 19 in the *Journal of the American Heart Association* looked at 281,135 obesity-related cardiovascular deaths between 1999 and 2020 and found age-adjusted mortality rates increased by a factor of three in the group of black adults with the highest incidence of obesity during that period.

The CDC says people who are overweight or obese are at increased risk for all-cause morbidity.

'Neither Kind Nor Compassionate'

The partnership with Bryant is only one facet of Dove's efforts. A page on Dove's website encourages consumers to sign a petition for the Campaign for Size Freedom and announces a partnership with the National Association to Advance Fat Acceptance and the Fat Legal, Advocacy, Rights and Education Project.

"Join us to make body size discrimination illegal in the U.S.," the website states. "Body size discrimination has a devastating impact on body confidence, and all areas of life." The website offers no information on ways to combat excessive weight through diet and exercise.

The CDC encourages the use of terms such as "adults with obesity" instead of "obese adults."

Obesity is more than a body confidence issue, says Chad Savage, M.D., president of DPC Action and a policy advisor to The Heartland Institute, which publishes *Health Care News*.

"Despite the appropriate desire to be polite and kind to people with a variety of medical disorders, attempts to celebrate and glamorize morbid obesity are neither kind nor compassionate," said Savage. "They support behaviors that can lead to the destruction of that person's joints, leading to a loss of mobility, crippling strokes, devastating heart attacks, certain cancers, severe respiratory conditions such as obesity hypoventilation, and premature death."

'Institutionalized and Celebrated Unhealthiness'

It is important to note that obesity is one of the biggest cost drivers in health care, says Eric Novak, M.D., an orthopedic surgeon in Arizona.

"We have abandoned the role of personal responsibility for maintaining and addressing our health needs," said Novak. "All the fancy health plan designs in the world will do little in the face of institutionalized and celebrated unhealthiness, but it will funnel trillions [of dollars] to people whose job it is to maintain the fiction that much of health costs little, … so the healthy massive supermajority is willing to massively overpay to inefficiently subsidize the 5 percent of people who spend half of all health care dollars."

Dove's campaign is by no means unique, with multiple companies featuring obese models in advertisements in recent years.

"Though we should all behave with kindness and compassion toward people who struggle with weight issues, it is not truly compassionate to support the behaviors of someone you love in their own self-destruction," said Savage.

'Americans Inherently Understand'

It is encouraging that people still spend a great deal of money on gym memberships, supplements, and weight-loss programs, indicating they recognize the health risks or don't find obesity attractive, says Savage.

"Despite the attempts to glamorize obesity, the overwhelming demand by the populace for blockbuster weight-loss drugs such as Wegovy indicates that Americans inherently understand this," Savage said.

Wegovy is a prescription drug approved by the Food and Drug Administration in 2021 for those with a BMI of 30 or greater, or 27 or greater with other health problems.

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

"Despite the appropriate desire to be polite and kind to people with a variety of medical disorders, attempts to celebrate and glamorize morbid obesity are neither kind nor compassionate. They support behaviors that can lead to the destruction of that person's joints, leading to a loss of mobility, crippling strokes, devastating heart attacks, certain cancers, severe respiratory conditions such as obesity hypoventilation, and premature death."

CHAD SAVAGE, M.D.
PRESIDENT, DPC ACTION

Whole Foods Founder Launches 'Cash-Only' Health Care Company

By Ashley Bateman

John Mackey, well-known as the founder of Whole Foods, has launched a new health care company called Love.Life.

In July 2023, Mackey sent out a promotional letter describing the initiative as "an integrated health and wellness company that makes lasting health and longevity attainable."

The company promises an "integrated care team," of doctor, nutritionist, and health coach; an investigative "root cause" approach; customizable labs; and advanced genetic testing to tailor nutrition.

John Mackey
Founder
Whole Foods

PHOTO COURTESY GAGE SKIDMORE/FLICKR.COM

'Cash-Only' Direct-Pay System

The company's website lists 10 available doctors, with combined licensure across all 50 states.

Love.Life is a "cash-pay only" service. A single, 60-minute new-patient visit costs $350, with the same cost for a 60-minute follow-up.

Patients can sign up for a membership under the company's Healthy Lifestyle Program at $175 per month plus lab tests, or the Longevity Plan designed for individuals with existing health problems, at $499 per month. The most comprehensive plan, the Concierge Program, promises to look at "every facet of health." That cost is not listed.

Love.Life will file insurance claims but doesn't guarantee reimbursement, its website states.

A monthly Love.Life Telehealth newsletter including physician commentary, webinar schedules, testimonials, recipes, and other news is available for free subscription via email.

Testimonials on the site emphasize compassionate, individualized care by highly competent physicians, with cutting-edge testing within a holistic approach to health care that includes a plant-based diet.

Entrepreneurship, Innovation

Well-known entrepreneurs continue to move into the health market space as overbooked practitioners, care shortages, high insurance costs, and general dissatisfaction with the primary care system increasingly plague the industry. Ventures by Amazon and Mark Cuban are two recent examples.

None has followed the "health mecca" vision Mackey is rolling out. Virtual health initiatives are half of the strategy. The other half focuses on physical locations with health food restaurants, medical centers, gyms, and other restorative and wellness treatments such as acupuncture, infrared saunas, and physical therapy, Mackey said in an interview posted on the Fast Company website in July.

