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The Pulse

FDA Approves COVID-19 Shots for Toddlers, Infants

By Harry Painter

The U.S. Food and Drug Administration (FDA) has granted emergency use authorization for mRNA coronavirus injections for children aged six months and older, making the United States the only nation to approve them for children under five.

On June 17, the FDA recommended both the Pfizer-BioNTech and Moderna shots be administered to infants and toddlers. Previously, the shots were recommended for ages five and up.

The FDA took this action based on a unanimous recommendation from an advisory panel, despite

INFANT VAX, p. 4

Role for Pregnancy Aid Centers Grows Post-*Roe*

By AnneMarie Schieber

The U.S. Supreme Court (SCOTUS) decision returning abortion jurisdiction to the states is bringing renewed attention to groups that provide medical, material, and emotional support to pregnant women.

Nonprofit pregnancy-aid organizations go by a variety of names but generally share an overall mission: helping women find options other than abortion.

POST-ROE, p. 6

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Congressional Republicans Propose Big Health Care Reform

By Bonner Russell Cohen

Congress is considering legislation that would undo key provisions of Obamacare and promote choice in how Americans receive health care.

The bill would "eliminate the individual and employer mandates under the Patient Protection and Affordable Care Act [ACA, or Obamacare], to expand beyond that Act the choices in obtaining and financing affordable health insurance coverage, and for other purposes." Several reporting requirements tied to the individual and employer mandates would also be eliminated.

The Health Care Equality and Modernization Act of 2022 (H.R. 7258) is largely an updated version of a measure current bill sponsor Pete Sessions (R-TX) and Sen. Bill Cassidy (R-LA) introduced in 2016.

Sen. Bill Cassidy (R-LA)

PHOTO COURTESY GAGE SKIDMORE/FLICKR.COM

Tax Credits for All

One of the bill's most innovative features is a proposal to take all healthcare-related tax and spending subsidies and direct the money to create a refundable tax credit for everyone not on a government program such as Medicaid or Medicare. The bill also makes employer-provided health insurance portable and allows 24/7 access to "direct primary care" without having to go to the emergency room at night or on weekends.

Sessions' bill would also clarify an employer's ability to reimburse employee premiums for the purchase of individual health insurance under a health reimbursement arrangement.

ACA provisions such as requiring coverage of people with preexisting conditions, prohibitions on discrimination based on health status, and mandated coverage of dependents through age 26 would remain in place.

More Options

The bill would give states flexibility to ensure a competitive health insurance market outside the Obamacare exchanges.

"With respect to health insurance coverage offered in a State, the State may, in consultation with the Secretary [of HHS], take such steps, such as limiting the availability of general open enrollment periods, imposing delays in the effectiveness of coverage, permitting differentials in premiums based on age and other factors, as the State determines necessary in order to ensure an orderly market for health insurance coverage in the State that is not offered through an Exchange," the bill states.

The bill would also allow states to "provide for the enrollment of residents of the State who are uninsured in default health insurance coverage … and establishing a Roth HSA [Health Savings Account] for such residents who do not have a Roth HSA unless the resident has affirmatively elected not to be so enrolled and not to have such an account, respectively. If a State makes such an election, the state shall permit eligible residents to enroll in such coverage on a continuous basis."

In addition, the bill would allow states to "permit the adjustment of risk among health insurance coverage" in the individual market, like the risk adjustment used in Medicare Advantage plans.

Back to Insurance Basics

In keeping with the bill's goal of enhancing consumer choice, Sessions' legislation encourages states to offer "basic health insurance" on exchanges serving state residents. The bill defines basic health insurance as "such health insurance coverage as a State may specify and includes limited benefit insurance."

Defenders of the ACA sometimes refer to basic health insurance as "junk plans," indicating their clear preference for government-directed insurance coverage.

Up for Debate

With Democrats in control of Congress and the White House, Sessions' bill has no chance of passage this year. It could pick up steam if Congress changes hands in the November midterms. Even then, it would face a certain presidential veto, and the bill would then become part of the health care debate leading up to the 2024 presidential election.

"The Sessions health plan is an idea whose time has come," said John Goodman, president of the Goodman Institute and co-publisher of *Health Care News*. "The core concept: take all the spending and tax subsidies we now provide to private health insurance and use that money to give every American not on a government plan a refundable tax credit."

"This would empower people instead of employers and insurance companies," said Goodman. "Competition in the marketplace would be the vehicle to meet consumer needs."

'Real Health Reform'

Dean Clancy, a senior fellow in health care policy with Americans for Prosperity, approves the proposed expansion of choice.

"The Health Care Equality and Modernization Act would give Americans a personal option instead of a one-size-fits-all government option, empowering them with more choice and control and removing barriers between patients and medical professionals they trust," said Clancy. "This is what real health reform looks like."

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

FDA Approves COVID-19 Shots for Toddlers, Infants

Continued from page 1

incomplete efficacy data. The Centers for Disease Control and Prevention (CDC) followed with its approval on June 18, making the 17 million U.S. children under age five eligible for the injections.

Efficacy Questions

Pfizer and Moderna, the two pharma giants that manufactured most of the shots available to Americans, conducted efficacy trials before getting their products authorized by the federal government.

Moderna's reported estimate for efficacy in children ages six to 23 months was 51 percent for a two-dose series. Pfizer's two-dose series did not register an immune response by the FDA's definition, leading the agency to delay its evaluation until a three-dose test was available.

Serious Doubts

When Pfizer estimated an 80 percent efficacy for three doses of its mRNA injections for young children, CDC advisers called that estimate unreliable. The estimate was based on a group of only 10 children, three of whom received a placebo.

"That 80 percent figure for efficacy you've seen reported is worse than a joke, it's essentially a fabrication," independent journalist Alex Berenson wrote on his "Unreported Truths" blog after the announcement.

"Here's what the Food and Drug Administration and Pfizer did; they only counted cases after the THIRD mRNA dose," Berenson writes. "But of the 375 Sars-Cov-2 infections in the trial, **365** occurred before the third dose. Only 10 occurred after the third dose" (emphasis in original).

That means Pfizer based its efficacy figure on less than 3 percent of all the infections recorded in the trial.

"I think what the trial did was to put a rubber stamp on a conclusion that had already been reached. The government had already paid for 100 million doses or so of the vaccine. Doctors were already being told by medical societies how to get supplies so they could start jabbing kids the instant this decision came down."

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

Big Differences

Pfizer first received emergency use authorization for its COVID-19 shots after it announced on November 9, 2020 that the shots were 90 percent effective seven days after the second dose. The trial involved 43,538 participants.

The trials for infants and toddlers were markedly different, writes Berenson.

"Count the other 97 percent of the infections, and the vaccine was roughly 20 percent effective over the entire trial—far, far below what the FDA said was approvable in 2020," Berenson writes.

The confidence intervals in the Pfizer study were below zero for children two and under, so "the possibility that the vaccine *increased* the risk of infection cannot be excluded," Berenson writes (emphasis in original).

Children have long been considered to be at low risk of COVID-19 mortality. In addition, in February 2022 the CDC acknowledged natural immunity is superior to the protection the coronavirus shots provide.

Trial Errors

Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons and a policy advisor to The Heartland Institute, which co-publishes *Health Care News*, discussed the trial evidence on June 23 with *Health Care News* managing editor AnneMarie Schieber for the *Heartland Daily Podcast*.

"The [Pfizer] trial was a disgrace from a scientific standpoint," said Orient. "Supposedly they were going to have something like 3,000 kids in each group [control, test], but they only ended up checking the antibody levels in 10 percent of the participants," said Orient.

"So they have no idea what the antibody levels were in the others," said Orient. "In general, kids in this age group, already 75 percent of them probably do have antibodies because they had COVID and it was probably not apparent. What is the emergency?"

According to the CDC, 75 percent of children under 18, and more than half of U.S. citizens overall, have antibodies for COVID-19.

Orient says the high number of children dropping out of the trial is unusual.

"That ought to really disqualify it from serious consideration," said Orient.

Foregone Conclusion

Instead of the trial providing sufficient evidence to justify approving the injections, it was used to support a decision the government had already made, says Orient.

"I think what the trial did was to put a rubber stamp on a conclusion that had already been reached," Orient said. "The government had already paid for 100 million doses or so of the vaccine. Doctors were already being told by medical societies how to get supplies so they could start jabbing kids the instant this decision came down."

Even though experts testified against giving the shots to young children, "the supposed expert committee members all voted in favor of it, and then the FDA with warp speed and the CDC after that put their rubber stamp on it," said Orient.

Widespread Resistance

Florida Gov. Ron DeSantis said his state would resist the federal agencies' decision, speaking at a June 16 news conference.

"We are not going to have any [state] programs where we're trying to jab six-month-old babies with mRNA," said DeSantis. "That's just the reality."

Florida-based grocery store chain Publix, which offered coronavirus shots during the pandemic, is refusing to administer the shots to children under five.

Less than 30 percent of children ages five to 11 nationwide have received the full sequence of COVID-19 injections, according to the CDC.

A survey by the Kaiser Family Foundation found less than one-fifth of parents of children younger than five would be eager to vaccinate them immediately. Almost 40 percent of parents said they would take a wait-and-see approach, and about the same percentage said they would decline or only get their child vaccinated if required.

A campaign aimed at children to encourage the shots, featuring Elmo and his Muppet dad, Louie, was recently launched by the nonprofit educational organization Sesame Workshop.

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

Do Puberty Blockers, Cross-Sex Hormones Lower Youth Suicide Risk?

By Bonner Russell Cohen

Youth suicide rates rose significantly in states that allow minors to receive gender-transitioning medical treatment without parental consent, a new study finds.

Advocates of gender transition by minors claim providing such medical treatment reduces suicides among preteens and adolescents. Gender-affirming care uses puberty blockers and cross-sex hormones to alter a person's sexual characteristics and was largely unknown in the United States as recently as 15 years ago.

In states where young people are allowed to undergo medical treatments without parental consent, suicide rates among that age group rise, says Jay P. Greene, Ph.D., a senior research fellow at The Heritage Foundation's Center for Education Policy, in a working paper titled "Puberty Blockers, Cross-Sex Hormones, and Youth Suicide," released on June 13.

"In the past several years, the suicide rate among those ages 12 to 23 has become significantly higher in states that have a provision that allows minors to receive routine health care without parental consent than in states without such a provision," writes Greene.

Rising Suicide Rates

Greene analyzed youth suicide rates by state over 20 years and found little difference among the states before 2010.

"Starting in 2010, when puberty blockers and cross-sex hormones became widely available, elevated suicide rates in states where minors can more easily access these medical interventions became observable," writes Greene. "Rather than being protective against suicide, this pattern indicates that easier access by minors to cross-sex medical interventions without parental consent is associated with higher risk of suicide."

As various states adopted laws and regulations to restrict or facilitate access by children and youth to medical treatments, Greene found the difference in suicide rates became substantial, *The Daily Signal* reported on June 16.

"The Heritage study found that the 33 states with legal provisions for children to receive health care without parental consent experienced 1.6 more suicides per 100,000 preadolescents and young adults ages 12 to 23 than the 17 states without such provisions," states *The Daily Signal*, which is published by The Heritage Foundation. "That represents a 14% increase in the average state suicide rate among the same ages from 1999 to 2020."

'Thin and Weak' Evidence

Gender transition advocates say denying such treatment harms children and "laws and systems barring gender-affirming health care will contribute to higher rates of significant mental health problems, including deaths by suicide," writes Greene.

