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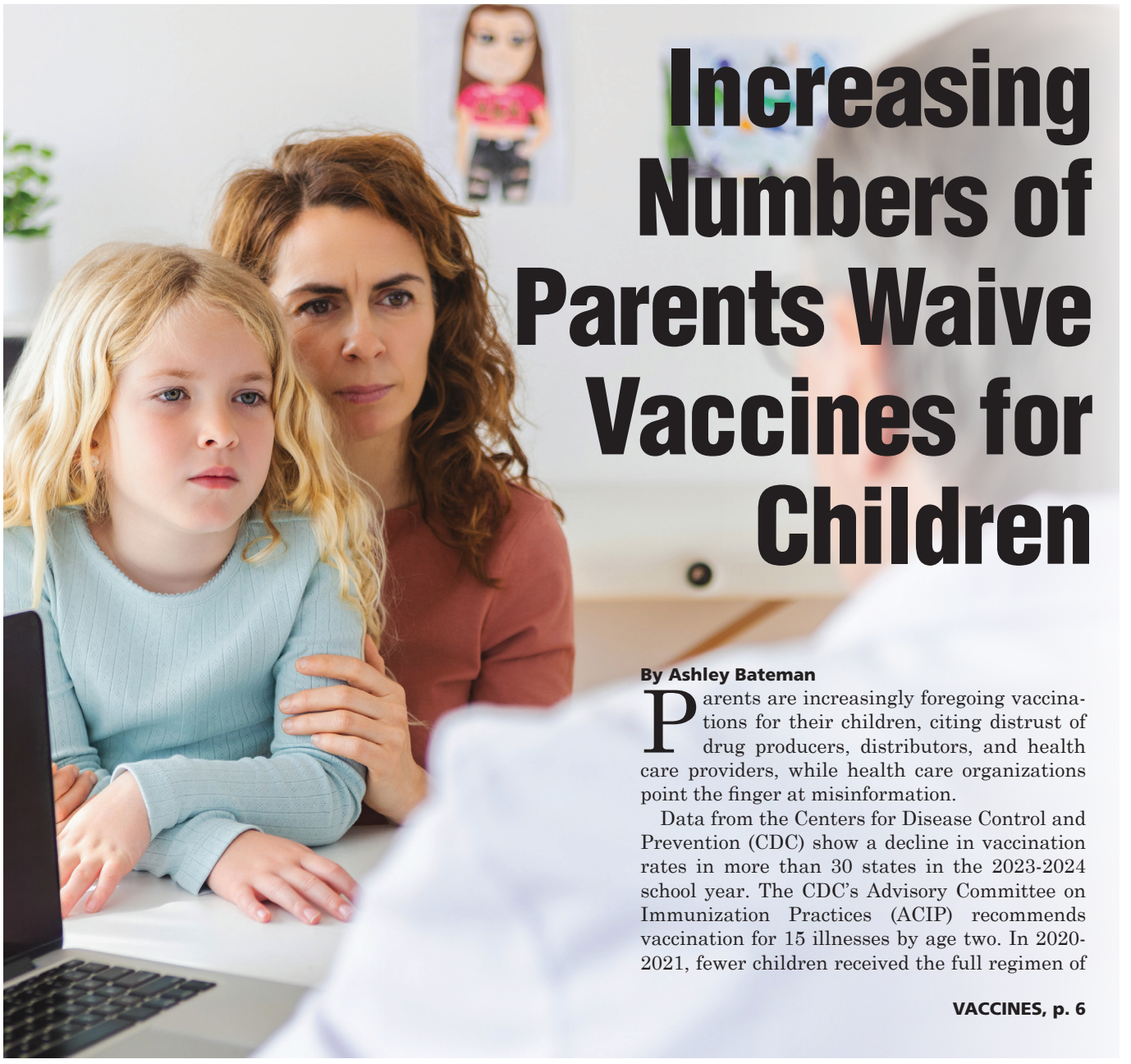
The Pulse



Increasing Numbers of Parents Waive Vaccines for Children

By Ashley Bateman

Parents are increasingly foregoing vaccinations for their children, citing distrust of drug producers, distributors, and health care providers, while health care organizations point the finger at misinformation.

Data from the Centers for Disease Control and Prevention (CDC) show a decline in vaccination rates in more than 30 states in the 2023-2024 school year. The CDC's Advisory Committee on Immunization Practices (ACIP) recommends vaccination for 15 illnesses by age two. In 2020-2021, fewer children received the full regimen of

VACCINES, p. 6

Feds Demand Personal Information from Physician Practices, Others

By Joe Barnett

New financial disclosure requirements that would sweep in many medical professionals were temporarily put on hold under an order from a panel of the Fifth Circuit Court of Appeals.

A Biden administration rule would have required an estimated 33 million small businesses, including some nonprofit entities, to report personally identifying information about their "beneficial ownership or interest" by January 1. Enforcement of the paperwork filing was blocked by the appel-

FED DEMANDS, p. 4

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1

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2

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3

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4

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Report: Child Died During Clinical Trial of COVID-19 Shots

By Bonner Russell Cohen

Concerns about the safety and efficacy of mRNA COVID-19 shots have increased after a January 3 report that drug maker Moderna failed to inform the U.S. government of the death of a child during clinical trials of its vaccine, as required by law.

"A preschool-aged child died of cardio-respiratory arrest after getting a booster shot of Moderna's mRNA Covid vaccine in the company's main clinical trial of the jab," former *New York Times* reporter Alex Berenson wrote on Substack.

Instead of disclosing the death to clinicaltrials.gov, a federal government website where companies must legally report trial results, Moderna posted the incident on "an obscure database run by the European drug regulatory agency," wrote Berenson.

The child died in late 2022 or early 2023, Berenson reported.

Government, Media Push

Moderna launched its KidCOVE clinical trial in March 2021 after the success of its original mRNA COVID-19 vaccine in adults 18-years-old and older. Pressure from public health authorities and the media had been building for some time to vaccinate children against the coronavirus, although mounting evidence showed the very young were at little risk of contracting or spreading COVID-19.

With the emergence of the Omicron variant in November 2021, Moderna and other vaccine companies developed boosters, which Moderna included in another phase of its child trial.

"Because this portion of the trial did not include a placebo-blinded arm, the company would have known immediately that the death followed vaccination," wrote Berenson.

Moderna's report to regulators lists the death as "cardio-respiratory arrest," not related to the vaccine, and did not explain how the company came to that conclusion, Berenson wrote.

Moderna has made no public comment about the death as of this writing.

FDA Reliance on Reporting

Before the death of the child, Moderna announced in October 2021 its trial had succeeded among children ages six to 11-years-old, and in March 2022 for children six months to five-years-old. The Food and Drug Administration (FDA) then issued an Emergency Use Authorization (EUA) for the company's booster for kids.

"One death after Moderna's COVID-19 vaccine is one death too many, as almost all children have had the infection once and recurrent illnesses are no different than the common cold."

PETER A. MCCULLOUGH, M.D.

Now that the post-vaccination death of the child has finally been reported to an overseas database, the FDA will be under pressure to explain its failure to disclose the fact.

"In its statement [responding to Berenson's email questions before publication on January 3], the FDA says only that 'no deaths [were] reported' in the trials 'that were the basis of the Emergency Use Authorization' for the shot for children in 2022," wrote Berenson. "In fact, the KidCOVE trial was the basis of the authorization, though the death occurred after the authorization. The agency did not answer follow-up questions."

Sen. Ron Johnson (R-WI) plans to subpoena the agency to find out what it knew and when, Berenson reported on January 6.

Lack of Informed Consent

Moderna's actions raise a huge red flag, says Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons.

"It appears that Moderna seriously violated a clear federal law by failing to properly report a child's death in an experimental trial," said Orient

Reporting the death could have affected the EUA, Orient says.

"[The FDA] might well have withdrawn the EUA, especially since Omicron was not an emergency, especially for children," said Orient. "The EUA requires informed consent, and it is doubtful that parents would have consented knowing that a child had died of a cardiorespiratory arrest, a highly unusual event in a previously healthy child, after getting an experimental shot.

"The problem is not just this product, but the company and the regulatory process itself," said Orient. "Dr. Makary should immediately act on this."

Calls for a Ban

Peter A. McCullough, M.D., a Dallas-based cardiologist, says the mRNA vaccines should be withdrawn.

"As a medical doctor, I am greatly concerned that children in some states are effectively forced to take COVID-19 vaccines as part of the routine schedule required to attend schools," said McCullough. "One death after Moderna's COVID-19 vaccine is one death too many, as almost all children have had the infection once and recurrent illnesses are no different than the common cold.

"I support the World Council for Health, the American Association of Physicians and Surgeons, and many other leading figures in health care in calling for immediate removal of all COVID-19 vaccines from human use," said McCullough.

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

Feds Demand Personal Information from Physician Practices, Others

Continued from page 1

late court in an order issued on December 26.

The obligation to file with the Financial Crimes Enforcement Network (FinCEN), a small office in the U.S. Department of the Treasury, carries criminal penalties of up to two years in federal prison and a $10,000 fine. The FinCEN rule was authorized by the Corporate Transparency Act (CTA), which was enacted as part of the Anti-Money Laundering Act in 2020, a measure to fight terrorism rather than enforce federal tax law.

The rule would require disclosure of information such as Social Security numbers, birthdates, driver's license numbers, and the home addresses of corporate officers and other individuals who "substantially" benefit from or control the covered entities. The only entities required to file are those with less than $5 million in annual revenue and fewer than 20 employees.

'Federal Overreach'

The stay on enforcement of the FinCEN rule resulted from litigation by the Association of American Physicians and Surgeons (AAPS) challenging the constitutionality of the CTA in a federal court in Amarillo, Texas.

U.S. District Court Judge Matthew J. Kacsmaryk issued a preliminary nationwide injunction against enforcement of the FinCEN rule on December 3, 2024, which was immediately appealed to the Fifth Circuit by the U.S. Department of Justice.

The AAPS notes on its website that information in the resulting database could be widely shared by federal agencies.

"This is a vast expansion in federal police power, with its political bias that has worsened. Fortunately, multiple provisions of the U.S. Constitution stand firmly against this federal overreach."

ANDREW L. SCHLAFLY
AAPS GENERAL COUNSEL

"This is a vast expansion in federal police power, with its political bias that has worsened," stated AAPS General Counsel Andrew L. Schlafly, the lead attorney for the plaintiffs, in a press release on December 7. "Fortunately, multiple provisions of the U.S. Constitution stand firmly against this federal overreach."

State Authority

The federal government has no business taking over activity reserved to the states, says Ron Friedman, a certified public accountant (CPA) and certified tax resolution specialist in Tarrytown, New York who deals with the Internal Revenue Service daily.

"The Corporate Transparency Act is something the states should implement because the formation of corporations is under state jurisdiction," said Friedman. "This is a massive overreach by the federal government to collect information that is likely collected by the states anyway. Additionally, the notion of creating a mandatory reporting system, in the hopes of catching a few bad actors, is foolish at best. How about enforcing the laws on the books already?"

FinCEN is designed to collect the required information for use by other federal agencies, says Bill Eastland, an Arlington, Texas tax accountant. "It's an office with only 80 employees, so they aren't going to enforce the law," said Eastland. "But they are creating a database that could be used by law enforcement agencies, and unlike federal tax law, there is no requirement for probable cause to share the information."

The rule is redundant, anyway, says Eastland.

"This ownership information is already filed with state corporation offices in most states," said Eastland.