Cure for Chronic Spending

Mackey's vision for better wellness began as a flagship effort around 15 years ago, in response to excessive spending on chronic illness among Whole Foods employees.

"About 80 percent of health care spending is on 20 percent of the population," said Devon Herrick, a health economist and policy advisor to The Heartland Institute, which publishes *Health Care News*. "John Mackey found at Whole Foods it was more like 90/10, where 10 percent of employees with chronic diseases accounted for 90 percent of Whole Foods' health care spending."

In response to this imbalance, Mackey's former company sent 4,000 employees through Total Health Immersion, a program that harnessed lifestyle practices to manage chronic disease.

"Mackey was amazed at the results and wants to bring a similar program to people interested in leading healthier lives," Herrick said. "It will be interesting to watch how the company grows."

Employee Resistance

Although Whole Foods' Total Health Immersion program was deemed largely successful, lifestyle makeovers have not proven very effective in many corporations, says Herrick.

"One problem with corporate chronic disease management programs is the unhealthy employees are the least likely to participate, while the healthy workers are already doing what they're supposed to," said Herrick.

'Direct' Approach on Rise

The Mackey approach has elements of direct primary care (DPC), which has been tailoring health care to individuals for years and remains one of very few free-market ideas in practice in the industry today, having experienced rapid growth. DPC is "cash pay only," and its hallmark is affordability. The usual fee is about $100 a month.

"Expansion of DPC practices is happening continuously," said Lee Gross, M.D., president of the Docs 4 Patient Care Foundation. "On the linear level, we're seeing steady growth. In 2010, maybe there were a dozen of us. Now there are thousands, with clinics launching every single day, in many states with legislative protection."

DPC expansion is being led by consumer demand, not corporations' interests, says Gross.

"I love that there's so much innovation offered in the space. I'm glad they're developing a program. Their prices are above the price point most people can afford, but that doesn't mean they don't have value and shouldn't exist. That's the beauty of the free market."

LEE GROSS, M.D.
PRESIDENT
DOCS 4 PATIENT CARE FOUNDATION

"It's getting harder and harder for people who want traditional, personalized care [to find it]," said Gross. "The growth is there, and the interest is there—that's why DPCs are thriving."

Whereas a traditional third-party payer practice needs 2,000 patients just to keep the lights on, DPCs need only about 300 to turn a profit, says Gross.

Care Combination

Love.Life also offers telehealth visits with top doctors. It's important for DPC providers to offer in-person visits as well, as Love.Life does, says Gross.

"Telemedicine is part of the practice of direct primary care, but it's not the sole practice," said Gross. "Direct primary care physicians could do house calls, parking lot visits, telehealth, or in-office during the pandemic. It's the combination of all those things that is the perfect balance: convenience and technology, with the old-fashioned touch of physical touch.

"The continuity is also critical," said Gross. "For management of chronic disease and knowing the patient's complex social situation, it's so important to develop a relationship with patients."

Despite its higher cost than conventional DPC, Mackey's venture is a welcome addition to a dysfunctional market, says Gross.

"I love that there's so much innovation offered in the space," said Gross. "I'm glad they're developing a program. Their prices are above the price point most people can afford, but that doesn't mean they don't have value and shouldn't exist. That's the beauty of the free market."

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

COMMENTARY

Are HSAs in Obamacare Plans Designed to Fail?

By Joel White

Democrats decry health savings accounts (HSA) as a tax haven for the rich that provides coverage that is unaffordable to average Americans.

Many Democrats specifically target the HSA requirement that the health insurance accompanying the HSA has a minimum deductible—currently set at $1,500 in 2023—as burdensome on the middle class and poor. They say it is difficult, if not impossible, for low-income families to put away several hundred dollars a month in an HSA to finance their out-of-pocket costs.

Dispute Over Deductibles

U.S. Rep. Lloyd Doggett (D-TX), ranking member of the Health Subcommittee on Ways and Means, put it clearly.

"There are data showing that the majority of U.S. households have less than $3,000 in their checking and savings accounts, but the average deductible for an HSA is about $2,500," said Doggett. "So, for many who have an HSA, an emergency can still wipe out families' savings. ... Having an account doesn't mean you have much—or any—money in it."

Doggett's solution? Everyone should get an Obamacare plan or a new government-run health policy.

There's just one problem: average deductibles on Obamacare's exchanges are $2,000 more for the typical plan than the HSA average.

Government to the Rescue?

Pursuing an agenda to put more people in a program where they pay more (and get less access to doctors and drugs) isn't compassionate—it is dogmatic adherence to ideology.

HSAs have been a staple of the health plan market for 20 years, with about 35 million accounts covering 67 million people. The average account holds $3,725, far from being a tax haven for the wealthy but enough to pay for a typical plan's deductible. Seventy-eight percent of health savings account holders have a household income of less than $100,000.

But no matter your income, high deductibles are coming for all Americans. The question is, will Congress help all HSA account owners with smart policies that allow people to use tax-free dollars to pay for their health coverage obligations? Congress could pursue several ideas.

> **"There are data showing that the majority of U.S. households have less than $3,000 in their checking and savings accounts, but the average deductible for an HSA is about $2,500. So, for many who have an HSA, an emergency can still wipe out families' savings."**
>
> U.S. REP. LLOYD DOGGETT (D-TX)

Options to Modernize HSAs

The first option is to reform the outdated rules on deductibles. The point of having a deductible is to encourage insured people to be more careful in accessing care. In practice, high-deductible health plans may discourage access to predictable, necessary care, such as insulin for diabetics, as costs may be front-loaded and unaffordable.