The studies that have been done to prove this have been poorly executed and fail to demonstrate a causal relationship between suicide and denial of chemical intervention, says Greene.

"My study highlights how thin and weak the evidence is to support the suicide threat and shows that examining the evidence in a better way reveals that these drugs may actually elevate suicide risk," Greene told *Health Care News*.

'Horribly Rotten Core'

Transition advocates are using suicide claims to advance their cause, says Greene.

"Only by threatening that young people will kill themselves could they get policymakers, parents, and school officials to overcome their natural hesitancy and get on board for a radical gender ideology," said Greene.

Parents are told they must affirm and consent to treatment if they value their children's lives, says Virginia Gentles, director of the Education Freedom Center at the Independent Women's Forum.

"At its horribly rotten core, the culture created by the question, 'Do you want a dead daughter or a live son?' intentionally drives a painful wedge between parents and children unless parents consent without question to immediate social and medical transition," said Gentles at a June 14 Heritage Foundation press conference on Greene's study.

'Pathway to Sterilization'

Hormone therapy has irreversible effects when given to adolescents and prepubescent children, says Jay Richards, director of the DeVos Center for Life, Religion, and Family at The Heritage Foundation.

"They are a pathway to sterilization," said Richards at the Heritage event. "Injecting huge amounts of testosterone in girls leads to sterilization."

There is strong pressure on many children to self-identify as transgender, says Gentles.

"Many young people are caught up in the social contagion of gender identity," said Gentles.

In most cases, time and maturation provide a natural cure, says Richards.

"For many children, puberty has been a way out of gender dysphoria," said Richards.

'The Tide Is Turning'

President Joe Biden issued an executive order directing the U.S. Department of Health and Human Services (HHS) to design policies to protect access to gender-affirming care and prevent "discriminatory legislative attacks" by states, on June 15.

HHS had already released guidance on transition care that includes unsupported claims, says David Gortler, a former safety official at the Food and Drug Administration (see article, page 19).

Sen. Tom Cotton (R-AR) and Rep. Jim Banks (R-IN) introduced identical bills in the U.S. Senate and U.S. House of Representatives to allow adults who underwent gender-transition procedures as minors to sue the medical practitioner for up to 30 years after turning age 18, on several grounds, on June 22.

"In the past several years, the suicide rate among those ages 12 to 23 has become significantly higher in states that have a provision that allows minors to receive routine health care without parental consent than in states without such a provision."

JAY P. GREENE, PH.D.
SENIOR RESEARCH FELLOW
THE HERITAGE FOUNDATION

The "Protecting Minors from Medical Malpractice Act" defines "biological sex" as "the genetic classification of an individual as male or female, as reflected in the organization of the body of such individual for a reproductive role or capacity, such as through sex chromosomes, naturally occurring sex hormones, and internal and external genitalia present at birth, without regard to subjective sense of identity of the individual."

The word is getting out about how harmful gender-altering treatments can be, says Greene.

"I sense the tide is turning on this gender ideology issue," said Greene.

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

INTERNET INFO

Jay Green, Ph.D., "Puberty Blockers, Cross-Sex Hormones, and Youth Suicide," The Heritage Foundation, June 13, 2022: **https://www.heritage.org/gender/report/puberty-blockers-cross-sex-hormones-and-youth-suicide**

Role for Pregnancy Aid Centers Grows Post-*Roe*

Continued from page 1

The SCOTUS ruling in *Dobbs v. Jackson Women's Health* returned to the states the authority to facilitate, regulate, or ban abortions. That means more women facing crisis pregnancies will be looking for help, says Rachel Morrison, J.D., a fellow at the Ethics and Public Policy Center.

"Thankfully, there are already thousands of pregnancy centers across the country ready and willing to help a pregnant woman and her child by offering free resources and support ranging from counseling and education to diapers and baby clothing to referrals for medical and other support services," said Morrison.

"Right now, state and federal lawmakers have a prime opportunity to explore and champion pro-life and pro-family policies that help pregnant women, their unborn children, and the organizations that support them."

RACHEL MORRISON, J.D.
ETHICS AND PUBLIC POLICY CENTER

Pregnancy Center Growth

A pregnancy center in Grand Rapids, Michigan, was already working to expand its space and services before the *Dobbs* decision.

Currently, space is so tight at HELP Pregnancy Aid the hallways are lined with baby items, and the building is not a comfortable environment for women going there for the first time, says HELP Executive Director Paula Veneklase.

"They are fearful; they're confused," said Veneklase. "It just compounds what they are going through. Every situation is different, so we want to be vigilant that we are respecting them and their confidentiality, and right now our space isn't conducive to that."

The center will conduct more pregnancy tests, ultrasounds, exams, and lab work and will provide Natural Procreative Technology for advanced natural family planning. The proposed expansion will also include more space for programming, a "Kid Zone," storage for the truck-loads of donated baby items the organization receives daily, and designated waiting rooms for medical services and family support.

HELP has raised $2.1 million toward its $3.6 million expansion funding goal.

Changing Landscape

The abortion industry has changed significantly since the 1973 SCOTUS decision in *Roe v. Wade* struck down states' restrictions on abortion in Michigan.

The use of drug-induced medical abortions has grown over the past two decades. Today, 54 percent of all abortions at eight weeks of gestation are induced by taking a combination of two drugs approved by the U.S. Food and Drug Administration (FDA) in 2000, according to the Kaiser Family Foundation (KFF).

The pills must be taken within the first 10 weeks of pregnancy to be considered safe for the woman. The first drug, mifepristone, known as the abortion pill or RU-486, blocks the production of progesterone, a hormone needed for a successful pregnancy. The second drug, misoprostol, is taken 24 to 48 hours later, usually at home. Misoprostol empties the uterus by causing cramping and bleeding.

Telemed Option

Telemedicine can give women access to abortion pills without physically visiting a physician, but like surgical abortions, the pills present a risk, says Veneklase.

"With telemed, no ultrasound would be necessary; women don't even need to hear the heartbeat," said Veneklase. "Women go home, alone. How is that good for women?"

According to the KFF, 19 states have policies that restrict telehealth for medical abortion. Michigan, where HELP is based, is not one of them.

"It is so important that we get in front of the culture instead of always trying to catch up," said Veneklase. "We really need to be out in front. With this expansion, this vision, we will move into the forefront to get ahead of medical abortion."

Reversal Pill

One goal of expanded HELP services in Michigan is to make Abortion Pill Reversal (APR) kits widely available.

APR uses hormones to overpower the effects of the first abortion pill. Designed for women who have changed their minds, the pill can be successful if administered within 72 hours, says Veneklase.

"We have a window of time where we can make an impact of changing the tide of that woman who changes her mind," said Veneklase. "If we can get that window between the first pill and the second pill, we can make good efforts to save her pregnancy."

HELP's medical director is a physician who specializes in APR, says Veneklase.

"We want to have the service here, right now, when she calls, when she is ready to change her mind," said Veneklase.

AMA Abortion Support

The pro-life movement is facing new headwinds because the American Medical Association (AMA) has changed its stand on abortion from opposition to support, says Marilyn Singleton, M.D., J.D.

"The AMA, which had a history of being against abortion, now is advancing one resolution declaring abortion is a human right and another seeking to make abortion pills more available," said Singleton. "Fortunately, there are many physicians who believe that two lives are at stake in the abortion debate."

Dismissing fetal life as morally irrelevant reduces respect for life in general, says Singleton.

"Everything in society is connected," said Singleton. "When physicians and policymakers openly devalue life, it is no wonder misguided individuals find it so easy to kill others."

'Culture of Death'

Pregnancy centers provide an important alternative for women in states that enshrine a right to abortion in state laws and constitutions, says Singleton.

"As some states descend further into the culture of death, more pro-life advocates are spurred on to actively stop the carnage by opening such clinics," said Singleton.

Lawmakers should support the growing demand for aid to pregnant women, says Morrison.

"As more women rely on pregnancy centers for care, these centers will need increased support from their communities," said Morrison. "Right now, state and federal lawmakers have a prime opportunity to explore and champion pro-life and pro-family policies that help pregnant women, their unborn children, and the organizations that support them."

AnneMarie Schieber (**amschieber@heartland.org**) *is the managing editor of* Health Care News. *A version of this article was published by LifeSite News on June 21, 2022. Reprinted with permission.*

FDA to Put 'Grandfathered' Drugs Through the Regulatory Wringer

By Ashley Bateman and AnneMarie Schieber

The Biden administration is requiring drugs that have been used for decades to undergo costly approval by the U.S. Food and Drug Administration (FDA).

The U.S. Department of Health and Human Services announced its plans to reinstate its Unapproved Drug Initiative (UDI) in the *Federal Register* (FR) on May 27, 2021. As the FDA's process moves forward, price hikes and unavailability may be on the horizon for patients.

The number of unapproved drugs is not known precisely, but *The Pink Sheet*, a biopharma information service, identified about 2,400 such drugs in 1984. The list included atropine, codeine, digitalis, and phenobarbital.

Grandfathered Drugs Booted

The FDA launched initiatives to remove unapproved drugs from the market in 2006 and again in 2011, says health economist Devon Herrick, Ph.D., editor of the Goodman Institute Health Blog and a policy advisor to The Heartland Institute, which co-publishes *Health Care News*.

"Some of the unapproved drugs the FDA tracked down for approval were nitroglycerine tablets for angina; colchicine, a gout drug based on a 3,000-year-old remedy; neostigmine, a drug to reverse the effects of anesthesia during surgery; and guaifenesin, commonly known as Mucinex, based on a 500-year-old remedy," said Herrick.

FDA approval for commercial drugs is required by the 1938 Federal Food, Drug, and Cosmetic Act. In 1962, the Act was amended to give the FDA the authority to approve drugs for efficacy as well as safety. Drugs "generally recognized as safe and effective" were "grandfathered" in and exempt from lengthy testing.

Requiring these drugs to undergo testing and FDA approval raised their cost to consumers, says Herrick.

"Of those grandfathered, many, possibly most, were probably out of production and replaced by newer products," said Herrick. "However, those drugs that were still in widespread use were tested and approved, after which the average price increased."

Trump's FDA Ended Initiative

The Trump administration ended the UDI in 2020, stating the FDA failed to follow the required notice-and-comment rulemaking process when it launched the UDI in 2006 and revised it in 2011.

The Trump-era regulatory change was "legally and factually" inaccurate and done without consulting the FDA, states the Biden administration's HHS.

The FDA also granted market exclusivity for the tested drugs to entice manufacturers to comply with the process, says Herrick.

"The Trump administration terminated the UDI because it provided nothing in the way of added drug safety but raised the drugs' prices substantially," said Herrick.

Prices of drugs that received approval under UDI increased by 525 percent to 1,644 percent (see figure), according to an analysis by Vizient, a health care services company.

Off-Label Use in Peril

Physicians have extensive clinical experience with drugs that have been on the market for decades, and requiring proven efficacy in addition to safety doesn't make sense, says Jeffrey Singer, M.D., a surgeon and senior fellow at the Cato Institute.

"There are numerous nongovernmental institutions, including academic clinical institutions, that are constantly evaluating the efficacy of drugs and were doing so long before there even was an FDA, and there has never been a good reason to concentrate that decision-making in a government monopoly agency that was initially created to ensure safety," said Singer.