Caught in the Middle

After the appeals court ruling, the FinCEN website noted covered entities may continue to "voluntarily" file the disclosure forms, but the requirement is confusing to small business owners, says Owen E. Barnett, CPA (the writer's brother), who has an independent practice in Arlington, Texas.

"Several of my clients have asked me to file the information for them," said Barnett. "I told them they could do so themselves—it's just a two-page form on the FinCEN website—but as this is not a tax matter, I would not do it for them, as I could be criminally liable for any errors."

The law also applies to volunteers, as AnneMarie Schieber, the managing editor of *Health Care News*, found out in her capacity as a board member of a small homeowner's association.

"I was surprised to learn I had to fill out one of these forms even though we have explicit bylaws and are governed by state law," said Schieber. "Upon hearing the penalties for making what might be a tiny filing error and learning my personal information would be shared with any number of federal law enforcement agencies, I wonder whether serving is worth the risk."

Trump Card?

"The injunction against FinCEN is back in place, apparently at least until oral argument in March," Schlafly told *Health Care News*. "It is possible that the Fifth Circuit could issue a permanent injunction then. It is also possible that [President] Trump could suspend enforcement of the rule."

In response to the Fifth Circuit ruling, the DOJ petitioned the Supreme Court of the United States, arguing the injunction should not be in place while the issues are being considered.

"There may be another round of briefing in SCOTUS now," said Schlafly.

Before the initial deadline, FinCEN warned the millions of physicians and small business proprietors scrambling to comply about "Fraud Schemes Abusing FinCEN's Name, Insignia, and Authorities for Financial Gain," in an alert on its website, underscoring the potential pitfalls of the rule.

Joe Barnett (**JoePaulBarnett@att.net**) *writes from Arlington, Texas.*

$1 Million Prize at Stake in Debate on Safety, Effectiveness of COVID-19 Shots

By Kevin Stone

A businessman is offering $1 million to anyone who can prove the mRNA COVID-19 inoculations did not kill more people than they saved.

Entrepreneur, vaccine critic, and alternative therapy advocate Steven Kirsch, the inventor of the optical mouse and founder of Infoseek, Frame Technology Corp, Abaca, and OneID, issued the challenge during the COVID-19 crisis. Four years later, Kirsch has a taker.

The platform Rootclaim is administering the debate, and the taker is Rootclaim founder Saar Wilf, an Israeli entrepreneur, businessman, and angel investor. The event is now underway.

"In a sense, to ask the question is to answer it. One must acknowledge that people were killed by the vaccine. If so, it becomes a quantitative argument. How many more? You have people who took the vaccine and died, but how do you prove it was the vaccine?"

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

Final Answer?

Phil Kerpen, president of American Commitment and a free-market policy analyst and political organizer, says he doubts the debate will change people's opinions.

"The structure and the wager are unlikely to make either side's arguments more compelling to opponents who have already formed their own strong views," said Kerpen. "So, this exercise is unlikely to resolve anything, unfortunately."

John Dale Dunn, M.D, J.D., a physician, attorney, and policy advisor to The Heartland Institute, which co-publishes *Health Care News*, says a debate at this stage could be futile.

"The data on deaths and complications of COVID-19 and the shot are so corrupted there is no way to get credible evidence that is competent and probative," said Dunn. "All those legal terms describe the nature of admissible evidence. The issue is so corrupted by politics that nothing will come of the challenge."

Variable Overload

Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons, says the debate requires the pro-vaccine side to prove that more lives were saved than were lost to side effects.

"In a sense, to ask the question is to answer it," said Orient. "One must acknowledge that people were killed by the vaccine. If so, it becomes a quantitative argument. How many more? You have people who took the vaccine and died, but how do you prove it was the vaccine? You have people who took the vaccine and didn't die, but why? Maybe they wouldn't have gotten COVID-19, or would have gotten a less virulent strain, or would have fought it off successfully. And people who didn't take the vaccine and either died or didn't.

"As stated, it is impossible to prove," said Orient. "There are just too many variables, and too much speculation is required, even if you could get honest data—and you can't."

Officials' Claims

The debate is predicated on claims the efficacy of the mRNA vaccines has been vastly lower than the manufacturers and health officials originally claimed and dangerous side-effects have been greatly underreported.

Public health officials promoting the vaccines during the pandemic claimed taking the vaccine meant you would neither be able to catch the virus nor transmit it. In fact, evidence shows neither claim was true.

According to the Vaccine Adverse Effect Reporting Service (VAERS), severe adverse effects of COVID-19 vaccines from 2020 to 2022 totaled 68,519. The widely used seasonal flu vaccines over a three-year period (2019-2022) registered just 709 reports.

A study published by the National Institutes of Health (NIH) found adverse effects from the COVID-19 mRNA shots included "serious clinical manifestations such as acute myocardial infarction, Bell's palsy, cerebral venous sinus thrombosis, Guillain–Barré syndrome, myocarditis/pericarditis (mostly in younger ages), pulmonary embolism, stroke, thrombosis with thrombocytopenia syndrome, lymphadenopathy, appendicitis, herpes zoster reactivation, neurological complications, and autoimmunity (e.g., autoimmune hepatitis and autoimmune peripheral neuropathies)."

Government Benefits

The broad indemnity granted to the vaccine manufacturers in the emergency use authorization (EUA) is frequently cited as a reason the debate over the COVID-19 shots will ultimately be resolved. The government agencies that pushed the EUA benefited from drug royalties, as did the drug makers.

For example, Moderna paid the NIH $400 million for using a molecular stabilizing technique borrowed from government and academic researchers in its mRNA-based COVID-19 vaccine, according to the drug maker's 2022 earnings report. The agreement also grants the NIH "low single-digit royalties on future COVID-19 vaccine sales,' which amounted to nearly $5 billion in 2023.

Potential Liability

The royalties the drug makers paid to the federal agencies appear to be the tip of the iceberg and are driving some of the interest in whether the COVID-19 shots killed more people than saved.

The debate could open a floodgate of information that could call into question the EUA indemnity by officials with apparent conflicts of interest, says Dunn.

"The word 'vitiate' is key," said Dunn. "It means that certain types of misconduct would extinguish the immunity conferred on manufacturers and distributors under the Emergency Use Authorization. Specifically, the courts can authorize and enable lawsuits if they rule that reckless or intentional tortious conduct occurred."

Censorship Factor

There is another big problem with the EUA, Dunn says.

"In order for the Emergency Use Authorization to be conferred, the situation had to be that there was no currently available effective treatment," said Dunn. "That was why it was so important to the malefactors to discredit any claims that hydroxychloroquine and/or ivermectin worked. [White House coronavirus response leaders Anthony] Fauci and [Deborah] Birx worked hard on that one and recruited research to condemn HCQ and ivermectin after some initial studies claimed benefit."

Censorship of other opinions cleared the way for the EUA, says Dunn.

"How fortunate for the shot makers," said Dunn. "Recall that not only was it not tested by the normal protocols, it wasn't a vaccine. It was a new technology different from vaccines, a twofold adventure that benefited the shot makers for sure, with billions in revenue."

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

Increasing Numbers of Parents Waive Vaccines for Children

Continued from page 1

vaccines than was reported for the year before. From 2023 to 2024, exemptions increased in 40 states, with 14 states reporting more than 5 percent.

In its weekly report on September 26, 2024, ACIP said decreases in vaccination could lead to a resurgence of measles, varicella, and rotavirus.

Personal Objections

A CDC survey in June and July of 2024 asking parents why they requested vaccination exemptions found most were driven by "philosophical or personal belief objection."

More than 20 percent of those polled cited "difficulty meeting school requirements by the deadline." More than 30 percent of those polled said they were unconcerned about unvaccinated children attending school with their children, even if they vaccinated their own children.

Not included in the survey was the effect of concerns about adverse events associated with vaccines. Vaccine side effects attracted increased attention during the COVID-19 pandemic when the mRNA shots were quickly given emergency use authorization. On January 3, 2025, investigative journalist Alex Berenson reported a COVID-19 vaccine trial involving children may have resulted in a death not fully disclosed by the vaccine maker (see page 3).

Reports of adverse events have gone beyond the COVID-19 shots. In December 2024, the Food and Drug Administration released a document showing the Phase 1 trial of two Moderna RSV vaccines was halted due to adverse effects. It is unclear who halted the trial: the FDA, Moderna, or both.

The CDC says vaccines are tested for safety and effectiveness in a trial process that can take 10 to 15 years.

"We forced a COVID vaccine on kids without any proof that it worked, was safe, or necessary. Now parents understandably are questioning everything recommended about vaccines. And since people don't see polio any more, they think, rightly or wrongly, 'What's the point?"

CHAD SAVAGE, M.D.
INTERNIST
YOURCHOICE DIRECT CARE

Loss of Trust

Trust in health care providers started taking a nosedive at the height of the COVID-19 pandemic, as lockdowns, school closures, and mask mandates gripped the nation. A *JAMA* survey showed patient trust in doctors and hospitals declined by 31 percent from April 2020 to January 2024. The survey found a correlation between trust and whether an adult received the COVID-19 shot.

"Unfortunately, it is indicative of a generalized lack of trust in health care as a whole," said Chad Savage, M.D., founder of YourChoice Direct Care and a policy advisor to The Heartland Institute, which co-publishes *Health Care News*.

"If people lack faith in their doctors, they will also lack faith in the recommendations of their doctors," said Savage. "It has been shown that if patients understand that the physician is working in their best interest, they are much more likely to adhere to treatment recommendations. Thus, by eroding the doctor-patient relationship, the overreach of the bureaucrats will result in harm far beyond the direct relationship to their COVID-19 mandates."

Pandemic Doubts

In 2021, Peter McCullough, M.D., a cardiologist and a highly published scholar, publicly questioned the safety, efficacy, and long-term effects of the COVID-19 shots before a U.S. Senate panel. The testimony cost McCullough his job at a major medical center, which led him to focus on pediatric vaccines in general and post his findings on his *Courageous Discourse* blog.

"Like most physicians, I accepted all vaccines based on blind faith as safe and effective, until the COVID-19 vaccine debacle opened my eyes," McCullough told *Health Care News*.

The pandemic controversies affected parents as well. A summer 2022 survey by the University of Michigan School of Public Health found up to 13 percent of parents believed childhood vaccines were less safe, less important, and less effective than they previously thought.

The pandemic crackdowns changed people's attitudes toward experts, says Savage.

"We forced a COVID-19 vaccine on kids without any proof that it worked, was safe, or necessary," said Savage. "Now, parents understandably are questioning everything recommended about vaccines. And since people don't see polio any more, they think, rightly or wrongly, 'What's the point?"

Parents are now analyzing the costs and benefits of vaccinations, says McCullough.

"Parents watching the nightmare of COVID-19 vaccine injuries, disabilities, and deaths have turned to other opinions on vaccination outside of the medical orthodoxy and have realized healthy children who forego all routine vaccines have reduced risk of childhood allergic diseases and neuropsychiatric disorders," said McCullough.

Regulatory Distortion

The federal government's rewarding of medical practices for pushing certain health care policies pits doctors against patients, says Savage.

"Currently, some doctors are being paid, via pay-for-performance programs, on vaccination rates," said Savage. "This could put their self-interest at odds with the wishes of the patient," because when patients don't comply, the practice may no longer see them.

The same medical establishment decrying the decline in vaccinations undermined their credibility by not telling the truth about them, says Jane Orient, M.D, executive director of the Association of American Physicians and Surgeons.

"Who is to blame?" said Orient. "Government, for removing product liability from this privileged class of drugs as well as for poor regulatory standards; pharma, for taking advantage of it; doctors, for taking incentives to jab everybody and succumbing to groupthink; state lawmakers, for mandates?"

