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HEALTH CARE NEWS

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President Joe Biden

PHOTO COURTESY GAGE SKIDMORE/FLICKR.COM

Biden Proposes Rule to Restrict Short-Term Plans

By AnneMarie Schieber

The Biden administration moved to confine short-term, limited-duration insurance (STLDI) to four months with no option to renew.

The proposed rule, announced on July 7, would restore limits imposed by the Obama administration in 2014. President Donald Trump lengthened the period by executive order, allowing plans to last one year with two years of renewal.

Congress failed to pass legislation making the expansion permanent, setting the stage for Biden's reversal of the reform. After a 60-day comment period, Biden's plan would take effect on January 1, 2024.

BIDEN RULE, p. 6

Judge Sets Guardrails to Stop Government Censorship

By AnneMarie Schieber

Calling it "the most massive attack against free speech in the United States," a federal judge took early action in a lawsuit to stop the Biden administration from pressuring social media companies to silence viewpoints critical of the president and his policies.

Judge Terry A. Doughty of the U.S. District Court for the Western District of Louisiana issued a preliminary injunction and 155-page opinion on Independence Day.

The injunction is in response to

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Push to Stop Non-Compete Clauses in Doctor Contracts Gains Momentum

By AnneMarie Schieber

Indiana Gov. Eric Holcomb signed into law a bill expanding the state's restriction on non-compete clauses in physicians' contracts with hospitals.

Non-competition agreements can restrict physicians' access to patient records and contact information and may require a physician to move hundreds of miles away to continue practicing.

Given the shortage of health professionals and the trend toward the employment of doctors by health care systems, non-compete clauses can drive up health care prices. In 2020, 80 percent of physicians in the Hoosier State worked for a hospital.

"[Non-compete clauses have] been used more as handcuffs to lock physicians into contracts and keep them from leaving, because physicians are scarce."

ADAM HABIG, J.D.
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'Bans Are Expanding'

Indiana enacted a law in 2020 requiring noncompete clauses in employment contracts with physicians to include a buyout provision and put some protections in place to preserve the doctor-patient relationship.

The new law, effective July 1, ends enforcement of non-compete clauses for primary care physicians in three situations: if the employer fires the physician without cause, the physician terminates employment for cause, or a contract expires and the terms have been fulfilled by both parties. It also narrows the use of non-competes for specialists.

The amended law is a huge step forward in making health care more competitive, says Adam Habig, J.D., president and co-founder of Freedom Healthworks, LLC, a firm that helps physicians set up direct-pay practices.

"I know of one hospital that is already eliminating the clauses," said Habig. "Hospitals see the writing on the wall. The momentum is there, and bans are expanding state by state. Even at the federal level, it has become a bipartisan issue."

Options for Physicians

Non-compete clauses have been stretched beyond their original intent, says Habig.

"They've been used more as handcuffs to lock physicians into contracts and keep them from leaving, because physicians are scarce," said Habig. "Physicians are difficult to find and expensive to recruit, in many cases."

Young physicians leaving medical school and clinical training with hundreds of thousands of dollars in debt may be eager for financial security, and working for a large hospital system is attractive, says Habig.

"Many do not realize that independent practice is still an option, or a direct care model," said Habig. "The bans will allow doctors more freedom of movement so that they can pursue models that are innovative and unique, models that may better serve their patients."

Momentum for State Reforms

Indiana and about a dozen other states have restricted the enforcement of non-compete contracts, but hospitals are resisting.

Members of the South Carolina General Assembly attempted to foil non-competes this year as part of a package of bills that repealed most of the state's Certificate of Need (CON) laws regulating the opening of new health care facilities.

Due to opposition, the proposal was dropped, says Marcello Hochman, M.D., a Charleston, South Carolina surgeon and president of IndeDoc, a group that promotes independent practice, who lobbied for the reforms.

"We wanted to pursue the non-compete ban this time around," said Hochman. "We had it as an amendment to the CON repeal bills, but it was dropped because it would have killed everything. It just goes to show that the non-compete clause is more important [to hospitals] than certificate of need. So next year we're going to pursue it because the environment is ripe for giving people options to do different things and protect the patient's right to see whoever they want."

Federal Rule Proposed

The Federal Trade Commission (FTC) proposed a rule in January that would prevent businesses from adding non-compete clauses in any employment contracts and rescinding such clauses already in place.

According to the FTC, one in five workers is bound by a non-compete clause and the new rule would increase worker earnings by $250 billion to $296 billion a year. The FTC is currently reviewing the 26,813 comments it received and could issue a final rule this year.

In some circumstances, a non-competition provision makes sense, says Hochman.

"I don't have a problem with negotiated restricted covenants in employment contracts," said Hochman. "The problem is these hospitals have blanket non-compete clauses for everybody. The hospital may give you $1,000, … but generally, it's non-negotiable. So, young doctors coming out of training sign a non-compete and five years later want to go off and do something on their own, and guess what: they can't."

The legal profession has traditionally avoided non-compete clauses for attorneys because they harm the client, says Habig.

"What does it say when the 'attorney-client' relationship is so important that we can't have them, but the 'physician patient' one is not?" asked Habig.

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

Judge Sets Guardrails to Stop Government Censorship

Continued from page 1

Missouri v. Biden, a lawsuit filed by the attorneys general of Louisiana and Missouri and private individuals. They are suing the Biden administration for pressuring and colluding with social media sites such as Facebook, Twitter, and YouTube to "suppress conservative-leaning free speech" on the origin of COVID-19, the efficiency of masks, the effectiveness of COVID-19 shots, the lockdowns, the 2020 election, the Hunter Biden laptop, and other issues.

"Although this case is still relatively young, and at this stage the Court is only examining it in terms of Plaintiffs' likelihood of success on the merits, the evidence produced thus far depicts an almost dystopian scenario," Doughty wrote. "During the COVID-19 pandemic, a period perhaps best characterized by widespread doubt and uncertainty, the United States Government seems to have assumed a role similar to an Orwellian 'Ministry of Truth.'"

"Today, we won an historic injunction against the Biden administration, preventing it from censoring the core political speech of ordinary Americans on social media. The evidence in our case is shocking and offensive, with senior federal officials deciding that they could dictate what Americans can and cannot say on Facebook, Twitter, YouTube, and other platforms about COVID-19, elections, criticism of the government, and more."

JEFF LANDRY
LOUISIANA ATTORNEY GENERAL

Biden Admin Pushes Back

The federal government petitioned the Fifth Circuit Court of Appeals to stop the preliminary injunction.

"The district court has rejected the government's attempt to stay that ruling, and now it has an emergency petition to have the Circuit stay it," said John J. Vecchione, a senior litigator at the New Civil Liberties Alliance, which is representing the private plaintiffs in the case.

"We expect the injunction to stay in place while the appeal continues, at least because the government has demonstrated no harm to it from the preliminary injunction," said Vecchione.

"The government can point to no great catastrophe emerging from Americans using social media presumably free of government coercion," said Vecchione.

"Our clients were silenced in the virtual public square by exactly the sort of unconstitutional actions the government evidently wants to continue while its appeal proceeds," said Vecchione. "That harm should not be renewed while the Fifth Circuit considers the government's arguments as to why it should be able to renew this censorship while we still have a First Amendment."

On July 14, the Fifth Circuit granted a temporary stay of the injunction.

Threats and Pressure

The injunction stops more than a dozen federal agencies and specific individuals from talking to social media companies for "the purpose of urging, encouraging, pressuring, or inducing in any manner the removal, deletion, suppression, or reduction of content containing protected free speech." The ban does not apply to matters involving crime or national security.

Judge Doughty, on page 119 of his decision, addressed the defendant's argument that its actions are protected "government" speech.

"[I]t was not the public statements that were the problem," wrote Doughty. "It was the alleged use of government agencies and employees to coerce and/or significantly encourage social-media platforms to suppress free speech on those platforms."

The judge's opinion states the government used "various meetings, emails, follow-up contacts, and the threat of amending Section 230 of the Communication Decency Act" to intimidate the media outlets. At one point, then-White House Press Secretary Jen Psaki mentioned to reporters that Biden supported a "robust antitrust program" and there could be "legal consequences" for social media companies that do not stop "misinformation," the judge's opinion notes.

'Vast Censorship Enterprise'

Attorneys General Andrew Bailey (MO) and Jeff Landry (LA) filed the motion for the injunction as part of their lawsuit. The case highlighted 1,400 facts from more than 20,000 pages of evidence to show a "vast censorship enterprise" coordinated among dozens of agencies in the federal government, a news release from Bailey's office states.

"We must build a wall of separation between tech and state to preserve our First Amendment right to free, fair, and open debate," said Bailey in a statement.

"Today, we won an historic injunction against the Biden administration, preventing it from censoring the core political speech of ordinary Americans on social media," said Landry in a press statement. "The evidence in our case is shocking and offensive, with senior federal officials deciding that they could dictate what Americans can and cannot say on Facebook, Twitter, YouTube, and other platforms about COVID-19, elections, criticism of the government, and more."

Media Complicity

Big media outlets are taking the government's side in this censorship case, says Jeffrey Tucker, president of the Brownstone Institute.

"There was a time when the media was the biggest champion of the 'public's right to know,'" Tucker told *Health Care News*. "Now everyone from *The Washington Post* to *Slate* denies the government was involved in any censorship. Judge Doughty meticulously described what the government was doing, who was doing it, and when. Did any of these reporters even read the decision?"

In an op-ed in *The Epoch Times* on July 11, Tucker commented on why the media is in denial.

"There's no question about why: they want monopoly control of the public conversation because they want to be in charge of what you think," wrote Tucker.

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

FDA Approves Over-the-Counter Oral Birth Control Pills

By Harry Painter

The U.S. Food and Drug Administration (FDA) has approved the first over-the-counter (OTC) oral contraceptive in the United States.

The decision on July 13 came after a panel of advisors gave the go-ahead to approve the sale of Perrigo's Opill, an oral hormone-based birth control drug that currently requires a prescription from a physician.

The panel came to its nonbinding conclusion in May after two days of deliberation over whether the pill is safe and effective for women to take without consulting a medical professional.

"Nonprescription availability of Opill may reduce barriers to access by allowing individuals to obtain an oral contraceptive without the need to first see a health care provider. Almost half of the 6.1 million pregnancies in the U.S. each year are unintended," stated an FDA news release.

In its news release, Perrigo did not say when OTC sales will begin.

The FDA's approval of an OTC oral contraceptive applies only to Opill, though it could set the bar for other drug makers to apply for over-the-counter availability.

"Nonprescription availability of Opill may reduce barriers to access by allowing individuals to obtain an oral contraceptive without the need to first see a health care provider. Almost half of the 6.1 million pregnancies in the U.S. each year are unintended."

FDA NEWS RELEASE

Questions About Safety, Effectiveness

The panel's unanimous recommendation came despite pushback on multiple fronts from FDA scientists who reviewed the company's 880-patient study of Opill's safety and effectiveness.

"We have an application with many complicated issues and uncertainties, including questionable reliability," FDA's Pamela Horn, M.D., told the panelists.

The panelists raised concerns about study participants' inability to understand and follow the instructions on the product's label. The labeling says the drug is contraindicated for use by women who may be pregnant or may have breast cancer or undiagnosed abnormal uterine bleeding, and that other medications could interact with Opill's effectiveness. The labeling advises users to take the pill at the same time every day and to discuss menstrual bleeding patterns "with a health care provider."

An especially alarming problem was that 68 percent of women who had unexplained vaginal bleeding incorrectly said Opill would be safe to take. Some women with breast cancer also mistakenly told researchers they could take the pill.

Another problem identified was that close to 30 percent of participants reported taking more pills than they were given.

The panel sidestepped those issues in making its recommendation to the FDA, prioritizing the benefit of having more effective birth control available to more people, particularly young and low-income groups.