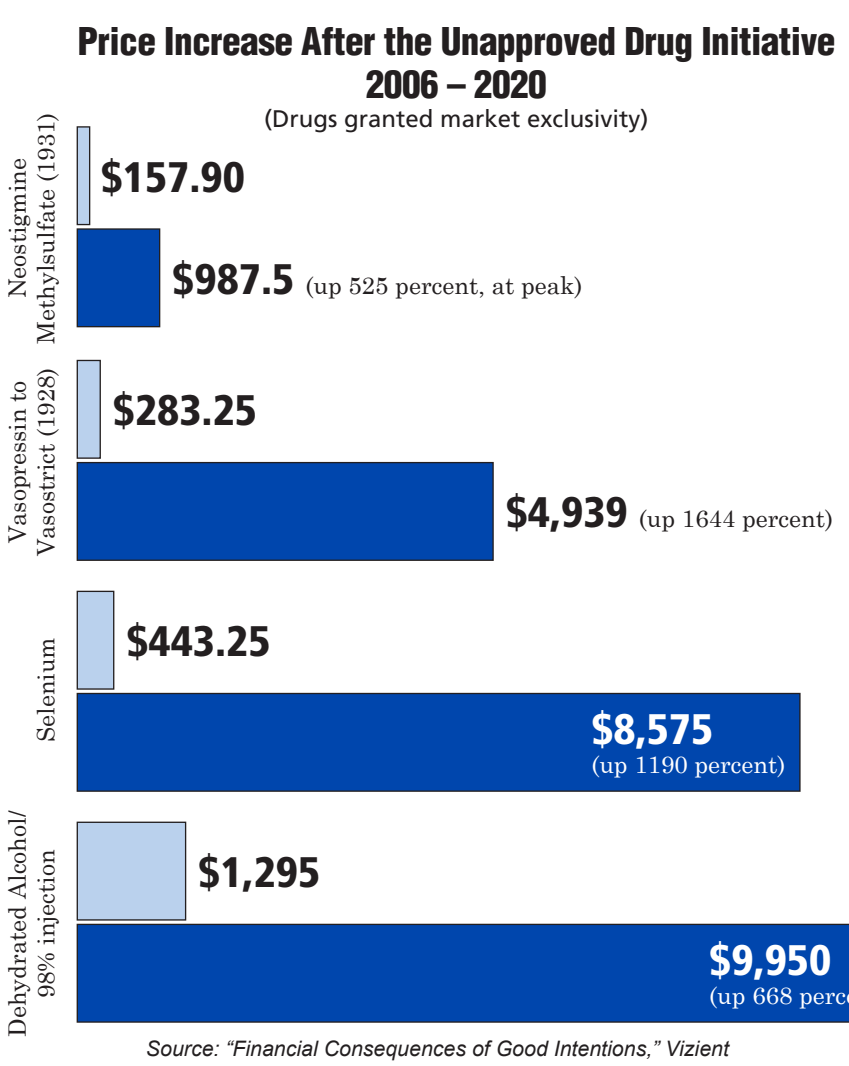
Additionally, prescribing drugs for uses not approved by the FDA is a common practice, says Singer.

"In fact, roughly 20 percent of all drugs prescribed in the United States are prescribed for off-label uses," said Singer.

When drugs don't work for a particular condition, clinicians try other drugs, says Singer.

"They don't need government bureaucrats to tell them what the clinical literature and their own experience are already telling them," said Singer.

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



Unusual 2021 Death Patterns Raise Questions about COVID-19 Vaccine

By Bonner Russell Cohen

Unusual patterns in 2021 U.S. death rates (see related article, page 9) are raising questions about the safety of COVID-19 vaccines.

At their peak during the pandemic, deaths from respiratory diseases for younger age groups differed from the peaks for the oldest age groups, unlike previous years' mortality, writes Genevieve Briand, Ph.D., assistant director of the Advanced Academic Program at Johns Hopkins University, in a working paper titled "Age Distribution per Cause: U.S. Monthly Deaths 1999-2021."

"In September 2021, recorded COVID-19 deaths show 65- to 74-year-olds died in greater numbers than [persons] 75 years and older, and COVID-19 deaths for the 45- to 54-year-olds were as high as for the 85 years and older [group]," wrote Briand. "This has never happened before for deaths due to respiratory diseases, from 1999 to 2019."

'Vaccine Deaths Hypothesis'

One explanation for this unusual age distribution is that some people may have died from complications after receiving the COVID-19 vaccines and boosters authorized in August and September of 2021, writes Briand.

"These September 2021 peaks for 'younger' age groups are consistent with the vaccine deaths hypothesis," wrote Briand. "This hypothesis should further be tested with deaths data for groups of individuals who all have been vaccinated, such as individuals in the Armed Forces," wrote Briand.

"If these vaccines can lead to death, then they can certainly lead to conditions requiring hospitalization," wrote Briand. "This hypothesis could thus also be further tested by looking at hospitalization data related to such documented conditions."

'Cause for Concern'

The possibility the vaccines themselves contributed to the rise in mortality should be investigated, says Twila Brase, president and cofounder of the Citizens' Council for Health Freedom and a policy advisor to The Heartland Institute, co-publisher of *Health Care News*.

"If Americans could be dying from the COVID injection, we need answers to serious questions," said Brase. "Why have the CDC and the FDA seemingly turned a blind eye to soaring non-COVID deaths? Why did they just approve the COVID shot for our youngest citizens?

"Americans can no longer count on the CDC or the FDA as a source of truth on the COVID infection, COVID statistics, or the COVID injection," said Brase.

Are Vaccines Ineffective?

There is evidence the shots don't do much good and may cause harm, says Joel Hirschhorn, Ph.D., author of *Pandemic Blunder*.

German government reports claim there were 2,255 fatalities following COVID-19 injections, but health insurance claims from the European Medicines Agency (last updated March 26, 2022) show 31,254 deaths, stated Hirschhorn in the *Pandemic Blunder Newsletter* on April 7.

Similarly, the claim that nearly one million Americans died from COVID before the vaccines became available is inaccurate because it includes deaths from other causes, thus exaggerating the effect of the vaccine suggested in the lower later numbers, Hirschhorn told *Health Care News* (see related article, page 9).

"All the COVID death data from the U.S. and other countries [can be] seen as proof that COVID vaccines have always been a failure, contrary to the often-cited assertions that they may not prevent illness but [they do] curtail deaths; the data disprove this, especially the figure of one million U.S. COVID deaths," Hirschhorn told *Health Care News*.

"We must recognize that vaccines are unlikely to ever become as effective against respiratory virus diseases like influenza and COVID as vaccines against the stable smallpox, polio, and measles viruses. Instead, SARS-CoV-2 mutates far faster than the 6 to 9 months it takes for a new mRNA vaccine to be approved and distributed. By the time the vaccine hits the market, the virus it targets will be long gone."

DAVID R. USHER
CIVITAS ECONOMIC ENGINEERING

Were Deaths Preventable?

Nearly one million additional deaths after the vaccines became available could have been prevented if every eligible adult had received the shots, according to an analysis by National Public Radio (NPR) in consultation with Brown University and Microsoft AI Health, NPR's *All Things Considered* reported on May 13, 2022.

"One tragic fact about the nearly 1 million people who died of COVID-19 in the U.S. is that a huge share of them didn't have to," states the NPR report.

That assumes the vaccines are effective, whereas COVID-19 is different from other pandemics ended by mass inoculation campaigns, writes David R. Usher of Civitas Economic Engineering.

"We must recognize that vaccines are unlikely to ever become as effective against respiratory virus diseases like influenza and COVID as vaccines against the stable smallpox, polio, and measles viruses," wrote Usher. "Instead, SARS-CoV-2 mutates far faster than the 6 to 9 months it takes for a new mRNA vaccine to be approved and distributed. By the time the vaccine hits the market, the virus it targets will be long gone."

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

STUDY

COVID-19 Mortality Overstated Because of Government Policies

By Bonner Russell Cohen

The deaths of Americans with COVID-19 who had other diseases were reclassified to indicate COVID was a primary cause, distorting U.S. mortality statistics, an analysis by a Johns Hopkins University (JHU) researcher reveals.

The Centers for Disease Control and Prevention (CDC) instructed physicians, coroners, and medical examiners to include COVID-19 as a "primary" cause of death even if a person suffered from other illnesses, on March 24, 2020.

As a result, the distribution of deaths during the recent pandemic differs markedly from patterns over the previous two decades, writes Genevieve Briand, Ph.D., assistant director of Advanced Academic Programs at JHU, in a February 2022 working paper titled "Age Distribution per Cause: U.S. Monthly Deaths 1999-2021."

Briand plotted monthly U.S. mortality rates per age group for each of the six disease categories that are the leading causes of death—heart, cancer, respiratory, cerebrovascular, Alzheimer's, and diabetes—and deaths attributed to COVID under the International Classification of Diseases (ICD).

"COVID-19 deaths numbers were overstated, as, logically, had [the CDC's] new ICD-10 code not been created, all these deaths would have found a home in other cause of death categories," wrote Briand.

Multiple Mortality Peaks

There have been peaks in mortality during the pandemic as high as the April 2020 figure that led to prolonged shutdowns, according to Briand.

A surge in deaths two months after the U.S. outbreak alarmed public health officials and served to justify far-reaching measures to stem the virus's spread. The CDC data shows two other comparable peaks, in January and September of 2021, writes Briand.

"The COVID-19 numbers have been fuzzy, inaccurate, and not credible from the start. The CDC guideline telling doctors to put COVID on the death certificate as a cause of death even if they weren't sure was the beginning of the number inflation. Extra federal funds for every hospitalized COVID patient also encouraged inflation of COVID numbers. And the combining of pneumonia, influenza, and COVID into a batch number (PIC) allowed further inflation."

TWILA BRASE
PRESIDENT AND COFOUNDER, CITIZENS' COUNCIL FOR HEALTH FREEDOM

"A peak in deaths in January 2021 is not unexpected—as peaks of deaths, more often than not, occurred in January," wrote Briand. "The fact that the April 2020 peak is lower than the January 2021 one, by a larger magnitude than the January 2018 peak compared to it, and the fact that the September 2021 peak is nearly as high as the April 2020 peak, give further ground that the so-feared April 2020 peak was not as alarming as [we were] led to believe."

'Counterproductive Policies'

U.S. COVID-19 mortality is much higher than in some other developed countries, according to an analysis of COVID death rates in the United States, South Korea, and Sweden (as of December 2021) by David R. Usher of Civitas Economic Engineering, published at *Intellectual Conservative* on February 20, 2022.

"The United States COVID [death] rate since the beginning of the pandemic is 30.9 times higher than South Korea's and 1.6 times higher than Sweden's, even though vaccination rates of these countries are between 60 percent and 80 percent—a difference unlikely to be a significant factor affecting deaths (even if vaccines are assumed to be effective)," wrote Usher.

The U.S. death rate is higher because the government's response to the pandemic violated the rules of epidemiology, Usher concludes.

"[U.S.] policy did not focus on reducing deaths of high-risk individuals over the age of 65, but [was] counterproductively applied to everyone," wrote Usher. "Focusing on infection rates caused a pandemic of experimental, counterproductive policies and scared the general population."

'Fuzzy, Inaccurate' Official Numbers

Briand's findings make sense, says Twila Brase, president and cofounder of the Citizens' Council for Health Freedom.