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

Is Vaccine Hesitancy Causing a Surge in Infectious Diseases?

By Ashley Bateman

An uptick in mentions of measles in 2024 online discussions and forums shows many people are wondering whether vaccine hesitancy is contributing to recent increases in the incidence of the disease.

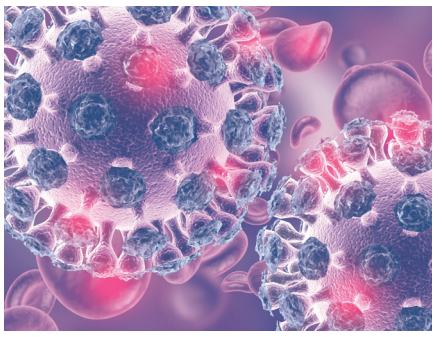
According to the Centers for Disease Control and Prevention (CDC), 284 cases of measles were reported in 32 states and the District of Columbia in 2024, with 16 defined as outbreaks involving three or more people. There were four outbreaks in 2023.

Peter McCullough, M.D., a cardiologist who closely follows childhood vaccination recommendations and reports his findings on the *Courageous Discourse* Substack, says he doubts vaccine hesitancy is causing increases in childhood infectious diseases. Vast improvements in sanitation, diet, living conditions, and antibiotics have been much more important than vaccinations over the decades, says McCullough.

"[This] gives us great reassurance that if vaccination for the masses stopped [altogether], there would be no return of legacy diseases of human crowding and squalor," McCullough told *Health Care News*.

Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons, agrees with McCullough.

"Deaths from childhood diseases had plummeted long before the vaccines were available," said Orient. "Since the diseases never went away, they will come back to some extent [at times]. Parents may choose to get some vaccines if they do, but health outcomes may still be better [even] if most are unvaccinated. 'Prevention is better than treatment' is a sacred cow, which is not always true but creates lots of doctor visits and prescriptions."



"Deaths from childhood diseases had plummeted long before the vaccines were available. Since the diseases never went away, they will come back to some extent [at times]. "

JANE ORIENT, M.D.
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RFK Influence

Robert F. Kennedy Jr., a vaccine critic and President Donald Trump's choice to head the (HHS), is expected to consider major changes in health care policy, including vaccine regulations and mandates. HHS oversees the CDC, the Food and Drug Administration, and the National Institutes of Health.

Kennedy has criticized the 1986 liability shield for vaccine companies, argued against mandates for vaccinations, and supports a safety review of all inoculations and the combinations in which they are given to children. Kennedy has said there is a misunderstanding about his views on vaccines, and that testing should involve placebo-controlled trials, which currently are not required.

Chad Savage, M.D., an internist and founder of a direct primary care practice in Michigan, says he hopes Kennedy will halt 'pay-for-performance' programs (see article, opposite page) that incentivize doctors to push vaccines.

"The relationship needs to be between the doctor and the patient, not between the government or insurance company and the patient," said Savage.

Orient says RFK would be an effective health care policy leader.

"I disagree strenuously with RFK on many things but agree with him on the need to investigate vaccine harms and to remove corruption in regulatory agencies, like revolving doors and royalties," said Orient.

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

Lockdowns Caused Changes in Teen Brains, Study Finds

By Harry Painter

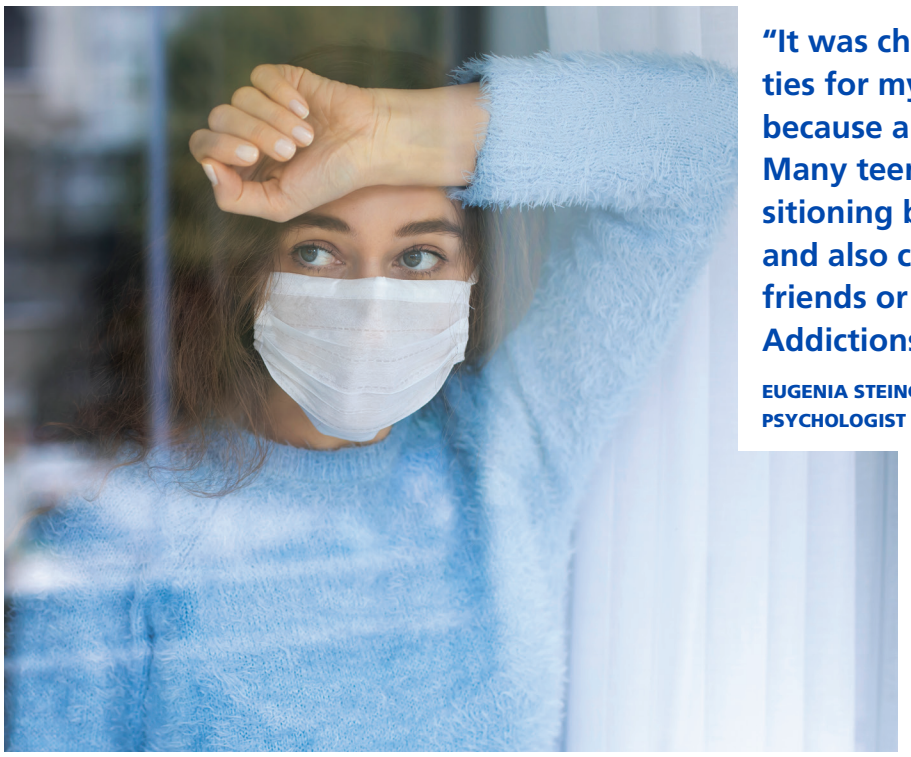
The COVID-19 lockdowns caused significant changes in adolescents' brains, a scientific study has found.

Researchers at the University of Washington in Seattle used MRI data to show the normal thinning of the cortex that happens during adolescence was accelerated in teens during the lockdowns. The effect was greater in female brains than in male brains, the scientists found.

This is cause for concern because "accelerated brain maturation has been associated with increased risk for the development of neuropsychiatric and behavioral disorders," the authors of the paper write.

The authors suggest that lockdown stress caused the changes.

"Accelerated brain maturation as a result of chronic stress or adversity during development has been well documented," the scientists write. "These findings suggest that the lifestyle disruptions associated with the COVID-19 pandemic lockdowns caused changes in brain biology and had a more severe impact on the female than the male brain."



"It was challenging to find facilities for my young patients in need, because all of them were overbooked. Many teenagers struggled with transitioning back to going to schools, and also couldn't reconnect with their friends or create new friendships. Addictions to screens also soared."

EUGENIA STEINGOLD, PH.D.
PSYCHOLOGIST

Lockdown Isolation

Adolescence is the peak period for the emergence of many psychiatric disorders, such as anxiety and depression. In general, young females are at a higher risk of developing anxiety and mood disorders than young males.

The new study could help explain the negative mental health effects that followed the social disruptions caused by the COVID-19 lockdowns, says Ann Liebert, a research fellow at the Kolling Institute at the University of Sydney, who focuses on autism and Parkinson's disease.

"If you don't have enough stimulation—isolation, as you can see—it can affect your development," said Liebert.

"It happens in elderly people—we know that—but increasingly the isolation we can now see can affect children," said Liebert. "And children are very vulnerable up until puberty, at about 14. So that's why the adverse experiences of social isolation hit [that group] harder. Those people are the most vulnerable."

Mental Illness 'Explosion'

The lockdowns had a horrendous effect on teens, says Eugenia Steingold, Ph.D., a psychologist based in New York.

"We had an epidemic explosion of mental illnesses, many of which were so severe that hospitalization was required," said Steingold.

"It was challenging to find facilities for my young patients in need, because all of them were overbooked. Many teenagers struggled with transitioning back to school, and also couldn't reconnect with their friends or create new friendships," said Steingold. "Addictions to screens also soared. Overall, the consequences were so complicated and multilayered that it is difficult to quantify them, and serious, rigorous research is very much needed."

Brain Care

The development of the brain reaches a critical stage during the teen years, says Liebert.

"The brain apparently starts to prune—all the synapses—in the teenage years, to change so that you become an adult," said Liebert. "So, this is an absolutely critical time when we must look after sleep, hygiene, exercise, and social activities. Not just family at home, but in hubs, and that's where the community comes into it, and the things associated with school and associated with churches and other community activities, it is crucial for teenagers to have that."

Liebert says all these factors help brain development and establishment of good sleep patterns.

"And so, when we have all the computer screens and television and lockdown and not being able to go out and exercise, I think that is why you've got the result that you have," said Liebert.

During the COVID-19 lockdowns, some schools had good strategies to "keep children really engaged socially, to get them out into the natural environment, to keep them off the computer, and help with the sleeping and have exercise," said Liebert.

All those things "can reverse and stop the isolation that then has the secondary problems with diminishing the brain size," said Liebert.

PBM Research

Liebert and her husband, Brian Bicknell, a microbiologist and research associate at the University of Sydney's Brain and Mind Centre, are two of the world's leading experts in a type of light therapy known as photobiomodulation, or PBM.

If you don't get enough light or enough Vitamin D, your microbiome becomes disrupted and you're "more likely as an adult to get Parkinson's disease and multiple sclerosis," Liebert says.

Although those debilitating diseases are the worst that can happen, "psychiatric illnesses and other things are also heavily influenced by the microbiome," said Liebert.

'Restorative Processes'

Although it is still considered a cutting-edge technology, PBM has been in use for more than 30 years for a variety of ailments, including "brain diseases, depression, anxiety, traumatic brain injury—a lot of different things," Bicknell says.

"It seems to work quite well, and it doesn't seem to matter how you deliver the light to the brain," said Bicknell.

"What the light does is increase the energy levels in cells by the mitochondria," said Bicknell. "So, it specifically targets mitochondria, it increases energy levels in the cells, and that leads on to a whole bunch of restorative processes."

Liebert says she hopes PBM will gain acceptance and be covered by health insurance "with the new, hopefully bipartisan Congress and everything that you have coming forward."

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

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Report: Hospital Executives Are Being Paid Millions of Dollars a Year

By AnneMarie Schieber

Crain's Detroit Business published a list of the 25 highest-paid hospital executives in Michigan, and all received compensation in seven figures, based on data from 2022.

Philip Incarnati of McLaren Health Care topped the list at $10,783,705 a year, a 9 percent increase in 2022, which happened at the tail end of the COVID-19 restrictions as Incarnati opened the doors of a new $600 million facility.

John Fox, the former CEO and president of Beaumont Health, came in a close second at $10.2 million. Fox's compensation was related to his retirement package in 2022. Beaumont merged with Spectrum Health, the largest hospital system in Grand Rapids.

Rounding out the top five are Wright Lassiter III, the former CEO and president at Henry Ford Health, at $6 million; Mike Slubowski, director, president, and CEO of Trinity Health Corp., at $5.3 million; and Tina Freese Decker, CEO and president of Corewell Health, the new name for the Beaumont-Spectrum merger, who was paid $4.5 million in 2022.

> **"It is dispiriting when hospital staff are told to work for less because their employer is a nonprofit, only to discover the CEO is paid like a rock star. It is also disheartening for patients struggling with high medical bills to find out the hospital executives are paid salaries that often run into the millions of dollars a year."**
>
> **DEVON HERRICK, HEALTH CARE ECONOMIST**

Number 25 on the list is David Mazurkiewicz, who received $1,989,988. Mazurkiewicz is the EVP and CFO at McLaren Health Care in Grand Blanc, Michigan, population 7,925.

Sore Spot

Hospital CEO salaries, especially at nonprofit organizations, have drawn increased attention as surprise medical bills and unpaid insurance claims escalate (see articles on pages 13, 18).

