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The Pulse

FDA Wants to Expand Authority to Include Lab-Developed Tests

By Dvorah Richman

After 30 years of wrangling with industry and Congress, the Food and Drug Administration (FDA) is in the formal process of trying to expand its authority to regulate lab-developed tests (LDTs).

The agency is reviewing some 6,707 comments it received during the 60-day comment period, which ended on December 4. The FDA contends LDTs are medical devices subject to FDA authority under the Food, Drug, and Cosmetic Act (FDCA).

LAB-DEVELOPED TESTS, p. 6

Patient Denied Telehealth Access to Out-of-State Doctor

By Bonner Russell Cohen

A Boston-based physician who specializes in the treatment of rare childhood cancers is suing the New Jersey State Board of Medical Examiners for barring out-of-state physicians from telehealth consultations with Garden State patients across state lines.

Shannon MacDonald, M.D., et al. v. Otto Sabando was filed in the U.S. District Court for New Jersey on December 13 after the board reinstated restrictions on interstate telehealth suspended during the COVID-19 pandemic.

TELEHEALTH BAN, p. 4

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Medicare Cuts Physician Reimbursements

By AnneMarie Schieber

Medicare has cut payments to doctors for 2024 by 1.25 percent through a 3.34 percent reduction in the "conversion factor" used to calculate reimbursement rates under the Physician Fee Schedule.

The cut follows a 2 percent physician payment reduction in 2023. Medicare's "conversion factor" is a complicated system that assigns value to a service based on the physician's work, practice expense, and malpractice coverage.

Physicians decried the cuts, says Anders Gilberg, senior vice president of government affairs at the Medical Group Management Association (MGMA), in a news release.

"Despite appeals from MGMA and hundreds of physician organizations, this afternoon CMS finalized a substantial reduction to the 2024 Medicare conversion factor—further increasing the gap between physician practice expenses and reimbursement rates, and dangerously impeding beneficiary access to care," said Gilberg.

Congress requires the Centers for Medicare and Medicaid Services to be "budget-neutral," but setting payment rates can be tricky. Containing costs is important in keeping Medicare sustainable for taxpayers and future beneficiaries and affordable for enrollees. Setting rates too low, however, discourages physicians from participating in the program.

"Enacting yet another government-driven approach to payment would only replicate the same problems and fail to balance access to care with fiscal sustainability."

JOE ALBANESE
SENIOR POLICY ANALYST
PARAGON HEALTH INSTITUTE

Goal: Balanced Approach

Doctors' dissatisfaction with Medicare's reimbursement setting presents an opportunity for reform, argues a Paragon Health Institute report by Senior Policy Analyst Joe Albanese, published in December.

Although Medicare's payment policies have done a good job of containing costs, expenditures can rise over time because of an increase in the volume of physician services and Part B spending, the paper notes.

"Physician payment in Medicare continues to rely on a fee-for-service approach that incentivizes quantity of care over quality and administrative pricing that misestimates the value of health care services," wrote Albanese.

The goal should be a balanced approach where physician payments account for the costs of providing care and the system keeps patient expenses and government spending under control, Albanese told *Health Care News*.

"Some policymakers propose adjusting rates for inflation using the Medicare Economic Index (MEI), but this could lead to excessive cost growth," said Albanese. "It would be better to apply only a portion of the MEI and to pair this with other reforms. The most basic would be to offset higher spending by reducing Medicare overpayments in areas like outpatient hospital services and Part B drugs."

Lessons from Medicare Advantage

Medicare Advantage (MA), the alternative to Medicare's fee-for-service option, uses private health care companies. MA provides another resource for reform, says Albanese.

"Using data from MA contracts would improve payment calculations since private plans have more incentive than the government to align reimbursement with the value of care and do not need to make these decisions through the political process," Albanese said.

Albanese's paper argues policymakers should also strengthen budget neutrality requirements by reviewing utilization estimates based on the previous year and making adjustments. The paper also recommends oversight of new codes.

Another improvement would be to eliminate or significantly reform alternative pay models, such as the "value-based" Merit-Based Incentive Payment System, which are subject to political whims.

"Years of tinkering with Medicare payment policy for physicians have not produced a suitable long-term approach," wrote Albanese. "Enacting yet another government-driven approach to payment would only replicate the same problems and fail to balance access to care with fiscal sustainability."

Resistance to Innovation

Although MA offers lower premiums and simplicity, the plans are under attack because the model is far different from traditional fee-for-service Medicare, says Albanese.

"The U.S. health care system has no shortage of waste that drives up costs without improving patient health," said Albanese. "This is bad for seniors who face higher expenses and for the fiscal sustainability of public programs.

"MA plans can offer more generous coverage precisely because they are able to manage care more efficiently than traditional Medicare," said Albanese. "Enrollees in Medicare Advantage also have the ability to switch plans if they don't like their coverage."

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

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Patient Denied Telehealth Access to Out-of-State Doctor

Continued from page 1

Follow-up Consultations

After learning in 2012 their 18-month-old son, Jun Abell, was suffering from a rare, aggressive brain tumor, the toddler's parents, then living in New York, reached out to Shannon MacDonald, M.D., a pediatric oncologist and proton therapist at Massachusetts General Hospital. MacDonald treated the child successfully over two months of intensive care, after which Jun was discharged.

Now in his early teens, Jun has remained cancer-free but undergoes periodic checkups via remote consultations with MacDonald to make sure the tumor hasn't returned. Meanwhile, the Abell family moved from New York to New Jersey.

With New Jersey having reimposed pre-pandemic restrictions on telehealth, MacDonald is being charged by New Jersey officials with practicing medicine across state lines without a license from the state.

'Benefits No One'

New Jersey—and other states—require physicians who engage in telehealth for the state's residents to be licensed in the state. MacDonald is licensed in several states but not New Jersey.

The restriction on licensure harms patients, says the Pacific Legal Foundation (PLF), which represents MacDonald.

"Limiting access to specialists in rare cancers benefits no one," states a summary of the case on the PLF website. "Patients seek out highly accomplished medical specialists because of their expertise. Without telehealth, these patients are less likely to receive treatment from those specialists."

Constitutional Issues

The PFL says the restriction is not only wrong but unconstitutional.

"Placing undue burdens on both out-of-state physicians and New Jersey patients that far outweigh any benefits violates the Constitution's Dormant Commerce Clause and Privileges and Immunities Clause," states the PLF. "Also, just as physicians have a First Amendment right to speak with potential and existing patients via telehealth, physicians and their patients have the right to receive information from each other."

The restriction also violates the parents' 14th Amendment due process rights, says the summary, stating, "parents have the fundamental right to direct the lawful medical care of their children."

Pandemic Proof

PLF argues the suspension of telehealth restrictions by every state during the pandemic should be made permanent. "This small, common-sense act unleashed a new era in patient care," the organization states.

"Cancer care in particular benefitted from the rules," the PLF notes. "At the pandemic's peak, cancer care was the most common condition addressed in interstate telehealth visits, fully accounting for 10% of those visits nationwide."

The public health emergency showed telehealth is a viable way to increase access to care, says Matt Dean, a senior fellow for health care policy outreach at The Heartland Institute, which publishes *Health Care News*.

"Telemedicine's trial-by-fire, beginning in March 2020, was one of the few good things to come out of the COVID-19 pandemic," said Dean. "Since then, doctors have stepped up and found ways to safely treat patients remotely. Billing, data security, and safety concerns were addressed without almost any of the biggest problems predicted by opponents of telemedicine."

"In the context of telemedicine, duplicative licensure requirements can be deadly when they limit access to specialty care not readily available in a patient's home state. New Jersey, and all states that haven't done so, should update their rules to allow licensed physician-specialists to consult and follow up with patients wherever they may be. Such reforms increase patients' access to care without putting the public's health at risk."