'Plan B' Already OTC

The science is on the side of approving Opill for over-the-counter sales, says Jeffrey A. Singer, M.D., a senior fellow in health policy at the Cato Institute.

"The American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, and the American Medical Association believe it is safe for females of all ages," said Singer. "The worst that can happen is some premenstrual bleeding. The panel has called for it to be available for women of all ages, just like the more potent Plan B is."

The "Plan B" or "morning after" pill, an emergency contraceptive that prevents fertilization, underwent fierce debates in the 1990s before being approved for over-the-counter status.

"The government should get out of the way of medically proven harm-reduction strategies—particularly one like this, that is available OTC in many countries around the world and has been advocated by medical experts for decades," said Singer.

Singer writes in a *Reason* op-ed coauthored by Josh Bloom that there are far more dangerous medications already available over the counter, including Tylenol and Benadryl.

"And if we have fewer young girls with unwanted pregnancies, we will have fewer abortions," Singer told *Health Care News*.

Medical Issues Set Aside

Not everyone agrees with making Opill more accessible or with the role of government in determining who can use it. Catholic organizations, including the U.S. Conference of Catholic Bishops, have spoken out against approving its availability without supervision of a medical professional, arguing it violates the medical ethic of "first, do no harm."

The FDA should not let alleged social benefits override medical safety considerations, says David Gortler, Pharm.D., a fellow at the Ethics and Public Policy Center.

"The bottom line here is that these products are not completely safe and shouldn't be OTC," Gortler told *Health Care News*.

Gortler says the proposal to make Opill available over the counter is driven more by politics than sound science.

"The FDA is only supposed to consider safety in its decisions, not convenience or access or abortion-type politics," said Gortler.

Compliance, Cost Concerns

In a recent editorial for the Brownstone Institute, Gortler notes the synthetic progestin used in birth control pills can lead to increased risk of breast cancer, cervical cancer, STDs, and mood disorders.

There are also compliance concerns. If Opill is sold over the counter, there is no professional monitor.

"Oral contraceptives require discipline and self-control, something which minors tend to not have," Gortler wrote.

It is not clear how much Opill will cost. Making it OTC means insurers do not have to pay for it, unlike prescription oral contraceptives under the Affordable Care Act.

Anticipating Opill's approval, Senate Democrats introduced legislation that would force insurers to cover OTC oral contraception.

Behind-the-Counter Option

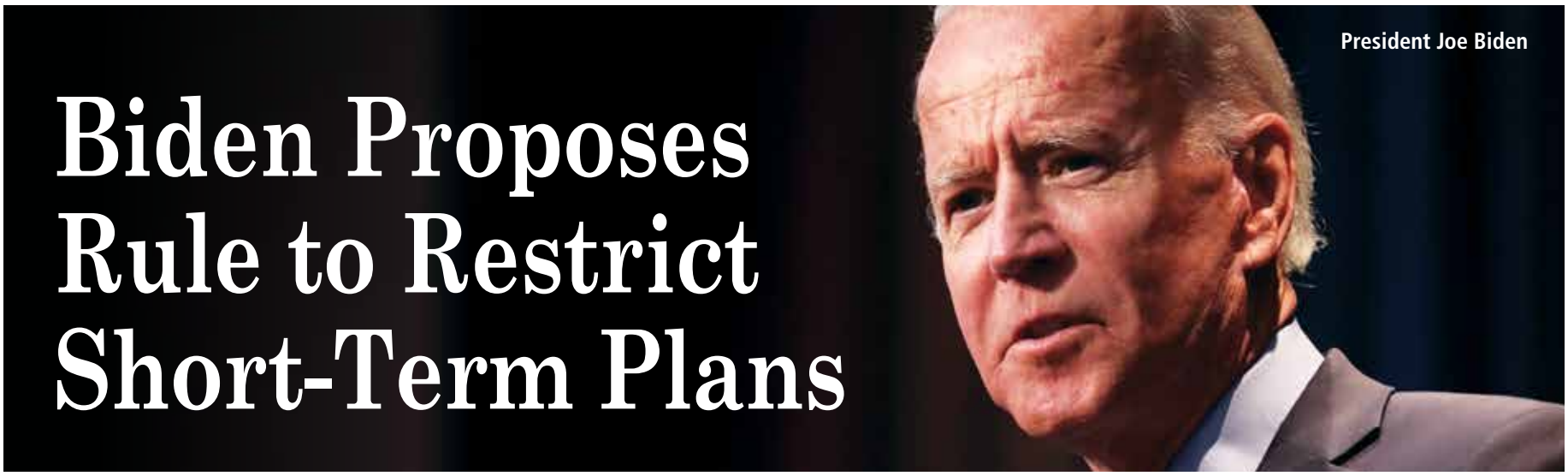
An alternative the FDA could have considered is selling Opill "behind the counter," whereby a pharmacist would have to interact with the consumer before purchase.

The GoodRx.com website explains why some drugs are sold only behind the counter.

"Some are kept there for safety purposes," GoodRx states. "That's because they can cause harm if they aren't used exactly as directed (like insulin). Other medications are behind the counter because they carry a risk of misuse or dependency. And in other cases, they can be used illegally to make highly addictive drugs."

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

Biden Proposes Rule to Restrict Short-Term Plans



President Joe Biden

PHOTO COURTESY GAGE SKIDMORE/FLICKR.COM

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Lower Cost, Broader Networks

STLDI is a type of health insurance designed to fill gaps in coverage. The plans are a fraction of the cost of Obamacare plans and offer broader coverage networks. Consumers can purchase the plans at any time during the year and can choose from a variety of deductibles and co-pays.

STLDI is cheaper because the plans are not subject to the same coverage requirements as Obamacare plans. STLDI is attractive to consumers who have no health problems but want financial protection in case of a catastrophic health event and are not covered by an individual plan.

The Trump rule allowed even more protection by giving consumers the option to repurchase the plan for up to two more years at the same price, even if they became sick. Under Biden's proposed rule, the plans will "cancel" at four months and consumers will have to apply again from scratch. The new plan would not cover any ongoing health treatment.

The only option at that point would be for the person to wait to sign up for an Obamacare plan, enrollment for which is open only for a limited time each year. Additionally, the Obamacare plan might not cover the same providers.

"The Biden regulation will keep families from buying health insurance that meets their financial and medical needs," said John C. Goodman, president of the Goodman Institute for Public Policy Research and co-publisher of *Health Care News*.

"The Biden administration, like the Obama administration, views [short-term, limited-duration insurance (STLDI)] as a threat. Obamacare plans thrive on getting healthy people to pay higher premiums to subsidize the sick, who can jump onto the plans even after they get sick. STLDI offers an escape plan for people who don't want to pay for coverage they don't want or need and if they do need it, don't want to be restricted by Obamacare's narrow networks."

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

Threat to Obamacare

Biden has called STLDI "junk insurance."

"New proposed rules would close loopholes that the previous administration took advantage of that allow companies to offer misleading insurance products that can discriminate based on pre-existing conditions and trick consumers into buying products that provide little or no coverage when they need it most," a fact sheet from the White House states. "These plans leave families surprised by thousands of dollars in medical expenses when they actually use health care services like a surgery."

Obamacare plans are the real "junk insurance," says Michael Cannon, director of health policy studies at the Cato Institute.

"For one, Obamacare plans are driving consumers to short-term plans because short-term plans offer broader provider networks," said Cannon. "If the goal is to increase the number of insured, STLDI does it. The plans reduce the number of uninsured by one to 2.3 million people.

"By limiting STLDI, President Biden is literally trying to mandate the very practice of stripping coverage from the sick that he said Obamacare would end," said Cannon. "It's the equivalent of requiring automakers to rip airbags and seat belts out of cars."

'Anti-Consumer and Anti-Patient'

Deductibles are prohibitively high under Obamacare, says Joel White, president of the Council for Affordable Health Coverage.

"The typical deductible on an Obamacare 'silver' plan, on top of what the consumer is already paying in premiums, is $4,753, while the average deductible on a high-deductible employer plan linked to a health savings account (HSA) is about half that," said White.

"Congress has pursued policies to weaken employer coverage while encouraging people to join Obamacare," said White. "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's fundamentally anti-consumer and anti-patient."

Tailored to Needs

STLDI is not the problem, it's the solution, says Goodman.

"Short-term health plans have been around for many years, and they've been attractive because they only cover risks that people care about," said Goodman. "The plans can exclude people with preexisting conditions, they may not cover prescription drugs or maternity care or substance abuse, and this is fully disclosed. Buyers of the plans don't want to pay for something they don't think they'll need."

Limiting short term plans serves political interests, not the public, says Goodman.

"The Biden administration, like the Obama administration, views STLDI as a threat," said Goodman. "Obamacare plans thrive on getting healthy people to pay higher premiums to subsidize the sick, who can jump onto the plans even after they get sick. STLDI offers an escape plan for people who don't want to pay for coverage they don't want or need and if they do need it, don't want to be restricted by Obamacare's narrow networks.

"It's amazing Republicans did not lock in the Trump reforms when they had control of Congress," Goodman said.

Legal Issues

Cannon says it is not clear the Biden administration has the statutory authority to limit STLDI.

"The change defies a 2020 ruling by the U.S. Court of Appeals [District of Columbia Circuit] which stated, 'nothing in [federal law] prevents insurers from renewing expired STLDI policies,'" said Cannon.

Goodman says STLDI could be a key part of real health care reform.

"Let STLDI function as an unregulated market, give everyone the same tax relief regardless of what insurance market they choose, let Obamacare function as a quasi-risk pool with subsidies to keep premiums affordable for the really sick, and let the exchanges offer specialty plans that cover specific health conditions," said Goodman (see related article, page 21).

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

FDA Refuses to Remove Alleged Misinformation from COVID Shot Labeling

By Dvorah Richman

A group of drug safety advisors and academics is speaking out against a decision by the Food and Drug Administration (FDA) to amend the labeling for the Pfizer and Moderna mRNA inoculations for COVID-19.

The labeling for the shots is "obsolete" and fails to warn the public about harms, an op-ed in *The Hill* stated on June 9.

"Product labeling should be informative and accurate, not promotional. The law requires it, and following the law shouldn't be optional," wrote Peter Doshi, Ph.D., an associate professor, and Linda Wastila, Ph.D., a department chair, both at the University of Maryland School of Pharmacy, and Kim Witczak, a drug safety advocate.

On January 31, the op-ed authors and the Coalition Advocating for Adequately Labeled Medicines (CAALM) submitted an FDA Citizen Petition (petition) requesting updates to the labeling on the mRNA COVID shots.

The FDA denied virtually all petition requests in its response on April 18. That same day, the FDA announced Moderna and Pfizer-BioNTech's COVID-19 Emergency Use Authorizations (EUAs) for bivalent mRNA vaccines were amended to "simplify" vaccine schedules and the companies' monovalent COVID vaccines wouldn't be allowed in the United States.

The agency is expected to authorize the reformulated monovalent COVID-19 shots this fall.

"It's becoming clear that COVID-19 vaccines may precipitate or accelerate serious health problems, but prescribers still counsel patients based on incomplete and obsolete labeling from the government and pharmaceutical industry."

LINDA WASTILA, PH.D.
DEPARTMENT CHAIR, UNIVERSITY OF MARYLAND SCHOOL OF PHARMACY

'Appropriate Labeling Is Important'

Labeling includes package inserts, EUA fact sheets for vaccination providers, patient-oriented materials such as EUA fact sheets for recipients and caregivers, and patient package inserts.

Wastila told HCN "appropriate labeling is important for many reasons, one being informed consent. Without truthful, accurate, current, and easily accessible information on safety and effectiveness, prescribers cannot appropriately counsel patients about risks and benefits, and individuals cannot make truly informed consent."