Congress should amend the 20-year-old rules that set minimum HSA deductibles ($1,500 in 2023) by separating the HSA from the high-deductible health plan requirement. If a plan provides a minimum value (70 percent paid in medical claims, for example), the plan should be able to escape the minimum deductible requirement. Plans could provide zero-dollar coverage for preventive care, insulin, telehealth services, and so on.

Another option Congress should pursue is creating new gig-worker HSAs by allowing multiple employers (DoorDash, Walmart, etc.) to deposit funds into an HSA, and allow the gig worker to buy an individual policy without triggering reclassification as an employee. This helps the millions of gig workers who may go without coverage because they are ineligible for a full-time employee plan.

Additionally, Congress should provide HSA options for people who qualify for Medicaid, Indian Health Service, or Veterans Affairs benefits, including a government deposit to help with out-of-pocket costs. For low-income people, Congress should allow government subsidies to be deposited into new HOPE accounts if patients engage in value-based care arrangements, such as the Healthy Indiana Plan that rewards Medicaid enrollees for taking better care of their health.

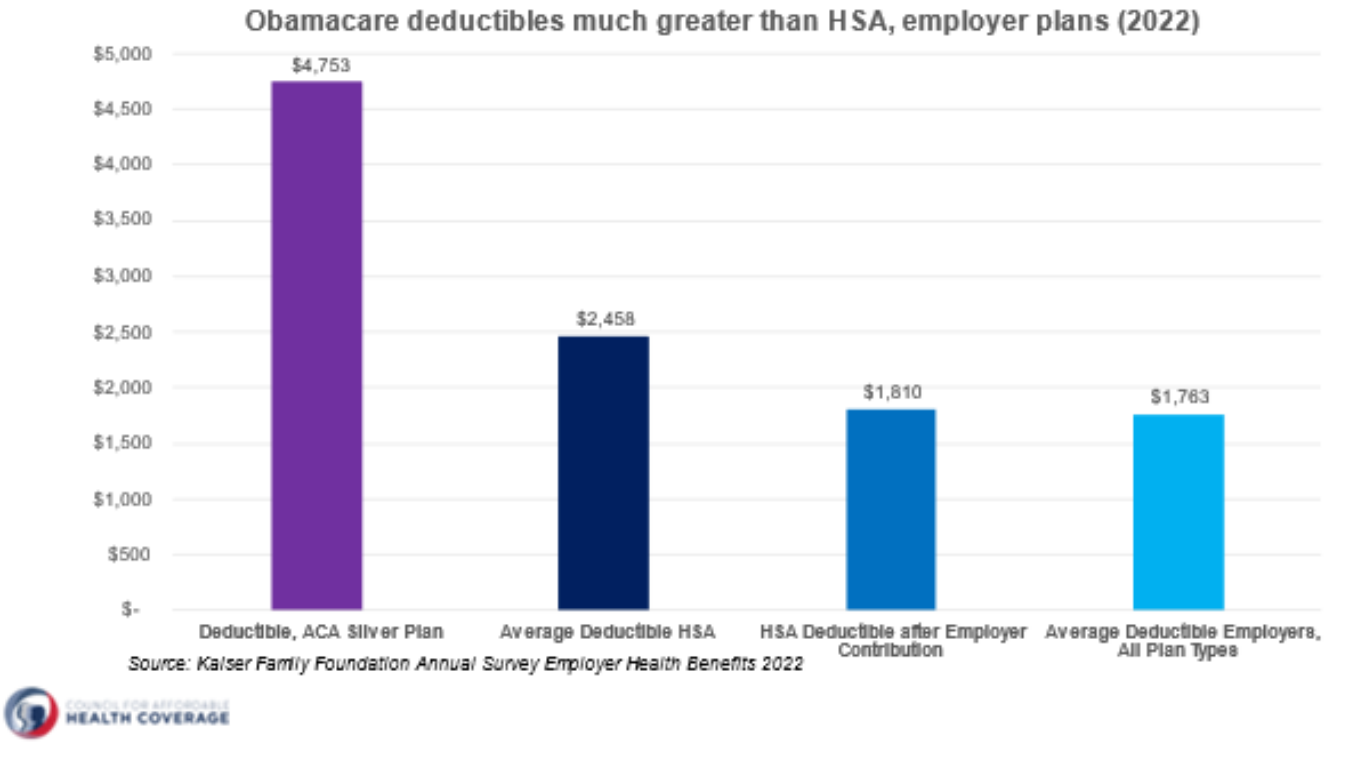
Choice or Compulsion

The health care coverage and funding system in this country is a hybrid consisting of a wide range of funding sources: the federal government, state funding, unions, large and small employers, and ultimately individuals through premiums or tax dollars.

Some argue the government (i.e., taxpayers) should be the only source of funding and the only choice. Others want to build on options for the individual, employers, and those who don't want to be forced into a government model. That means building on the "choice" model that has worked to provide coverage for 90 percent of Americans in Medicare and employer coverage.

Now, with tens of millions of Americans benefiting, Democrats should decide whether they want to support people where they are with what they have or force them into a program where they will pay more.