Reining in those salaries is on a list compiled by investigative journalist Alex Berenson of what he says Robert F. Kennedy Jr. should do if he wants to succeed as Secretary of Health and Human Services.

"Limit compensation of executives at non-profit hospitals and chains, by, for example, saying that no non-profit executive can receive more than $1 million annually in total compensation as a condition of Medicare participation. (Make it $2 million if you must.)," wrote Berenson on his *Unreported Truths* news site on November 20.

'Paid Like a Rock Star'

Hospitals have become huge operations over the years, with revenues comparable to any large company, and executives work hard to limit workers' pay, says Devon Herrick, a health care economist and editor of the Goodman Institute Health Blog.

"Hospital care is a labor-intensive business," said Herrick. "Salaries and wages make up about 60 percent of hospital expenses. As a result, hospitals work hard to hold the line on labor costs. In addition, two-thirds of hospitals are nonprofit organizations with a charitable mission."

Multimillion-dollar pay packages for nonprofit hospital executives deserve more scrutiny, says Herrick.

"It is dispiriting when hospital staff are told to work for less because their employer is a nonprofit, only to discover the CEO is paid like a rock star," said Herrick. "It is also disheartening for patients struggling with high medical bills to find out the hospital executives are paid salaries that often run into the millions of dollars a year.

"It's almost like the more ways a hospital CEO figures out how to price-gouge employer plans and insurers, the better they're paid," said Herrick.

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

Congress Tries, Fails to Fix Price Transparency in Lame Duck

By Bonner Russell Cohen

The Lower Cost, More Transparency Act (LCMTA) and the Health Care PRICE Transparency Act 2.0 (HCPTA 2.0) will have to be reintroduced in 2025 in the wake of the GOP winning control of the White House and Senate and keeping its slim majority in the House.

Two bipartisan health care bills failed to gain traction in the narrowed-down continuing resolution (CR) aimed at averting a partial government shutdown in the final days of the 118th Congress.

The two bills addressed price transparency by providers and insurers in a highly complicated health care system. Price transparency for prescription drugs has been limited because drug prices are negotiated between pharmaceutical companies and insurers.

People with prescription drug coverage in their health plans frequently do not know the actual price of their medications because they are covered at least in part by the premiums they pay.

President Joe Biden

PHOTO COURTESY GAGE SKIDMORE/FLICKR.COM

"With a new administration taking office soon, there should be ample opportunity to address price transparency and a host of other issues. Our health care system is larded with waste and fails to meet patients' needs. DOGE, coupled with new leadership at federal health agencies, has a real shot at turning things around."

CRAIG RUCKER
PRESIDENT
COMMITTEE FOR A CONSTRUCTIVE TOMORROW

Exposing Negotiated Charges

The LCMTA would require health care providers and insurers to disclose certain information on the costs of care provided to patients. It was introduced by Rep. Cathy McMorris Rodgers (R-WA) in September 2023 and would have to be reintroduced to be considered by the current Congress.

"[T]he bill provides statutory authority for regulations that require hospitals to annually publish their prices and related information, including the discounted cash price and negotiated charges," the Congressional Research Service (CRS) summary of the bill states. Imaging centers, labs, and ambulatory service centers that participate in Medicare would also have to publish this information.

The bill included specific provisions for drug plans.

"Pharmacy benefit managers (PBMs) must semiannually report to health plan sponsors certain information on spending, rebates, and fees that are associated with covered drugs," the CRS summary states. "Contracts with PBMs for employer-sponsored health plans must also allow health plan fiduciaries to audit certain claims and cost information without undue restrictions."

The bill would require drug price parity in Medicare "for certain drug administration services at off-campus hospital outpatient departments to be the same as that for other provider settings (i.e., physician offices)," wrote CRS. In Medicaid, "the bill requires pass-through pricing models, and prohibits spread-pricing, for payment arrangements for PBMs," the report states.

User-Friendly Price Transparency

HCPTA 2.0 was introduced by Rep. Warren Davidson (R-OH) in January 2023, with a companion measure sponsored by Sens. Mike Rounds (R-SD) and Bernie Sanders (I-VT). It, too, would address price transparency in health care.

"Specifically," a CRS summary states, "hospitals must publish in their list of standard charges certain rates negotiated with insurers, discounts for cash payments, and billing codes. Further, hospitals generally must publish the standard charges for the services provided by the hospital that may be scheduled in advance."

The bill included specific requirements for insurance plans regarding in-network and out-of-network charges for covered items, including prescription drugs. Insurers would also have to provide a consumer-friendly tool for price searches and give additional information about costs if policyholders request it.

New Administration, New Agenda

Although the future course of legislative changes to health care policy can never be known for certain, voters elected Donald Trump president in 2024 after he promised to appoint outspoken critics of the status quo.

These include Robert F. Kennedy Jr. (Health and Human Services) and Dr. Mehmet Oz (Centers for Medicare and Medicaid Services). Medicare Advantage, a frequent target of regulatory harassment during the Obama and Biden administrations, may receive more favorable treatment under Trump, with Oz having advocated the adoption of Medicare Advantage for All (see related commentary, page 12).

Another influence on health care policy will be the Department of Government Efficiency (DOGE), the advisory commission headed by Elon Musk and Vivek Ramaswamy, which is dedicated to eliminating waste in the federal bureaucracy.

"DOGE has already highlighted the problem of improper payments, sharing a Government Accountability Office report that found improper Medicare payments totaled $51.1 billion in fiscal 2023—22% of improper payments across the federal government and the highest of any federal program," wrote Thomas Savidge, a research fellow at the American Institute for Economic Research, on December 24.

Legislation and Regulatory Changes

"Passing any major health care reform in the coming Congress will be difficult, but leaders will be wise to focus on price transparency from PBMs," said Jeff Stier, a senior fellow at the Center for Consumer Choice.

"In this closely divided Congress, bipartisan support will be necessary," said Stier. "Perhaps the only area where this will be possible will be at the margins. There's an emerging consensus that PBMs, which are owned by health insurers and [are] no longer simply independent price negotiators, require additional oversight."

This is why transparency is critical, says Stier.

"When PBMs negotiate on behalf of insurers and take a share of rebates offered by pharmaceutical companies, are they truly containing medical costs for patients, or are they incentivized to keep prices high?" said Stier. "Consumers, as well as policymakers, will need more transparency through the entire supply chain if there is to be any hope for lower drug prices. Certainly, even if legislation passes that requires more transparency from PBMs, there's no guarantee for significant cost savings for patients; but without it, we are guaranteed not to make progress."

"With a new administration taking office soon, there should be ample opportunity to address price transparency and a host of other issues," said Craig Rucker, president of the Committee for a Constructive Tomorrow. "Our health care system is larded with waste and fails to meet patients' needs. DOGE, coupled with new leadership at federal health agencies, has a real shot at turning things around."

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

COMMENTARY

Why are So Many People Angry at Health Insurers?

By John C. Goodman

The public reaction to the fatal shooting of UnitedHealthcare CEO Brian Thompson has been nothing short of shocking. A post on X wishing that the killer would never be caught racked up 95,000 likes.

UnitedHealthcare's own bereavement message online was cruelly mocked by 77,000 laughing responses.

What causes that kind of reaction? Before delving into what's wrong with the American health insurance system of health insurance, let's not overlook what's right with it.

"Despite a popular misconception, more than two-thirds of Americans rate their health insurance as 'good' or 'excellent,' a KFF (Kaiser Family Foundation) survey found. That holds for all kinds of insurance: employer plans, Obamacare marketplace plans, Medicare, and even Medicaid."

Survey Says: Satisfaction

Despite a popular misconception, more than two-thirds of Americans rate their health insurance as "good" or "excellent," a KFF (Kaiser Family Foundation) survey found. That holds for all kinds of insurance: employer plans, Obamacare marketplace plans, Medicare, and even Medicaid.

Even among people who say they are not in good health (and who, presumably, need medical care), a substantial majority give positive ratings to their health plans.

The KFF survey's other two descriptive options for health insurance are "fair" and "poor." Only a tiny percent of the public gives their health insurance the bottom rank of "poor." That includes only 5 percent of people with health problems.

Even so, many of those in the "tiny percent" apparently have extraordinarily strong feelings about the matter, as we learned from the murder of Brian Thompson. Why is that?

Meeting Needs

In general, people view health insurance as being different from other types of insurance, and that perception is accurate. You can see evidence of that difference by merely looking at television and print ads.

In a free market, all sellers of goods and services know that the key to making a sale is to convince potential customers you can meet their needs. In fact, meeting a buyer's needs is usually a more important selling point than the price.

Casualty insurers, for example, sell their products by emphasizing the risks of bad things happening and assuring potential customers that their insurance is ideal protection. Allstate, for example, virtually owns the phrase "You're in good hands."

Different Rules

In a free market, you make money by finding people who have problems and meeting their needs. In that sense, the casualty insurance market is just like any other market.

By contrast, when is the last time you saw a health insurance ad that says you will be "in good hands" if you get cancer or heart disease, or if you need a hip or knee replacement? I bet you haven't.

There is a reason for that. Under federal law, health insurers are not allowed to make a profit by meeting the needs of people with medical problems. In fact, they are required to charge the same premium to otherwise similar enrollees, regardless of their medical problems.

Horrible Incentives

With one exception described below, no insurer in our health care system wants a sick person. No employer. No commercial insurer in the marketplace. No Medicaid managed care plan. And no safety net institution.

Every time someone with an expensive medical problem enters one of these plans, the organization loses money. If the patient leaves the plan (for whatever reason), the plan makes money. If the plan develops a reputation for being really good at handling serious medical problems, it will attract more sick people and incur more losses.

Given the horrible economic incentives that government regulation has created, the surprise is not that some patients experience mistreatment. The surprise is how few there are.

A Better Way

How could things be different? They already are, in the Medicare Advantage (MA) program.

More than half of Medicare enrollees are now in private health insurance plans. Like everyone else in the country, they pay community-rated premiums that are independent of their health status. But unlike everyone else, their premiums are topped up by Medicare, based on individual risk assessments.

As a result, the total premium that the plans receive makes the healthy and the sick equally attractive from a financial point of view.

It gets better. Medicare Advantage is the only place in our health care system where a doctor who discovers a change in a patient's health status can send that information to an insurer (in this case Medicare) and receive a higher payment—reflecting the new expected costs of care.

Accordingly, MA plans have financial incentives to discover patients' problems early and solve them. These plans make money by getting patients the care they need and keeping them away from the emergency room and out of the hospital.

And, unique in our health care system are MA plans that specialize in chronic conditions such as diabetes, heart disease, cancer, etc. Unbelievably, MA plans seek to enroll patients that conventional health insurance would like to avoid.

Positive Influence

MA costs less than traditional Medicare and is of higher quality. As good as that system is, it could be better. For example, United Healthcare is said to deny about one-third of its claims. But there are MA plans in Houston that have denial rates as low as 3 percent.

There are often good reasons to deny a claim. But how many are successfully appealed and how long does it take to adjudicate them? Insurance companies should be free to advertise these facts and compete on how well they take care of their enrollees after they get sick.

Then, we should explore ways of making individualized risk adjustment available to the rest of the health care system. Economist John Cochrane believes that would happen naturally in a free market for health insurance. Maybe it's time to give that idea a try.