"The COVID-19 numbers have been fuzzy, inaccurate, and not credible from the start," said Brase. "The CDC guideline telling doctors to put COVID on the death certificate as a cause of death even if they weren't sure was the beginning of the number inflation. Extra federal funds for every hospitalized COVID patient also encouraged inflation of COVID numbers. And the combining of pneumonia, influenza, and COVID into a batch number (PIC) allowed further inflation."

The way health agencies identified COVID-19 caused further inaccuracies, says Brase.

"The use of oversensitive PCR tests and the continual push to do COVID PCR testing on Americans led to many people being diagnosed with COVID when what was actually being found, as Dr. Fauci once said, were 'dead nucleotides, period,'" said Brase.

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

INTERNET INFO

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Telehealth Company Investigated for Overprescribing Adderall

By Kevin Stone

The Federal Trade Commission (FTC) and federal prosecutors are investigating a telehealth company accused of overprescribing controlled substances, *The Wall Street Journal* (WSJ) reported in multiple articles.

The FTC is investigating the business practices of Cerebral Inc. after numerous patients complained they could not cancel monthly subscription fees and prescription refills.

Pharmacies at Walmart, CVS, and Cerebral's preferred pharmacy partner, Truepill Inc., refused to fill orders after they detected a pattern of overprescribing controlled substances, such as Adderall, that contain amphetamines, the WSJ reported.

Nurse practitioners at the company claim they felt pressured to prescribe stimulants such as Adderall and Vyvanse to treat attention-deficit hyperactivity disorder (ADHD) and other problems.

"The FTC's Civil Investigative Demand follows a subpoena the company said its medical group received in early May from federal prosecutors as part of an investigation into possible violations of the Controlled Substances Act," the WSJ reported.

Limited Drawdown

Cerebral Inc. is a start-up firm offering online mental health services, including virtual diagnoses and prescriptions for drugs to treat depression, anxiety, and ADHD.

Cerebral cofounder and Chief Executive Officer Kyle Robertson told the staff the company would no longer prescribe Adderall for new patients, in an email in May. In a separate email to clinicians, Chief Medical Officer David Mou stated the company will continue to prescribe controlled substances for other conditions, including benzodiazepines to treat anxiety, and will continue to treat existing ADHD patients with stimulant medications.

Cerebral's board of directors fired Robertson and replaced him with Mou, the WSJ reports.

"Cerebral vaulted to a $4.8 billion valuation less than two years after it launched its services," the WSJ reports. "It grew quickly advertising online mental-health treatment, first for depression and anxiety and later for attention-deficit hyperactivity disorder."

Growing Scrutiny

Telehealth providers face growing scrutiny over the liberal prescription of controlled substances such as Adderall, which is classified as a Schedule II controlled substance by the federal government because of its high potential for abuse.

Although telehealth was beneficial for patients during the COVID-19 crisis, oversight is important, says Matt Dean, a senior fellow for health care policy outreach at The Heartland Institute, which co-publishes *Health Care News*.

"Telehealth has performed extremely well throughout the pandemic and has helped meet the mental health crisis created in part by the pandemic itself," said Dean. "However, in-person mental health care cannot be entirely replaced. The risk of substance abuse, accidental overdose, and suicide cannot be appropriately dealt with through a telephone-only care system."

'Study Skittles' for Friends

Pharmacological interventions for mental health present a particular challenge for patient care, says Dean.

"A patient who has become dependent on Adderall or Vyvanse may have been told by his doctor that he needs to wean off the drug," said Dean. "That patient may be able to immediately get a prescription from Cerebral, because there is no doctor to see. Instead, he will merely complete a quick telephone consultation to get a new bottle delivered in a discrete package that looks more like cosmetics than pharmacology."

Some teenagers and young adults obtain prescriptions to sell their medications illegally, says Dean.

"Without eyeballing a patient, it is sometimes difficult to tell if he may be concealing dependency or if he may be reselling Adderall—aka Study Skittles—to friends on campus for $10 apiece," said Dean.

'Needed Expansion of Care'

Telehealth doesn't require more regulation than any physician's physical practice, says Charlie Katebi, a health policy analyst at Americans for Prosperity.

"We see the same risks in telehealth as in-person prescribing in terms of discretion and discipline," said Katebi. "The earlier opioid crisis was, after all, driven by in-person visits. Telehealth represents a needed expansion of care services, but we need to assure that the same safeguards that exist for in-person visits remain in place for telehealth."

Druggists are an important factor in managing health care, says Katebi.

"Given that, in this case, the overprescription of Adderall was noted and acted upon by pharmacies filling the prescriptions, pharmacy oversight may be key, although the level of discretion they exercise may be open to further discussion," said Katebi. "In the end, pursuing greater enforcement in the process of providing greater access is the goal."

'Barriers … Are Necessary'

The health care system has multiple gatekeepers to control health care costs and prevent harm to patients, says Dean.

"Telehealth has performed extremely well throughout the pandemic and has helped meet the mental health crisis created in part by the pandemic itself. However, in-person mental health care cannot be entirely replaced. The risk of substance abuse, accidental overdose, and suicide cannot be appropriately dealt with through a telephone-only care system."

MATT DEAN
SENIOR FELLOW
THE HEARTLAND INSTITUTE

"Barriers in medicine are necessary," said Dean. "Patients want access to things that make them feel better, but unrestricted access to Schedule I narcotics like heroin, for example, creates social problems that are not easily fixed. So, then, we create a criminal, legal barrier."

The drug-control system worked when pharmacists recognized Cerebral's predilection to prescribe controlled substances, says Dean.

"The law places licensed prescribers between patients and medications to make sure that the drug is safe, efficacious, and necessary," said Dean.

Cost-Cutting, Prevention of Abuse

Controls on prescription drugs help reduce costs and prevent abuse, says Dean.

"Insurers sometimes place another gatekeeper between you and a medication that your doctor prescribes, requiring prior authorization before you get an expensive drug," said Dean. "Sometimes a patient must meet face to face with a prescriber before receiving a drug or try a less expensive one before a more expensive one. These barriers attempt to control abuse of addictive drugs and slow the flow of very expensive medications, particularly when a low-cost generic drug may be just as effective."

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

INTERVIEW

Congress Should Fix Incentives to Overuse Telehealth, Budget Watchdog Says

Telehealth soared in popularity after Medicare started covering claims for virtual services during the pandemic. When the pandemic emergency declaration ends (expected after the midterm federal elections), claims will be reimbursed for five more months only, unless the program is extended. Before making telehealth reimbursement permanent, Congress should put up guardrails to prevent waste, fraud, and abuse, says Joshua Gordon, director of health care policy at the Committee for a Responsible Federal Budget.

***Health Care News*:** What happened during the pandemic when Medicare began covering telehealth visits? Was there a flood of claims?

Gordon: The data are still coming in, but it is pretty clear. Before the pandemic, 1 percent or less of all health care claims involved telehealth use. At the peak of the pandemic, in April 2020, about 13 percent of all Medicare and private insurance claims were telehealth, and now it has settled down to 5 percent.

***Health Care News*:** How much did doctors like telehealth?

Gordon: There was hesitation before COVID because it required specific technology providers that tended to be expensive and tied into electronic medical records and software. It was certainly a lifeline during the pandemic, when people were afraid of in-person interaction. Doctors were financially supported and, in some cases, kept afloat by this vast expansion of telehealth. So I do think doctors like it.

But that is one of the things we are concerned about over the long term. Providers have a lot of say in how often we interact with them, because we tend to do what our doctors want us to do, and if they want us to have a follow-up

over telehealth, we're not going to say no. So, doctors will have a lot of control over the utilization of telehealth, and we're worried that some of the incentives may lead to increased utilization and costs. Not in every case, but in the aggregate.

***Health Care News*:** Because doctors have been paid the same for a telehealth visit as a physical one?

Gordon: Yes. At least in Medicare, we are reimbursing on parity with in-person. We think if telehealth is reimbursing at the same amount as in-person, that will be a perverse incentive that will increase utilization.

***Health Care News*:** Can't telehealth save costs by attending to medical problems before they become more complex and more expensive to treat?

Gordon: Clearly, there will be more cases where this happens. Simple interaction will replace more intense interaction with doctors, and maybe even avoid emergency situations. I do think that is why telehealth is here to stay and will be in our continuum of care going forward.

What concerns me is the incentives in our health care system. Right now, health care is often fee-for-service, where the more things your doctor does, the more they get paid. If doctors are paid to see a specific patient over the course of the year and it's up to the doctor to decide how to treat the patient cost-effectively without harming their care, then doctors can choose the moment to use telehealth that will be most advantageous for the patient and not cost the doctor too much.

Having telehealth as part of a value-based payment system makes a lot of sense. Having it fee-for-service is what concerns me.

***Health Care News*:** What about the argument telehealth might reduce some of the "upsell" that can take place during an in-person visit, which can add up in a fee-for-service platform?

Gordon: I have a feeling doctors will figure out ways to upsell via telehealth just as they do in person. I don't want this to sound like I'm angry at doctors or think they don't know what they're doing. I'm just concerned that when you have misaligned incentives, that could be a problem.

***Health Care News*:** Do you think if there are too many restraints on telehealth it could discourage innovation?

Gordon: There is no going back, I think, to a time when you had to travel to a specific [physical] site to use this technology. That doesn't make sense. The key is how to incentivize innovation without overutilization. That is a problem Medicare has across the board with all new technologies: they can make things more expensive, not less.

"I have a feeling doctors will figure out ways to upsell via telehealth just as they do in person. I don't want this to sound like I'm angry at doctors or think they don't know what they're doing. I'm just concerned that when you have misaligned incentives, that could be a problem."

JOSHUA GORDON
DIRECTOR OF HEALTH CARE POLICY
COMMITTEE FOR A RESPONSIBLE FEDERAL BUDGET

***Health Care News*:** What guardrails should Congress put in place regarding telehealth to prevent overuse?

Gordon: Congress should extend these authorities for two years [not just five months] after the public health emergency ends, to allow us to gather more data from a time when the COVID pandemic is not the most dominant factor in how we see our doctors. We should not rush into anything permanent, because it's always harder for Congress to change things already in law.

Also, if Medicare can, open telehealth up more in alternative payment models in Medicare Advantage and not fee-for-service.

On waste, fraud, and abuse, we will want to pay specific attention to audio-only [telehealth visits]. For example, you might have providers cold-call seniors on Medicare, convincing them to have a new interaction with a doctor and that doctor then gets paid.

We are also concerned about health care apps where just interacting with the app instead of being a very patient-driven thing becomes reimbursed by Medicare at very high in-person rates.

INTERNET INFO

"Fiscal Considerations for the Future of Telehealth," Committee for a Responsible Federal Budget, April 21, 2022: **https://www.crfb.org/papers/fiscal-considerations-future-telehealth**

Medicare Limits Payment for New Alzheimer's Drug

By Kevin Stone

The Centers for Medicare and Medicaid Services (CMS) will cover the Alzheimer's disease drug Aduhelm only for patients enrolled in clinical trials.

The U.S. Food and Drug Administration (FDA) approved Aduhelm under its accelerated approval pathway in April 2021. The FDA gave the drug the green light despite objections from 10 of the 11 members on its advisory panel, who said Aduhelm had failed to demonstrate efficacy.

The decision prompted such a strong reaction that on June 8, 2022 the U.S. House of Representatives passed legislation to require drug companies to conduct large-scale follow-up trials on drugs that were quickly approved.

CMS had announced its restrictions on covering Aduhelm under Medicare on April 7.