Called for Caution

Among many requests, CAALM asked the FDA to update adverse-event labeling to include multisystem inflammatory syndrome in children, pulmonary embolism, sudden cardiac death, neuropathic and autonomic disorders, decreased sperm concentration, heavy menstrual bleeding, and detection of vaccine mRNA in breast milk.

Using peer-reviewed articles, post-marketing studies, and data from the government's Vaccine Adverse Event Reporting System (VAERS), CAALM argued these items meet the regulatory standard of "some basis to believe there is a causal relationship between the drug and occurrence of the adverse event."

Citing Pfizer study data, CAALM requested a clear statement that vaccine efficacy wanes two months after receiving dose two. CAALM also asked for clarification that certain studies were not designed to, nor did they, provide substantial evidence of immunization efficacy against COVID transmission or death.

Citing "inaccurate" statements by government officials, the petition states "there is a widespread (but inaccurate) notion that efficacy against infection and transmission [has] been established by substantial evidence, and that these vaccines contribute to herd immunity."

FDA Rejected Requests

The FDA rejected all but one of the petitioners' requests. Ignoring the "some basis to believe" regulatory standard, the FDA said a "causal relationship" wasn't shown for the adverse events.

Contrary to ongoing collaborative efforts with foreign regulators, the FDA did not agree to certain adverse event labeling adopted elsewhere, including Europe.

Different Strokes for Different Pokes

The FDA is treating the COVID shots differently from other products, says Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons.

"If a serious event occurs, the treatment is suspect until proven otherwise," said Orient. "A few events can get a drug recalled without waiting for more people to die or for a very expensive study to be launched and reported. But the government treats COVID shots differently. They must be proved guilty beyond a reasonable doubt, and if not proved guilty, allowed to go free.

"The VAERS database is used by the FDA when it pleases, but disregarded for this product," said Orient. "Why hasn't a better system been developed, when its flaws have been known for decades?"

The FDA disregarded concerns about public confusion regarding COVID transmission and death, saying the petitioner used "selective statements" and did not include "countervailing statements."

Although the agency agreed to update data regarding Pfizer's randomized trials of bivalent boosters, it denied CAALM's request to update Moderna's data because it hadn't yet evaluated it.

Orient says the response could reflect pressure from the pharmaceutical industry, political blowback, or an effort to save face.

Labels Have Consequences

"Had prescribers better understood the potential safety implications of the vaccines, as well as their waning effectiveness, perhaps they could better counsel patients who receive them, including not recommending them for infants, children, young and middle-aged adults, and pregnant women who are not at risk for severe COVID sequelae but who are very much at risk for adverse vaccine effects," said Wastila.

"It's becoming clear that COVID-19 vaccines may precipitate or accelerate serious health problems, but prescribers still counsel patients based on incomplete and obsolete labeling from the government and pharmaceutical industry," said Wastila. "The lack of accurate, accessible, and current data needed to provide appropriate informed consent is a major reason for the erosion of trust in national and state public health agencies and has fueled vaccine hesitancy."

Knock-On Effects

The FDA's decision means upcoming vaccines are likely to have incomplete labeling, says Wastila.

"This is unfortunate because the pharmaceutical pipeline is crammed with new vaccines and other products in development using the vaccine's mRNA platform," said Wastila. "By ignoring safety concerns not balanced against effectiveness, [there will be] continued tremendous injuries to patients."

Wastila says she is concerned reformulated vaccines will be modeled on virus variants that no longer exist.

That will create "massive safety concerns and ongoing failures to provide fully informed consent, particularly if there are government mandates for these novel technologies," said Wastila.

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

FDA Commissioner Called Out for Remark on Non-Addictive Painkillers

By Kevin Stone

The head of the U.S. Food and Drug Administration (FDA) has come under fire for failing to acknowledge the agency's role in burying a non-addictive painkiller.

When asked during a Senate Appropriations subcommittee hearing on April 19 how he would tackle the opioid crisis, Commissioner Robert Califf stated, "It is a tough job, but we are not successful in having nonaddictive pain medicines coming through the pipeline. We need to do everything we can do to push industry and make this happen."

There is such a drug, Toradol, and it should be in every medicine cabinet but is not, because of the FDA, says Charles L. Hooper, president of the health care consultancy Objective Insights and author of *Should the FDA Reject Itself*?

"Syntex [the developer] got Toradol approved by the FDA, but it had kind of a tortured path," said Hooper on the *Heartland Daily Podcast*.

Toradol, the brand name for ketorolac, is a nonsteroidal anti-inflammatory drug that could provide morphine levels of pain relief without the same abuse potential as opioids. There is also an oral form of the drug.

'A Forgotten Failure'

Hooper worked at Syntex when the FDA approved the injectable form of the drug in 1989. During the approval process, the company accepted the advice of an FDA employee who recommended it be administered with a "loading dose" at twice the regular dosage. Gastrointestinal bleeding caused by the drug at high dosage killed 97 users between 1990 and 1993.

By the time the FDA modified the dosage instructions to eliminate the loading dose, the damage had been done.

Injectable Toradol IV/IM is still in use, especially as an emergency room treatment. Consumers prefer oral medications for home use, however, and although the FDA approved the oral version in 1991, FDA guidance effectively killed it.

"The drug reviewer, John Harder, had previously worked at Syntex and had been fired by the company," said Hooper. "He came down hard on Toradol, putting three severe restrictions on the label, limiting dosage to 10 mg, adding a five-day limitation for dosage, and requiring users to start with an injection of Toradol IV/IM.

"So, you had to start off with a shot and then get a tablet that was one-sixth to [one]-third of the effective dose of 30 to 60 milligrams," said Hooper. "Instead of Toradol oral being Syntex's billion-dollar drug, it ended up being a forgotten failure."

'Bad Optics'

The rest is history, says Hooper.

"If a company came out with a 30 milligram version of Toradol oral, I have no doubt it would be one of the most widely used drugs in the country, but there's no way I can see that they could make money from it," said Hooper.

Toradol oral would be categorized as a new drug, so the FDA would require expensive clinical trials.

"The company would have a period of market exclusivity, but very quickly generic versions would come in and take market share," said Hooper. "Also, for the FDA to approve it, they would have to say that they were wrong before, and that's bad optics."

> **"For the FDA to approve it, they would have to say that they were wrong before, and that's bad optics."**
>
> **CHARLES L. HOOPER**
> **PRESIDENT**
> **OBJECTIVE INSIGHTS**

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

INTERNET INFO

"Did the FDA Sabotage a Non-Addictive Pain Killer? (Guest: Charles L. Hooper), *Heartland Daily Podcast*, July 12, 2023: **https://heartland.org/podcasts/did-the-fda-sabotage-a-non-addictive-pain-killer-guest-charles-l-hooper/**

Lawsuits Challenge Medicare Drug Price Controls

By Ashley Bateman

Drug makers Merck and Bristol Myers Squibb (BMS) and the U.S. Chamber of Commerce have filed separate lawsuits challenging Medicare's new authority to negotiate drug prices.

In August 2022, President Joe Biden signed into law the Inflation Reduction Act (IRA), which established the Drug Price Negotiation Program. Starting in September 2023, the Centers for Medicare and Medicaid Services (CMS) will select 10 drugs for price cuts to go into effect in 2026. Drug companies can accept the price or face a tax on their revenue if they want Medicare to cover the full price of the drug.

Merck filed its suit in the U.S. District Court for the District of Columbia on June 6. BMS filed suit in the U.S. District Court for the District of New Jersey on June 16, and the Chamber filed its case on June 9 in federal court in the Southern District of Ohio.

Negotiation or 'Extortion'?

The lawsuits claim there is no real negotiation or agreement between the government and the drug companies, despite the program's name.

"It is tantamount to extortion. And it violates the Constitution in at least two obvious respects," the Merck complaint states.

The Merck and BMS suits claim the program violates the First Amendment's compelled-speech protection and infringes Fifth Amendment rights by failing to provide "just compensation" when taking property for public use.

The suits are based on some bold arguments, says Gregg Girvan, a scholar at the Foundation for Research on Equal Opportunity.

"It is easy to see how many might view the IRA's drug price negotiation program as coercive," said Girvan. "It forces drug companies to accept the government's price in Medicare with very little recourse if they don't agree with the price. On the other hand, participation in Medicare is voluntary, meaning no one forces drug companies to sell their products to Medicare recipients.

"Therefore, I think it is likely the lawsuits will not succeed," said Girvan.

Market Unlike Any Other

The suits claim government interference in the market, but the drug companies operate more like a public utility, says John Abramson, M.D., a lecturer at Harvard Medical School and author of *Sickening: How Big Pharma Broke American Health Care and How We Can Repair It*.

"There is no mechanism for informing coverage decisions and doctors about which new drugs are actually superior to older drugs and what their value is based on that superiority. In the United States, one out of three to one out of four are superior new drugs. The market is being constrained by the situation of Merck being able to charge whatever it wants for that new drug … even years after a patent should run out and generic competition [occur]."

JOHN ABRAMSON, M.D.
LECTURER
HARVARD MEDICAL SCHOOL

The federal government is one of the industry's biggest customers, and third-party drug payment programs detach consumers from control over prices, says Abramson.

"The American people have been ripped off for all these years because there's no price negotiation in the United States for new drugs," said Abramson. "The drug companies are maximizing their revenues for their investors, but what we have is a monopoly … [what amount to] unregulated public utilities. The IRA is going to rein in their pricing to what would be a reasonable price in a fair market after patents wear off."

Patent Power

Girvan says current laws and regulations promote monopoly pricing.

"We have a broken patent system that allows companies to exclude competitors far longer than what lawmakers intended," said Girvan. "The [Food and Drug Administration] grants a minimum 12-year exclusivity to biologic drugs while small-molecule drugs get just five years. And even if a biosimilar is approved, the manufacturer must complete switching studies to obtain an interchangeability designation and therefore be eligible for automatic substitution at the pharmacy level.

"These are all barriers to market entry that lawmakers have built through statute and regulation, to the benefit of incumbent drug companies," said Girvan.

Stifling Innovation

Merck points out the high cost of drug research and development, in a statement on its lawsuit.

"On average, it takes a decade and more than $2.5 billion to develop a new drug," the company stated. "Since 2000, companies like ours have invested more than $1.1 trillion in the search for new treatments and cures, including $102.3 billion in 2021 alone. This investment has led to incredible breakthroughs for patients."

Merck said "this progress is now at risk due to unconstitutional provisions in the Inflation Reduction Act (IRA), necessitating the legal action."

Alternative to Price Controls

The claim that the Drug Price Negotiation Program will "curtail innovation and produce a winter chill—this idea is a bluff," said Abramson.

"Merck more specifically is trying to frame this question as if the market is working and the government is going to take overly aggressive action to curtail the market from working, through those penalties," said Abramson. "The market is not working."

As an alternative to price controls, there should be a system that could rate drugs based on value, says Abramson.

"There is no mechanism for informing coverage decisions and doctors about which new drugs are actually superior to older drugs and what their value is based on that superiority," said Abramson. "In the United States, one out of three to one out of four are superior new drugs. The market is being constrained by the situation of Merck being able to charge whatever it wants for that new drug … even years after a patent should run out and generic competition [occur]."

Girvan says he is encouraged by the debate.

"Americans are fed up with the high price of branded prescription drugs and are hungry for solutions," said Girvan. "The good news is both sides of the aisle are engaging on the issue and are advancing bipartisan bills to address these issues."

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

FDA Launches 'Rumor Control' Campaign

By Ashley Bateman

The U.S. Food and Drug Administration (FDA) has launched a "Rumor Control" webpage to attack "the growing spread of rumors, misinformation, and disinformation about science, medicine, and the FDA."