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

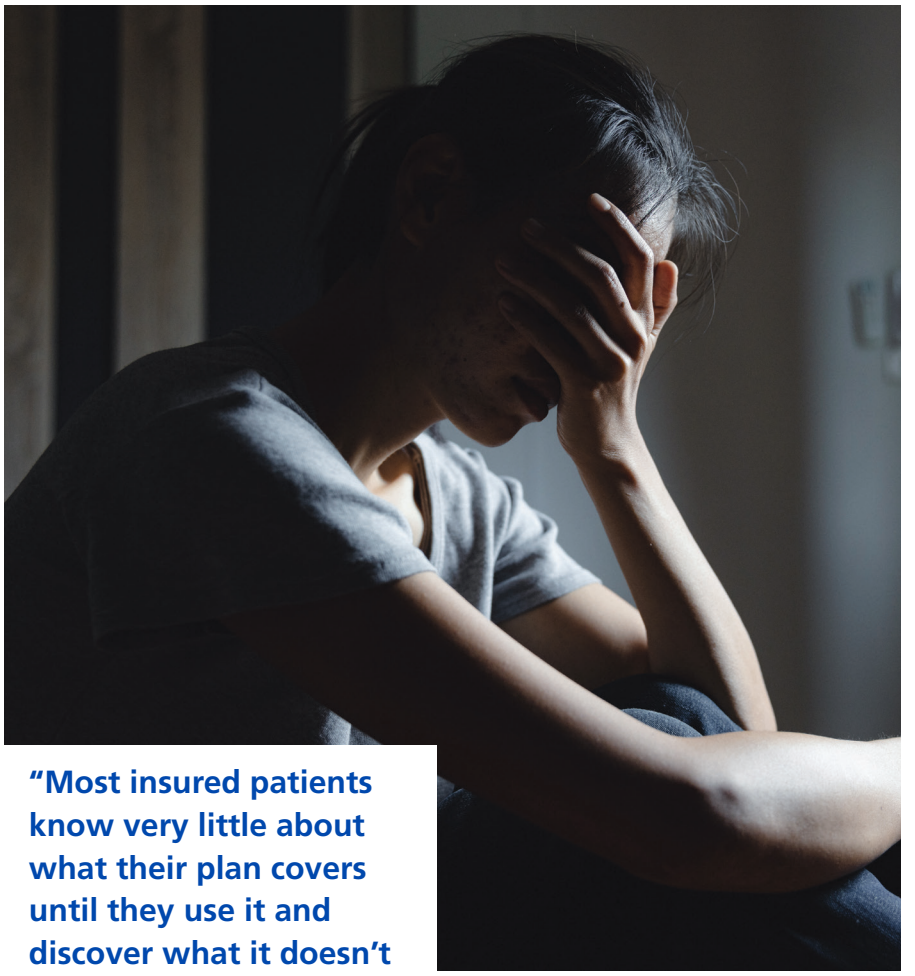
Health Insurers Denying, Delaying More Claims

By Joe Barnett

The murder of UnitedHealthcare CEO Brian Thompson on December 3 focused national attention on the denial of coverage claims by health insurers, purportedly a motive for the killing.

After Thompson's death, patients and doctors aired their personal stories on social media, while others posted vitriolic comments about insurers, and Thompson's alleged assassin became a media sensation.

In a viral post on X, New York emergency medicine physician Zachary Levy, M.D., said UnitedHealthcare denied coverage for one of his patients who was in a coma, on a ventilator, and suffering from heart failure, "Because I haven't proven to them that caring for her in the hospital was 'medically necessary,'" *Newsweek* reported on January 1.



"Most insured patients know very little about what their plan covers until they use it and discover what it doesn't cover. Hospitals and insurance companies spend a lot of money to keep it that way."

MARK BLOCHER, M.D.
CEO, CHRISTIAN HEALTHCARE CENTERS

Denial Rates Vary Widely

Health insurers increasingly deny patients' claims, wrote Elisabeth Rosenthal, an editor at *KFF Health News*, in an opinion piece published in *The Washington Post* in 2023.

"It's a handy way for insurers to keep revenue high—and just the sort of thing that provisions of the Affordable Care Act [ACA] were meant to prevent," wrote Rosenthal (see related article, page 17).

There is a wide variation in claim denial rates among health insurers offering policies on the ACA exchanges, according to a 2023 analysis of data from the Centers for Medicare and Medicaid Services (CMS) by the KFF research organization.

In Obamacare marketplace policies, "nearly 17 percent of in-network claims were denied in 2021," stated KFF. "Insurer denial rates varied widely around this average, ranging from 2 percent to 49 percent."

Few Appeals Filed

Most patient-claim denials are for unstated reasons, KFF reports.

"Of in-network claims, about 14 percent were denied because the claim was for an excluded service, 8 percent due to lack of preauthorization or referral, and only about 2 percent based on medical necessity. Most plan-reported denials (77 percent) were classified as 'all other reasons,'" the study states.

Few of the denied claims were appealed to the insurer, and even fewer claim denials were reversed, KFF said.

"In 2021, HealthCare.gov consumers appealed less than two-tenths of 1 percent of denied in-network claims, and insurers upheld most (59 percent) denials on appeal," KFF reported.

Preauthorization Harm Cited

Most doctors say prior authorization requirements imperil treatment outcomes and employee productivity, according to a nationwide survey of 1,000 physicians by the (AMA), released on June 20, 2024.

"Nearly a quarter of physicians (24 percent) reported that prior authorization led to an adverse event for a patient, and more than nine in 10 reported prior authorization has a negative impact on patient outcomes (93 percent) and delays access to care (94 percent)," the AMA reported.

"More than a quarter of physicians (27 percent) reported prior authorization requests are often or always denied, and more than four in five (87 percent) reported prior authorization requirements lead to higher overall use of resources that result in unnecessary waste," the AMA stated.

'Insurance Companies Interfere'

Doctors often cite prior authorization as a reason for turning away from traditional insurance payment models, says Mark Blocher, M.D., CEO of Christian Healthcare Centers and author of *Missionary Medicine: Restoring the Soul of Healthcare*.

"One of the frustrations expressed by physicians who have left the fee-for-service system is how insurance companies interfere with treatment decisions," Blocher told *Health Care News*. "Although prior authorizations have declined with regard to some treatment decisions—for example, imaging services—they have increased for brand-name medications."

Insurers are directing doctors' medical decisions, says Blocher.

"Frequently, insurance companies require doctors to try treatments the doctor knows will not work for the patient, in order to finally authorize prescribing a medication that would work best for the patient," said Blocher. "This frustrates both patients and providers, delays effective treatment, and can lead to worse outcomes."

'Willing to Bankrupt Patients'

Health insurers are very coy about disclosing coverage details to patients, says Chad Savage, M.D., founder of the Your Choice Direct Care medical practice and a policy advisor to The Heartland Institute, which co-publishes *Health Care News*.

"Absolutely, insurers are intentionally obtuse," said Savage. "This results in surprise bills where patients learn unexpectedly that a service is not covered, sometimes many months after the service is received."

This lack of transparency is unique to health care, says Blocher.

"Health care is the only U.S. industry that conceals the true cost of its services and does not disclose to its 'customers' what its services cost until after they've been delivered. What other industry is allowed to operate that way?" (See related article, opposite page.)

"Not only is there a lack of transparency, but there is also a lack of accountability," said Blocher. "This is an industry that forces people to sign blank checks for the services it provides, and is willing to bankrupt patients when they are unable to pay its grossly inflated charges."

'Patients Know Very Little'

Federal law requires hospitals to disclose prices to patients, but CMS is not enforcing it, says Blocher.

"Although transparency rules were enacted in 2021, requiring hospitals to publish prices for their services, according to the Office of Inspector General, 46 percent of the 5,879 hospitals that were required to comply did not make information on their standard charges available to the public," said Blocher. "CMS only fined three hospitals for noncompliance out of the thousands of U.S. hospitals covered by the rule. The few who do comply find ways to work around the rule, publishing only a small number of prices.

"Most insured patients know very little about what their plan covers until they use it and discover what it doesn't cover," said Blocher. "Hospitals and insurance companies spend a lot of money to keep it that way."

Joe Barnett (**JoePaulBarnett@att.net**) *writes from Arlington, Texas.*

Consumers Seek Solutions to Health Insurance Shortcomings

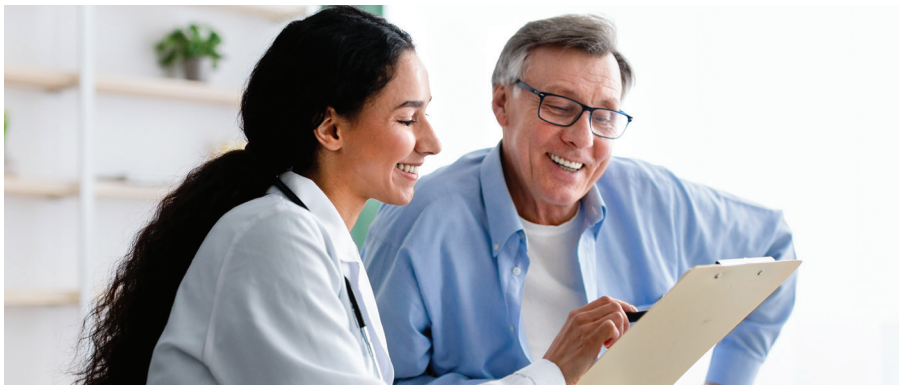
By AnneMarie Schieber

Consumers are increasingly looking for ways to safeguard themselves financially in the event of a catastrophic illness or injury when health insurance runs out or an insurer denies coverage.

Insurance denials are up, according to recent reports (see page 13); and this year, new limitations on short-term, limited-duration health insurance (STLDI) policies go into effect. In response, the use of supplemental health insurance is rising, reports Precedence Research. The firm forecasts the market for supplemental coverage could almost double by 2033, from $36.8 billion to $62.57 billion.

"As consumers become more educated about the risks and costs associated with healthcare, they are increasingly looking out for insurance products that provide additional economic protection," the report states.

Consumers have resorted to STLDI plans to avoid pricey Obamacare plans, which the Biden administration limited to a maximum of four months. The Biden administration limited the plans to a maximum of four months. If insurance runs out during an extended medical claim, an individual's only hope for coverage is to enroll in Obamacare, which will accept an enrollee with a preexisting medical condition. However, Obamacare enrollment is only available during a limited period at the end and beginning of the calendar year.



"Let people buy health insurance that meets their financial and medical needs," wrote Goodman. "At the end of the day, if there are any remaining and socially important unmet needs, those should be the limited focus of government."

JOHN C. GOODMAN
PRESIDENT
GOODMAN CENTER FOR PUBLIC POLICY RESEARCH

Cash, Not Coverage

One option for financial protection is to purchase supplemental coverage such as an indemnity plan, "if you can find one," says Beverly Gossage, president of HSA Benefits Consulting and a Kansas state senator (R-District 9). "The [Affordable Care Act] tied the hands of insurance carriers to offer plans other than those that are not underwritten."

Indemnity-style plans, which are not major medical insurance, pay a cash benefit in the event of hospitalization, surgery, or injury. Blue Cross, UnitedHealthcare, Cigna, and other insurers offer such plans.

"They are regulated as insurance, but they are not subject to Obamacare regulations." wrote John C. Goodman, co-publisher of *Health Care News* and president of the Goodman Center for Public Policy Research, in a *Forbes* column in 2019.

Goodman says another alternative to Obamacare plans is health sharing ministries, organizations that pool together funds to pay health claims directly.

Direct to Customer

Critical illness insurance indemnity plans will grow the fastest over the next eight years, reports Precedence. Dental indemnity plans still comprise the largest segment of the supplemental market. Consumers can also buy plans that cover expenses related to accidents, plus vision care or health care expenses not covered by a typical health insurance plan. Unlike traditional health insurance, the benefits are paid directly to the insured person.