Joel White ***(jwhite@horizondc.com)*** *is president of the Council for Affordable Health Coverage. An earlier version of this article appeared at* RealClearPolicy. *Reprinted with permission.*



COMMENTARY

Obamacare's Dirty Little Secret

By John C. Goodman and Beverly Gossage

When the Affordable Care Act passed in 2010, President Barack Obama and virtually every Democrat in Congress repeatedly made the same argument: the act would make good health insurance at affordable premiums available to people with preexisting conditions.

Now, suppose at the same time advocates were making this argument in public, there was an evil genie back in the congressional Legislative Counsel's Office. The genie's assignment: create a plan that makes health insurance as good as possible for the healthy and as bad as possible for the sick.

We don't think there really was an evil genie. But the law looks like it was designed by one.

If you must buy your own health insurance in America today, have an average income and never get sick, your options have never been better. But if you have a serious health problem, your options have never been worse.

Former President Barack Obama

PHOTO COURTESY GAGE SKIDMORE/FLICKR.COM

"In the last two sessions of Congress, Democrats had an opportunity to reverse some of the worst aspects of Obamacare. Instead, $30 billion of new 'enhanced subsidies' will make health insurance cheaper for healthy people making as much as several hundred thousand dollars a year."

JOHN C. GOODMAN, PH.D.
PRESIDENT AND FOUNDER
GOODMAN INSTITUTE FOR PUBLIC POLICY RESEARCH

BEVERLY GOSSAGE
PRESIDENT
HSA BENEFITS CONSULTING

Favoritism for the Healthy

According to President Joe Biden, health insurance is free or almost free ($10 a month or less) for 80 percent of people who acquire it in an Obamacare exchange. Plus, preventive medicine (the only kind of care healthy people require) is also free.

If you are sick, things are different. Take a middle-aged couple in Dallas, Texas earning $70,000 a year, with two children who have significant disabilities. Though this family will pay no premium for a Blue Cross bronze plan in the Obamacare exchange, they will face a $9,100 deductible for each child. Their total out-of-pocket exposure is $18,200—every year.

If the family doesn't qualify for a subsidy (because of high income or some other reason), they will face an annual premium of $12,312. All told, health care for this family, according to HealthCare.Gov, will cost $30,512 every year!

'Skinny Networks'

It gets worse. Patients with special needs often require the care of highly trained specialists who often work at centers of excellence. Our Dallas family will discover their Blue Cross Obamacare plan is not accepted at the University of Texas Health Science Center—one of the top medical centers in the whole country. Nor will it be accepted at MD Anderson Cancer Center in Houston.

When a patient with Obamacare coverage goes out of network, the plan usually pays nothing, and the cost does not apply to the deductible or out-of-pocket maximum.

In addition, Obamacare imposes an implicit tax on the earned income of the sick. Suppose our Dallas family earned only $60,000. Their children would qualify for the Children's Health Insurance Program (CHIP), and HealthCare.gov says they would not be allowed into a private exchange plan. The parents could select a plan with a zero premium and, staying healthy, would have no out-of-pocket expenses.

Penalties for Earning More

So, the penalty for earning an extra $10,000 of income is $18,200 of higher medical costs—even after Obamacare's subsidy. That's a marginal tax rate of 182 percent!

Even with the children on CHIP, the parents could have their own serious medical problems. If they do, they will be punished for every extra dollar they earn. At an income, say, of $30,000, the best option is a silver plan with a small premium and deductible. But if their income doubles, rising to $60,000, their out-of-pocket exposure will increase by $14,500. That's an implicit marginal tax rate of 38 percent, on top of all the other taxes they pay.

Special-Interest Benefits

One thing is clear. Obamacare plans are trying to attract the healthy and avoid the sick.

Healthy people tend to buy on premium alone and ignore all other features of a health plan. So, when premiums are set so low the enrollee pays nothing, the plan will attract enrollees who cost almost nothing (because they seldom use medical services). But they will generate government subsidies worth thousands of dollars to large insurance companies.

By contrast, sick enrollees are potentially financial losers. High deductibles and narrow provider networks deter the sick, who are very much guided by these plan features. If a sick potential enrollee chooses a competitor's plan, so much the better.

If you wonder why Obamacare was designed this way, start with the fact it wasn't designed by President Obama or by the Democratic leadership in Congress. It was designed by special interests.

Insurance Company Bonanza

Obamacare has been pouring about $60 billion a year in new money into the health care system, lining the pockets of insurance companies, hospitals, and some doctors—although it doesn't appear there has been any overall increase in the amount of health care being delivered.

Actual patients had no say in any of this.

There is no question most people with serious health problems who must buy their own coverage would be much better off in the pre-Obamacare health care system—in just about every state.

In Texas, there was a risk pool for folks who delayed buying a plan until they really needed one. Premiums were twice what others were paying, but much less than Obamacare premiums are today. Subsidies were available for low-income buyers. A typical offering was a standard Blue Cross plan with reasonable deductibles and generous networks.

In the last two sessions of Congress, Democrats had an opportunity to reverse some of the worst aspects of Obamacare. Instead, $30 billion of new "enhanced subsidies" will make health insurance cheaper for healthy people making as much as several hundred thousand dollars a year.

John C. Goodman, Ph.D. (**johngoodman@goodmaninstitute.org**) *is co-publisher of* Health Care News *and president and founder of the Goodman Institute for Public Policy Research. Beverly Gossage* (**beverly@hsabenefitsconsulting.com**) *is president of HSA Benefits Consulting and a state senator in Kansas.* *An earlier version of this article appeared in* The Wall Street Journal. *Reprinted with permission.*

COMMENTARY

Doctors Are Using People Declared Brain Dead as Lab Rats

By Heidi Klessig, M.D.