Aduhelm's developer, Biogen, presented mixed evidence of the drug's effectiveness. One trial, announced in October 2021 after the original approval, found patients receiving high doses of Aduhelm fared better than those receiving a placebo. The other trial found no meaningful benefit.

The FDA approval was controversial because it could open the door for Medicare to cover a drug with questionable efficacy that has a big price tag. An estimate of the minimum cost to Medicare if the drug were approved for widespread use is $29 billion annually, or about $56,000 a year per Alzheimer's patient.

Decision Applies Broadly

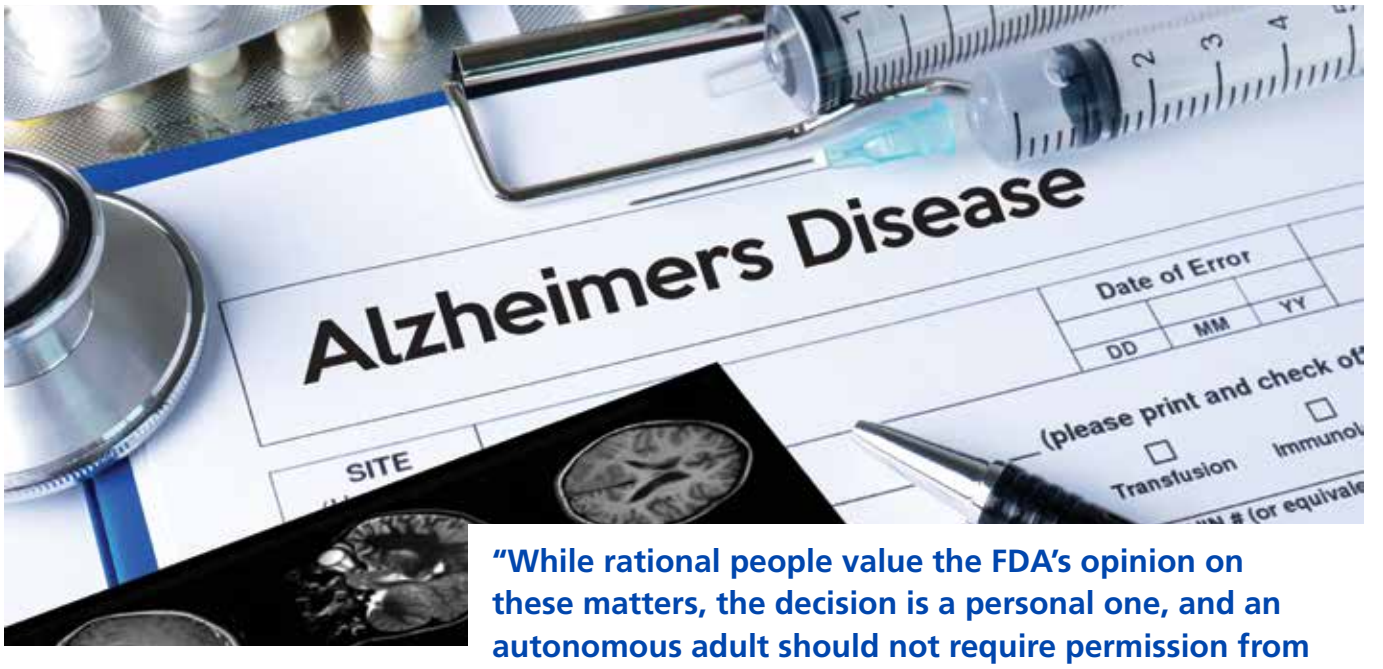
The CMS's requirement for enrollment in an approved, randomized controlled trial applies to all beta amyloid-directed monoclonal antibody treatments, not just Biogen's, indicating doubts about this approach as an effective treatment for Alzheimer's.

The decision casts doubt on the FDA's approval process, Michelle McMurry-Heath, president and CEO of the Biotechnology Innovation Organization, said in a statement.

"With this decision, CMS is not just saying it has no confidence in Alzheimer's drugs approved under the FDA's accelerated approval pathway," said McMurry-Heath. "It also is undermining confidence in FDA's traditional drug approval process more broadly."

FDA Process Delays Access

Although the Medicare decision was correct, the FDA approval process imposes unnecessary delays in drug development, says Jeffrey A. Singer, M.D., a senior fellow at Cato Institute.



"I think CMS made the right decision, but this is probably an isolated decision, not a policy shift," said Singer. "The controversy … is another example of why the FDA should not base the approval process on its determination of a drug's efficacy. That falls under the realm of real-world clinical research. Efficacy requirements add years to the approval process."

CMS showed unusual common sense in rejecting full coverage for the drug, says Michael F. Cannon, director of health policy studies at the Cato Institute.

"Refusing to purchase medical care that doesn't even work seems like a reasonable limit," said Cannon. "Unfortunately, this has not been Medicare's historical practice. Medicare pays for tons of medical care that does not work, which serves only to injure Peter and enrich Paul's health care providers, without benefiting Paul at all."

Only Treatment Available

Opening the gate to new treatments could yield unknown benefits, says Edward Hudgins, founder of the Human Achievement Alliance and author of a policy paper titled "A Modern System for Approving the Cures of the Future," published by The Heartland Institute, which co-publishes *Health Care News*, in 2019.

"No doubt the costs of the treatment played a part in the CMS decision to only cover patients in clinical trials," said Hudgins. "Policymakers have an incentive to keep costs down in the short term and ignore the long-term implications of this policy."

"While rational people value the FDA's opinion on these matters, the decision is a personal one, and an autonomous adult should not require permission from the government when they want to try to save their life. If the patients themselves are paying for the drug, they and their doctors will perform much better due diligence before committing their own money to what might be a dry hole."

JEFFREY A. SINGER, M.D.
SENIOR FELLOW, CATO INSTITUTE

Making the treatment widely available could reveal more patients would benefit, says Hudgins.

"While it has shown results only in limited circumstances so far, Aduhelm is the first treatment in almost two decades to treat Alzheimer's," said Hudgins. "It would be better for this treatment to be tested as widely as possible, because if it does in fact prove effective for a wider category of sufferers, it would reduce one of the worst scourges afflicting the elderly and reduce health care costs as well."

Patients Could Choose, Pay

One way to get around the cost concerns of testing innovative drugs is a reform proposal known as Free to Choose Medicine, says Hudgins.

"The sponsor could offer Aduhelm on such a track to all who desired it," said Hudgins. "Results would be logged in a database which would supplement clinical trials and allow researchers to more quickly evaluate the treatment's efficacy. Further, if the treatment proves successful, over time it would be refined and the market for the treatment would expand, bringing down costs."

The decision to participate in efficacy trials should be left to patients, not regulators, says Singer.

"I think patients should be allowed to purchase and try drugs that may have not been approved by the FDA but are approved by other credible third-party certifiers," said Singer. "With such a serious and fatal disease as Alzheimer's, many patients don't have the time to wait for the FDA to give them permission to save themselves from this terrible fate."

Social Benefits Possible

Allowing patients to use unproven drugs they pay for themselves would create social benefits, says Singer.

"While rational people value the FDA's opinion on these matters, the decision is a personal one, and an autonomous adult should not require permission from the government when they want to try to save their life," said Singer. "If the patients themselves are paying for the drug, they and their doctors will perform much better due diligence before committing their own money to what might be a dry hole."

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

Community Health Care for Veterans Could Be Limited, Says VA Secretary

By Harry Painter

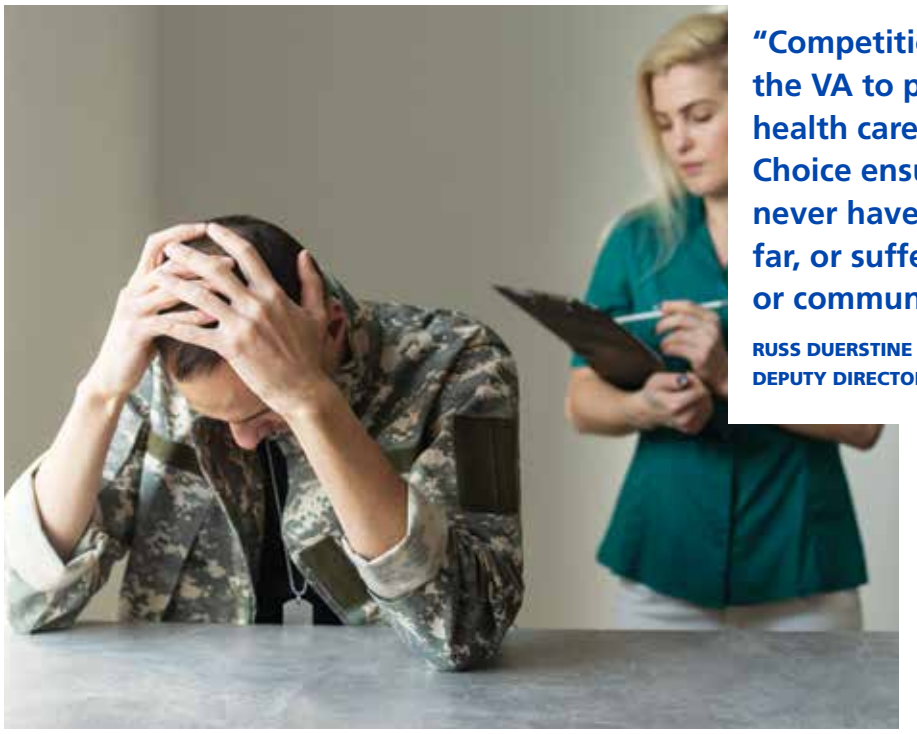
The U.S. Department of Veterans Affairs (VA) may limit access to community care, a popular means of getting quicker treatment, VA Secretary Denis McDonough says.

The VA currently spends one-third of its health care budget on community care.

"[Thirty-three percent is] a high number, and that's the highest number yet of the three years of the MISSION Act," McDonough told a U.S. Senate committee hearing on June 14.

The 2018 VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act allows vets more access to community care by non-VA providers when wait times for an appointment at VA hospitals and clinics become too long. The MISSION Act specifies the circumstances under which vets can receive non-VA care.

"Care overall, as you have seen in the budget, is growing," McDonough told the committee. "Care in the community as a portion of that is growing. ... My hunch is that we should change access standards."



"Competition is the only incentive for the VA to provide quality and timely health care and good customer service. Choice ensures that the veteran will never have to wait too long, drive too far, or suffer poor quality from the VA or community care provider."

RUSS DUERSTINE
DEPUTY DIRECTOR, CONCERNED VETERANS FOR AMERICA

Deliberately Creating Obstacles

A 2021 Freedom of Information Act (FOIA) request by Concerned Veterans for America (CVA) revealed the VA was creating confusion over data on community care and was actively discouraging veterans from seeking out non-VA benefits, CVA Deputy Director Russ Duerstine told *Health Care News*.

"Guidance being used by the VA discourages VA employees from offering to review eligibility for community care for veterans unless they ask for it themselves," said Duerstine.

The VA provides misleading responses to inquiries, says Duerstine.

"The VA is actively providing sample scripts for employees to use when talking to veterans eligible for community care," said Duerstine. "The VA's script actively dissuades veterans from choosing community care by using inaccurate community wait-time data and placing the expectation on the veteran to ensure their care is coordinated and to obtain their medical records."

Veterans become eligible for community care after their wait for an appointment exceeds 20 days for primary care or 28 days for specialty care.