The webpage, which invites consumers to "[l]earn and share FDA facts to help stop the spread of misinformation," debuted on June 3, 2023, nearly a year after FDA Commissioner Robert Califf stated controlling misinformation would be a top priority at the agency.

The site features a video stating "some individuals and organizations promote opinions online disguised as fact" and "misinformation can spread 6x faster than facts."

The webpage shares links to Facebook, Instagram, LinkedIn, TikTok, Twitter, WhatsApp, and YouTube where users can report information they "believe to be false or misleading."

Most of the site features short videos on such topics as how to tell whether something is "Really 'FDA' Approved" and how "Bivalent COVID-19 Vaccines Provide Broad Protection Against COVID-19."

"What is bizarre about this is that the FDA chose to title it 'Rumor Control,' not a fact check or getting the facts. People have opinions; some are fact-based, some are not. The FDA should engage in giving its view on claims that it feels are false, but the choice of 'Rumor Control' as a title is tone-deaf."

LINDA GORMAN
DIRECTOR, HEALTH CARE POLICY CENTER
INDEPENDENCE INSTITUTE

Rumors, Opinions, Facts

Instead of providing information, the webpage disputes matters of opinion, says Linda Gorman, director of the Independence Institute's Health Care Policy Center.

"What is bizarre about this is that the FDA chose to title it 'Rumor Control,' not a fact check or getting the facts," said Gorman. "People have opinions; some are fact-based, some are not. The FDA should engage in giving its view on claims that it feels are false, but the choice of 'Rumor Control' as a title is tone-deaf."

Inside the FDA Mindset

In the 60-second video "What Does FDA Regulate?" a narrator says the FDA controls a sizable chunk of what consumers spend on products: "20 cents of every dollar."

Another video, "Why Does the FDA Exist?" notes contaminated food sparked a crisis at the turn of the twentieth century when scientists detected formaldehyde, borax, and other toxic preservatives in U.S.-manufactured foods.

This led to the Pure Food and Drugs Act of 1906, the video notes. Since then, about every 30 years, major categories have been added to the FDA's purview, from the regulation of cosmetics in 1938 to biologics and medical devices in the 1970s.

Such marketing provides insight into the mindset of government regulators, says Gorman.

"The FDA, like many of the state and federal health bureaucracies, has a history suggesting that those who staff it are not happy with the level of free speech guaranteed by the U.S. Constitution," said Gorman.

"People asking inconvenient questions about how bureaucrats go about their jobs means they have to explain themselves," said Gorman. "This is often difficult, boring, and time-consuming. It makes it harder for an agency to achieve its aims—aims which may or may not be in the best interest of the people who fund it."

Prosecuting Alleged 'Misbranding'

One area that has received much scrutiny is the agency's use of the 1962 Kefauver-Harris Amendments that expanded the FDA's authority to regulate drug efficacy in addition to safety and criminalized the misrepresentation of a drug's effects.

"The FDA bureaucracy went to work and, because government never knows when to stop, ended up trying to prosecute manufacturers for misbranding even when they disseminated truthful statements about off-label uses," said Gorman.

A 2021 study, "A Legislative/Legal History of Prescription Drug Advertising and Promotion Regulation," highlighted agency overreach and cited lawsuits that proved drug manufacturers can communicate accurate information without FDA oversight.

Turf Protection

With the average cost of developing a new drug having risen to more than $2 billion, physicians tend to look for multiple uses beyond the narrow ones approved by the FDA.

"Drug manufacturers' representatives would tell physicians that other doctors were getting good results using drug X for condition Y, distribute peer-reviewed articles describing additional uses, or provide unpublished study results," said Gorman. "The FDA did not like this at all. It went after the drug companies."

Courts have sided with physicians and ruled the FDA has no business blocking accurate information about off-label use, says Gorman.

"As long as off-label prescribing is allowed, physicians, not the FDA, should control the medical practice," said Gorman. "This hasn't stopped the FDA from trying to practice medicine.

"The FDA is free to use surplus agency resources to offer its opinion on the speech that it labels rumors," said Gorman. "However, it might be better off focusing on the quality of generic drugs. Recent scandals have shown that it is woefully lacking."

Oversight Failures

In 2020, Harry M. Lever, M.D., a cardiologist at the Cleveland Clinic, published an article outlining failures in FDA oversight of multiple generic drugs from countries with poor safety records. Some 1,159 lots from one class of drugs, angiotensin receptor blockers, had to be recalled because of contamination concerns, Lever noted.

"This has made it hard to write prescriptions for this class of drugs because at any one time it is difficult to know which lots have been contaminated," wrote Lever. "The testing of individual lots of internationally sourced generic drugs for potency and purity is not consistently done, and even when it is, it is not reported to practicing physicians."

Lever wrote that he complained to the FDA but it took 18 months to get a response.

Safety vs. Speech Codes

The FDA has also been criticized for its "unresponsiveness" to safety concerns over the COVID-19 shots. In addition, the agency is being sued for approving the abortion pill mifepristone without sufficient consideration of safety concerns.

"Rumors are simply speech," said Gorman. "The FDA should stick to drug approval rather than approving sources of information."

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

Insurance Now Covers Removal of Healthy Breasts

By AnneMarie Schieber

A surgeon says "chest masculinization" surgery is a growing part of her medical practice.

Insurance coverage has made it possible for the doctor's breast care clinic to perform nearly 350 of these procedures since 2017. So says Amie M. Hop, M.D., a breast surgeon from the Corewell Health West Comprehensive Breast and Gender Affirmation Clinic in Grand Rapids, Michigan and a clinical assistant professor at Michigan State University's College of Human Medicine.

Corewell Health markets the surgery by posting success stories online.

"This is uncharted territory. Sex change operations have been going on sub rosa for decades, but likely not in the numbers needed to have concrete data. Informed consent is a cruel joke."

MARILYN SINGLETON, M.D., J.D.
VISITING FELLOW, DO NO HARM

Insurance Required

In a "Diversity, Equity and Inclusion Grand Rounds" webinar on "chest masculinization" surgery for continuing medical education credit, Hop says she has been in surgical practice for seven years and gravitated to "chest masculinization" surgery four years ago.

"We have a unique perspective in our office as a vast majority of gender-affirming surgeries are performed by plastic surgeons," said Hop.

In 2019, Michigan began covering sex change surgery under the state's Medicaid program. Private health plans followed suit. Insurance coverage is a must, says Hop.

"We don't do a self-pay option because we're operating in the hospital, where things can be quite expensive," said Hop.

Most insurance carriers, as well as Hop's clinic, require a letter of support from a qualified mental health professional, and there must be a diagnosis of "persistent and well-documented gender dysphoria; typically, at least six months in duration," said Hop. Patients must provide the letter before consultation, said Hop, "because finding a therapist is not easy."

Hop says mental health problems must be under control because "stressors" may arise after surgery.

Transgender, Non-Binary Patients

Most of the women who seek breast removal describe themselves as "transgender/non-binary," though occasionally a patient will describe "themself" as having body dysmorphic disorder, an intense dislike of one's appearance.

The clinic does not treat minors but offers informational visits, with a parent attending. The median age of the clinic's patients is 25 years, and 90 percent have a history of mental health problems, with 11 percent having attempted suicide.

Hop says the clinic has gone to great lengths to be "inclusive." Intake forms require patients, including women seeking a mastectomy for cancer, to state their pronouns. The color pink and the use of the word "breast" have been mostly eliminated because Hop said it can "trigger" some trans patients. Hop showed the webinar participants she wears a prominent rainbow on her badge.

Outcomes and Complications

Removing breasts does not eliminate the need for breast cancer screens in the future, as some breast tissue may be left behind, and the patient will require imaging that might not be covered by insurance, Hop says.

Because the clinic has been performing the surgeries for only seven years, it has little long-term data. Over the seven years, 20 percent of patients suffered hematomas, seromas, surgical site infection, or nipple necrosis. Internal surveys have found 59 percent "strongly agree" they were satisfied with the outcome and 97 percent "strongly disagreed" that they regretted the surgery.

Hop said "detransition" is rare but data is limited.

Sanitized View?

In her presentation, Hop shared two photos of biological females who underwent surgery. Both photos showed a chest wall undistinguishable from that of a biological adult male.

The photos were a marked contrast to a photo shared in a Substack post by Peter McCullough, M.D. on July 6, 2023. The patient bears a huge, visible scar across the entire chest wall, and the nipples look unnatural.

Informed Consent 'a Joke'

There is not enough valid data on the long-term outcomes of such surgeries to allow patients to give informed consent, says Marilyn Singleton, M.D., J.D., a board-certified anesthesiologist and visiting fellow at Do No Harm, an advocacy group.

"This is uncharted territory," said Singleton. "Sex change operations have been going on sub rosa for decades, but likely not in the numbers needed to have concrete data. Informed consent is a cruel joke."

Medicaid likely considers breast removal medically necessary, but it is difficult for enrollees to obtain psychological treatment for dysphoria, says Singleton.

"I'd like to know the extent of Medicaid coverage for mental health counseling," said Singleton. "Finding a mental health professional who accepts Medicaid patients is difficult because of the low reimbursement. From a financial standpoint, mental therapy is time-consuming and can last years. By contrast, the surgery is presumably 'one and done.' Of course, this does not contemplate the complications."

Cost No Longer a Guardrail

Insurance has often been a guardrail against risky procedures that aren't medically necessary, because of the out-of-pocket cost to the patient, says Singleton.

"It is an equity issue now," said Singleton. "In the past, only the rich could afford to be transgender."

Medicaid may also now look at breast removal surgery as a discrimination issue under the Affordable Care Act (ACA), after the Biden administration reversed a Trump administration rule on June 15, says Singleton.

"The announcement from the Department of Health and Human Services concerns one of the most notable parts of the ACA: the provision in Section 1557 that prevents health care providers and insurance companies from discriminating on the basis of 'race, color, national origin, sex, age or disability in certain health programs and activities.' Effective immediately, the agency says it will interpret that provision to encompass discrimination against someone based on their sexual orientation or gender identity in health care," said Singleton.

By that logic, Medicaid and insurance could cover cosmetic breast enhancement surgery for non-transitioning women as medically necessary, says Singleton.

"I would argue that a person seeking bigger breasts is also suffering from a self-image disorder," said Singleton. "So perhaps we should petition insurance to pay for that, too."

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

Down Syndrome Patient's Family Sues Hospital for Do Not Resuscitate Order

By AnneMarie Schieber

The family of a deceased Wisconsin patient is suing the hospital and staff for issuing a Do Not Resuscitate (DNR) order without authorization.

Grace Schara, a 19-year-old with Down Syndrome, was admitted to St. Elizabeth's (Ascension) Hospital in Appleton, Wisconsin on October 7, 2021, upon the suggestion of an urgent care center where she had been taken for a COVID-19 diagnosis. The hospital admitted her for monitoring.

The DNR was issued without the family's consent, and Grace received a lethal combination of anesthesia drugs for no apparent medical reason, states the wrongful death complaint filed in Wisconsin Superior Court on April 11, 2023.

"We would have never considered this would be a dangerous place to put her in," said Scott Schara, Grace's father, in a video posted on the website of Our Amazing Grace's Light Shines On, Inc., a nonprofit founded by the family.


Grace Schara

Family Refused DNR

Grace's blood oxygen was at safe levels on the second day of her hospitalization, when the hospital asked for blanket consent to put her on a ventilator at any time. The family refused permission.

After the first few days, the hospital refused to permit Scott Schara to be at Grace's bedside, and an armed guard removed him, according to Schara. Grace's mother was confined to the family's home, recovering from COVID-19.

In the video, Grace's sister Jessica Schara, who served as her bedside advocate under the Americans with Disabilities Act, says the hospital staff did not keep her informed about Grace's progress.

"The communication was so poor," said Schara. "No doctor or nurse came to me to tell me what they were doing. I had to overhear what they were saying. They were making decisions on their own."