Doctors at the University of Alabama at Birmingham and the NYU Langone Transplant Institute in New York City reported successfully implanting genetically modified pig kidneys into two "brain dead" men in August.

The New York patient, a 57-year-old man, has demonstrated continuous kidney function for over a month, the longest time that a gene-edited pig kidney has functioned successfully in a human. The team planned to observe the patient's kidney functioning through mid-September, during which time he would be provided with cardiopulmonary support in a critical care setting.

In Alabama, a 52-year-old man with both brain death and renal failure underwent removal of his kidneys and was implanted with a pig kidney that had received 10 genetic modifications. In contrast to last year's results (in which a xenograft kidney placed into a brain-dead person failed to function properly), Jayme Locke, M.D. and her team reported that this time the xenograft kidney functioned well for the full seven-day study period, which included daily kidney biopsies.

"These xenografts not only made urine, but they cleared ... toxins and maintained normal renal function, and really, stability in this model for a full seven days," said Locke in a video. "And, in fact, at study completion, the kidneys were still working."

Experiments Without Consent

Medical ethicists are less impressed. Joel Zivot, M.D., discussed the importance of establishing "a bright line between life and death," in an opinion piece for *MedPage Today*.

"Death is the permanent absence of the signs of life. Permanence remains a problem in the case of 'brain death' as we can't know the durability of the state of death until it proves itself durable. Mistakes have been made in determining death."

JOEL ZIVOT, M.D.

"Broadly, the rightness or wrongness of this type of procedure [is] the consequence of a series of moral choices, thus far unreported and unexamined, and include[s] the problems of brain death, human experimentation, consent, rationing, and animal rights," writes Zivot.

The concept of brain death has turned people into resources, commodities to be used for the valuable vital organs they possess, Zivot argues. Most people are not receiving a real informed consent opportunity when they selflessly sign a donor card at the Department of Motor Vehicles; they have no idea that they can be considered dead while they are still breathing and have a beating heart.

They also are unaware that doctors currently are not following the legal definition of death by neurologic criteria under the Uniform Determination of Death Act (or UDDA, some form of which has been passed into law by all 50 states).

Loosened Standards

Although the UDDA requires "cessation of all functions of the entire brain, including the brainstem" for a diagnosis of brain death, doctors now generally follow the 2010 American Academy of Neurology Guidelines, which require only documentation of coma, a bedside test of brainstem reflexes, and an apnea test. No other special studies of "the entire brain" are required.

"Death is the permanent absence of the signs of life," writes Zivot. "Permanence remains a problem in the case of 'brain death' as we can't know the durability of the state of death until it proves itself durable. Mistakes have been made in determining death. ...

"Brain death determination continues to have uncertainty," writes Zivot. "It is conceivable that a tiny remnant of brain function may elude detection. As functional brain imaging advances, we will likely detect brain activity we thought absent. How comfortable are we with the possibility that some deep brain function might still be present in those we call brain-dead?"

Respecting the Dead?

In 2008, the President's Council on Bioethics published a white paper on "Controversies in the Determination of Death." The Council justified continuing the neurological standard for brain death because of strong moral convictions about the respect owed to the newly dead.

However, the two "brain dead" men discussed above are receiving no such respect. The patients are being maintained on ventilators as xenograft hosts until the experiment is terminated and they are sacrificed for pathological examination. It is very unlikely that these men were given the chance to consent to this treatment.

"Current advance directives contain no language for such postmortem wishes," writes Zivot. "Individuals may sign up to be organ donors in advance of death, but donating one's entire brain-dead body to host a xenograft transplant is without clear precedent. ... Brain death, as a criterion for death, must constantly reflect what is known and justify why the possibility of a wrong brain death diagnosis can be set aside if a xenograft experiment, or any other experiment, is at stake."

The best possible outcome might be that some of these "brain dead" people now being used as xenograft hosts would demonstrate neurological improvement during the time they are being given top-flight ICU care as medical test subjects.

The diagnosis of brain death is usually a self-fulfilling prophecy, with these unfortunate people either quickly becoming organ donors or having their medical support withdrawn. More and more people, however, such as Zack Dunlap, Jahi McMath, Taylor Hale, Trenton McKinley, and others, are proving doctors wrong about their brain death diagnoses.

These "brain death" survivors prove that this diagnosis can be made in error and that using these people for medical experimentation is ethically unjustified.

*Heidi Klessig, M.D. (***semper25reformanda@gmail.com***) is a retired anesthesiologist and pain management specialist. A version of this article appeared in* American Thinker. *Reprinted with permission.*

Move to Change Clinical Death Definition Cancelled

By AnneMarie Schieber

The Uniform Law Commission (ULC) has postponed indefinitely an effort to revise the Uniform Determination of Death Act (rUDDA) to give hospitals and doctors more leeway in declaring patients clinically dead.

"In consultation with ULC leadership, and based on feedback from the first reading and our efforts to date, we have decided to pause the rUDDA effort," said Committee Chair Samuel Thumma, Committee Vice Chair Eric Weeks, and Committee Reporter Nita Farahany in an email to participants.

"The result of this pause is that, although we will continue to hope mid-level principles will become apparent, no further drafting committee meetings will be scheduled at this time," the group said. "We will continue to monitor developments in this area, and if we see promising signs of a possible path forward toward a widely enactable revised act, we can then reassess having the committee resume its work."