CALEB R. TROTTER, LEAD ATTORNEY, PACIFIC LEGAL FOUNDATION

'Requirements Can Be Deadly'

This case is an instance of the widespread problem of restrictions on work in the United States, Caleb R. Trotter, PLF's lead attorney, told *Health Care News*.

"A general problem with occupational licensure in the United States is that industry incumbents regulate and oversee the profession," said Trotter. "Time and again, studies show that licensure boards act on the self-interested incentives inherent in their structure, rather than in the best interest of the public."

Patients are harmed by such regulations, says Trotter.

"In the context of telemedicine, duplicative licensure requirements can be deadly when they limit access to specialty care not readily available in a patient's home state," said Trotter. "New Jersey, and all states that haven't done so, should update their rules to allow licensed physician-specialists to consult and follow up with patients wherever they may be. Such reforms increase patients' access to care without putting the public's health at risk."

Interstate Compacts

With pandemic-era waivers now gone, some 30 states have reimposed restrictions. States can work together to restore the benefits of telehealth, says Dean.

"Many states are participating in interstate compacts and licensing reciprocity agreements to allow provider-patient relationships to continue as the special COVID-19 laws that allowed that care finally sunset," said Dean. "The success of these new laws, such as the counselors compact, which connects patients and their counselors across 28 states, recognizes the ability of states to protect patient safety while increasing access through telemedicine."

Criminalizing Care

The unlicensed practice of medicine is a criminal offense, says Dean.

"Doctors should not be criminally charged for treating a patient to whom they owe a duty of care," said Dean. "Indeed, doctors could be placed in a Sophie's Choice: either continue to treat the patient and violate state law—in this case, New Jersey's—or violate the American Medical Association's professional code of conduct, which calls for the doctor to treat the patient even if it puts the physician in harm's way.

"A good case could be made that terminating the relationship could constitute negligence, given the serious consequences of terminating care compared with the relatively arbitrary compliance rules," said Dean.

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

Why Are Republicans Losing the Health Care Debate?

By Ashley Bateman

A new survey reports three in five American voters view the Affordable Care Act (ACA) favorably, more people trust the Democratic Party on health care issues, and most voters believe a Republican president would repeal Obamacare.

The progressive Navigator political research group sampled 1,000 registered voters online from November 30 to December 4, 2023 and conducted additional interviews for the survey released on December 7. Navigator did not state the margin of error.

Navigator polls are led and funded by Democrat-leaning groups such as the Center for American Progress, Planned Parenthood, and the polling firm Global Strategy Group to "inform allies," elected officials, and the media.

Dodging Discussion

An October 2022 report by Horizon Government Affairs found Republican candidates tend to avoid discussing health care and have inconsistent messaging. Democrats, by contrast, run on consistent policies, generally government-controlled options with more "for free" promises. That stable approach has led to increased trust over time.

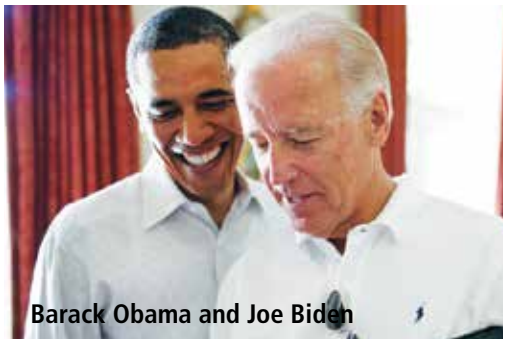
Republicans "run away" from the topic in primetime debates and lose the trust of voters even as they work on real solutions in Congress, says Dean Clancy, a senior health policy fellow at Americans for Prosperity (AFP).

"But on Capitol Hill, Republicans have been quite forward-leaning, introducing a lot of good health care bills," said Clancy. "In fact, the House GOP leadership has been actively working on advancing ideas like expanding [health savings accounts] and direct primary care access, among others."

Promoting Health Savings Accounts

As health care spending climbs and life expectancy declines, Americans need options with a better track record than the ACA and other government-controlled health care, and employers want to get out of the insurance business and fund health savings accounts (HSAs) instead, says Kansas state Sen. Beverly Gossage (R-Johnson County).

"We want every American to have the opportunity to choose the doctor and care that they want to meet their needs and the freedom to choose a private, portable, personalized health insurance plan to cover unexpected catastrophic events," said Gossage.


Barack Obama and Joe Biden

Providing employers with tax deductions and easing the burden of shopping for and managing plans, HSAs give employees freedom to buy the plan they want with funds that they take with them when they leave their place of employment.

Offering Alternatives to Single-Payer

U.S. Rep. Pete Sessions (R-TX) introduced a bill in May that would create a universal tax credit and individual accounts for after-tax savings for medical expenses to be invested and remain tax-free.

AFP endorsed the bill, the Health Care Fairness for All Act, because it would establish "sensible reforms that ensure lower prices, less hassle, and more personal choice and control without new taxes," making health care "dramatically fairer."

"At AFP we are supporting and trying to drive up the co-sponsorship of about 30 different good congressional health reform bills, some small, some more ambitious, and to my knowledge, none of these bills threatens employer health care or takes anything away from people," Clancy said.

According to AFP polling and focus groups, voters like and are surprised by Republican health-care reform ideas.

"I think if Republicans speak up a little louder about what they support, they will find voters respond positively," Clancy said.

'Amazing, But No Surprise'

The Navigator poll results show the Republicans have thrown away a great opportunity, says John C. Goodman, president of the Goodman Institute for Public Policy Research and co-publisher of *Health Care News*.

"Given the mess the Democrats have made in the individual market, this is truly amazing, but no surprise," said Goodman. "The [National Republican Congressional Committee], for the past several election cycles, has been telling all Republican candidates for Congress not to even discuss health care."

An Obamacare "repeal" sounds risky to voters because it is undefined, says Goodman.

"If we returned to pre-Obamacare government rules, the individual market coupled with risk pools would be much better for people with chronic conditions than the market today," said Goodman. "But those risk pools no longer exist. You can't just repeal Obamacare: you need a well-thought-out replacement."

Goodman says he favors reform, not a repeal, with access to health insurance, doctors, and medical centers that fit individual needs. Such a plan aligns with the desires most Americans have indicated in many polls: private coverage that is cheaper, less complicated, and managed by an employer.

"If we returned to pre-Obamacare government rules, the individual market coupled with risk pools would be much better for people with chronic conditions than the market today. But those risk pools no longer exist. You can't just repeal Obamacare: you need a well-thought-out replacement."

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

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FDA Wants to Expand Authority to Include Lab-Developed Tests

Continued from page 1

Dual Regulatory Regimes

LDTs are tests used for collecting, preparing, and examining human specimens, such as blood and tissue, to detect, treat, and prevent diseases and conditions. In vitro diagnostics (IVDs) are used for the same purpose.

LDTs and IVDs are both widely used in connection with a vast array of medical problems. These include, for example, cardiovascular disease, cancer, autism, and diabetes. The chief difference between LDTs and IVDs is that LDTs are "designed, manufactured and used within a single laboratory," according to the FDA's traditional definition, whereas IVDs, which are defined in FDA regulations, are produced by conventional manufacturers.

LDTs are largely regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). IVDs are regulated under the FDCA.

Many products manufactured by laboratories are "functionally the same" as IVDs. The FDA wants to "redress the [oversight] imbalance" between LDTs and IVDs to "protect the public health."

Longstanding Issue

For years, the FDA has vigorously contended that LDTs are medical devices subject to the FDCA.

Facing fierce opposition, the agency has repeatedly capitulated. While arguing LDTs are medical devices, the FDA exercises "enforcement discretion" over them. Accordingly, except for certain high-risk products, LDTs have not been subject to FDA enforcement, including pre-market submissions, quality requirements, adverse event reports, and other medical device requirements.