In recent years, politicians and activists have attacked indemnity plans as "junk insurance," wrote Goodman in a 2024 *Forbes* column on the topic.

"Let people buy health insurance that meets their financial and medical needs," wrote Goodman. "At the end of the day, if there are any remaining and socially important unmet needs, those should be the limited focus of government."

Regulatory Uncertainty

In his first administration, President Donald Trump allowed STLDI plans to last up to 36 months. Gossage says she hopes Trump will restore that rule in his second administration.

"I certainly hope so, for the sake of the consumer who does not fall into the low-income earnings category and could be forced to pay very high premiums for coverage with a nearly $10,000 out-of-pocket potential," said Gossage.

Gossage says lasting reform will require Congressional action.

"We must codify this into law rather than merely through regulation that is subject to the whim of a new administration," said Gossage.

Gossage, who advises consumers on health care coverage, says she is on the fence about telling people whether STLDI is a good deal under the Biden administration's new rules.

"It depends on the situation," said Gossage. "There are folks who need a few months before their job insurance is effective or before they are entitled to start Medicare. The STLDI fills the gap.

"They can save nearly 70 percent in premiums with an STLDI plan if they pass the few underwriting questions," said Gossage. "But being made to be re-underwritten every three months is cumbersome and frightening."

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

INTERVIEW

There Is a Way to Avoid Paying for Other People's Health Care

As health care spending soars (see page 20) and health insurers increasingly delay or deny claims (see pages 7, 17), some consumers are turning to indemnity-style insurance protection, which pays a cash benefit for adverse health events. Indemnity-style health insurance is a feature of Plan for America (PFA), a voluntary private savings proposal designed to rescue Medicare and Social Security from insolvency, pay off national and state debt, reduce all taxes, and provide comprehensive health care with no exclusion for preexisting conditions.

PFA coauthor Terry Nager, a certified financial planner and founder and president of an investment advisory firm, talked with Health Care News *about how the health care component of the plan works and why it may be the only way the United States can get around the Obamacare behemoth.*

"We designed our plan with both Democrats and Republicans in mind. Democrats will like the idea of universal health coverage that doesn't penalize people for preexisting conditions. Republicans would like the idea that the plan encourages responsible spending."

TERRY NAGER
COAUTHOR, PLAN FOR AMERICA

Health Care News: You have said one of the hallmarks of PFA is that it provides a $1 million lifetime comprehensive health insurance policy in a way that "nobody (i.e. the taxpayer) pays for someone else's health care." How would this work?

Nager: It is a classic indemnity-style plan. The insurance company is not making decisions on whether a claim is valid or not, as long as it is in the health care realm. The individual and the doctor would make the decision, and the company would pay the claim. But people are going to be careful about their claims because the lifetime cap is $1 million. There is also a health savings account feature that incentivizes people to wisely spend their health care dollars.

Health Care News: Would participants have to purchase this plan each year, and how much would it cost?

Nager: The plan would cost $11,200 each year, and it is not mandatory. The cost is tax-deductible and includes a $1,200 health savings account that will cover the $1,200 co-pay and deductible for the plan. Participants can keep the amount and spend it as they wish if they don't use it.

The co-pays and deductibles disincentivize utilization. Today, families are paying upwards of $20,000 or more before health coverage even kicks in. The PFA health coverage could be a lot cheaper and a lot less grief because there will be no claim haggling.

Health Care News: How would PFA accounts be funded?

Nager: People will fund their personal accounts with the 15.3 percent payroll tax equivalent (Social Security and Medicare) they would no longer have to pay to the government. That money will be invested in an index of U.S.-domiciled companies managed by a trust we call the For America Security Trust, or FAST, which will also grow, and that growth will be distributed to participants.

Health Care News: What would happen if a participant exceeded their $1 million cap early in their participation in the plan? Could they leave PFA and go back to enrolling in Social Security, Medicare, Obamacare, or Medicaid?

Nager: There is no provision to do that, because the PFA would be set up as a contract between the trust and the federal and state governments. PFA is voluntary, and I suppose someone could jump out of it to get coverage under Medicaid, but why would they do that? The benefits are so much better in the PFA health plan.

For example, Medicaid may not cover your long-term care, but the PFA plan covers that. And there could be other benefit limitations in government programs.

Health Care News: What if someone used up their $1 million cap? What would be their alternative to getting additional health care coverage?

Nager: Once they reach their cap, the account assets will be at risk. However, participants can take out an interest-free loan to cover their medical costs without a cap from the trust. Participants would pay off that loan with assets in their account over a period of time.

All loans would be backed up with a life insurance policy (price added to the loan) so the trust is always made whole in the event of death. The loans would be paid off slowly and steadily to allow the existing account assets to grow.

Health Care News: Even though the PFA would offer indemnity-style coverage, is it possible the insurers could engage in haggling or restrict networks or tell you where to go because prices are better?

Nager: No. That is the beauty of this. The individual has the power, not the institution, or the drug companies for that matter. In fact, all these parties will be required to publish their prices because people will need to know how their health care dollars are being spent, given their lifetime cap.

Health Care News: There are so many entrenched interests in health care. Do you think PFA could ever become a reality?

Nager: We have talked to a great many people about PFA, and few to no people find anything wrong with it. The only qualm is whether it can pass politically, due to the special interests.

We designed our plan with both Democrats and Republicans in mind. Democrats will like the idea of universal health coverage that doesn't penalize people for preexisting conditions. Republicans would like the idea that the plan encourages responsible spending.

We would love to hear what Elon Musk and Vivek Ramaswamy have to say about it, because this is right in line with what they are doing with [the Department of Government Efficiency].

States Differ in Responses to 340B Program Abuse

By Bonner Russell Cohen

Widespread and longstanding abuse of a federal program designed to provide prescription drugs to low-income patients has prompted lawmakers in Minnesota and Michigan to try to rein in the 340B program in the absence of significant reforms by the federal government.

Minnesota recently enacted a law requiring covered entities to begin providing annual reports with data related to their 340B prescription drug purchases in 2024 to the state's Department of Health (MDH).

A lively debate over 340B is underway in Michigan, where two bills attempting to protect the program failed to reach the governor's desk before the 2024 legislative session ended on December 31. The legislation, sponsored by Democrats, who controlled both legislative chambers, would have prohibited drug companies from denying access to certain drugs in the program.

The bills, HB 5350 and SB 1179, were fiercely opposed by businesses and groups that advocate cutting government waste.

"Everyone else must pay higher prices for drugs, to enable some hospitals to spike their revenues. There is little evidence that this law helps low-income residents or leads to more charity care. In Michigan, hospitals lobbied hard to extend that program to pharmacies with which they had contracts. That would have made it even more wasteful."

JARRETT SKORUP
MACKINAC CENTER FOR PUBLIC POLICY

Unintended Direction

Enacted in 1992 and administered through the Health Resources Services Administration, the 340B Drug Pricing Program requires manufacturers participating in Medicaid to sell drugs at a steep discount of 20 to 50 percent to "covered entities" such as federally funded community hospital centers.

The goal was to make medications more affordable for people with limited means. In practice, large hospitals and hospital chains often prescribe drugs they have bought on the cheap to well-heeled patients who pay higher, market rates, enabling hospitals to profit handsomely from the spread.

Reform Calls

In a November 24 blog item, Citizens Against Government Waste President Thomas Schatz said large hospitals and contract pharmacies "have enriched themselves by siphoning off the money that is supposed to help patients."

Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group, launched a nationwide campaign in 2023 calling for 340B reform.

"There is clear evidence many hospitals are exploiting loopholes in the 340B program, driving up costs for patients, employers, and taxpayers in the process," the organization stated in October.

"They prescribe more expensive medicines and are less likely to prescribe biosimilars," PhRMA wrote. "They are driving provider consolidation, buying up smaller hospitals and physician practices. And they significantly markup medicine prices."

Explosive Growth

The program has ballooned far beyond its original mission, says Merrill Matthews, a resident scholar at the Institute for Policy Innovation.

"While hospitals were the initial target for 340B, participating entities have expanded," said Matthews. "Thousands of clinics also participate in 340B, as do retail pharmacies that contract with participating hospitals and clinics. The number of participating contract pharmacies grew from 789 nationwide in 2009 to 32,500 today."

Spending rose just as dramatically, says Matthews.

"With many more hospitals and pharmacies participating in 340B, spending exploded from $6.6 billion in 2010 to $43.9 billion in 2021, according to the Congressional Budget Office—a nearly sevenfold increase in a decade," said Matthews.

Minnesota Report Released

The Minnesota Department of Health released its first report on the matter in November 2024 under the state's new law enacted that same year.

"Minnesota providers participating in the federal 340B Drug Pricing Program earned a collective net 340B revenue of at least $630 million for the 2023 calendar year," the report states. "Based on national data, MDH believes this figure may represent as little as half of the actual 340B revenue for Minnesota providers."

The state's "largest 340B hospitals benefited most from the 340B program, representing 80 percent—more than $500 million—of the statewide net 340B revenue," the report states. "Conversely, Safety-Net Federal Grantee clinics generated the least net 340B revenue."

Other findings include a "sizeable volume of net 340B revenue was generated from Minnesota Health Care Programs—Medical Assistance/Medicaid and Minnesota Care—totaling about $87 million," and "payments to contract pharmacies and third-party administrators were over $120 million, representing approximately $16 out of every $100 of gross 340B revenue generated paid to external parties."

Concerns in Michigan

The Michigan Health Purchasers Coalition, Michigan Manufacturers Association, and other business groups sent a letter to state lawmakers criticizing the state's 340B program and citing illegal activity.

"340B provides strong incentives for hospitals to acquire independent outpatient physician offices in wealthy and better-insured areas than the parent hospital, designate them as 'child sites,' and maximize profits by tapping into employers and working families they insure," stated the letter. "340B encourages hospitals to establish networks of external retail chain and mail-order pharmacies—a practice not grounded in statute."

The letter urged lawmakers to oppose HB 5350 and SB 1179 because "the proposed legislation represents a step backward and would exacerbate 340B's upward pressure on costs without improving access or affordability for low-income patients."

Hospital Moneymaker

Hospitals profit from the program while consumers pay higher prices, says Jarrett Skorup, vice president for marketing and communications at the Mackinac Center for Public Policy.

"The federal 340B law shifts money from drug manufacturers to hospitals," said Skorup.

"Everyone else must pay higher prices for drugs, to enable some hospitals to spike their revenues," said Skorup. 'There is little evidence that this law helps low-income residents or leads to more charity care. In Michigan, hospitals lobbied hard to extend that program to pharmacies with which they had contracts. That would have made it even more wasteful."

Congressional Responsibility

Congress has responsibility for the 340B program, and President Donald Trump has promised greater attention to government waste with the formation of the Department of Government Efficiency (DOGE), the independent advisory commission headed by Elon Musk and Vivek Ramaswamy.

Musk and Ramaswamy met with members of Congress during the lame duck session and are expected to pursue numerous legislative and administrative actions to eliminate waste, which could include 340B reforms.

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

COMMENTARY

What Health Insurance Should Be, But Isn't

By William M. Briggs

Now that a health insurance guy has been whacked by an assassin, it's useful to review why health insurance is such a mess now.

Here is an expanded version of a thread I did on Twitter—which is all a repeat of (ignored) arguments I made back when Obamacare was being discussed.

Health insurance should be, but isn't, a bet you make that you hope you will lose. Instead, health insurance has become an inefficient form of socialized medicine, increasing costs.