Given Dangerous Drugs

Grace was not put on a ventilator. Medical records show she was given Precedex, a short-term intravenous sedation drug that is indicated for no more than 24 hours, for four days.

Hours before her death, Grace was given Lorazepam, an anti-anxiety drug, and then morphine, an opioid that depresses respiration. These drugs should not be combined with similar medications because of possible coma or death, according to their labels.

"To use them [as] they did in a person with a diagnosis of acute respiratory distress is beyond believable as to intention," a doctor who reviewed the records told the family, according to a news release from the family's nonprofit.

After Grace received the drugs, her vital signs dropped to dangerous levels. "There were 30 to 40 nurses in that hallway. No one lifted a finger," says Jessica on the video.

By phone, Grace's parents also urged intervention. Scott Schara says that is when they learned the doctor had put a DNR order in place. Grace's parents watched their daughter die on FaceTime, seven days after she was admitted for care.

Lethal Incentives

Seeking hospital treatment led to Grace's death, Scott Schara told the *Heartland Daily Podcast* on June 1.

"If we never admitted her, Grace would be alive today," said Schara. "I know that with certainty because I went into a different hospital three days later. I was substantially worse, and that hospital turned me around in 24 hours."

According to the news release, COVID-19 treatment incentives played a role in Grace's death. If the hospital had been authorized to put Grace on a ventilator and then diagnosed her with COVID-19 and listed COVID-19 as her cause of death, it would have received $65,000 in bonuses from Medicare, Grace's insurance provider.

"The average time on a ventilator is 22 days, so when you add up all the money the hospital would have received, it's about a $300,000 payday," the press release states.

Obamacare Angle

The Schara family says physician-assisted death for the disabled is encouraged by Section 1553 of the Affordable Care Act, which prohibits discrimination complaints against a doctor or hospital when it involves "assisted suicide, euthanasia, or mercy killing."

"Grace was taken out as euthanasia," says Schara in the podcast. "This is legal."

The family filed a complaint with the Wisconsin Department of Safety and Professional Services, and the agency said nothing in state law prohibits the doctor's actions.

The family also discovered a training document for health care professionals from the Palliative Care Network of Wisconsin titled "Palliative Care for Patients with Down Syndrome."

"After they set the stage that people with Down Syndrome are nothing but problems, they assume the family doesn't want them," said Schara. "Grace was nothing but a blessing to us."

'Incredible Medical Hubris'

The purpose of the lawsuit is to shed light on wrongdoing, Schara says in the podcast.

"There is almost no money in these lawsuits," said Schara. "We have said if we get any money, we're going to disclaim it. We are paying for our own lawsuit. We believe God is behind us and we're going to win."

Issuing a DNR in these circumstances is bad medicine, says Heidi Klessig, M.D., a retired anesthesiologist, pain management specialist, and founder of Respect for Human Life.

"At best it sounds like incredible medical hubris, and at worst it sounds like straight-up medical murder," said Klessig.

There is no ethical justification for issuing a DNR order without patient consent, says Jane Orient, M.D., executive director of the Association for American Physicians and Surgeons.

"This patient was a precious and unique human being," said Orient. "The hospital appears to have assigned negative value to her life. It appears from the information given that her father was correct: she probably would have had a better chance at home."

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

For access to documents and Heartland Daily Podcast: **https://heartlanddailynews.com/2023/06/down-syndrome-patients-family-sues-hospital-for-do-not-resuscitate-order/**

Montana Outlaws Sharing of Genetic Data Without Consent

Private companies that offer genetic testing in Montana must now get a consumer's consent before sharing that data with anyone else.

SB 351, sponsored by state Sen. Daniel Zolnikov (R-Billings), was signed into law by Gov. Greg Gianforte on June 7. Companies like Ancestry.com and 23andMe can no longer share genetic data with researchers or law enforcement unless they get permission from the person who has provided the genetic material.

The Citizens' Council for Health Freedom (CCHF) ran a grassroots campaign urging Gianforte to sign the bill.

"CCHF appreciates Sen. Zolnikov's work to protect genetic privacy rights in Montana," said CCHF president and cofounder Twila Brase in a news release. "[This] legislation, now law, should be replicated state by state, protecting citizens from outsiders making claims upon their most private data—their genetic code."

The law aims to address "true ownership" of genetic information, says Zolnikov.

"Our genetic information is the ultimate foundation of our being and can be utilized to predict our current and future behaviors, health, tendencies, and much more," said Zolnikov in a statement. "By setting this precedent, we put individuals in the driver's seat of their own precious personal information instead of leaving it up to the discretion of companies and non-existent federal regulations.

"Time and time again, the data of Americans has been abused," said Zolnikov. "By protecting our DNA today, we can prevent future abuse that could range from identifying predictive behavior through genetic analysis and trends, to creating a massive pool of data to use to profile and market to individuals. The future is unknown, but today we have drawn a clear line in the sand of ensuring that the individual is involved in the conversation."

—Staff reports

HHS Moves to Change HIPAA 'Privacy' to Protect 'Reproductive Health Care'

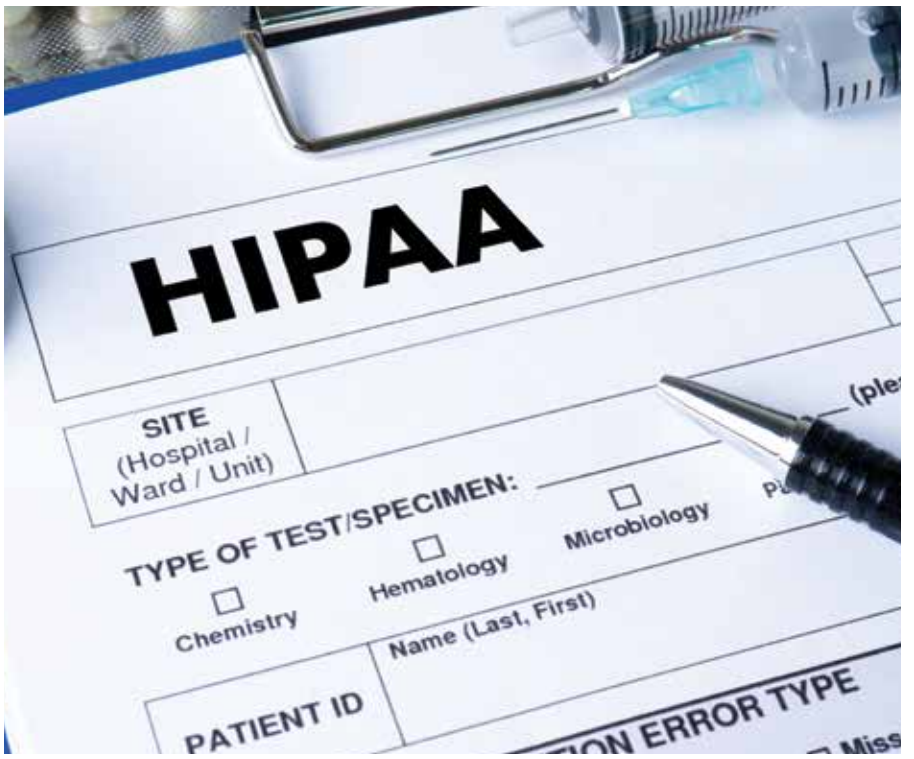
By AnneMarie Schieber

The U.S. Department of Health and Human Services (HHS) moved to limit state access to private medical records related to abortion and the treatment of gender dysphoria in minors.

HHS has proposed a rule that would prevent states from using the information to investigate violations of laws on "reproductive health care," most notably limits on abortion but also laws restricting transgender medical and surgical treatments on minors.

HHS published the rule change, "HIPAA Privacy Rule to Support Reproductive Health Care Privacy," on April 17. The comment period ended on June 16. The agency received 25,905 comments.

The proposed regulation "repeats the lie" that HIPAA (the Health Insurance Portability and Accountability Act of 1996) protects privacy, says Twila Brase, the author of *Big Brother in the Exam Roo*m and founder and president of the Citizens' Council for Health Freedom.



"HIPAA allows data-sharing of private medical records without the patient's consent, except apparently now for abortion and other 'reproductive health care,' which will suddenly be exempted from the definition of 'public health' when referring to surveillance and investigations," said Brase. "Suddenly, HIPAA is a threat to the agenda of the pro-abortion and perhaps the pro-trans crowd."

TWILA BRASE
FOUNDER AND PRESIDENT
CITIZENS' COUNCIL FOR HEALTH FREEDOM

"HIPAA allows data-sharing of private medical records without the patient's consent, except apparently now for abortion and other 'reproductive health care,' which will suddenly be exempted from the definition of 'public health' when referring to surveillance and investigations," said Brase. "Suddenly, HIPAA is a threat to the agenda of the pro-abortion and perhaps the pro-trans crowd."

Rule Highlights HIPAA Hoax

Brase says HIPAA really protects health care providers when they share patient data, as they increasingly do through electronic health records. The proposed change makes this apparent, says Brase.

"The government has proposed a revision of the HIPAA rule to make abortion and reproductive services data a special class of protected data, unavailable to anyone seeking to use it to enforce state laws against abortion," said Brase.

"People getting an abortion likely believe that HIPAA protects the privacy of that abortion, but regulators know that HIPAA does not protect anyone's privacy," said Brase. "So, to advance their reproductive agenda, they're now trying to give people seeking reproductive, transitioning, and abortion services the privacy that every patient in America wants, the privacy that every patient thinks they have under HIPAA, and the privacy that every patient is deprived of every day because of HIPAA, which is really a permissive data-sharing rule."

'Violence to Federalism'

"The proposal's poor draftsmanship and confusing structure alone are enough to render it in violation of the Administrative Procedure Act, if not the Due Process Clause of the Constitution," wrote Roger Severino, a former director of the HHS Office for Civil Rights, in his comment on the proposed rule.

More concerning is the attack on federalism, writes Severino, especially after HHS Secretary Xavier Becerra "made it abundantly clear" after the U.S. Supreme Court restored abortion regulation back to the states he would "double down and use every lever we have to protect access to abortion care."

"HIPAA simply cannot be drafted to get in their [states'] way without doing violence to federalism and the rule of law," Severino wrote. "The Department's proposal is arbitrary, capricious, and would create intolerable conflicts with law."

Protecting Children, Crime Victims

The public interest law firm Alliance Defending Freedom (ADF) said in its comment the proposed rule could extend to enforcement of laws limiting or prohibiting transgender surgeries and medical treatments on minors.

"The proposed rule goes far beyond abortion: it defines "reproductive health care" so broadly that it sweeps in information about sterilizing interventions sought by persons identifying as members of the opposite sex, such as puberty blockers, cross-sex hormones, and genital surgeries," wrote ADF attorneys Julie Marie Blake and Timothy Garrison.

"All of the problems in the proposed rule identified in the abortion context are thus extended and multiplied to this context as well, given that an increasing number of states regulate and prohibit these procedures, especially for minors," wrote Blake and Garrison.

Human Trafficking Concerns

Brase notes the proposed rule mentions a "personal representative" under "reproductive health care."

"Is this 'representative' section intended to circumvent parents?" asks Brase. "Is it also meant to make sure that health care providers fear transgressing HIPAA and being hit with hefty penalties? Due to the prohibition on sharing such data, the charges will never be explained to the media or the public, likely leaving the provider with a tarnished reputation."

The proposed rule could hamper investigations into human trafficking, say Blake and Garrison.

"Criminals who victimize women or girls who may become pregnant as a result of a sex crime have an obvious and nefarious interest in obtaining abortions: the abortion destroys evidence of the crime and, in the case of sex trafficking or serial sexual abuse, preserves the ability of the criminal to continue to victimize the mother of an aborted child," wrote Blake and Garrison.