The ULC, a nonprofit organization that drafts model legislation for legislatures, grappled with the issue at its annual meeting in July. Commissioners considered changing the word "irreversible" to "permanent" in determining the cessation of circulatory or respiratory functions and using the phrase "permanent coma, cessation of spontaneous respiratory functions, and loss of brainstem reflexes" in place of "all functions of the entire brain."

Concerns About Publicity

"During the ULC meetings, 'publicity' was one of the reasons that kept coming up to explain the trouble they were having in coming to a consensus," said Heidi Klessig, M.D., a retired anesthesiologist who works with respectforhumanlife.com (see related article, opposite page) and is author of the upcoming book *The Brain Death Fallacy*.

Several organizations, including National Right to Life and The Arc, filed statements opposing the change. A primary concern has been the growth in the organ procurement industry. Patients must be alive for hospitals to be able to harvest organs such as the heart or lungs.

The decision to leave the UDDA unchanged is welcome news to Julie Grimstad, vice president of the Healthcare Advocacy and Leadership Organization and grandmother of a young man who recovered from a comatose condition after a car accident.

"Josh is now home with his family (mom, dad, and nine younger brothers and sisters), getting around in a power chair, communicating with eye-gaze technology, and going to neuro-physical rehab five days a week for six hours a day," said Grimstad in an email to supporters. "He is gaining abilities and strength, even starting to speak again and he has not lost his sense of humor or his intellectual curiosity. When the accident happened, Josh was in his second year at Tarleton University in Stephenville, TX. He is hoping to be able to return to school one day!"

Education Mission

Grimstad says there is pressure to loosen the definition of death.

"I can guarantee that this is not the end of efforts to make the legal criteria for determination of death less rigorous," Grimstad told *Health Care News*. "Furthermore, those of us who believe every life is worth living must work tirelessly to educate the public that 'brain death' is not biological death, that such a diagnosis does not guarantee the person will not recover to a greater or lesser degree and cherish his or her life."

Grimstad said her organization advocates repealing the current UDDA and replacing it with new language recommended by Paul A. Byrne, M.D., a board-certified pediatrician and neonatologist and the founder and president of the Life Guardian Foundation.

The proposed definition reads, "No one shall be declared dead unless respiratory and circulatory systems and the entire brain have been destroyed. Such destruction shall be in accord with universally accepted medical standards."

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

"I can guarantee that this is not the end of efforts to make the legal criteria for determination of death less rigorous. Furthermore, those of us who believe every life is worth living must work tirelessly to educate the public that 'brain death' is not biological death, that such a diagnosis does not guarantee the person will not recover to a greater or lesser degree and cherish his or her life."

JULIE GRIMSTAD
VICE PRESIDENT
HEALTHCARE ADVOCACY AND LEADERSHIP ORGANIZATION

Florida Fines Medicaid Providers for Trans Care

With Medicaid providers sometimes coming under fire for denying care to enrollees, Florida has taken the unusual step of doing the opposite in the case of transgender treatments.

Since August 2022, Florida's Agency for Healthcare Administration (AHCA) has banned the use of taxpayer funds to pay for transgender treatments. After an audit in August, Florida discovered five Medicaid providers—Simply, Sunshine, Children's Medical Services, Molina, and Humana—had ignored the rule. Each has received unspecified fines for providing cross-sex hormones and puberty blockers for children.

Simply Healthcare was sanctioned and received a $30,000 penalty for covering a double mastectomy for a minor seeking "gender-affirming care."

Sanctioning can block a provider from receiving future state contracts.

"The agency has not been challenged for any of the fines," said Baily Smith, a spokesperson for the AHCA. "Florida Medicaid will continue to solicit audits of health plans and providers to ensure the integrity of Florida's program."

Federal Court Action

On September 1, U.S. District Judge Robert Hinkle refused to issue a preliminary injunction blocking Florida's law limiting transgender treatments on children and on adults. The law, SB 254, signed by Gov. Ron DeSantis this spring, requires patients to sign informed-consent forms written by state medical boards, allows only physicians to prescribe cross-hormone treatments, and bans the use of telehealth to receive such prescriptions.

Doctors are prohibited from ordering transgender treatments for children but allowed to continue treatment in some circumstances for minors already receiving the drugs.

Hinkle said he would be open to issuing a narrowly tailored injunction for individual plaintiffs after reviewing detailed medical records. Hinkle had temporarily blocked portions of Florida's law in June.

Related cases involving transgender treatment restrictions in other states are working their way through the federal courts and could ultimately affect what happens in Florida. Until then, Florida plans to continue audits of Medicaid providers.

"Florida was the first state in the nation to review the scientific research on the effectiveness of these treatments," said Smith. "Similar to other developed nations that have outlawed these treatments, Florida puts evidence over eminence."

"Florida was the first state in the nation to review the scientific research on the effectiveness of these treatments. Similar to other developed nations that have outlawed these treatments, Florida puts evidence over eminence."

BAILY SMITH
AGENCY FOR HEALTHCARE ADMINISTRATION

—Staff reports

Voters Reject Child Trans Procedures, Survey Finds

By Tom Gantert

A majority of U.S. voters say children should not undergo transgender interventions, even with parental permission, a nationwide poll by The Center Square news agency found.

Medical interventions such as gender-changing surgery or puberty blockers for children younger than 18 years old were opposed by 58 percent of the 2,500 registered voters surveyed, including 62 percent of men and 54 percent of women.