"Here's what insurance should be. You bet with an insurer that you will get cancer, say. If you get it, the insurer pays costs of care X. If you lose and remain cancer-free, you pay Y. You re-bet every month (or whatever). You pay Y every time you lose. The X and Y are negotiated between you and the insurer, and the risk of cancer is decided by you and separately by the insurer. That is the bare bones of true insurance. Or, indeed, of any bet."

The Bet

Here's what insurance should be. You bet with an insurer that you will get cancer, say. If you get it, the insurer pays costs of care X. If you lose and remain cancer-free, you pay Y. You re-bet every month (or whatever). You pay Y every time you lose. The X and Y are negotiated between you and the insurer, and the risk of cancer is decided by you and separately by the insurer.

That is the bare bones of true insurance. Or, indeed, of any bet.

You can also group diseases, say cancer and congestive heart failure. Then you pay Y_1 + Y_2 (say) and the costs are X_1 + X_2. The result is a contract bet just the same. But with higher stakes for both.

Now, suppose you already have cancer and bet the insurer you'll get it. You immediately win the bet! The insurer must pay X. How much should the insurer charge you for this sure-thing bet? X. After all, your "preexisting condition" is a sure-thing bet the insurer is bound to lose, so he has to charge you the entire amount he is risking or he will take a loss. Under those terms, there is no sense in you making the bet.

Unless a ruler steps in and says, "Insurer, you must take this bet!" Which, of course, happens. Then the insurer must spread the cost of X to others.

The Spread

If the insurer doesn't spread the costs, he has a sure loss. That means if you bet you have cancer when you do, when your neighbor makes a bet for cancer when he doesn't have it, he must pay Y+S, where S represents the spread. The more people in the system, the smaller S is.

Voilà! With coverage mandates, insurance automatically becomes socialized medicine. It is very inefficient, too, because not only are we paying a private entity to manage this and take his profits, we also pay bureaucrats to monitor it all. Costs must increase. Health care won't get better, but costs must rise.

Protection for Everything

In fact, it's worse than all this!

It's worse because people insist on having general coverage for an entire range of diseases without regard to whether they will get any of these diseases. To most, any risk is too large. Safety first!

Of course, the more diseases you add to the bet, the greater the probability you will "win" on at least one.

This increases the Y you must bet, of course, because you have increased the X the insurer might have to pay, which is now cumulative. And, of course, general coverage encourages people to "win" and claim their X by going to the doctor for sniffles, etc.

Add to that employer mandates, which require employers, because they are employers, to pay the Y for their employees because they are employees—thus creating a servile, slave-like caste. This point cannot be overemphasized. The system creates oligarchy.

These large additional costs must be spread by the insurer among the insured. Again, costs rise, medicine is socialized, and health care at best does not improve. It can get worse because too many patients choke the system.

A Losing Bet for All

This is all before insurer greed comes into the picture, which has the obvious effect of increasing Y for all. Again, health insurance costs rise, but health does not. In fact, mandates encourage insurers to deny claims because there is only so much spreading that can be done.

What needs to happen, but won't, is the elimination of this form of bastardized insurance. If it were made a true bet again, and all had to pay for losing this bet (monthly or whatever), and for only a limited range of conditions (different per person), costs would decrease on average.

It is an entirely separate question whether it is more or less moral for medical care to be socialized, and to what extent.

Somebody reacted to the original thread by asking how you would "feel" if it was your relative who was denied "coverage" for some preexisting condition. That kind of unthinking reply is common. But it's wrong. The correct way to put this is that your relative has been denied having his medical care paid for by others.

William Briggs **(matt@wmbriggs.com)** *is a statistician.* *A version of this article appeared on the author's* Science is Not the Answer *blog on December 5, 2024. Reprinted with permission.*

COMMENTARY

Where to Draw the Line on Outrageous Health Care Prices

By Devon Herrick

I often write about high prices in health care. Some gene therapy drugs cost more than $1 million for a one-time treatment.

The latest oncology drugs are especially expensive.

Danyelza (for neuroblastoma) and Kimmtrak (uveal melanoma) cost $1.2 million and $1.1 million, respectively. The average annual cost of a new cancer drug is more than $250,000. Nearly half (44 percent) of new cancer drugs are priced at more than $200,000. Numerous cancer drugs cost $70,000 to $120,000 a year.

Debt.org reports the average daily cost of a hospital stay is about $3,000, although it's not clear what that covers. Joint replacement surgery costs anywhere from $20,000 to more than $50,000, with about $40,000 being the average. An inpatient stay for a hip replacement is one to three days, so there are obviously a lot of other charges being tacked on to that $3,000 per day.

Debt.org reports the average hospital stay is 4.6 days, at an average cost of $13,262. If surgery is involved, hospital costs soar through the roof. Some of the most common surgeries have price tags that top $100,000.

"Even if marginal Medicare revenue is below the average cost, it is above the marginal cost, or providers would drop out. Except for military hospitals, virtually all hospitals accept Medicare. In fact, about 96 percent of hospitals get at last half of their revenue from Medicare, and 82 percent of hospitals get two-thirds or more of their revenue from the federal program. While Medicare is a huge, volume buyer of medical services, it is not clear that price controls based on Medicare prices would not lead to shortages of services."

Charges All Over the Map

Physicians are billing simple tasks, like removing a splinter or freezing off a skin tag, as surgical procedures costing nearly $500.

Recently, Northwestern Memorial Hospital billed a colonoscopy as two procedures: one for inspecting the colon and another for removing two polyps. Because these colonoscopies were billed as separate procedures, the total cost came to $19,000.

Then there are the $50,000 air ambulance charges and unceasing "surprise medical bills." I described this phenomenon back in March 2019. "Surprise medical bills occur when patients unknowingly receive medical care from physicians and therapists, or in hospitals, clinics, and labs that are not in the provider networks of a patient's health plan," I wrote. "Many out-of-network providers purposely refused to join provider networks so they can charge fees many times higher than the usual and customary fees reimbursed by health plans."

Market Prices Unknown

Charging high prices or refusing to join a network is neither illegal nor immoral. The immoral part is in not informing patients ahead of time so they can decline the service and look elsewhere. Not quoting binding prices ahead of services should make it more difficult to collect for those services if there is a billing dispute.

What is the appropriate price? Nobody knows, and that's the problem. The appropriate price for medical care is the market-clearing price, where the quantity of services supplied equals the quantity of services demanded. We don't know what the market-clearing price is, because we don't have a free market to indicate market-clearing prices.

Then there is the fact that the market-clearing prices will be much lower than the current prices because many people will lack the money to contract for the service of a surgeon, for example. In other words, the market-clearing price for patients with health insurance is different (much higher) than for patients without health insurance. In a self-pay market, the demand for $1 million therapies is nearly zero, since most patients will not have $1 million to spend.

What About Price Controls?

Controlling the price seems to be the obvious solution. However, this could backfire. If the price ceiling is too low, it will reduce the supply and increase the demand. The result is shortages, rationing, or a degrading of the quality of the goods and services whose prices are set below the market-clearing level.

There is no easy way to determine what the true market prices are outside of a market, and there are thousands of medical prices. The process would likely become political rather than based on efficiency.

Some suggest consumers might be better off with a Medicare Prices for All arrangement. Providers claim they lose money participating in Medicare, but there is no evidence backing up that claim. In fact, only 1.1 percent of physicians have formally opted out of Medicare.

Even if marginal Medicare revenue is below the average cost, it is above the marginal cost, or providers would drop out. Except for military hospitals, virtually all hospitals accept Medicare. In fact, about 96 percent of hospitals get at last half of their revenue from Medicare, and 82 percent of hospitals get two-thirds or more of their revenue from the federal program.

While Medicare is a huge, volume payer of medical services, it is not clear that price controls based on Medicare prices would not lead to shortages of services.

Bottom Line

What are the appropriate prices for medical care? Economists do not really know, except that prices should be far lower than they are. The reason for outrageous medical prices is perverse incentives and a lack of competition.

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

COMMENTARY

Shakedown Lawsuits, Not Safety, Explain Drug Shortages

By AnneMarie Schieber

U.S. Sen. Richard Blumenthal (D-CT) called on U.S. Food and Drug Administration (FDA) Commissioner Robert Califf, M.D. to take "appropriate actions to investigate and recall products with unacceptable levels of benzene."

In a letter to Califf on October 31, 2023, Blumenthal alleged an "independent quality assurance company," a fancy phrase for a lab, found "unacceptable" levels of benzene in popular over-the-counter acne treatment products in a "study" conducted in March 2023. Benzene, Blumenthal wrote, is a "known hormone disruptor and carcinogen."

Blumenthal left out three key facts. First, the FDA had already found "methodological deficiencies" in at least four areas of Valisure's laboratory work. Second, a federal judge chastised Valisure for subjecting the heartburn drug Zantac to unrealistic temperatures to show the product contained a carcinogen. Third and finally, Valisure is in Blumenthal's home state. More on that in a moment.

If Blumenthal gets his way, a recall of acne treatment products will do more than just anger some teenagers. Product recalls can lead to drug shortages, higher prices on everything and for everybody, and a hard stop on research and development. Who would want to put a new product on a shelf, a product that meets FDA safety standards, when recall threats and lawsuits are so easy?

Fear Factor

Many consumers have no idea what benzene is let alone its health risks. If given the choice, consumers would probably opt not to have any dangerous-sounding chemical in a health and beauty product.

Without chemicals, however, these products would be ineffective. People have been using acne products for decades, and while cancer rates persist, it is impossible to pinpoint a specific cause. The human body is a complicated machine, and humans are constantly exposed to countless risk factors. Carcinogens abound, but not everyone gets cancer.

Consider the specific case of acne medications. Valisure is what many might call a "hired gun." These are the "experts" we see in lawsuits hired by plaintiff attorneys to implicate deep-pocketed defendants.

The acne medication industry is a $5 billion cash cow. As with Zantac, evidence suggests Valisure heated acne products to 158 degrees to produce the carcinogen. Naturally, the pigs are lining up at the trough. Google "acne lawsuits" and you will find no shortage of law firms willing to help consumers with a "claim," which will require the person to fill out all kinds of paperwork, and if the attack lawyers prevail, could garner the consumer with something like a $12.50 check.

The lawyers, by contrast, will collect typically one-third of each award, sometimes hundreds of millions of dollars, depending on where the jury pool lives.

Holy Grail of Lawsuits

As if the shakedown lawsuits weren't enough, consider the latest development. With the political help of Blumenthal and another Connecticut politician, Rep. Rosa DeLauro (D-CT), Valisure has secured a contract with the Department of Defense (DoD) to "generate objective drug quality data through independent chemical testing of certain drugs, " states a Valisure news release.

Laughably, the release goes on to say, "Drug quality issues are the reason for the majority of drug shortages currently plaguing the nation."

Thank you, Valisure, for contributing to that plague! The DoD will be a bonanza of potential lawsuits, given that the department maintains the massive Defense Medical Epidemiology Database (DMED). That will be a huge "get" for lawyers to mine for potential lawsuits.

Consumers Losers

Under the "Cooperative Research and Development Agreement," DoD will establish a "working group" to "assess risks to the Department's pharmaceutical supply chain," to "complement FDA efforts by conducting independent testing of medicines and generating meaningful and *actionable*

transparency to drug quality" (emphasis added).

As at least one lawsuit has shown and as the FDA's own report against Valisure suggests, "independence" comes with strings attached. In fact, Valisure doesn't have to indict any one company specifically. The lab could use the opportunity to sell "certification" programs to keep companies out of the clutches of plaintiff attorneys.