Real Patient Privacy

"The department's proposed regulation to protect abortion data highlights why HIPAA needs to be a real privacy law, not a fake privacy law," said Brase. "Every American should demand restoration of pre-HIPAA consent requirements and the longstanding—back to the Hippocratic Oath—ethical and legal obligations of health care practitioners and other providers to protect the privacy and confidentiality of patient data."

States should have the authority to draft their own health privacy laws, says Brase.

"Then, in the case of this issue, the states would decide what they do about abortion and reproductive services data, and the feds could not intervene," said Brase.

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

Secrecy Surrounds WHO Health Regulations

By Bonner Russell Cohen

The World Health Organization (WHO) is revising its International Health Regulations (IHR) after the COVID-19 pandemic.

More than 300 amendments to the IHR are under consideration by 196 states. Delegates wrapped up their third session in April and planned to have three more this year—in July, October, and December—before presenting the changes to the World Health Assembly in May 2024.

After all revisions have been agreed upon, the goal is to adopt a WHO "pandemic treaty" that will guide the global response to the next outbreak of a highly infectious disease.

The WHO stated the proposals under examination are "amendments related to public health response, core capacities for surveillance and response, collaboration, and assistance, as well as six newly proposed articles and one new Annex," in a press release.

"COVID showed the world how vulnerable we all are and what needed fixing in the global health architecture if we are to be better prepared for the next big event," Ashley Bloomfield, former director-general of Health New Zealand and co-chair of the IHR Working Group, said in the press release.

"WHO's disastrous response to the COVID-19 affair should disqualify it from serving as an authoritative source of advice. It is highly politicized, corrupt, and riddled with incompetence. The United States should withdraw."

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

Accord, or Treaty?

Parallel to the process of amending the IHR, governments are negotiating a WHO document on pandemic prevention, preparedness, and response, also referred to as a pandemic accord.

The prospect of the WHO overseeing the drafting and adoption of a pandemic treaty has raised questions about the extent to which member countries will be obligated to abide by the document's terms. The WHO could adopt a pandemic accord, which would supposedly not have to be ratified by WHO member states, to minimize political controversies.

This was the model used by the United Nations Intergovernmental Panel on Climate Change in adopting the Paris Climate Accords in December 2015. The climate pact was nonbinding and had no enforcement mechanism but has been used by its supporters to determine signatories' climate policies.

Failed Pandemic Response

The U.S. Department of Health and Human Services (HHS) denies WHO regulations or agreements could override U.S. laws.

"It is false to claim that the World Health Organization has now, or will have by virtue of these activities, any authority to direct U.S. health policy or national emergency health response actions," HHS said in a statement to the Associated Press. "The WHO has no such enforcement mechanisms, and its non-binding recommendations to member states are just that: non-binding. Any associated actions at the national level will remain reserved to sovereign states, including the United States."

The WHO's performance during the pandemic is ample reason not to entrust it with new responsibilities, says Jeff Stier, a senior fellow at the Consumers Choice Center.

"It is imperative that we learn the lessons from WHO's failed response to COVID-19," said Stier. "When an institution riddled with corruption fails its biggest test, we should be decreasing funding and authority. Yet WHO, so detached from reality, demands more of each. The United States must become responsible donors by immediately demanding reform."

Failure to Confront China

The WHO came under widespread criticism for failing to confront the Chinese government regarding its claims about the coronavirus.

"Preliminary investigations conducted by the Chinese authorities found no clear evidence of human-to-human transmission of the novel #coronavirus (2019-nCoV) identified in #Wuhan, #China," the WHO posted on Twitter on January 14, 2020.

An investigation launched by WHO into the origins of the coronavirus, including a possible lab leak at the Wuhan Institute of Virology, failed to reach any definitive conclusions after Chinese authorities refused to cooperate.

Biden's WHO Reversal

The public should be skeptical of any role the WHO plays in the global health arena, says Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons and president of Doctors for Disaster Preparedness.

"WHO's disastrous response to the COVID-19 affair should disqualify it from serving as an authoritative source of advice," said Orient. "It is highly politicized, corrupt, and riddled with incompetence. The United States should withdraw."

President Donald Trump stopped funding the WHO and began the process of withdrawing from the group on July 6, 2020. President Joe Biden rescinded Trump's executive order on his first day in office.

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

Florida Laws Target 'Medical Authoritarianism'

By Bonner Russell Cohen

Florida Gov. Ron DeSantis (R) signed into law four bills designed to protect Floridians from medical mandates, empower doctors, and prohibit gain-of-function research.

Responding to the nation's traumatic experience during the COVID-19 pandemic and embracing the concept of "medical freedom," the landmark legislation signed on May 11 "safeguards residents' freedoms by ensuring that no patient is forced by a business, school, or government entity to undergo testing, wear a mask, or be vaccinated for COVID-19," states a press release from the governor's office.

"Our early actions during the pandemic protected Floridians and their freedoms," DeSantis said. "We protected the rights of Floridians to make decisions for themselves and their children and rejected COVID theater, narratives, and hysteria in favor of truth and data. These expanded protections will help ensure that medical authoritarianism does not take root in Florida."

Governor Ron DeSantis

PHOTO COURTESY GAGE SKIDMORE/FLICKR.COM

"A physician should not have to risk his medical license for treating a patient with the most appropriate therapy that is legal, safe, and effective. Legislation designed to protect the free speech and professional discretion of doctors to treat patients will benefit public health and get politics out of the equation. Now doctors face retribution from some state medical boards and attorneys general if they prescribe or even share certain views on public health."

MATT DEAN
SENIOR FELLOW
THE HEARTLAND INSTITUTE

'Comprehensive Medical Freedom'

Senate Bill 252, titled "Most Comprehensive Medical Freedom Bill in the Nation," prohibits businesses and government from requiring proof of vaccination or recovery from any disease to gain access or receive service.

Employers are prohibited from refusing employment to a job candidate, or firing, disciplining, or demoting a current employee based on vaccine or immunity status. The bill outlaws discrimination against any Florida resident based on COVID-19 vaccination or immunity status.

House Bill 1387 bans research designed to boost the virality of pathogens, called "gain of function" research. Senate Bill 238 deals with public records access to protect individuals from discrimination based on health care choices.

Senate Bill 1580 protects physicians' freedom of speech. Specifically, the new law allows health care providers and payers to opt out of participation or payment for certain health care services based on conscience objections. It requires notification of such objections, protects provider and payer whistleblowers, and stops state medical boards and the Florida Department of Health from taking disciplinary action against a professional's license for specified conduct.

'COVID's Silver Lining'

Marilyn. M. Singleton, M.D, J.D., a California-based physician, welcomes the new laws, particularly the legal protections afforded to doctors who speak out on medical issues.

"COVID's silver lining was that our eyes were opened to the fact that decisions of big-government experts are neither always right nor in the best interest of the people," said Singleton. "Whether out of ignorance or malice, the federal government is so entrenched in its bureaucracy that it cannot see its failures. The great advantage of our constitutional form of government is that the states can govern their own people consistent with their values."

The bills give physicians the freedom to treat patients ethically, says Singleton.

"The federal government gutted its medical conscience protections, [and] physicians practice medicine with the fear of Big Brother as their copilot," said Singleton. "Senate Bill 1580 gives physicians the freedom to ethically treat their patients using their broad-based knowledge and according to their conscience.

"This is a win for patients as well as for physicians, regardless of their political affiliation," said Singleton.

'Freedom to Treat'

Matt Dean, a senior fellow for health care policy outreach at The Heartland Institute, which publishes *Health Care News*, says he's not surprised a state like Florida enacted such far-reaching legislation.

"Patients and doctors are moving to places like Florida because they want the freedom to treat and be treated without the heavy hand of government getting in the way," said Dean.

"The doctor-patient relationship is a sacred trust bound by confidentiality and an oath taken by the physician to always put the interest of the patient first," said Dean. "At the heart of the doctor-patient relationship is consent, but doctors are more and more being put into a position where the government is overruling the decision to provide or not to provide treatment."

Some people want doctors to be forced to render whatever services patients demand, regardless of ethical considerations, says Dean.

"Patients are being told in some instances that they can define and demand care from a physician who believes he or she cannot perform because it violates a personal conviction or an oath to 'first of all, do no harm,'" said Dean. "States like Florida are moving in the opposite direction to provide more protections for the doctor-patient relationship, and that's a good thing."

Protecting Medical Licenses

Florida was the state where one of two cases involving physician freedom of practice gained national attention.

Police removed John Littell, M.D. from a Sarasota Memorial Hospital board meeting in March after he discussed using ivermectin for the treatment of COVID-19. In Minnesota, Scott Jensen, M.D. has fended off multiple attacks on his medical license after he spoke publicly about pandemic financial incentives to list COVID-19 as a cause of patient deaths and place patients with positive COVID-19 tests on ventilators.

Free Speech for Physicians

Gov. Gavin Newsom of California signed into law last year a measure allowing state medical boards to penalize doctors for spreading COVID-19 "misinformation." The state is facing several lawsuits over the law.

"A physician should not have to risk his medical license for treating a patient with the most appropriate therapy that is legal, safe, and effective," said Dean. "Legislation designed to protect the free speech and professional discretion of doctors to treat patients will benefit public health and get politics out of the equation," said Dean. "Now doctors face retribution from some state medical boards and attorneys general if they prescribe or even share certain views on public health.

"The COVID-19 pandemic led to state-sponsored restrictions on constitutionally protected freedoms—such as the freedom of speech and assembly—and showed how quickly these freedoms could be taken away," said Dean.

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

Bipartisan Deal Would Remove Medicare Loophole

By Bonner Russell Cohen

With Medicare facing insolvency before the end of the decade, a bipartisan trio of senators is proposing savings by reforming the sprawling program's billing practices.

Sens. Mike Braun (R-IN), Maggie Hassan (D-NH), and John Kennedy (R-LA) introduced the Site-based Invoicing and Transparency Enhancement (SITE) Act. The bill would adopt some site-neutral payments in Medicare and increase the transparency of hospital billing, according to the sponsors' joint press release on June 12.


Sen. Mike Braun

PHOTO COURTESY POOL/POOL/GETTYIMAGES

'Excess Costs': $40 Billion

"Due to Medicare's billing structure, even if care is received at an off-campus outpatient facility, it can be billed as though the care was provided at the main hospital campus," states the press release. "This means the higher hospital rate is charged.

"This issue has become more prevalent as more and more small physician-owned practices and off-campus facilities are acquired by larger hospital systems," the press release states. "In 2020, the Congressional Budget Office estimated that taxpayers will pay close to $40 billion in excess costs to Medicare due to exorbitant facility fee payments over the next decade."

The billing practice and resulting higher costs are rooted in a provision of the 2015 Bipartisan Budget Act. That law established "site-neutral" payments under Medicare for services received at off-campus outpatient facilities but exempted most hospitals.

Ending Exceptions

The SITE Act (S. 1869) "would end the 2015 Bipartisan Budget Act site-neutral exceptions, [and] prevent off-campus emergency departments from charging higher rates from on-campus emergency departments when standalone emergency facilities are located in close proximity to a hospital campus," states the press release.

In addition, the bill would "require that health systems establish and bill using a unique National Provider Identifier number for each and every off-campus outpatient department, direct [the U.S. Department of Health and Human Services] to treat outpatient departments as subparts of the parent organization and to issue these subparts unique provider identifiers, and remove liability for services rendered for payers that are not billed in accordance with this section's requirements."

Savings earned from the revisions to Medicare billing practices would go toward filling the shortage of nurses by creating a graduate nursing education program that would provide payments to cover the costs of training.