The FDA's proposal would amend agency regulations to make it explicit that IVDs are medical devices, including when the manufacturer is a laboratory.

"The Proposed Rule, at least in part, is likely intended to prod Congress to enact legislation explicitly giving FDA authority to regulate LDTs as medical devices," said Joel Zinberg, M.D., J.D., a senior fellow at the Competitive Enterprise Institute and director of the Public Health and American Well-Being Initiative at the Paragon Health Institute, which published an analysis of the FDA's proposal in a paper titled "Unwise and Unauthorized: FDA Regulation of Laboratory Developed Tests."

"Laboratories need to be able to develop, validate, and continually improve tests in response to advances in technology and medical knowledge. FDA regulation would end this typical practice, locking tests in place and preventing labs from meeting ever-increasing patient needs."

ROGER KLEIN, M.D., J.D., CHIEF MEDICAL OFFICER, LABCORP

Expansion Argument

The preamble to the FDA's Proposed Rule provides the agency's rationale for regulating LDTs.

"LDTs are generally, among other things, used more widely, by a more diverse population, with an increasing reliance on high-tech instrumentation and software, and more frequently for the purpose of guiding critical healthcare decisions," the FDA stated.

Modern LDTs are increasingly complex, pose greater risks than older LDTs, cause harm, and provide no assurance they work, the proposal states. The CLIA doesn't substitute for FDA oversight, the proposed rule states, and the FDA claims it has statutory authority to regulate LDTs.

Statutory Silence

The Center for Science in the Public Interest, AdvaMed, and others support the FDA's effort. Other players, such as the American Hospital Association, National Independent Laboratory Association (NILA), and American Clinical Laboratory Association (ACLA), oppose it.

"FDA must overcome the fact that the FDCA doesn't mention laboratories, laboratory services, or LDTs and has many sections that appear contrary to FDA's claim of regulatory authority," Zinberg told *Health Care News*. Zinberg's paper cites court decisions in *Brown & Williamson Tobacco Corporation* and *West Virginia v. Environmental Protection Agency* as indicating courts will not assume agency authority if the statute is silent.

Comments by the NILA and ACLA noted laboratories and commercial companies differ in function, and thus LDTs are not devices but "medical services" or "diagnostic tools developed and used in the context of patient care."

FDA's argument LDTs are unreliable, inaccurate, and harmful is based on weak evidence, says Roger Klein, M.D., J.D., chief medical officer of LabCorp and a policy advisor to The Heartland Institute, which publishes *Health Care News*.

"FDA has never shown systematic problems with laboratory-developed tests or given reason to believe FDA intervention with LDTs would improve the quality of laboratory testing in the United States," said Klein.

Impediment to Access

Other commenters on the proposed rule contend current regulation is sufficient, the rule would impede patient access to critical testing, and laboratories would bear huge new regulatory burdens.

Klein agrees with comments that additional regulation will stifle innovation.

"Laboratories need to be able to develop, validate, and continually improve tests in response to advances in technology and medical knowledge. FDA regulation would end this typical practice, locking tests in place and preventing labs from meeting ever-increasing patient needs," said Klein.

Comments expressed concern the FDA will be unable to hire qualified staff and does not have the capacity to review existing LDTs, let alone new LDTs.

"FDA lacks the resources to accomplish what it has proposed in a four-year timeline and perhaps ever," Klein said. "There are likely hundreds of thousands of LDTs in clinical use."

Compliance Question

The FDA is "proceeding expeditiously," and a final rule could be published by April. There is little question the rule will be litigated.

"Because FDA does not have sufficient enforcement capability, my guess is many laboratories would not comply [if the rule is finalized]," said Klein. "This would undermine the regulatory framework and harm public perception of FDA's effectiveness."

"The current arrangement works reasonably well," Zinberg said. "Changes giving FDA authority over LDTs should come from Congress, which must ensure that proposals actually improve public health and preserve the development of lifesaving innovation."

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

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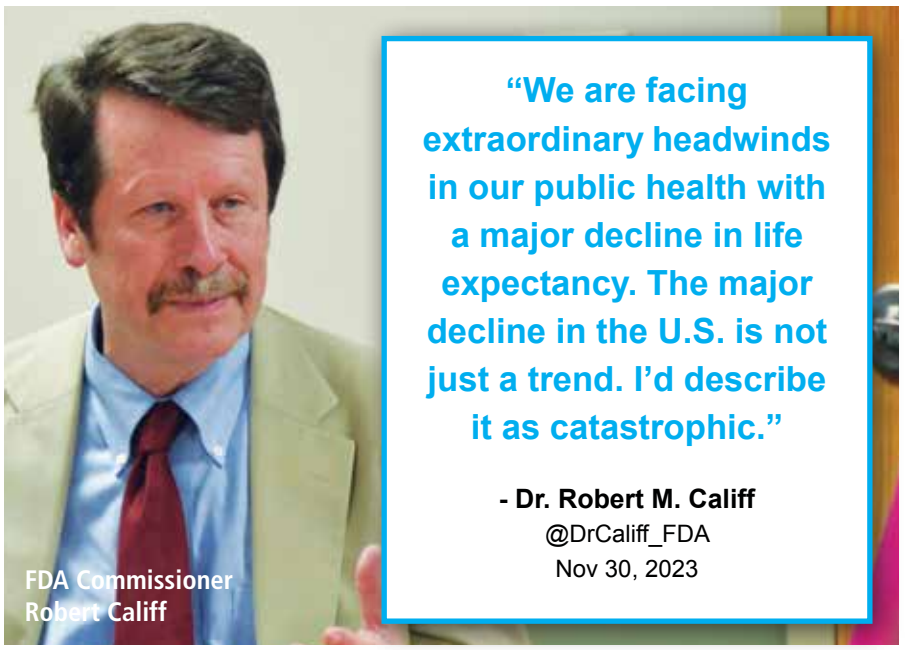
FDA Commissioner: Life Expectancy Decline Is 'Catastrophic'

By AnneMarie Schieber

The decline in Americans' life expectancy has drawn the attention of Food and Drug Administration (FDA) Commissioner Robert Califf, who tweeted on X, "We are facing extraordinary headwinds in our public health with a major decline in life expectancy. The major decline in the U.S. is not just a trend. I'd describe it as catastrophic."



"The decline in life expectancy is recent and sharp. Why now? What changed? What are the causes of death? During COVID, there was not a spike in excess deaths. If older, sicker people died of COVID, we should be seeing fewer deaths after the culling effect, not more."

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

PHOTO COURTESYGOV EARL RAY TOMBLIN/FLICKR.COM

Reversing Course

In remarks to the Association of Professors of Medicine two weeks before the tweet, Califf said the FDA must examine its level of accountability even though "blame is toxic." Califf suggested several ways to reverse course.

Califf proposed his agency "create and sustain a post-market evidence generation system" to evaluate medical products after FDA approval and "teach about the need for participation in evidence generation." Califf noted clinicians are currently under financial pressure not to participate.

Another policy to increase life expectancy would be to counter medical "misinformation," Califf said.

"While vaccination is an obvious example, we could go through the list of leading causes of death and disability and find that misinformation is much more pervasive in the lives of susceptible people and communities than valid, reliable scientific information," said Califf.

Califf also called for expanding the clinical workforce and wider use of artificial intelligence to "lift clinicians out of box-checking hell."

'Vaccine Skepticism and Fatigue'

Better alignment of resources with needs might also help optimize health outcomes, said Califf.

"And as we all know, these poor outcomes are far from uniformly distributed," said Califf. "Disparities as a function of race, ethnicity, wealth, education, and geospatial location are profound and widening. A college degree is associated with an 8.5 year longer life, and differences of more than a decade in life expectancy are common when we go from urban areas and university towns to rural areas."