The Office of the Inspector General (OIG) found the VA presents flawed performance data to the public, despite reforms instituted after news reports of negligent and physically abusive treatment of patients at VA hospitals in 2014.

Starting the Clock Later

The VA uses misleading methodology and incomplete data sets to calculate patient wait times, creating confusion about the health care needs of veterans and the department's performance, said Inspector General Michael J. Missal in a memorandum published on April 7.

"VHA [Veterans Health Administration] has sometimes presented wait times with different methodologies, using inconsistent start dates that affect the overall calculations without clearly and accurately presenting that information to the public," wrote Missal.

The VA's Access to Care website for patients logged wait times using the "create date"—when the appointment was booked—instead of the "request date," when the appointment was scheduled, as required by federal statutes and regulations. This results in wait times appearing shorter, writes Missal.

"VHA has published wait time data based on start dates that are inconsistent with VHA policy and publicly stated methodologies, and the stated description of methodologies on its website may be misleading," wrote Missal.

Obtaining services from the VA's network of community care providers requires preauthorization. Documents the Americans for Prosperity Foundation obtained through a FOIA request in early 2022 show the VA created an additional layer of review after a veteran is found eligible for community care. The VA policy, which is not required by the MISSION Act, calls for "clinical review" to "determine if the requested services are clinically appropriate to be authorized for delivery in the community."

Rationing by Waiting

The VA system is like the socialist Canadian health care system, says John C. Goodman, president of the Goodman Institute and co-publisher of *Health Care News*.

"Like the Canadian system, VA health care engages in rationing by waiting," said Goodman. "Throughout its history, the ability to see private doctors to get timely care has either been denied or very restricted. Long waits for care put patients at risk and in some cases lead to premature deaths. Health care delayed is health care denied."

Goodman's 2020 book *New Way to Care* recommends several ways VA patients can get better access to care. One is to allow private pharmacies to fill prescriptions for vets at the discounted prices to which they are entitled. Currently, the VA must approve prescriptions by private physicians, which further increases VA wait times.

Promoting Competition

Greater access to non-VA providers provides better service all around, says Duerstine.

"Competition is the only incentive for the VA to provide quality and timely health care and good customer service," said Duerstine. "Choice ensures that the veteran will never have to wait too long, drive too far, or suffer poor quality from the VA or community care provider.

"If the VA or community care provider is not providing the health care that meets the veteran's needs, then they can pick another provider, just like they can with their other health insurance," said Duerstine.

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

INTERNET INFO

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Soldiers Battle Military's COVID-19 Vaccine Mandate

By Bonner Russell Cohen

Retired generals, high-ranking officers, physicians, and attorneys held a two-hour news conference to assail the military's year-old policy of mandatory COVID-19 vaccines.

Saying the Pentagon's no-exceptions policy for all military personnel treats soldiers, sailors, and airmen as "chattel of patent holders," attorney Todd Callender blasted the U.S. Department of Defense (DoD) for violating the Uniform Code of Military Justice.

"Biden's betrayal of our military with unlawful orders for all service members to be vaccinated with the experimental EUA COVID shot is weakening our military, jeopardizing national security, and putting every American at risk."

ELIZABETH LEE VLIET, M.D.
PRESIDENT AND CEO
TRUTH FOR HEALTH FOUNDATION

Military Personnel Rights

Callender's remarks came at a June 14 press conference hosted by the Arizona-based Truth for Health Foundation, a nonprofit public health watchdog advocating individual medical freedom. Callender was joined by another attorney specializing in the rights of those serving in the military.

Resistance to the vaccine mandate for the military dates to an August 24, 2021 memorandum from Defense Secretary Lloyd Austin directing the "Secretaries of the Military Departments to immediately begin full vaccination of all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard, who are not fully vaccinated against COVID-19."

Senior officers and officials responded to Austin's memo with strict measures to enforce the mandate. The order triggered widespread litigation over the military branches' restrictive approach to religious exemptions to vaccine mandates. Documentation of adverse reactions to the vaccines among people serving in the military has further inflamed public discussion of the policy.

Sen. Ron Johnson (R-WI) has sent several letters to Secretary Austin regarding unusual patterns of disease that DoD physician whistleblowers have observed in the military's database.

Readiness Effect

The U.S. Food and Drug Administration (FDA) approval of the COVID-19 vaccines under the emergency use authorization (EUA) meant the treatments were greenlighted without having to go through the FDA's customarily long testing process before signing off on new drugs. The EUA led to charges the vaccines were more experimental than the public was given to understand.

"Biden's betrayal of our military with unlawful orders for all service members to be vaccinated with the experimental EUA COVID shot is weakening our military, jeopardizing national security, and putting every American at risk," Elizabeth Lee Vliet, M.D., president and CEO of the Truth for Health Foundation, said in a statement.

"We are losing experienced and highly trained service members, reflecting billions in costs from taxpayer funds as well as seeing dramatically impaired military readiness such as pilots who cannot fly or cannot complete training, and troops who are too ill to carry out duties," she said. "This has drastically weakened national security at a time of rising tensions globally, which serves China and globalists' agendas to take America 'out of the fight' and take over globally."

Religious exemptions from medical treatments are allowed in the Uniform Code of Military Justice, but the Army, to cite one example, has been reluctant to grant them. The Army had separated 818 soldiers as of June 2 for refusing the COVID-19 vaccine, *Stars and Stripes* reported, citing service data. More than 4,450 religious exemptions have been requested, but the Army has approved only 11, the publication reported.

'Weaponizing Psychiatry'

At the press conference, Commander Robert Green, U.S. Navy, talked about what happened to a female Navy dentist, a lieutenant, who refused to take the vaccine on religious grounds.

"She was banned from her building, threatened with the loss of her dental license and with being dishonorably discharged, and was told she would have to undergo a psychological evaluation," Green said. "This is weaponizing psychiatry against service members who stand up for their rights."

By law, service members "have the right to refuse," Green said.

"What good does it do the military to deny members the dental services needed for readiness?" Green said.

Removals Despite Shortages

Lieutenant John Bowes, U.S. Air Force, filed for a religious exemption and was promptly removed from training to fly the F-16. Those in the military resisting vaccine mandates constitute "not a small contingent," Bowes said at the press conference.

"Some 136,000 are actively resisting vaccine mandates, according to the DoD," Bowes said. "More than 700 pilots are actively resisting vaccinations, and 357 pilots, including trainers, have been removed at a time when there is a shortage of 1,650 pilots. Many are leaving for the airlines."

Several speakers said harassment over vaccines extends into the service academies. Maj. Gen. Rod Bishop, U.S. Army (ret.), said the Coast Guard Academy has "formed cadres to follow unvaccinated cadets into bathrooms."

Noting reports of "serious medical conditions among young military people" after receiving COVID vaccinations, Vliet said in her press statement. "Why would the DoD continue forcing vaccine mandates? … People aged 25-44 stand little chance of contracting the virus, which primarily afflicts the elderly and the infirm.

"The CDC's own data is a smoking gun," Vliet said.

Allegations of Cover-Up

Attorney Mike Rose, who served in the Air Force, now fights for the rights of Air Force Academy cadets "being purged for not taking COVID vaccines." Rose told the press "there are no benefits from taking COVID-19 vaccines for people in this age group."

Johnson's Feb. 2 letter to Secretary Austin demanding an answer to the Pentagon whistleblowers' allegations that the DoD was covering up injuries from COVID shots "has received no response," Rose told the press.

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

Republicans Issue Health Care Reform Wish List

By Ashley Bateman

Congressional Republicans are offering a host of health care proposals designed to "harness technological innovations to improve Americans' lives and save taxpayer dollars."

The proposals released on June 1 by the Modernization Subcommittee of the Healthy Future Task Force include extending telehealth access after the COVID-19 public health emergency expires; eliminating waste, fraud, and abuse by rewarding states that crack down on improper payments; and expanding the use of technologies to improve patients' well-being.

"Instead of a government-run, socialized system that would destroy medical innovation, we need to modernize and personalize health care in America to improve people's lives and lower their costs," said task force cochairs Rep. Brett Guthrie (R-KY) and Rep. Vern Buchanan (R-FL) in a statement.

PHOTO COURTESY GAGE SKIDMORE/FLICKR.COM

Multiple Teams

The Healthy Future Task Force was created by House Republican Leader Kevin McCarthy and is comprised of 17 Republican members of the U.S. House of Representatives, including several physicians.

In addition to modernization, there are groups on treatment, security, affordability, and the doctor/patient relationship also working on policy solutions.

The Treatment Subcommittee recommends removing barriers to access for innovative treatments, devices, and, diagnostics; lowering drug costs by passing H.R. 19, the Lower Costs, More Cures Act of 2021, introduced by Rep. Cathy McMorris Rodgers (R-WA); and promoting medicines manufactured in the United States.

The Security Subcommittee's solutions include ensuring the nation is better prepared for pandemics, holding China more accountable for its role in COVID-19, increasing oversight of research money going to adversary nations, and requiring more transparency from federal health agencies.

Among the solutions the Doctor-Patient Relationship Subcommittee is considering are removing the COVID-19 vaccine requirement for health care workers and easing the complexity of electronic health records so doctors can spend more time with patients.

Obamacare Obstacle

The task force is punting on the most important reform, says John Goodman, president of the Goodman Institute for Public Policy and co-publisher of *Health Care News*.

"It is time for Republicans to be bold," said Goodman. "Rep. Pete Sessions' bill is a great place to start." (See related article, page 3.)

Sessions' (R-TX) Health Care Equality and Modernization Act of 2022, H.R. 7258, would repeal the remaining mandates in the Affordable Care Act and increase patient choice.

"Obamacare is unaffordable and deprives patients of access to the best care," said Goodman. "That's what Republicans should fix."

Privacy Headaches

The Healthy Future Task Force should also address the government's overregulation of health care technology, says Josh Umbehr, M.D., a family physician and founder of Atlas MD, a direct primary care practice in Wichita, Kansas. Privacy rules under the 1996 Health Insurance Portability and Accountability Act (HIPAA) intended to protect patient confidentiality have made it difficult for providers to share information and were relaxed because of the COVID-19 pandemic, says Umbehr.

"COVID was pretty unique," said Umbehr. "The [government] did something pretty atypical and changed 20-plus years of bad HIPAA rules in a good way. Too much security [under HIPAA] can make something so cumbersome it's unusable."

HIPAA rules also make it difficult for physicians to implement required use of electronic health records and websites, says Umbehr.

"[Patient] portals became so unusable with government requirements," said Umbehr. "While they might meet requirements, they have nothing to do with consumer usability. When things are easier, patients are more likely to get good health care. Security is probably not as important as we talk about."

Pay Issues

Growth of the direct-pay model, in which consumers, not insurance companies, reimburse providers for care, would reduce costs, says Umbehr.

"The goal should be that most health care is too cheap to insure," said Umbehr.

In its quest to improve health care, the task force is overlooking the key factor of compensating primary care physicians and nonsurgical specialists, says Rebekah Bernard, M.D., author of *Patients at Risk*.

"They are missing the number one issue—physician pay—which continues to be cut even while the cost of everything is going up," said Bernard. "I would like to see a focus on immediate reforms and increases to physician payment, without budget neutrality. This must emphasize primary care and 'cognitive,' nonprocedural specialties."

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

COMMENTARY

Like Soldiers, Physicians Can Suffer 'Moral Injury'

By Chad Savage, M.D.