Ten percent of those polled said children should be able to undergo these interventions if they choose, and another 21 percent said children should be able to undergo these interventions only with parental permission (see charts on this page).

The poll reports a margin of error of plus or minus 2.4 percent, was conducted by Noble Predictive Insights from July 31 to August 3, and surveyed 1,000 Republicans, 1,000 Democrats, and 500 independents.

'That's a Non-Starter'

The lack of public support for transgender interventions of minors is noteworthy, says Mike Noble, founder and CEO of Noble Predictive Insights.

"What's surprising—for how much you hear about it, how much it is 'in your face'—you look at the public opinion data and there's definitely not a majority who are in support of this," said Noble. "Six in ten are saying, 'That's a non-starter.'"

Of those who identified as "strong Democrat," 22 percent said children should be allowed to undergo gender-changing surgery or puberty blockers. Forty percent said such procedures should be allowed only with parental permission. Twenty-three percent identifying as "strong Democrats" were against allowing the interventions, and another 15 percent were unsure.

Sixty-four percent of voters with children under the age of 18 said minors should not undergo transgender medical interventions.

"The people who were the least on board were people who had children under the age [of] 18," said Noble. "The ones who are the most supportive are the ones who never had children."

Action, Reaction

Officials and legislatures in different states have taken diametrically opposed actions on the procedures for minors.

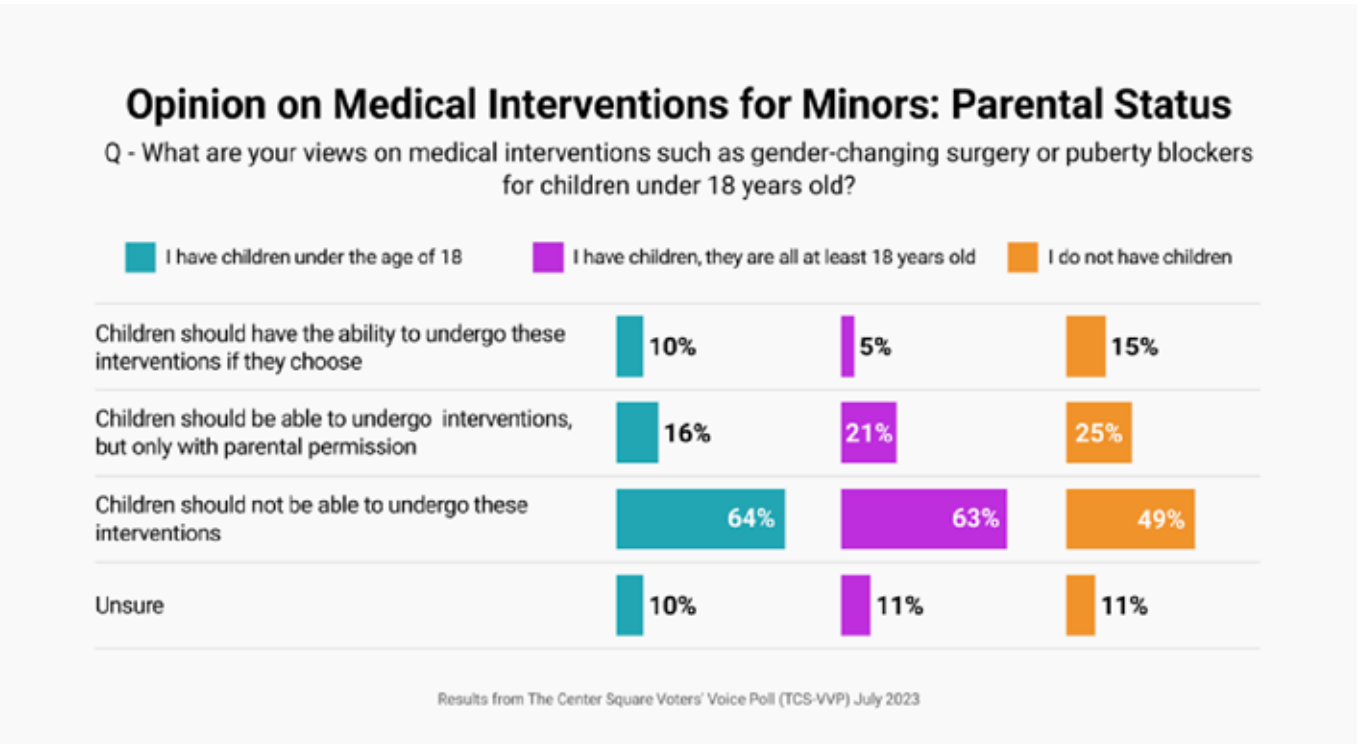
Arkansas, Florida, Georgia, Indiana, Missouri, North Carolina, Tennessee, Texas, and at least 10 other states have restrictions on trans procedures for children. Some of the legislation is being challenged in court.