Califf also recommended increased vaccination but did not mention the adverse reactions connected to the COVID-19 shots. Califf noted new vaccines for COVID-19, influenza, and respiratory syncytial virus infections.

"Yet, the combination of vaccine skepticism and fatigue have produced weak vaccination results and parents are seeking exceptions to vaccine requirements for their children in record numbers," said Califf.

Ignoring Excess Deaths

Califf did not even pose the obvious question, much less answer it in his remarks, says Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons.

"The decline in life expectancy is recent and sharp," said Orient. "Why now? What changed? What are the causes of death? During COVID, there was not a spike in excess deaths. If older, sicker people died of COVID, we should be seeing fewer deaths after the culling effect, not more. Perhaps more fentanyl [overdose deaths], more suicides? How many? Not enough to account for this."

Califf is ignoring the obvious, wrote Pierre Kory, M.D., and Mary Beth Pfeiffer in *The Hill* on December 12. "People are dying in abnormally high numbers even now and long since COVID-19 waned. Yet public health agencies and medical societies are silent," wrote Kory and Pfeiffer.

"Life insurers have been consistently sounding the alarm over these unexpected or, 'excess,' deaths, which claimed 158,000 more Americans in the first nine months of 2023 than in the same period in 2019," wrote Kory and Pfeiffer. "That exceeds America's combined losses from every war since Vietnam. Congress should urgently work with insurance experts to investigate this troubling trend."

Ignoring the Elephant

In researching the increase in excess deaths, researchers should consider the mass COVID vaccination campaign, says Orient.

"Certainly, vaccine status is something you should ask about when collecting all that data," said Orient. "You'd see a decline in life expectancy if more younger people are dying—as appears to be the case."

Califf is dancing around an issue that is on most people's minds, says Orient.

"Which is why they are declining more boosters," said Orient. "But there may still be delayed effects from earlier shots. There are red-alert levels of safety signals. They are demanding urgent, thorough investigation.

"Why isn't Dr. Califf calling for more autopsies and checking for effects of spike protein or integration of DNA fragments from vaccine production?" said Orient. "That a person didn't go to college is not the reason he died at age 35."

'Heads in the Sand'

Increasing life expectancy should be a major concern, says Scott Jensen, M.D., a family doctor and former Minnesota state senator and gubernatorial candidate.

"We see people putting their heads in the sand," said Jensen. "They don't want to take blame, but they want to be noble and say it's catastrophic."

Jensen says he takes exception to one of Califf's suggestions.

"The phrase 'evidence-based medicine' has become similar to 'follow the science,'" said Jensen. "'Evidence-based medicine' is whatever you want it to be. It allows you to pick and choose studies that suit your purpose. But it falls short of the mark. What does it mean, and what does it constitute in the practice of medicine?"

The FDA should examine the possible role of popular treatments such as statin drugs in the decline in life expectancy, says Jensen.

"There is now data coming out that indicates statin drugs may well be contributing to congestive heart failure," said Jensen.

FDA's Image Problem

When conservative-leaning media began focusing on excess deaths last summer, the FDA launched a "Rumor Control" webpage to target "the growing spread of rumors, misinformation, and disinformation about science, medicine, and the FDA."

The problem may go well beyond "misinformation," says Orient.

"The medical establishment has betrayed the people's trust," said Orient. "Can they ever get it back?"

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

Genetic Test for Opioid Addiction Wins FDA Approval

By AnneMarie Schieber

Patients now have access to a prescription genetic test that could indicate their risk of opioid use disorder (OUD) before beginning treatment with an opioid pain medication.

The Food and Drug Administration (FDA) approved AvertD, the first test of its kind, on December 19. The test, manufactured by AutoGenomics, Inc., can be used before a four-to-30-day prescription for pain medication, before a planned surgery, for example.

The test is conducted by swabbing a patient's cheek for a DNA sample that shows whether that individual matches the combination of genetic variants associated with OUD. The in vitro diagnostic test may give a false negative or false positive result.

'Reasonable Assurance' of Safety

AutoGenomics agreed to some modifications to its test when it sought premarket approval in October 2022, which led to the FDA's final decision.

"Given the totality of available evidence and the urgent need for medical devices that can make a positive impact on the overdose crisis, and specifically devices that can help assess the risk of developing OUD, the FDA determined that there is a reasonable assurance of AvertD's safety and effectiveness, taking into consideration available alternatives, patients' perspectives, the public health need and the ability to address uncertainty through the collection of post-market data," the FDA stated in a press release.

Neglect of Other Risk Factors

The genetic test could raise unnecessary red flags for patients seeking pain relief, says Jeffrey Singer, M.D., a surgeon and senior fellow at the Cato Institute.

"I think the genetics of opioid use disorder are still not well-known," said Singer. "While there are certainly some genomes that correlate with higher rates of opioid use disorder, genetics are only one of many correlates. Many people develop OUD without any genetic predisposition. On the other hand, most people with genetic predisposition don't ever develop OUD."

The most prevalent and consistent finding in people who go on to develop substance use disorder is a history of trauma during early developmental years, says Singer.

"It can be a single traumatic event or a cumulative series of events," said Singer. "Also, roughly two-thirds of people who develop substance use disorder have psychoneurological comorbidities, such as autism spectrum, ADHD [attention deficit-hyperactivity disorder], and OCD [obsessive-compulsive disorder]," said Singer. "Then, there's the matter of epigenetics: behavior and environment can affect the way genes express themselves."

Resistance to Simple Solutions

New information finds people with addiction disorder eventually outgrow it, says Singer. It is why researchers call addiction a behavior or learning disorder, not a physical disease.

"Bottom line: addiction is complex, and its causes are multifactorial. It can't be approached with simple, cookie-cutter strategies," said Singer.

Singer says patients should have access to the test like other medical products, but they should discuss the results with an addiction specialist who could do a more comprehensive review.

"I worry that, as our policymakers are wont to do, they will lock on to the results of genetic screening tests and attach much more significance to them than they should," said Singer. "They will take the results of genetic screening tests in a vacuum without adding individual social context and all of the other risk factors that play a significant role in the development of substance use disorder."

Greater Risk of Lawsuits

The screen may discourage health care providers from prescribing opioid pain medication, says Singer.

"[T]hey will be afraid of getting sued if a person for whom they prescribed an opioid develops an OUD after having tested positive on a screening test, even if they know that the screening test is only one very small piece of the opioid use disorder puzzle," said Singer.

"I worry that hospitals, health plans, and other facilities will misuse the test and require it before any patient can be prescribed opioids and, if the test is positive, deny patients adequate pain treatment," said Singer.

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

Biden Policy Threatens Rare-Disease Treatment Research

By Ashley Bateman

The federal government is moving to control drug costs by approving "march-in" authority on drug pricing.

The Biden administration on December 7 announced it would direct government entities to employ the "march-in" clause under the Patent and Trademark Act Amendments, also called the Bayh-Dole Act, to cut the prices of certain medications. The statute defines patent rights for inventions made with federal government assistance.

The announcement advises federal agencies to control the relicensing of high-priced drugs when "reasonable terms," as defined by the administration, are not met.

"Putting aside for a moment the ambiguous metric 'reasonable terms,' this announcement to aggressively pursue 'march-in' policies, coupled with the uncertainty already generated by the Inflation Reduction Act (IRA), will further cripple the orphan disease drug pipeline by reducing investment into research and raising uncertainty about treatments," said a spokesperson for the Rare Access Action Project (RAAP) in a December 12 press release. "As an organization whose focus is to advance access to therapies for rare-disease patients … [we] simply cannot support the Biden Administration's 'march-in' policy."

President Joe Biden

PHOTO COURTESY U.S. EMBASSY THE HAGUE/FLICKR.COM

"The Biden administration has been on a mission to 'lower drug prices' for three years. Instead of delivering lower costs to consumers, their plan is a recipe for fewer treatments, more disease, and worse health. The recently announced effort on 'march-in-rights' amounts to determining who produces products."