"Granite Staters who have been going to the same doctor for years are experiencing sticker shock when a hospital acquires a doctor's office or clinic and all of a sudden starts charging extra fees for the same services," Hassan stated. "Our bipartisan bill takes on the health care industry to eliminate unfair fees, lower costs for patients, and save taxpayer dollars—and then we use these savings to invest in the health care workforce."

Gaming the System

"Hospitals are gaming the system to charge Louisiana patients and taxpayers more for outpatient, off-site care," Kennedy stated. "That's wrong, and I'm proud to work with Sens. Braun and Hassan to make it right by correcting Medicare's billing policy."

The nonpartisan Committee for a Responsible Federal Budget said "adopting site-neutral payments will reduce the incentive for hospital consolidation, which can help lower overall costs and improve quality of care," in a press release supporting the SITE Act. "Furthermore, commercial insurance payment practices often follow Medicare's lead; site-based payments are no exception."

Price-Control Problem

The site-neutrality issue is part of the larger problem of Medicare price controls, says Merrill Matthews, resident scholar at the Texas-based Institute for Policy Innovation.

"The Medicare site-neutrality issue is an old story in a new setting," said Matthews. "When government imposes price controls, which is what Medicare does, the affected parties seek to game the system, to maximize their income."

Obamacare intensified the problem, says Matthews.

"Hospitals had been buying up physician practices for years to take advantage of the higher fees hospitals can charge," said Matthews. "The Affordable Care Act exacerbated the practice. Congress tried to address the issue in 2015, but hospitals found other ways to continue charging higher hospital rates.

"The SITE Act is yet another attempt to counteract the economic incentives that are created when price controls are imposed," said Matthews. "If it passes, it may work for a while, but it is a reasonable assumption that hospitals will find other ways to game the system."

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

COMMENTARY

Restoring the Patient-Physician Relationship Is the Key to Fixing Health Care

By Robert Koshnick, M.D.

Nearly 90 percent of the $4.3 trillion we spend each year on health care is paid by someone other than the person receiving the care.

That sounds like a great deal for health care consumers, but a third-party payer system creates waste and price distortions. Money is directed to the wrong places, and we end up cutting corners where we shouldn't.

What we have today in health care is a "managed" market, not a free one. If you look at all the successful markets in our economy—retail and tech, for example—none have succeeded in this way.

"By cutting out the middlemen and restoring the direct relationship between doctor and patient, we can get better and more timely care and cut down on that $4.3 trillion annual bill."

ROBERT KOSHNICK, M.D.

Promoting 'Medical Inflation'

When health care consumers are disconnected from payment, they tend to ignore primary care and not seek medical attention until the problem becomes more expensive to treat. There is no disincentive to act in this way, because someone else is footing the bill.

In addition, third-party payments weaken the patient-physician relationship, and when that happens, patients tend not to comply with medical advice, have poorer outcomes, and ultimately are less satisfied. Physicians are equally frustrated. Research from the Mayo Clinic found 62.8 percent of U.S. physicians exhibited at least one symptom of burnout in 2021.

In 1950, health expenditures accounted for 4.6 percent of U.S. gross domestic product. By 2021, health expenditures grew to 18.3 percent of GDP, or $12,914 per person per year. When health care spending began taking up a larger chunk of the economy, physicians became the scapegoats. Enter the introduction of "accountable care organizations," an attempt to manage physician costs despite not one shred of evidence of greed.

From Bad to Worse

This led to the Health Maintenance Organization (HMO) Act of 1973, which allowed corporations to practice medicine without a license and function as insurance companies while avoiding state insurance regulations. Health care expenditures soared as third-party payer costs and regulations increased, while patient and physician satisfaction declined.

Managed care then raised costs further and led to massive health care consolidation that reduced competition. Value-based pay and mandated patient satisfaction scores, conceived by the north central states to blunt unfair Medicare payments, further ballooned health care costs without improving quality or patient satisfaction.

Research has long found excessive prices, not excessive volume, are to blame for the growth in health care spending.

Goodbye, Marcus Welby

The corporatization of medicine, which added yet more cost, has disrupted the patient-physician relationship. The resulting loss of trust reduces the incremental care that improves health outcomes. Personal responsibility for the consequences of unhealthy living habits, the major factor in individual health outcomes, has also declined.

The corporatization of medicine has changed medical practice from a profession to a business, to the detriment of patient care and the patient-physician relationship. Physicians' loyalty should be to their patients, not the corporate bottom line and rules set by nonphysicians.

This thinking goes back as far as 1933 when the Minnesota Supreme Court stated in *Granger v. Adson* it is "improper and contrary to statute and public policy for a corporation or layman to practice medicine indirectly by hiring a licensed doctor for the benefit or profit of the hirer." The court further stated, "What the law intends is that the patient shall be the patient of a licensed physician not of a corporation or layman. There is no place for a middleman."

The court reaffirmed this in 2006 in *Isles Wellness, Inc. v. Progressive Northern Insurance Co.*, stating, "The related public policy considerations underlying the prohibition on corporate practice of a profession include concerns raised by the specter of lay control over professional judgment, commercial exploitation of health care practice, and the possibility that a health care practitioner's loyalty to a patient and an employer will be in conflict."

Repealing the HMO Act of 1973 and allowing states to enact and enforce laws regarding the corporate practice of medicine could return doctors' sole loyalty to their patients and restore the primacy of the patient-physician relationship.

Promise of Direct Primary Care

Another way to rescue the patient-physician relationship from corporate control is to have people directly pay or contract for physician services. Contracting with periodic payments is known as direct primary care (DPC), though this could be done for any physician service.

Congress should identify DPC as an allowable medical expense under health saving accounts (HSA), individual coverage health reimbursement accounts (ICHRA), employer health reimbursement accounts (HRA), and flexible savings accounts (FSA). DPC should not be considered insurance that can be regulated by state insurance commissioners.

Residency programs should give their residents training in how to set up and run DPC and specialty practices. States should enact legislation to allow Medicaid patients to opt into DPC. The federal government should allow Medicare patients to use DPC. Employers should emphasize DPC as a good option under HSA, ICHRA, HRA, and FSA accounts.

The 'Empowering-People Option Act'

I propose an Empowering-People Option Act (E-POA) that would give people the means to pay directly or contract for medical care, including DPC.

E-POA would establish a means-tested, refundable tax credit—$4,000 per adult and $2,000 per child—that could be set aside in an account like a health savings account. The Act also includes a price transparency provision.

By cutting out the middlemen and restoring the direct relationship between doctor and patient, we can get better and more timely care and cut down on that $4.3 trillion annual bill.

RobertKoshnick,M.D. **(bob.koshnick@gmail.com)** *is a retired primary care physician from Minnesota. Koshnick is chair of the policy committee of the Minnesota Medical Association and author of* Empower-Patient Accounts Empower Patients!

INTERNET INFO

Robert Koshnick, M.D., "Empowering-People Option Act": **https://heartlanddailynews.com/wp-content/uploads/2023/05/Empowering-People-Option-Act-.pdf**

COMMENTARY

The Unheralded Pandemic: Death by Queue

By Deane Waldman, M.D.

Mary began to experience abdominal pain but ignored it.

When she finally told me, I said, "I'm your husband, not your physician. Go see her, now." Mary got the next available appointment—seven months in the future. The diagnosis was inoperable pancreatic cancer. Twenty-two months later, my college sweetheart and wife of 54 years died. Might things have been different if she had been seen when symptoms started?

Everyone now knows of the COVID-19 pandemic. Few have heard of a pandemic killing millions of people with no media attention at all: death by queue.

Death by queue means dying while waiting in line for care that is technically possible but unavailable. Death by queue has long been a feature of delayed care in the British National Health Service, namely for heart attack victims and cancer patients.

Death by queue—the unheralded pandemic—has come to the U.S.A.

Not a Marketplace

In all marketplaces except health care, the consumer is the payer. The consumer/payer chooses whom he or she will pay and how much, based on the buyer's calculation of value received for money spent.

The seller must offer what the customer considers value and must price services or goods in competition with other sellers of similar products. The buyer is spending money out of pocket and thus has a strong incentive to economize. Competition among sellers drives down prices. There are only two "parties" in a true market: buyer-customer-consumer-payer—*demand*, in economic terms—and seller-provider—*supply*.

U.S. health care is not a true market. There are *three parties*: the patient or consumer; the provider or seller; and a third party—government and/or insurer—that makes all financial as well as medical decisions. The third party disconnects buyer from seller, supply from demand.

In health care, the buyer (patient) cannot choose the seller (provider): the third party does. The buyer (patient) does not pay the seller (provider): the third party does. The seller (provider) does not choose the services provided: the third party—Washington—does. Sellers (providers) can set whatever prices they like, but third parties will pay what they decide.

As a result of this disconnection, prices constantly rise and care is delayed: death by queue.

'Coverage' Without Care

Health care systems exist to ensure people get the medical care they need, when they need it. Lowering costs or saving money is important only *after* timely care is available.

Before Obamacare, the average maximum wait time to see a primary care physician was 99 days. Afterward, wait times increased to an unconscionable 122 days.

The end result of excessive wait times is death by queue. This happened to 752 Illinoisans, 47,000 veterans, and a 12-year-old boy, Deamonte Driver, who died of complications from a tooth cavity because no pediatric dentists in his area accepted Medicaid insurance.

Common wisdom says people with insurance get care and people without insurance do not. History shows the exact opposite, a seesaw effect: as the number of individuals covered by government-run insurance goes up, access to care goes down.

Democrats and the mainstream media hail the decrease in the uninsured rate from 15 percent in 2010 to 8.3 percent in 2021. Medicaid now covers 93 million Americans—28 percent of the population. As more Americans have insurance, more people will reasonably expect to receive the care they need when they need it. They will be disappointed.

Staff Shortages

Shortages of doctors, nurses, and mental health professionals contribute greatly to death by queue. The reason for the shortages is cultural: intense frustration. Caregivers believe they are doing honorable work, healing sick people. Doing this used to generate immense psychic reward.

Caregivers naturally assume the system in which they do their noble work would help them. Instead of making their professional lives easier, however, government regulations and insurance rules constrain, obstruct, and penalize care providers.

Washington's medical mandates and insurance controls have taken medical authority away from care providers. By "disconnecting" patients from their care providers, third parties deny those providers the psychic reward that would normally bring them to the operating room at 2 a.m.

Root Cause: Government

Death by queue is the direct result of federal control of health care and the resulting BARRCOE: bureaucracy, administration, rules, regulations, compliance, oversight, and enforcement.

First, there is the regulatory burden. Time that providers should spend with patients is consumed by regulatory and administrative compliance. This regulatory burden is largely responsible for physicians refusing Medicaid and other government-insured patients, and even for early retirement.

Second, there is "bureaucratic diversion" of money from clinical care to pay for BARRCOE. Every dollar spent on these nonclinical activities is a dollar taken away from patient care. Estimates of this expense range from 31 percent to more than 50 percent of all health care spending.

Prior to 1965, the U.S. spent 6.5 percent of gross domestic product on health care. Last year, it was 19.7 percent. The result of Washington's unrestrained spending is death by queue and the impending bankruptcy of Medicare.