It is not often you can say war veterans and doctors suffer from the same work-related injury, but it appears physicians suffer from "moral injury" at rates similar to those of combat veterans, according to a study in the *Journal of General Internal Medicine*.

The U.S. Department of Veterans Affairs says moral injury is the distressing psychological, behavioral, social, and spiritual aftermath of exposure to highly stressful events that go against a person's moral beliefs. Moral injury is often confused with Post Traumatic Stress (PTS), but in regard to military veterans it commonly means individuals caught in such predicaments as having to kill despite their Judeo-Christian belief that killing is wrong.

This type of mental anguish is becoming more recognized within the medical community, where it is probably the consequence of doctors becoming disempowered in the practice of medicine.

Historically, physicians collaborated with their patients to determine the best, mutually agreed-upon treatment. Today, centralized control has so undermined the doctor-patient relationship that many physicians feel superfluous to care management and are even required to implement treatments they do not agree with.

This artificial constraint on the practice of medicine, combined with obstacles to care and productivity pressures placed upon them by governmental and insurance payers, can make physicians feel disconnected from the care of patients.

Third-Party Killjoys

Physicians have become disillusioned by the destruction of a profession for which many sacrificed their twenties, believing in the nobility of their career. Instead, many caring and compassionate physicians have found themselves battling against a system that obstructs their efforts to provide quality care instead of facilitating it.

In the past, multiple generations of families were physicians. It was not unusual for physicians to say "my mom was a doctor" or "my dad was a doctor, and his dad was a doctor." The love of the practice of medicine was passed down and inculcated through generations. And for good reason. As a physician, you get paid to care for people. How cool is that?

However, that changed over several decades. Now, most physicians dissuade their children from following in their footsteps and physician suicide claims the equivalent of an entire medical school every year. Sure, caring for the sick and dying comes with its toll, but never have physicians abandoned the profession and their lives in such numbers.

What has changed is the destruction of the doctor-patient relationship via hurried pace, the abdication of decision-making, and all the other challenges that result from how we finance the health care system.

When doctors work for patients, their responsibility is to those patients. When they work for the insurance-governmental complex, patients are demoted to conduits for third-party payments. This dehumanizes patients and deprives physicians—who are turned into data entry clerks—of joy.

Marcus Welby Returns

Fortunately, a new form of medical care is emerging in the United States: direct primary care (DPC).

DPC physicians work for and are paid by their patients—directly, not by some third-party payer. Thus, their attention is undivided and there are no payer-induced conflicts of interest controlling them.

Many of us remember *Marcus Welby, M.D.*, the early 1970s American television drama that starred Robert Young as a compassionate family physician with a great bedside manner. DPC is like that.

DPC docs have smaller patient loads, so they can take more time with their patients in an unhurried approach that allows them to be more thorough and understanding. This less-hurried pace is great for patients—who benefit from physicians as well, as they avoid the crush of full schedules of 10-minute visits that sap the meaning out of their work.

Being a physician will always be hard. Every doctor knows this going into the profession. What most don't know about going in is the soul-crushing bureaucracy that works against them and their patients' well-being.

DPC returns the physician to the role of healer. With that restoration, becoming a doctor is something I can certainly encourage my children to do.

Chad Savage, M.D. (**info@d4pcfoundation.org**) *is a policy advisor to The Heartland Institute and president of DPC Action. A version of this article appeared in RedState on May 18, 2022. Reprinted with permission.*

"Being a physician will always be hard. Every doctor knows this going into the profession. What most don't know about going in is the soul-crushing bureaucracy that works against them and their patients' well-being. DPC returns the physician to the role of healer. With that restoration, becoming a doctor is something I can certainly encourage my children to do."

CHAD SAVAGE, M.D.
PRESIDENT, DPC ACTION

Cleveland Clinic Describes Sex as 'Assigned' at Birth

By AnneMarie Schieber

The prestigious Cleveland Clinic has begun using the terminology "assigned female at birth (AFAB)" and "assigned male at birth (AMAB)."

An April 5 article on the clinic's "Health Essentials" online blog about cancer screenings titled "The Galleri Test: A New Blood Test for Cancer Screening" was attributed to Eric Klein, M.D., emeritus chair of the Glickman Urological & Kidney Institute.

Cleveland Clinic spokesperson Erica Foreman told *Health Care News* the editor of the blog will be using "inclusive language" going forward, in response to a question about whether this is how the renowned hospital organization will be referring to biological sex in the future. At least one other article on the blog uses the terms Foreman described as inclusive.

Sex and Politics

"To me, it is fringe 'newspeak' language where they have fallen into the trap of deciding women aren't women and men aren't men," said Marilyn Singleton, M.D., J.D., on the *Heartland Daily Podcast* on June 21.

The terms AFAB and AMAB are part of the diversity, equity, and inclusion (DEI) movement and reflect the practices of people who don't refer to themselves by their genetic sex. The terms have made their way into workplaces, government, and schools. In health care, however, males and females are defined by their chromosomes, says Singleton.

"The people who are doing these things [using non-genetic terms] are social workers or someone other than a medical doctor, and they're being paid $250,000 a year to pull together all this diversity and equity stuff," said Singleton. "They're not even doctors."

Diagnosis: Confusion

Allowing the individual to decide whether to identify as male or female could lead to incorrect diagnoses, says Singleton.

"Patients don't tell the whole story all the time, for simple stuff like admitting they smoke even though they smell of cigarettes," said Singleton. "If a person is delusional about their sex identity and not comfortable about a decision they made and don't fess up and tell the doctor the truth, they could miss a serious diagnosis."

"The people who are doing these things [using non-genetic terms] are social workers or someone other than a medical doctor, and they're being paid $250,000 a year to pull together all this diversity and equity stuff. They're not even doctors."

MARILYN SINGLETON, M.D., J.D.

A 2019 article in the *New England Journal of Medicine* described a 32-year-old obese patient named Sam who was brought to the emergency room by a boyfriend, complaining of severe abdominal pain. The emergency medical record described the patient as male. The patient was taking testosterone, but an ultrasound revealed an advanced pregnancy, and the patient later delivered a stillborn baby.

Another concern is laboratory work. Tests are calibrated differently for males and females, and an incorrect identification can lead to inaccurate results.

'Equity' vs. Fairness, Care

To presume physicians are exhibiting bias by using the words "male" and "female" is to miss the important common premise behind all care, says Singleton.

"From the get-go, we are taught to treat all patients the same," said Singleton. "This whole health equity thing has gone beyond just teaching students and reminding doctors that you should treat everybody with the greatest care that you know how to give."

One state, Michigan, requires physicians to undergo DEI training in which the use of the terms AFAB and AMAB is encouraged. Medical schools across the country are mandating DEI training for staff and implementing it in their curriculums.

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

COMMENTARY

Did Activists Write HHS Guidance on Youth 'Gender Affirming Care'?

By David Gortler

The U.S. Department of Health and Human Services' Office of Population Affairs (HHS/OPA) guidance document titled "Gender Affirming Care in Young People" purports to outline an established standard of care for the social, pharmacological, and surgical "affirmation" of children and adolescents who identify as transgender. The document is one-sided, ignores crucial clinical and scientific evidence and safety considerations, and was released without consulting other relevant government agencies and private sector organizations.

Rachel Levine
Assistant Secretary
for Health

PHOTO COURTESY POOL/POOL/GETTY IMAGES NEWS

Announcing the new document, Assistant Secretary for Health Rachel Levine said, "There is no argument among medical professionals—pediatricians, pediatric endocrinologists, adolescent medicine physicians, adolescent psychiatrists, psychologists, etc.—about the value and the importance of gender-affirming care."

This extreme statement was not backed up by evidence, and physicians and members of Congress appropriately rebuked it.

Unapproved Treatments on Demand

The HHS/OPA document gives the impression that anyone and everyone should start writing prescriptions and scheduling surgical procedures to transition children.

As a pharmacologist, pharmacist, and research scientist who has dedicated his life to drug safety, drug development, and evidence-based clinical and nonclinical science and medicine, I have some important questions about the remarkable omissions in the document.

Puberty blockers and cross-sex hormones for gender transition are all off-label, non-FDA-approved uses, but there is no mention that any FDA or non-FDA drug safety databases were reviewed to assess risks. There is no indication the FDA was consulted.

The guidance fails to mention short- and long-term risks, shortcomings, disadvantages, and alternatives to the various proposed treatments and procedures. There is no mention who wrote the document and what their credentials are.

Slipshod Psychology

Even though the document refers exclusively to psychological sources, it makes no recommendation for any psychological evaluation or a list of criteria to be used before a patient would undergo this life-altering intervention.

Should there be a waiting or evaluation period prior to a pharmacological or surgical intervention period, or should clinicians—as the document implies—simply proceed on an on-demand basis?

OPA focuses on family planning, teen pregnancy, and adoption—according to its mission statement—so why is it even commenting on gender transition treatments?

Anyone looking for answers in the guidance document will come up short.

Work of Activists?

The HHS/OPA guidance document is only two pages long, including tables and references, and officials gave no indication it is anything other than a final agency position.

As a former senior executive FDA drug safety official, I must wonder why my 20,000-plus former FDA colleagues are not speaking out after being circumvented on transgender clinical pharmacology recommendations by an obscure, obviously unqualified HHS office.

HHS has a taxpayer-funded budget of more than $1.5 trillion, yet it has given taxpayers a demonstrably thoughtless list of propaganda points, likely written by activists in a rush to promote transgender ideology.

Although the HHS/OPA has its own, in-house Office of Research and Evaluation, its guidance ignored both clinical and scientific concepts and sought no comment or input from relevant federal agencies or nongovernmental organizations, despite having easy access to them.

The only studies cited in the document deal with psychological issues. There are no studies referenced to back up the pharmacological, genetic, medical, surgical, gynecological, and endocrinological dimensions of gender transition.

The document represents a "feeling," not the evidence-based justification health guidance requires.

'Guidance Failing'

Florida state Surgeon General Joseph Ladapo, M.D., Ph.D., has already pushed back on the guidance.

"The federal government's medical establishment releasing guidance failing at the most basic level of academic rigor shows that this was never about health care," said Ladapo. "It was about injecting political ideology into the health of our children. Children experiencing gender dysphoria should be supported by family and seek counseling, not pushed into an irreversible decision before they reach 18."

Likewise, the Society for Evidence-Based Gender Medicine (SEBGM) spoke out against the guidance, writing there are "misstatements of the effects of social transition on well-being" and an "unsupported claim of the reversibility of puberty blockers."

SEBGM said the document makes an inaccurate statement regarding the age eligibility for surgery and asserts "overreaching claims" on improvements to adolescent mental health.

The organization faults the document for omitting any discussion of risks and for "conflation of distinctly different concepts" and "misleading information on the incidence of suicide and suicidality."

Misinformation Monitoring

The federal government seems hyperfocused on "misinformation" in health care and other policy areas, yet it plays very loose with the facts itself.

In a May 2022 interview, FDA Commissioner Robert Califf, M.D., stated "misinformation is the leading cause of death in the U.S." He failed to acknowledge the federal government's role as a purveyor of misinformation.

The federal government's request for comments on health misinformation regarding COVID-19 should expand to include misinformation on transgender interventions, and the HHS/OPA transgender "guidance document" ought to be placed at the top of that list.