JOEL WHITE
PRESIDENT
HEALTH INNOVATION ALLIANCE

Not So Rare

So-called orphan drugs are at the center of the issue. These drugs are defined as "products used to treat, prevent, or diagnose a disease that affects fewer than 200,000 people in the United States or that will not be profitable within seven years following approval by the U.S. Food and Drug Administration (FDA)," according to the Council for Affordable Health Coverage (CAHC).

Though they are termed "rare," the diseases affect more than 30 million Americans, the CAHC states.

Rare diseases affect one in 10 people, more than the combined number of those with cancer or AIDS, according to Global Genes.

Incentives for Innovation

Historically, drug makers have been incentivized to pursue the development of medications and other treatments for rare diseases through the Orphan Drug Act. Since 1983, the law has provided a variety of benefits for drug makers and scientists working on orphan drugs, including tax credits for qualified human clinical trials, research grants, waivers of FDA review and approval fees, and up to seven years of market exclusivity.

The CAHC says the "law has worked as intended" though the number of orphan drugs approved is still a "small drop in the ocean" of needed treatments and cures.

That's why drug manufacturers often explore the use of one drug to treat multiple diseases. The IRA's policy provision would disincentivize potential repurposing of a drug by limiting benefits to only one marketed treatment.

"The final language included provisions … exempting the product from negotiations only for the first orphan indication," RAAP executive director Mike Eging told *Health Care News*. "Subsequent orphan therapeutic indications would be penalized and not permitted protections even though the new costs of research and development would be required."

Course Reversal

With 95 percent of known rare diseases having no FDA-approved treatment, adding the threat of license revocation after years of R&D and clinical trials would completely undercut investor interest, RAAP argued during the debate on the IRA.

These and other policies will have a "chilling effect" on the development of oral options and alternatives for the treatment of rare diseases, further eroding the orphan drug pipeline and disincentivizing investors, according to Eging.

'Sounds Like Socialism'

"The Biden administration has been on a mission to 'lower drug prices' for three years," said Joel White, president of the Health Innovation Alliance. "Instead of delivering lower costs to consumers, their plan is a recipe for fewer treatments, more disease, and worse health. The recently announced effort on 'march-in-rights' amounts to determining who produces products. If this sounds like socialism to you, you're right."

Around the world, this approach always results in fewer products for consumers, less development of new treatments, and worse access to care, says White.

"In the United Kingdom, citizens have access to fewer than half the cancer treatments available in the U.S.," said White. "In the rare-disease space, where incentives are already weak to explore new therapies, the impact will be even larger."

CAHC found some U.S. companies have already halted potential secondary-use R&D in anticipation of the IRA's full implementation. Alnylam Pharmaceuticals Inc. and Eli Lilly stopped work on rare disease treatments, citing the IRA's provisions.

'Need to Fight Back'

"This is the worst policy-led innovation environment for health care in U.S. history," said White. "To protect consumers, we need to fight back against price controls and stop the reckless proposed 'march-in' policy."

For now, the Centers for Medicare and Medicaid Services (CMS) should step in and protect benefits for secondary uses of orphan drugs, the CAHC stated in a blog post. Ultimately, Congress should amend the law to exempt these products from price controls, the organization states.

RAAP has explored a variety of out-of-pocket cost reductions for rare disease patients, including copay accumulator reform, pharmaceutical benefits manager transparency, and other changes.

"Lowering prescription drug costs is an important issue, but the solutions simply cannot come at the expense of rare-disease patients," said Eging.

House Support for Reform

"It is possible that there will be bipartisan support for a solution to protect subsequent orphan indications," Eging said.

As an example, Eging cites the ORPHAN Cures Act, which has bipartisan support in the U.S. House of Representatives. The bill would change the incentive structure within the IRA and encourage investment into "follow-on" or supplemental indications for orphan drug development.

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

Doctors Are Treating Genetic Disorders When Given the Chance

By Harry Painter

A debate is heating up over the treatment of unborn children diagnosed with genetic disorders and whether their cases are as hopeless as abortion proponents claim.

In December, Kate Cox gained nationwide attention for wanting to circumvent the abortion ban in Texas because her preborn child was diagnosed with Trisomy 18. Cox, who at the time was 20 weeks pregnant, sued for an exemption to state law so she could have her unborn daughter aborted. Texas law bans abortion in all cases except when the mother's life is in danger.

Trisomy 18, or Edwards Syndrome, is a rare genetic defect with typically grim prospects for survival. Many obstetricians counsel mothers to terminate their unborn children following a trisomy diagnosis. Cox's doctors testified the pregnancy was not viable.

Cox's complaint argued her life and ability to have future children were in danger unless the state allowed doctors to abort her unborn daughter. Cox fled Texas to terminate the pregnancy before the Supreme Court of Texas reversed a lower court ruling allowing the abortion.

Not a Death Sentence

As the media coverage unfolded, pro-life activists and families of children with Trisomy 18 were quick to protest the claim that Trisomy 18 is a death sentence.

When Trisomy 18 patients are given proper treatment, their prospects are nearly inverse to the prevailing wisdom, which holds that only 10 percent make it past the first year of life. Glenn Green, M.D., an otolaryngologist at the University of Michigan's Mott Children's Hospital, told lifenews.com that, based on his experience, 90 percent of babies with the syndrome make it home from the hospital and 77 percent reach the five-year milestone.

"Giving these kids medical care makes it possible for them to live past a year," Green told Live Action. Green is an expert on treating the airways of children with the syndrome, who often struggle to breathe.

Declining Respect for Life

The Cox case arose weeks after a high-profile case in the U.K. over eight-month-old Indi Gregory, who was diagnosed with mitochondrial disease, a rare genetic condition that affects the way cells burn food and oxygen to generate energy.

Britain's High Court ordered the child be removed from life support, despite the pleas of her parents and an offer from the government of Italy to transport and treat her there and give her citizenship.

"What I find disturbing is the erosion of our sense of decency and value of the life of a human being," said Marilyn Singleton, M.D., an anesthesiologist and senior fellow at Do No Harm. Singleton cites other examples such as the expansion of physician-assisted suicide and the new practice of composting human bodies.

"Every parent wants a healthy child," said Singleton. "Few people know how they would respond to the challenges of having a severely disabled child."

Health-Provider Hubris

It is unethical to kill the disabled, babies or otherwise, even if they have severe disabilities, says Heidi Klessig, M.D., an anesthesiologist and author of the book *The Brain Death Fallacy*.

"Health professionals should not substitute their personal feelings or biases for making a wide range of services—medical, psychological, and spiritual—readily available," said Klessig. "I don't think aborting or euthanizing inconvenient people is in any way compassionate. Compassionate care for disabled people is treating them as human beings and providing them with medical care just like anyone else."

Sometimes patients defy what common wisdom says is a death sentence.

"Death is a point of no return, whereas people declared 'brain dead' have recovered, and some have become nurses or accountants," said Klessig. "Doctors are not omniscient and can only make educated guesses about long-term outcomes."

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

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Have Fetal Tissue Experiments Gone Too Far?

By Bonner Russell Cohen

The alleged illegal harvesting of body parts from late-term aborted babies at the University of Pittsburgh (Pitt) is at the center of a two-year-old investigation by the U.S. Department of Health and Human Services' Office of Inspector General (OIG), recently obtained emails confirm.

OIG investigators are said to be focusing on lab experiments conducted from 2016 to 2021 by the UP's Genitourinary Development Molecular Anatomy Project, allegedly with funding from the National Institutes of Health (NIH), *The Daily Wire* reported on December 14.

Emails confirming the investigation were obtained through a Freedom of Information Act (FOIA) request by Judicial Watch and the Center for Medical Progress (CMP).