Restoring Autonomy

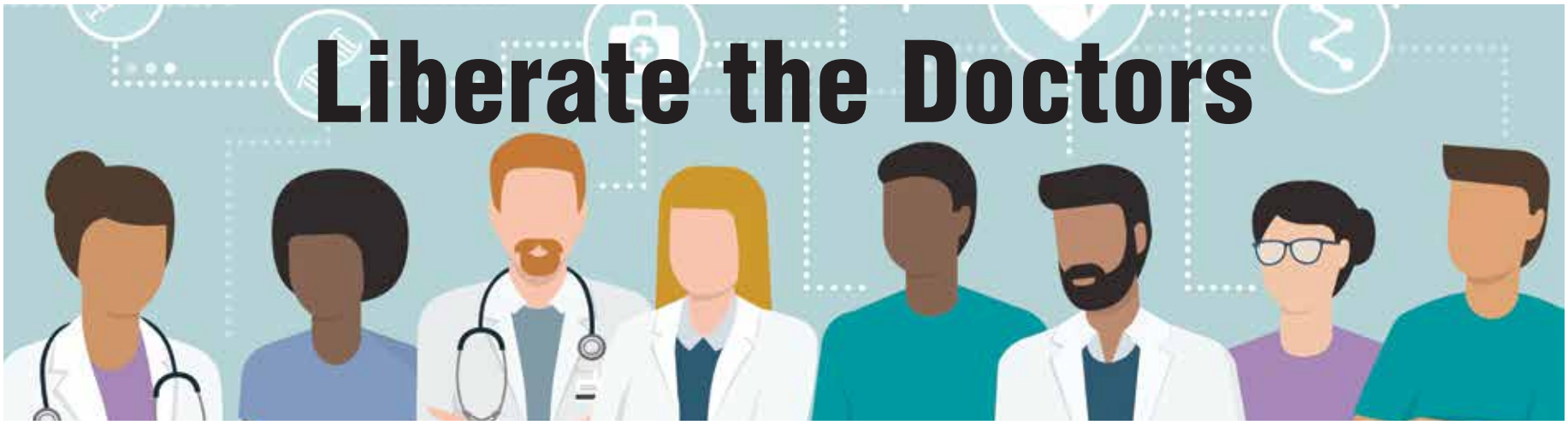
To eliminate death by queue, we must reconnect patients directly with doctors. Remove third parties—the federal government and insurance companies—from making medical and financial decisions for patients and stealing precious health care dollars from care.

Only by directly reconnecting patient with doctor can "We the People" recover our constitutionally guaranteed freedom: patients' medical autonomy!

Deane Waldman, M.D., MBA (**dw@deanewaldman.com**) *is a professor emeritus of pediatrics, pathology, and decision science at the University of Mexico and author of the multi-award-winning book* Curing the Cancer in U.S. Healthcare: StatesCare and Market-Based Medicine. *A longer version of this article was published in* Clinics in Nursing. *Reprinted with permission.*

COMMENTARY

Liberate the Doctors



By John C. Goodman

For almost half a century, this country has been seriously engaged in efforts to reform our health care system to reduce costs, improve quality, and expand access to care.

Participants in the effort have included politicians representing all points of view in Congress and in state legislatures, bureaucrats of all stripes and varieties, business executives, labor leaders, insurance company reps, hospital execs, academic health economists, and a slew of nonprofit foundations.

The one group that has been noticeably absent from these discussions is the doctors who actually deliver care.

Virtually every solution that has been tried involves people who don't practice medicine telling the doctors who do practice medicine how to manage their affairs. None of these solutions appears to work. Costs keep rising. Quality of care is not improving measurably. Access to care (as measured, say, by per-capita doctor visits or the length of time needed to see a doctor) seems to be getting worse.

"There are many ways to overcome regulatory obstacles to solve health policy problems. Other solutions include expansion of telemedicine, health savings account access to pay for DPC, and offering doctor-run specialty plans on the Obamacare exchanges. We should ask the practicing doctors to suggest many more."

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

Repackage, Reprice Services

Doctors are the only professionals in our society who do not have the freedom to repackage and reprice the services they offer in the marketplace. All other professionals—lawyers, accountants, architects, engineers, etc.—are free to change the services they offer and the fees they charge whenever technology changes, whenever science changes, or whenever there is a change in customer preferences.

Currently, there are 10,000 tasks that Medicare pays doctors to do. If there is a service that a patient needs that is not on the list, the doctor doesn't get paid anything. If the service is on the list, the doctor only gets paid Medicare's fixed price. There is no negotiation of these prices. The doctor must take it or leave it.

Large private insurance companies tend to pay the same way Medicare pays, using the same list. Their rates tend to be a percentage of what Medicare pays (e.g., 150 percent), and again there is no negotiation. It's take it or leave it.

No other professional is paid this way, and for good reason. Imagine you were charged with a crime and an outside entity set the fees your lawyer got for different tasks. Suppose, for example, the lawyer gets $50 an hour for jury selection and $500 an hour for preparing a final summation of your case. You might get a really excellent summation at the end of your trial, one that would ordinarily get you off scot-free, but (unfortunately for you) it's delivered to the wrong jury!

Even worse than mispricing is the presumption that anyone could think of everything a professional might do to help a customer and then put it on a written list. Until the pandemic, for example, consultations by phone, email, Zoom, Skype, etc., were not even on the list of services Medicare paid for except in rare circumstances.

Encourage Supply-Side Innovation

How do we know practicing doctors could improve on the current system? Because that is what happens whenever they provide services outside the third-party payer system. For cosmetic and Lasik surgery, for example, we see transparent package prices that have declined in real terms over the last two decades even as the cost of every other type of surgery kept on rising.

This happened despite a huge increase in demand and all manner of technological changes, which we are told raise costs everywhere else in medicine.

Direct primary care (DPC) is another example. DPC doctors provide all primary care for reasonable monthly fees (say, $50 a month for a mother and $10 for her child), and patients are usually able to reach their doctor by phone at night and on weekends, as an alternative to visiting the emergency room.

There are endless possibilities here. Giving doctors freedom to offer different services for different prices promises less-expensive, higher-quality care. It should be the goal of any responsible reform.

Unleash Specialized Plans

In an ideal world, doctors would be able to approach Medicare and make a deal. In return for being paid in a different way, they would guarantee lower costs and a higher quality of patient care. We shouldn't give up on that idea, but the odds will be much better if the payer is a private entity.

For example, DPC doctors initially refused to deal with any third-party payers. That has changed. One of the fastest-growing trends in private insurance is employer payment for direct primary care.

To my knowledge, no public sector insurance plan has taken advantage of this opportunity. Yet, there is an exception to this generalization. That is the Medicare Advantage (MA) program, where roughly half the beneficiaries are enrolled in private insurance plans. MA plans are allowed to specialize and become centers of excellence for specific types of care.

For example, there are special insurance plans for diabetes, for congestive heart failure, for lung disease, etc. These plans are becoming innovators in chronic disease management. Some doctor-run MA plans, for example, make insulin free, as well as consultations with an endocrinologist.

By investing in these upfront costs, the plans avert the greater costs of emergency room visits and hospitalization.

One way to think of these special-needs plans is to see them as an extension of the DPC model, applying it to specialty care. There is no reason in principle why doctor-run centers could not provide specialist services under all private-sector insurance plans.

Deregulate the Medical Marketplace

There are many ways to overcome regulatory obstacles to solve health policy problems. Other solutions include expansion of telemedicine, health savings account access to pay for DPC, and offering doctor-run specialty plans on the Obamacare exchanges.

We should ask the practicing doctors to suggest many more.

John C. Goodman, Ph.D. (**johngoodman@goodmaninstitute.org**) *is co-publisher of* Health Care News *and president and founder of the Goodman Institute for Public Policy Research.* *A version of this article appeared in* Forbes *on June 13, 2023. Reprinted with permission.*

Congress Tackles Health Care Options for Small Business Employers

By Bonner Russell Cohen

Capitol Hill lawmakers are advancing legislation to broaden the options small business owners have to offer their employees affordable health care coverage.

H.R. 3799, the CHOICE Arrangement Act, sponsored by Rep. Kevin Hern (R-OK), was approved by the House of Representatives on June 21 on a 220-209 vote and was sent to the Senate.

Broadens Employees' Choices

Hern's bill would codify two rules issued by the Trump administration.

A rule from 2019 offers employers a tax credit on contributions they make to employees toward purchasing their own health insurance plans on individual markets. These Individual Coverage Health Reimbursement Arrangements (ICHRAs), now called CHOICE accounts, would no longer limit employers to a select number of plans for their workforce but will empower employees to choose plans suited to their needs with funds provided by their employers.

The second Trump-era rule, dating from 2018, enables small businesses to join forces and receive the same benefits as those enjoyed by large companies.

"We've heard that 87 percent of small businesses say they want another way to provide health insurance for their employees without offering a traditional group plan, and 90 percent of individuals want to be able to take their health insurance with them if they change jobs," Rep. Jason Smith (R-MO), chairman of the House Ways and Means Committee, said in a June 20 statement on the bill.

Businesses Don't Know Options

Hearings leading up to the CHOICE Arrangements Act revealed only 30 percent of small businesses with fewer than 50 employees offer health insurance, down from 50 percent 20 years ago.

"Importantly, 70 percent of small businesses do not know that the federal government already allows for flexible health insurance coverage opportunities that could be beneficial to them and their employees—this includes CHOICE Arrangements, Qualified Small Employer Health Reimbursement Arrangements, and the Small Business Health Care Tax Credit," said Smith in his statement.

A provision inserted into the bill by Rep. Claudia Tenney (R-NY) requires the Treasury Department to notify small businesses of the tax-advantaged coverage options available to them.

H.R. 3799 also includes a provision to offer more flexibility in the definition of "association" for the purposes of Association Health Plans (AHP), plus a provision defining financial protection for small businesses opting for self-insurance. AHPs were a focus of Trump administration health care policy, but they have faced legal hurdles in court and enhanced regulation by the Biden administration under the Affordable Care Act.

'Virtuous Cycle'

Expanding the options of both employers and employees would create incentives that can improve health care coverage for millions of Americans, says Daniel Perrin, president of the Washington, D.C.-based HSA Coalition.

"ICHRA-compatible plans are only those compliant with the Affordable Care Act and sold in the individual market," said Perrin. "They receive the same tax benefits as traditional group plans, meaning premiums are exempt from federal income or payroll taxes. ICHRAs' anticipated impact on the individual market is substantial, catalyzing a virtuous cycle that can draw more insurers, induce competition, create an attractive market, and increase enrollment numbers, all without additional government spending."

Perrin says the Choice Act addresses a concern brought up often in the health care debate: the uninsured.

"The Treasury Department predicted in 2019 that by 2025 about 11 million people would be enrolled in the individual market using an ICHRA, approximately 100,000 of whom would otherwise be uninsured," said Perrin.

"The CHOICE Arrangement Act represents a significant step toward expanding coverage and providing more choice in health care," said Perrin. "It would greatly contribute to a more inclusive, accessible, and diverse health care market."

'An Important Step'

Paragon Health Institute President Brian Blase says he welcomes the effort to give employers and employees more choices in the health care arena.

"ICHRAs permit employers to provide tax-free contributions that employees can use to buy coverage that is best for them and their families," said Blase. "While reforms to the individual market to make such plans more attractive are important, ICHRAs represent an important step to giving Americans more control over their health care and help more employers offer health benefits."

"Personal and portable insurance is extremely popular with voters," said Goodman. "It's long overdue. But like the Trump executive order and the rule on which it is based, there is a hidden catch in the Choice Act. The insurance must be Obamacare-compliant."

JOHN C. GOODMAN
PRESIDENT
GOODMAN INSTITUTE FOR POLICY RESEARCH

Obamacare Compliance Snag

The CHOICE Arrangement Act falls short of what is needed, says John C. Goodman, president of the Goodman Institute for Policy Research and co-publisher of *Health Care News*.

"Personal and portable insurance is extremely popular with voters," said Goodman. "It's long overdue. But like the Trump executive order and the rule on which it is based, there is a hidden catch in the Choice Act. The insurance must be Obamacare-compliant. That means employees can only use their employer's money to purchase insurance sold in the [Obamacare] exchanges."

The lack of flexibility in contributions to, and coverage under, such plans has limited their appeal, says Goodman.

"Unfortunately, the insurance sold in the exchanges has higher premiums, higher deductibles, and narrower networks than most group insurance," said Goodman. "That means the opportunity won't be exploited in most places most of the time."

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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

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4

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