David Gortler, Pharm.D. (**think@heartland.org**) *is a pharmacologist, pharmacist, FDA and health care policy oversight fellow, FDA reform advocate at the Ethics and Public Policy Center, and policy advisor to The Heartland Institute. A version of this article appeared in* Newsweek *on May 19, 2022. Reprinted with permission.*

"The federal government's medical establishment releasing guidance failing at the most basic level of academic rigor shows that this was never about health care. It was about injecting political ideology into the health of our children. Children experiencing gender dysphoria should be supported by family and seek counseling, not pushed into an irreversible decision before they reach 18."

JOSEPH LADAPO, M.D., PH.D.
FLORIDA STATE SURGEON GENERAL

COMMENTARY

Health Care Loses a Freedom Fighter

Medicine has lost an important freedom fighter.

Vladimir "Zev" Zelenko, M.D., the New York physician who led the charge on early treatment using hydroxychloroquine for COVID-19, died on June 30 at age 48. While he was fighting fiercely to protect his patients, Zelenko endured a personal battle with cancer.

In March 2021, Zelenko told *The Heartland Daily Podcast* his early intervention protocol saved all but three of his 1,000 patients during the early stages of the pandemic when little was known about the virus. Zelenko fended off attacks from the medical profession, the media, and the government. Although he was being treated with chemotherapy and had only one lung, he said he didn't think a mask would offer him any extra protection.

Last year, an international group of physicians nominated Zelenko for the Nobel Peace Prize.

'Courageous Stance' Lauded

Health care professionals, physicians, and patients have been mourning the loss.

The Association of American Physicians and Surgeons (AAPS) released a statement calling Zelenko a hero.

"Dr. Zelenko's courageous stance in favor of patients and the ability of physicians to treat them will forever live on in his name," the AAPS stated.

"As misguided public health authorities demanded that physicians not use hydroxychloroquine and other inexpensive medications for treating patients early for COVID-19, Dr. Zelenko did not waver in his dedication to patients," the statement said.

'Zelenko Protocol' Saved Lives

When there was no other protocol available, Zelenko developed a treatment for COVID-19, using three drugs known to be effective against other diseases, that saved countless lives, according to the AAPS.

"He generously shared his 'Zelenko Protocol' with all other physicians, thousands of whom used it to save the lives of millions of patients suffering from COVID-19," the AAPS stated.

"Dr. Zelenko's leadership is timeless in how to treat COVID-19 patients, while not being intimidated by authorities who improperly interfered with use of his brilliant treatment protocol," the statement said. "Zev's shining example is what all physicians should aspire to be, and he will continue to be a model for the medical profession for generations to come."

—Staff reports

"Dr. Zelenko's leadership is timeless in how to treat COVID-19 patients, while not being intimidated by authorities who improperly interfered with use of his brilliant treatment protocol. Zev's shining example is what all physicians should aspire to be, and he will continue to be a model for the medical profession for generations to come."
ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS

COMMENTARY

Medical Science Should Welcome Unconventional Thinking

By Jeffrey A. Singer, M.D.

The medical science priesthood has a long history of treating outside-the-box thinkers harshly.

As a surgical resident in the 1970s, for example, I was taught to excise melanomas with about a five-centimeter margin of normal skin, on the theory dangerous skin cancer should be given a wide berth. A skin graft is needed to cover a defect that size. This approach was never evidence-based but had been universally accepted since the early 20th century.

In the mid-'70s, several clinical researchers challenged the dogma. Multiple studies revealed five-centimeter margins were no better than two-centimeter margins. Now, the five-centimeter rule is a thing of the past.

For decades, physicians thought the main cause of peptic ulcers was hyperacidity in the stomach, often stress-related. In the 1980s, gastroenterology resident Barry Marshall noted the consistent appearance of a bacterium, *Helicobacter pylori*, on the slides of stomach biopsy specimens. Suspecting the bacterium caused the ulcers, he ingested it, and it gave him ulcers. Marshall then easily cured himself with antibiotics.

Several studies confirmed Marshall's discovery by the early 1990s, and today *Helicobacter pylori* is recognized as the cause of most peptic ulcers.

"When the FDA approves a drug, it specifies the condition it is meant to treat. But it is perfectly legal to use the drug to treat other conditions. Roughly 20 percent of all U.S. drug prescriptions are off-label, often based on clinical hunches and anecdotal reports. Eventually, the off-label use stimulates clinical studies."

JEFFREY A. SINGER, M.D.

Prescribing Drugs Off-Label

Off-label use of drugs approved by the U.S. Food and Drug Administration (FDA) is another path to medical innovation.

When the FDA approves a drug, it specifies the condition it is meant to treat. But it is perfectly legal to use the drug to treat other conditions. Roughly 20 percent of all U.S. drug prescriptions are off-label, often based on clinical hunches and anecdotal reports. Eventually, the off-label use stimulates clinical studies.

Sometimes the studies fail to validate the initial hunches. But sometimes evidence from clinical trials supports off-label uses.

We surgeons use the antibiotic erythromycin to treat postoperative stomach sluggishness. Lithium was originally used to treat gout and bladder stones; now it is used to treat bipolar illness. Thalidomide was developed to treat "morning sickness" in pregnant women. Because thalidomide caused horrific birth defects, it is no longer used for that purpose. However, it was subsequently found useful in treating leprosy and multiple myeloma. Tamoxifen, developed as an anti-fertility drug, is now used to treat breast cancer.

These are just a few examples of the rapid advances in understanding and treating health conditions during my medical career made possible by an environment that welcomes heterodoxy. But even health care practitioners who recognize the value of unconventional thinking tend to bridle when they face challenges from nonexperts.

Democratic Health Science

Today, the internet gives everyone access to information previously shared only among medical professionals. Many lay people engage in freelance hypothesizing and theorizing, a development turbocharged by the COVID-19 pandemic.

Every physician can tell stories about patients who ask questions because of what they've read on the Internet. Sometimes those questions are misguided, as when they ask if superfoods or special diets can substitute for surgically removing cancers. But sometimes patients' internet-inspired concerns are valid, as when they ask whether using surgical mesh to repair hernias can cause life-threatening complications.

It may be true that, as writer Theodore Sturgeon said, "90 percent of everything is crap." But the remaining 10 percent can be important. Health care professionals who summarily dismiss their patients' self-guided journeys through the medical literature risk throwing the baby out with the bathwater.

Credentials ≠ Competence

In protecting their scientific "priesthood," medical experts often wave the flag of credentialism. If you don't have an M.D. or another relevant advanced degree, you ae expected to shut up and do as you're told. Credentials, however, are not proof of competence, and relying on them can lead to the automatic rejection of valuable insights.

We physicians like to ask, "What do you call the person who graduates last in his medical school class?" The answer: "Doctor."

Economists who criticize COVID-19 research are often dismissed because they are not epidemiologists. Yet they can provide a useful perspective on the pandemic.

Scott Atlas, former chief of neuroradiology at the Stanford University School of Medicine, has published and critically reviewed hundreds of medical research papers. He is a member of the Nominating Committee for the Nobel Prize in Medicine and Physiology. Yet when Atlas commented on COVID-19 issues, the priesthood and its journalistic entourage derided him because he is "not an infectious disease expert"—as if a 30-year career in academic medicine doesn't provide enough background to understand and analyze public health data.

Why did they dismiss Atlas? Because he had the temerity to contradict the public health establishment.

"He's an MRI guy," Ashish Jha, dean of Brown University's School of Public Health, told NPR. "He has no expertise in any of this stuff."

Expertise Aids Analysis

Credentialism would deny us the benefits of unconventional thinking in other fields as well.

Although David Friedman earned a Ph.D. in physics and never took a course for credit in either law or economics, he spent part of his academic career teaching law and economics at Santa Clara Law School. George H. Smith, despite never graduating from high school, published *The System of Liberty: Themes in the History of Classical Liberalism* through Cambridge University Press. Roy A. Childs Jr., who never graduated from college, was a major intellectual contributor to the libertarian movement in the second half of the 20th century.

It is certainly true the lack of a background in a specific discipline can impede critical analysis of scientific studies, making laypeople more vulnerable to quacks and charlatans. Training in the discipline can make it easier to detect data "cherry-picking" and anticipate alternative interpretations of the evidence. Experts are experts for a reason. The question is how we can maximize the benefits of scientific democratization while minimizing its costs.

Jeffrey A. Singer **(jsinger@cato.org)** *practices general surgery in Phoenix, Arizona and is a senior fellow at the Cato Institute. A version of this article appeared in the May issue of* Reason. *Reprinted with permission.*

Direct-Pay Health Care Takes Off in Montana, Prompts Online Hub

By AnneMarie Schieber

The rapid growth of direct-pay health care in Montana prompted the Frontier Institute to launch an online hub to help consumers navigate the new market.

Frontier, a free-market public policy group, launched the hub after Montana Gov. Greg Gianforte (R) signed sweeping direct-pay care (DPC) reforms last year.

"Last year Gov. Gianforte signed SB 101, the most expansive authorization of DPC in the country," states the Frontier Institute on its website. "While other states authorize DPC only for primary care, Montana is the first state in the nation to allow DPC with any health provider."

Flat Fees

DPC charges consumers a flat monthly fee, like a gym membership. In states where DPC is considered insurance, it is subject to regulation and oversight by state insurance commissions, which can make it difficult for DPC practices to offer affordable fees.

The Free Market Healthcare Hub provides a map of direct primary care and specialty care practices in Montana. The hub tells consumers whether the practices are actively accepting patients, advertise primarily as DPC practices, and list prices for all their services.

Frontier confirms the information submitted on its site with a third-party source, such as the Montana Direct Patient Care Association. The hub currently lists 16 DPC practices, with an average monthly cost of $77.

DPC grew dramatically after the reform measures were enacted, says Frontier Institute Communications Director Tanner Avery.

"Since Gov. Gianforte signed SB 101 into law, the number of providers in Montana has doubled," said Avery. "Slashing red tape and giving entrepreneurs the maximum freedom to innovate has led to a booming market for affordable health care options."

Care, Not Insurance

A lawsuit filed by the Institute for Justice (IJ) prompted the Montana Legislature to pass one of two DPC reforms, says Phil Eskew, D.O., J.D., founder of DPC Frontier, a website that tracks the growth of direct care nationwide, and a policy advisor to The Heartland Institute, which co-publishes *Health Care News*.

"A few years ago, Montana was easily the toughest state in the Mountain West to operate a DPC practice," said Eskew. "DPC physicians could have been accused of operating an insurance company without a license. SB 101 has provided clear guidelines that DPC physicians may follow to ensure they are not accused of unlawfully selling insurance."

Prescription Power

In addition, SB 374, prompted by the IJ lawsuit and signed into law on May 11, 2021, allows physicians to dispense prescription drugs in their offices. Medical practices in Montana were previously banned from dispensing drugs unless there was no community pharmacy available.

"SB 374 allows physicians—DPC or otherwise—to dispense medications directly to their patients, a practice that was already permitted in over 40 other states," said Eskew.

Many of Montana's reforms were based on DPC reform in nearby Wyoming, says Eskew.

"I still reference Wyoming's language when speaking with other states about what to draft," said Eskew. "Portions of it are included in language from Montana, Kentucky, West Virginia, and many other states."

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

INTERNET INFO

Free Market Healthcare Hub, Frontier Institute: **https://frontierinstitute.org/reports/free-market-healthcare-hub/**

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REPRESENTATIVE ISAAC LATTERELL
SOUTH DAKOTA

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

1

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2

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3

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4

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