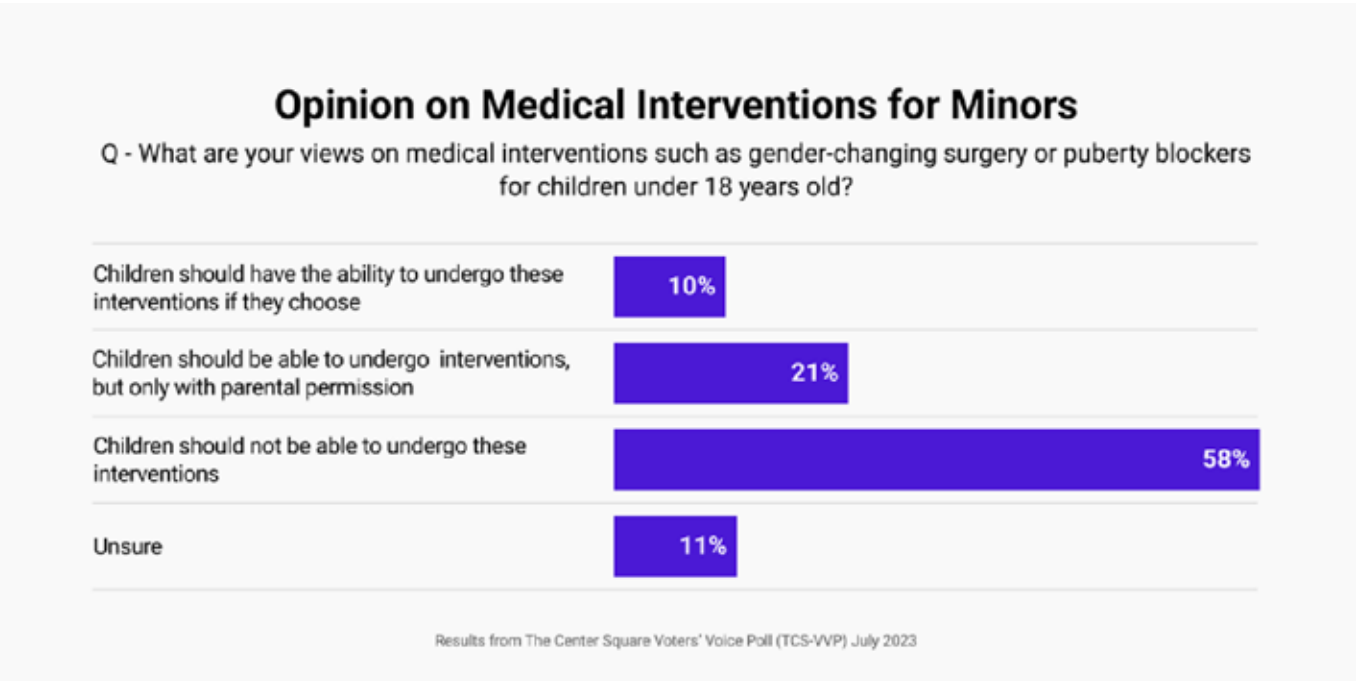
California leads a coalition of 20 mostly blue states in opposing Kentucky's and Tennessee's restrictions in federal court. Other states joining the suit to stop those states' policies include Illinois, Massachusetts, Michigan, New Jersey, New York, Oregon, and Washington.

Tom Gantert (**tgantert@thecentersquare.com**) *is the managing editor of* The Center Square*, where an earlier version of this article appeared. Reprinted with permission.*

"What's surprising—for how much you hear about it, how much it is 'in your face'—you look at the public opinion data and there's definitely not a majority who are in support of this. Six in ten are saying, 'That's a non-starter.'"

MIKE NOBLE
FOUNDER AND CEO
NOBLE PREDICTIVE INSIGHTS





Legislators:

Make Us Your New Legislative Aide!

Join Heartland's Legislative Forum today and stay on top of the latest research and policy solutions.

Why Join?

Simply, The Heartland Institute delivers what elected officials need. Busy elected officials have little or no staff and need a reliable source of research and commentary on the most important public policy issues of the day. For decades Heartland has been that resource.

Benefits of membership include:

- Travel scholarships to Heartland's Emerging Issues Forum
- Priority access to your very own free-market think tank
- Bringing experts to your state
- Invitations to Legislative Forum members-only events
- Complimentary copies of *Heartland Policy Studies* and books

Membership is limited to current elected officials and costs just $99 for a lifetime membership. As a lifetime member, you will enjoy the great benefits the Legislative Forum offers for your entire time in office, as well as alumni benefits thereafter.

Visit **heartland.org/sign-forum** to sign up.

For more information, please call 312/377-4000 and ask for a member of the government relations team.

"Heartland's research and advocacy for science-based policies that improve people's lives have been very helpful to me and my colleagues."

REPRESENTATIVE ISAAC LATTERELL
SOUTH DAKOTA

THE HEARTLAND INSTITUTE

The Heartland Institute is a national nonprofit organization based in Arlington Heights, Illinois. Its mission is to discover, develop, and promote free-market solutions to social and economic problems. For more information, visit our Web site at heartland.org or call 312/377-4000.

Goodman Institute
FOR PUBLIC POLICY RESEARCH

Turning Healthcare Ideas Into Public Policy

Dr. Goodman book tour stop at Cato Institute in Washington, D.C.

Dr. Goodman addressing The Economic Club of Indiana

What We Have Accomplished

Health Savings Accounts

More than 30 million people are managing some of their own health care dollars in accounts they own and control

1

Roth IRAs

19.2 million people own $660 billion of retirement money that will never be taxed again

2

Social Security

78 million baby boomers are able to work beyond the retirement age without losing retirement benefits

3

401 (k) Plans

Because of automatic enrollment in diversified portfolios, 16 million employees are enjoying higher and safer returns

4

Visit us at online at **www.GoodmanInstitute.org**