"The University of Pittsburgh has been a center for some of the most barbaric experiments, government-funded experiments, on the body parts of late-term aborted babies," CMP President David Daleiden told *The Daily Wire*. "We now have the first confirmation with these FOIA documents that this is all subject to a federal law enforcement investigation."

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DAVID DALEIDEN
PRESIDENT
CENTER FOR MEDICAL PROGRESS

Body Parts from 'Tissue Banks'

According to Pitt, UP Medical Center researchers obtain tissue of aborted babies "from repositories called tissue banks" at a hospital affiliated with the university.

"The Pitt Biospecimen Core, which provides central support for Pitt research programs, receives all fetal tissue from UPMC Magee-Women's Hospital," states the university's website.

Pitt hired an outside law firm to issue a report on the fetal tissue experiment program, which concluded the activities in question follow state and federal laws, according to a UP statement issued shortly after the OIG investigation is reported to have begun.

"As we have stated in the past: Fetal tissue research plays a critical role in advancing life-saving discoveries. We remain committed to maintaining robust internal controls and to extending our record of compliance at the state and federal levels, and we take these responsibilities seriously," a UP spokesman said.

Calls Investigation 'a Whitewash'

The status of the HHS investigation is unclear, and U.S. Rep. Chris Smith (R-NJ) says the department is engaging in "a whitewash."

"A truly transparent and comprehensive assessment would not have evaded the questions raised by public records, especially and including whether [Pitt] used the body parts of babies who were born alive and died from having their organs harvested, as well as if individuals procuring the baby body parts for the university altered abortion procedures to suit their gruesome research," Smith told Fox News in December.

"It is long past time for the federal HHS Office of Inspector General to conduct a full audit to determine whether infanticide or other misconduct is occurring," Smith said.

Companies Sell Tissue 'Donations'

Genevieve Marnon, legislative director at Right to Life of Michigan, says fetal tissue research and gruesome experimentation using baby body parts is not new and has been the subject of national debate and congressional investigations for decades.

"Sadly, while the various administrations tightened or loosened requirements surrounding the use of fetal tissue in experiments, it has never been banned or outlawed in practice, and the government has often funded it with taxpayer dollars," said Marnon.

"The other problem is that while the women who abort their babies are not allowed to be compensated for 'donating' their baby's body parts, the procurement companies can and do charge for processing, packaging, and shipping those parts," said Marnon. "So, until the practice of harvesting aborted fetal body parts and using them for research is outlawed, there will continue to be exploitation of the tiny human bodies."

There is also concern that aborted babies are kept alive to procure organs and that the removal of tissues and organs caused their death. Documentation revealed researchers were scalping five-month-old fetuses and stitching the scalps onto the back skin of lab rats.

Legality vs. Morality

Heidi Klessig, M.D., a retired anesthesiologist and author of *The Brain Death Fallacy,* says Pitt's claim it complies with state and federal law does not exempt it from criticism.

"I think most people would say that scalping unborn babies and transplanting their skin onto the backs of lab rats absolutely qualifies as wrongdoing, regardless of whether legal codes were followed," said Klessig. "And because these children are able to feel pain and do not receive anesthesia, a death by organ harvesting would be accompanied by terrible suffering.

"This is a cruel and unusual punishment for an infant whose only crime is being unwanted by his parents," said Klessig. "If this is indeed what is occurring at Pitt, one 22-week-old infant may be receiving lifesaving neonatal ICU care at the same time a less fortunate infant of the same age is being dissected to death for body parts. These are serious concerns, and it appears that the Office of Inspector General is taking them seriously by launching this investigation."

Bans Sidestepped

The Michigan Legislature passed a ban on fetal tissue research in 2022. Gov. Gretchen Whitmer (D) vetoed the bill. In 2023, Michigan repealed a law requiring the humane disposal of fetal remains.

"I fear the practice of fetal tissue research will proliferate in our state," said Marnon. "Michigan's law banning fetal tissue trafficking was passed in 2016 and remains in place, which means no money can be paid for the body parts, but it doesn't prevent tissue procurement companies and pharmaceutical companies from profiting from these tiny broken bodies, nor does it prevent universities and researchers from conducting experiments on tissue and organs from aborted babies."

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

How Safe Are mRNA Shots?

By Kevin Stone

A study in the scientific journal *Nature* is raising alarm about just how much was unknown about the mRNA shots for COVID-19 before billions of people received them.

The study, titled "N1-methylpseudouridylation of mRNA causes +1 ribosomal frameshifting," was published on December 5 and had 20 authors, led by researchers at Cambridge University's Medical Research Center (MRC).

"[T]he MRC Toxicology Unit team tested for evidence of the production of 'off-target' proteins in people who received the mRNA Pfizer vaccine against COVID-19," states a press release on the university's website. "They found an unintended immune response occurred in one third of the 21 patients in the study who were vaccinated—but with no ill-effects. … The team then redesigned mRNA sequences to avoid these 'off-target' effects, by correcting the error-prone genetic sequences in the synthetic mRNA. This produced the intended protein."

"The clinical trials that were done showed an enormous number of adverse effects, even over a period of a couple months, which were not revealed. Pfizer tried to conceal the documents [by deferring their release] for 75 years!"

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

Read Errors

At issue is a phenomenon called +1 ribosomal frameshifting.

Proteins are translated by reading trinucleotides, known as codons, on the mRNA strand. The amino acid methionine acts as a "start" codon, specifying where a sequence begins. Codons occur in groups of three. A shift of any number of nucleotides not divisible by three in the reading frame will cause subsequent codons to be misread, changing the ribosomal reading frame. Such changes create very different amino acid sequences.

The authors of the study say the COVID-19 vaccines are safe. Other experts claim the risks of using the mRNA technology are self-evident.

'Safer Going Forward'

Anne Willis, director of the MRC Toxicology Unit and joint senior author of the report, told reporters the ability to avert frameshifting will make new mRNA medicines safer.

"This technology is amazing and it's going to be revolutionary as a new medicine platform for all sorts of things, but we've just made it a whole lot safer going forward," Willis told reporters. "Willis adds it is very exciting that there is a way to fix the issue, which 'massively de-risks this platform going forward,'" *The Telegraph* reported.

Not Safe Yet

The idea of massively de-risking something indicates the item in question poses dangers, says Jeff Childers, attorney and author of the Covid and Coffee substack.

"Here's the simple version: the researchers discovered that a necessary ingredient in the mRNA vaccines (1-methylpseudouridine) has an unfortunate side-effect: it messes up RNA translation *one-third of the time* by slipping a gear every so often," wrote Childers on December 7 (italics in original). "Instead of making the intended *spike protein*, these tiny mistranslational slip-ups create … other things. Other *kinds* of proteins. New ones. And there's no way at all to predict what kind of protein it will create. It's stochastic (completely random)."

"The 'vaccine' creates stochastic proteins *one third of the time*," Childers wrote. "In one-third of *cells*, not *people*, like the *Telegraph* again mis-reported. There are *trillions* of mRNA packages in each shot. So—unless I'm missing something—what the study is saying, without actually saying it, is that *this is happening inside every single jab recipient*. And it's happening *a lot*."

Not a Problem?

There is "no evidence" the modified mRNA in COVID-19 vaccines is unsafe, says Joel M. Zinberg, M.D., J.D., a senior fellow with the Competitive Enterprise Institute and director of the Public Health and American Well-Being Initiative at Paragon Health Institute.

"Ribosomes sometimes translate mRNA incorrectly, [and] ribosome frameshifting is a well-documented phenomenon that occurs during translation of many naturally occurring mRNAs," said Zinberg. "This results in making small amounts of unintended proteins. The *Nature* researchers document that the modified ribonucleotide in the COVID-19 vaccine results in production of a small amount of frameshifted protein and that the body has an immune response to this protein. But there is no evidence this is harmful."