The contract will keep Valisure in business for years to come. DeLauro and Blumenthal gain bragging points in the next tight election in their home state, not to mention a deep stream of campaign contributions.

"Unfortunately, the losers will be the rest of us. Consumers will find fewer products on store shelves because of unnecessary recalls, higher prices due to shortages, and no exciting new products on the horizon."

Unfortunately, the losers will be the rest of us. Consumers will find fewer products on store shelves because of unnecessary recalls, higher prices due to shortages, and no exciting new products on the horizon.

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

COMMENTARY

Spending, Not Coverage, Is Biggest Problem in Health Care

By Douglas Holtz-Eakin

Roughly a decade ago, on October 1, 2013, the ignominious launch of the Affordable Care Act's (ACA) healthcare.gov website signaled the end of an era.

The years leading up to the passage of the ACA featured two pressing national health policy issues: covering more (or all) Americans with health insurance, and the cost (or value) of health care.

What should be the top priority? How should the goals be pursued? It was a vigorous debate and featured a first: every Republican running for president in 2008 had a comprehensive health care reform plan in the primary.

With the passage of the ACA, however, the die was cast. Despite some messaging (such as "it will bend the cost curve"), the ACA was a coverage-heavy reform that did nothing to alter the growth of costs.

Utilization Driving Costs

Roll the clock forward to 2024, and the top concern is no longer universal-coverage fantasies and Medicare for All but the cost of health care.

The National Health Expenditures (NHE) for 2023 show health care spending in the United States reached $4.9 trillion and increased by 7.5 percent in 2023, up from a rate of 4.6 percent in 2022 (see figure on this page).

That acceleration in health care spending growth reflected growth in nonprice factors such as the use and intensity of services (after notably slower growth in 2022). When adjusted for health care price inflation (as measured by the NHE, real health care spending increased by 4.4 percent in 2023—a higher rate than the increase of 1.4 percent for such spending in 2022 and higher than the growth rate of real GDP, which was 2.9 percent in 2023.

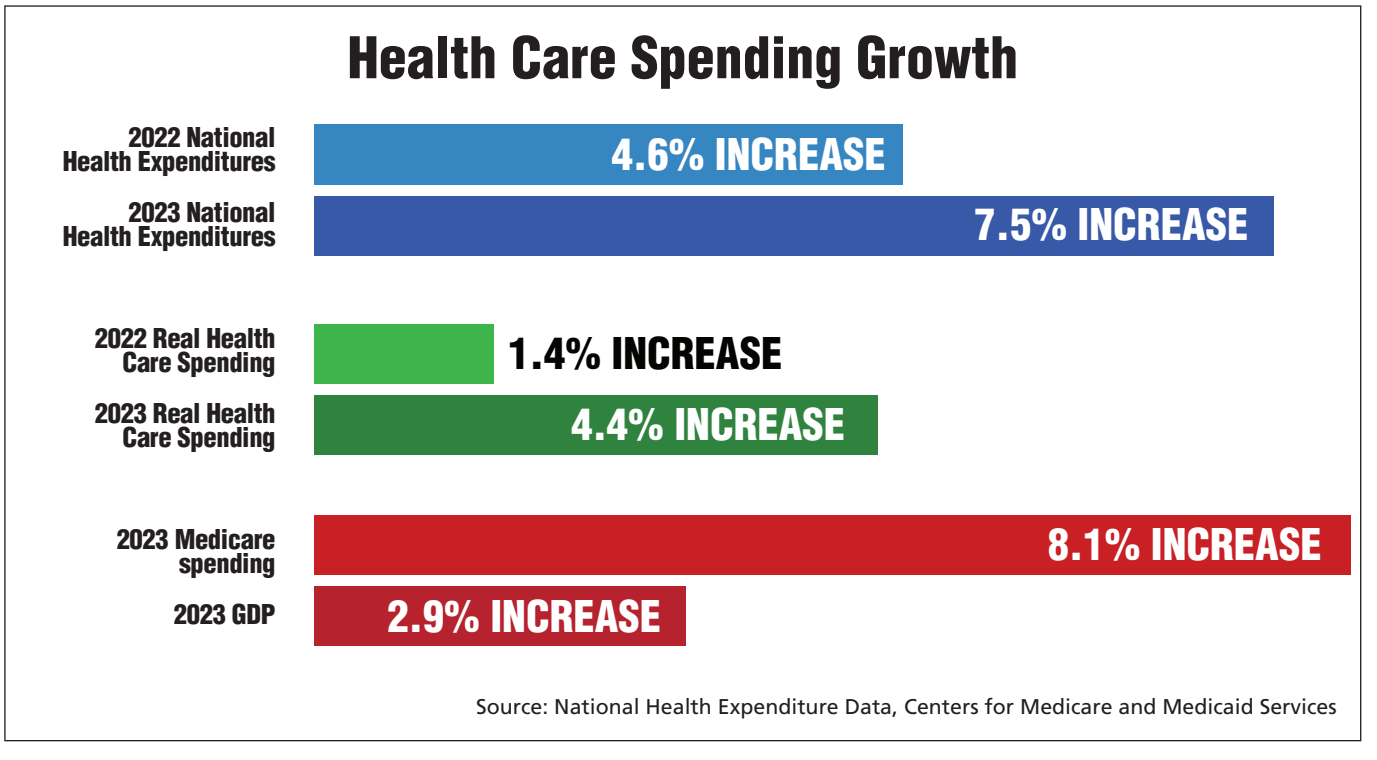
"One of the basic features of the pressing U.S. fiscal problems is that Medicare grows at 7.0 percent, much faster than the growth of the economy which dictates the growth of revenue. The cost trends indicate a near future in which health care could lie at the intersection of pressure on both federal and family finances."

More Out, Less In

That final fact is especially telling. The real growth rate of spending (4.4 percent) exceeds the growth rate of the income (2.9 percent) to finance that spending. This is a return to the bad old days that permitted NHE to grow from a small fraction of economic activity to nearly 20 percent of gross domestic product.

One of the basic features of the pressing U.S. fiscal problems is that Medicare grows at 7.0 percent, much faster than the growth of the economy, which dictates the growth of revenue. The cost trends indicate a near future in which health care could lie at the intersection of pressure on both federal and family finances.

Douglas Holtz-Eakin (**contact@americanactionforum.org**) *is president of the American Action Forum. A version of this article appeared on the* Daily Dish. *Reprinted with permission.*



COMMENTARY

What the FDA Gets Wrong About Drug Ads

By John C. Goodman

There are only two countries in the world where drug manufacturers are allowed to advertise their products directly to consumers: the United States and New Zealand.

Drug companies in the United States spend approximately $4 billion per year on TV ads alone. The typical TV drug ad these days usually touts the benefits of a drug—maybe with a lot of singing and dancing—and closes with a brief, rapid-fire list of possible side effects, as parodied on *Saturday Night Live*.

That's about to change. After 15 years of studying the matter, the U.S. Food and Drug Administration (FDA) is going to require that the ads show less about the benefits and more about the side effects and risks. A new bill in Congress would impose similar restrictions on social media platforms.

"Once a drug has been approved for one use by the FDA, doctors may find it has other uses, even though the effectiveness of these other uses has never been studied through an FDA-approved trial. These are called 'off label' uses. About 10 to 20 percent of all prescriptions are for off-label uses. It is hard to exaggerate how unreasonable FDA regulations are in this regard."

Ad Value

Under President Donald Trump, the regulations could become even harsher. Robert F. Kennedy Jr., Trump's pick to head the Department of Health and Human Services, has said he wants to ban drug ads. Kennedy claims drug ads are such an important source of revenue for the networks that they influence what is allowed on the regular programming (e.g., avoiding criticism of pharma).

Here is what the regulators and would-be regulators are missing. Our most important health care problem is not that people are taking too many prescription drugs. They are taking too few.

The social value of drug advertising is that it alerts patients to the fact that there is a possible remedy for a chronic illness. The payoff is that the viewer might seek medical advice from a doctor and get a prescription, where appropriate.

There is no social value in ads that list risks and negative side effects. The information will always be too clipped to be understandable; it won't be remembered anyway, and it is useless unless a doctor finds the patient is a candidate for the drug.

The time to discuss side effects is when patients are under a doctor's care.

Drugs Provide Best Return

Studies show that we get our best return in medicine from drugs. Per dollar spent, the return on investing in drug therapy is much higher than what we are getting from investing in doctor care or hospital therapies.

For example, Columbia University's Frank Lichtenberg has estimated that three quarters of the increase in life expectancy that we've enjoyed in recent decades resulted from our adoption of modern drugs.

We are underinvesting in drugs, as reflected in undertreatment rates for chronic illnesses in this country.

Take diabetes, for example. Studies show that only 2.4 percent of people with prediabetes receive a prescription for metformin (the preferred treatment) within a year of their diagnosis. Even among obese patients, the figure is only 10.4 percent. Three years after an initial diagnosis, when the patient is even more susceptible to the disease, the treatment rate is still surprisingly low: 3.9 percent overall and only 14 percent for obese patients.

Or consider hypertension. One out of every four patients with the problem is not being treated at all. Only half of adults with hypertension have their blood pressure under control.

Noncompliance Problem

Almost as bad as not getting the prescription people need is not taking the drug once it is in hand. Both problems arise for similar reasons.

Nearly half of all Americans suffer from at least one ongoing or chronic health condition, and nearly half of these are not adhering to a needed drug regime.

There are an estimated 125,000 deaths per year in the United States due to medication nonadherence. Further, an estimated 33 percent to 69 percent of medication-related hospital admissions result from poor adherence. The total cost estimates for medication nonadherence range from $100 billion to $300 billion every year, when both direct and indirect costs are included.

Nonadherence and failure to get a prescription in the first place occur for a variety of reasons: lack of information, misinformation, and unfounded fear, all of which can be combatted with more, not less, information.

Value of Off-Label Use

Not only are the new rules ill-advised, the ones in force right now are already causing considerable harm. That's because a drug prescribed by doctors—no matter how useful and widespread the application—cannot be advertised, even to doctors themselves, unless the use has been FDA- approved.

Once a drug has been approved for one use by the FDA, doctors may find it has other uses, even though the effectiveness of these other uses has never been studied through an FDA-approved trial. These are called "off label" uses. About 10 to 20 percent of all prescriptions are for off-label uses.

It is hard to exaggerate how unreasonable FDA regulations are in this regard. If researchers publish findings on the off-label use of a drug in *The New England Journal of Medicine*, a drug company is not allowed to share that article with doctors. If they do, the drug company's decision makers could wind up in prison!

When it comes to the potential of drugs to treat chronic conditions, more information is better than less. This is especially true in an age when there is so much misinformation on the internet.

We should let people learn about the positive benefits of drugs from TV ads and other venues. That will encourage them to seek a doctor's counsel. The doctor's office is the place where risks and side effects should be discussed.

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

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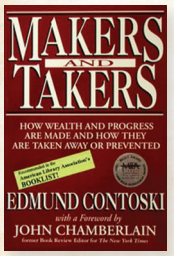

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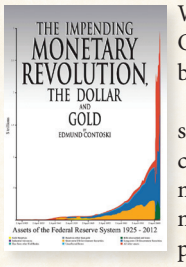

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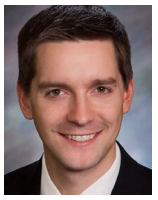

"Heartland's research and advocacy for science-based policies that improve people's lives have been very helpful to me and my colleagues."

REPRESENTATIVE ISAAC LATTERELL
SOUTH DAKOTA

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