The mRNA shots are designed to act like viruses in a way that triggers the immune system to make copies of the spike protein. The body responds to those proteins by making antibodies, which protect the body.

'No Evidence' vs. 'Unknown Effects'

The lack of information on risks in the mRNA vaccines is deliberate, says Jane M. Orient, M.D., executive director of the Association of American Physicians and Surgeons.

"The clinical trials that were done showed an enormous number of adverse effects, even over a period of a couple months, which were not revealed," said Orient. "Pfizer tried to conceal the documents [by deferring their release] for 75 years!

"Molecular biology, and the immune system, are incredibly complex," said Orient. "Nonspecialists, including most physicians, have a very superficial understanding. ... It is impossible to know long-term effects for years."

Those being offered mRNA vaccines have a right to full information about the risks, says Orient.

"Informed consent would have to include the fact that effects on fertility, cancer, and birth defects are unknown and that there is the risk of blood clots, heart damage, and sudden death, 'rare' but we don't know how rare," said Orient. "The safety signals are strong enough that the vaccines should have been taken off the market until the role of the vaccine could have been determined.

"Our regulatory agencies are not doing their job," said Orient. "There are pervasive conflicts of interest and billions of dollars at stake."

Not Convinced

Scientists presumed the mRNA would be quickly destroyed and the shots would produce only the spike protein, says journalist Alex Berenson, who called the *Nature* study a "bombshell" on his Unreported Truths substack on December 11.

"Yep, mRNA shots are great," wrote Berenson. "They're 'amazing'! And they're not exactly *unsafe*. But soon they'll be 'a whole lot safer.' How reassuring! Too bad over *1 billion people* have already received them."

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

Florida Surgeon General Calls for Halt to COVID-19 Shots

By Kevin Stone

Florida Surgeon General Joseph Ladapo has called for a halt in the use of the Pfizer and Moderna COVID-19 mRNA shots.

Ladapo made the statement on January 3 after the Food and Drug Administration and the Centers for Disease Control and Prevention declined to respond to his letter asking about reports of DNA plasmid contaminants and oncogenic SV40 promoter genes.

A study that detected nanogram to microgram quantities of undisclosed double-stranded DNA (dsDNA) in the bivalent Moderna and Pfizer vaccines was conducted by Medical Genomics under the direction of CEO Kevin McKernan and made available on a preprint server on April 10, 2023. The findings of the study have been confirmed by numerous researchers, and regulatory agencies have acknowledged the problem.

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DNA Contamination

At issue are two processes vaccine manufacturers use to create the spike protein mRNA from SARS-CoV2. Although both processes use modified E. coli bacteria to produce spike protein mRNA, the polymerase chain reaction (PCR) method on which emergency authorization approvals were granted is a "clean" process that is largely devoid of genetic contaminants.

However, the process used to mass-produce vaccines for public consumption is "dirty," utilizing fragments of oncogenic simian virus SV-40 to bind transcription factors that drag DNA into the cell, where they are then cut into smaller DNA strands by an enzyme. This second process can and does result in various DNA contaminants in the vaccines.

Due to the use of lipid nanoparticles to package vaccine components, contaminant dsDNA in the vaccines can be readily introduced into human cells, potentially triggering various health problems.

McKernan says the presence of dsDNA may contribute to blot clots; possible endotoxin contamination from E. coli, which can cause anaphylaxis; and an increased rate of mutagenesis caused by DNA contamination combined with disruption of the natural immune system and inhibition of tumor suppressor genes, which could explain the sharp increase in cancer rates since the vaccine rollout.

'I'm Kind of Alarmed'

Phillip Buckhaults, Ph.D., a professor at the University of South Carolina with expertise in cancer genomics, says the risks of these foreign DNA contaminants inserting themselves into a person's genome and becoming permanent are very real. Buckhaults has described himself as a "real fan" of mRNA technology but says DNA contamination is an issue that must be resolved.

Buckhaults recently testified on the subject before a South Carolina Senate Medical Affairs Ad-Hoc Committee, along with Sin Lee, M.D., Brigitte Konig, and David Speicher, who were co-witnesses and contributed to the findings.

"I'm kind of alarmed about this DNA being in the vaccine," Buckhaults told the legislators. "DNA is a long-lived information storage device. It's what you were born with, you're going to die with, and pass on to your kids. So, alterations to the DNA, … well, they stick around."

Buckhaults says the contamination was exacerbated by the unreported shift from PCR to the more problematic plasmid method in the vaccines administered to the public, with manufacturers then apparently attempting to cover the use of plasmids by adding an enzyme (DNAase) to cut the plasmid into tiny fragments.

"[Pfizer] chopped them up to try to make them go away, but they actually increased the hazard of genome modification in the process," said Buckhaults. "I don't think there was anything nefarious here. I just think it was kind of a dumb oversight. They just didn't think about the hazard of genome modification. … It's not all that expensive to add another process to get it out."

Risks Downplayed?

Jane M. Orient, M.D., executive director of the Association of American Physicians and Surgeons, says contamination risks are being downplayed and exacerbating factors such as lipid nanoparticle encapsulation and other means of enhancing transfection, or insertion of mRNA in vaccines, increase the risk DNA contamination.

"Out of an abundance of caution, the level of such residual DNA is to be kept to a minimum through careful purification steps taken during the vaccine production, and every vaccine lot is to be carefully tested for the residual level," said Orient. "Regulators claim that vaccines with higher-than-accepted levels are not supposed to be released for public distribution.

"Meanwhile, as manufacturers and regulators assert that any leftovers of plasmid DNA are biologically inert, there are plausible mechanisms for unwanted effects when DNA fragments are transfected during the vaccination process," said Orient. "Those adverse effects may occur mainly via DNA integration into, and hence modification of, the genomes of the transfected cells. This possibility is enhanced when those DNA fragments are packaged in lipid nanoparticles, along with the mRNA particles, as has occurred in the mRNA vaccines. Compared with accidentally encountered free strings of DNA, those peculiar DNA contaminants may have enhanced persistence and increased transfection efficiency."

Unanswered Questions

Lapado's letter asked whether drug makers "evaluated the risk of human genome integration or mutagenesis of residual DNA contaminants from the mRNA COVID-19 vaccines alongside the additional risk of DNA integration from the lipid nanoparticle delivery system and SV40 promoter/enhancer" and whether the FDA requested information from the drug makers to investigate such risk.

The letter also asked whether the current safety standards include consideration of the lipid nanoparticle delivery system used in the COVID-19 shots and whether the agencies evaluated the risk of DNA integration into reproductive cells in light of the "potentially wide biodistribution of mRNA COVID-19 vaccines and DNA contaminants beyond the local injection site."

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

Michigan Physicians Call Out Corporate Entities Practicing Medicine

By AnneMarie Schieber

The Michigan State Medical Society (MSMS) is urging State Attorney General Dana Nessel to investigate violations of a state law that prohibits unlicensed corporations from owning medical practices.

MSMS sent a five-page letter to Nessel on October 23 stating private equity groups have used a "series of deceptive legal loopholes" in Michigan and other states by hiring physicians to serve as sham owners to circumvent the Corporate Practice of Medicine doctrine (CPOM). The doctrine requires health care practices to be owned by licensed physicians only. The one exception is nonprofit organizations that employ doctors to provide health care.

Private Equity Ownership Growing

Private equity groups are buying up medical practices across the country and, as owners, they make decisions regarding the practice of medicine. The letter singles out the example of TeamHealth, which has been sued in at least one state for overcharging for services and not compensating physicians.

Some equity groups have served as staffing organizations, allowing them to file for bankruptcy, which causes disruptions in care. The letter also cites reports of private groups utilizing "efficiency consultants," understaffing, intimidating whistleblowers, and allowing nonphysician managers to question health care decisions.

"Michigan does have a law and we're asking that it be enforced," MSMS CEO Tom George, M.D., told *Crain's Grand Rapids Business Journal* on November 30.

Nessel's office made 110 announcements between the day the letter was sent and December 28, but none mentioned CPOM.

Physicians Concerned

Michigan is not the only state where physicians are crying foul. The Minnesota Medical Association (MMA) made private equity in medicine a top policy priority in 2023.

"Physician dual allegiance to corporate profits and the professional duty to work entirely for the benefit of our patients could be avoided if enforced corporate practice of medicine laws were enacted," said Robert Koshnick, M.D., MMA's policy committee chair in 2023. "This applies to both for-profit and nonprofit corporate medicine."

In a commentary in *Health Care News,* on July 11, Koshnick wrote, "The corporatization of medicine has changed medical practice from a profession to a business, to the detriment of patient care and the patient-physician relationship. Physicians' loyalty should be to their patients, not the corporate bottom line and rules set by nonphysicians."

The issue of corporate control of medicine prompted the formation of the advocacy organization "Take Medicine Back" in 2019. The group released a white paper in October 2023 calling for a national prohibition on the corporate practice of medicine.

"The problem with allowing the corporate practice of medicine is that doctors are no longer advocates for their patients. When physicians are employed by hospitals, private equity, health plans, or corporations, they answer to their employers rather than to their patients. That can result in unnecessary care and unnecessarily expensive care."

DEVON HERRICK
HEALTH ECONOMIST

FTC Challenges Monopoly Action

In September, the Federal Trade Commission (FTC) sued U.S. Anesthesia Partners and Welsh, Carson, Anderson & Stowe for buying up anesthesia practices in Texas metropolitan areas. The FTC has traditionally been slow to act on monopolistic practices in health care, notes Devon Herrick, an economist who writes for the Health Blog of the Goodman Institute, which co-publishes *Health Care News*.

"One reason the FTC has been slow to act on monopolistic practices in health care is the threshold for reporting acquisitions is high enough that firms can gradually gobble up physician practices one at a time without oversight," wrote Herrick on December 1.

It is important to understand why "corporate practice of medicine" laws were written in the first place, says Herrick.

"The problem with allowing the corporate practice of medicine is that doctors are no longer advocates for their patients," Herrick told *Health Care News*. "When physicians are employed by hospitals, private equity, health plans, or corporations, they answer to their employers rather than to their patients. That can result in unnecessary care and unnecessarily expensive care."

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

Texas AG Sues Drug Makers Over Adulterated ADHD Drugs

By Kenneth Artz

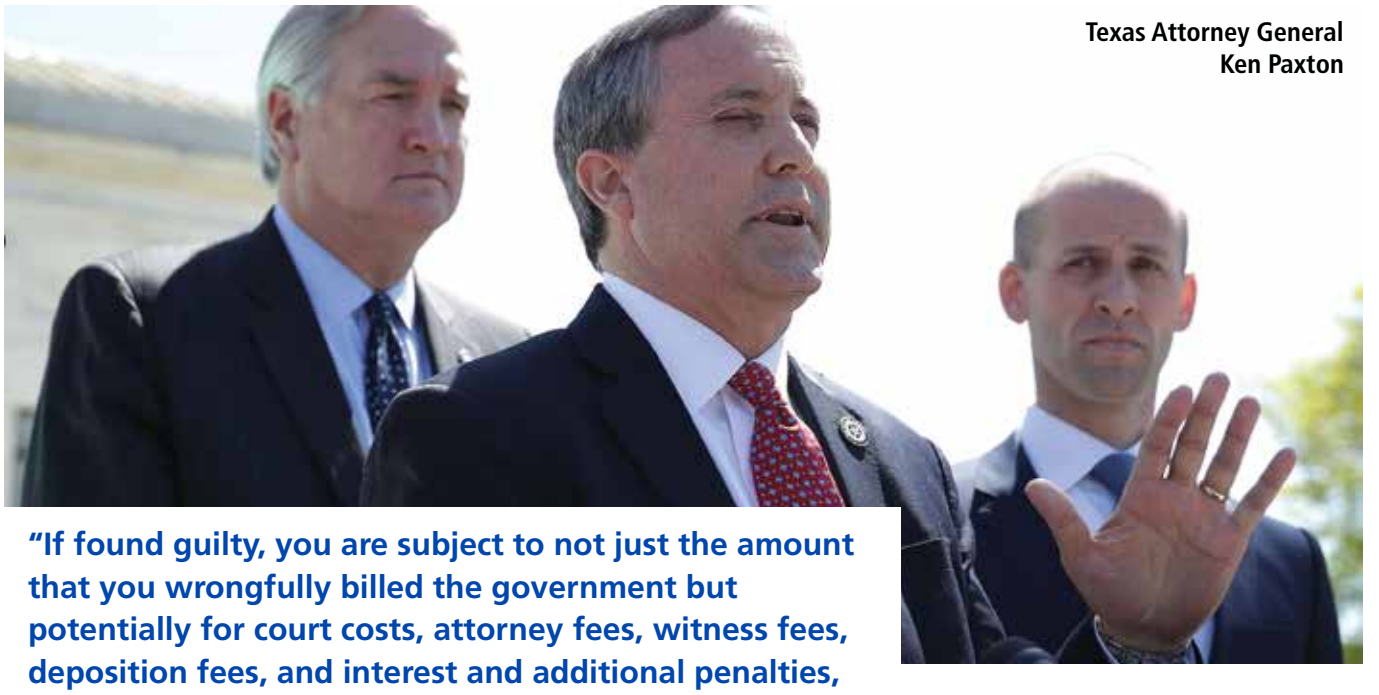
Texas Attorney General Ken Paxton is suing drug manufacturers Pfizer and Tris Pharma for allegedly selling adulterated attention-deficit/hyperactivity disorder (ADHD) medicine they said complied with Food and Drug Administration regulations.

Tris was under contract with Pfizer to manufacture the ADHD drug Quillivant XR for children enrolled in Medicaid. The Texas AG's lawsuit accuses the two companies of defrauding the Texas Medicaid program by distributing adulterated drugs to children in Texas.

The suit also claims the companies violated the Texas Medicaid Fraud Prevention Act (TMFPA).

Paxton states on his website that Pfizer distributed Quillivant to children on Medicaid knowing the drug failed quality-control tests because of flawed manufacturing practices. Paxton also alleges Tris altered the drug's testing method for years in violation of federal and state laws to ensure Quillivant passed regulatory hurdles and continued to be sold.

"I am horrified by the dishonesty we uncovered in this investigation," Paxton said in his news release.



Texas Attorney General Ken Paxton

PHOTO COURTESY ALEX WONG/STAFF/GETTYIMAGES

"If found guilty, you are subject to not just the amount that you wrongfully billed the government but potentially for court costs, attorney fees, witness fees, deposition fees, and interest and additional penalties, including but not limited to two times the amount of the payment or the value of the benefit."

QUENTIN BROGDON
PERSONAL INJURY TRIAL ATTORNEY
CRAIN BROGDON, LLP

'Companies Cheat'

The case raises big questions about who is guarding the henhouse, says John Dale Dunn, M.D., J.D., a physician and policy advisor to The Heartland Institute, which publishes *Health Care News*.

"I think the AG's lawsuit is a good one," said Dunn. "I think he's right because pharmaceutical companies cheat, and one of the reasons they get away with cheating is because of regulatory capture. Many of the people who are supposed to be regulating these companies have a conflict of interest because they are getting money indirectly or directly from the companies they are overseeing."

Dunn puts a new spin on an accepted truth.

"Have you ever heard of Hanlon's Razor?" asked Dunn. "Hanlon said, 'Well, a lot of times people do something bad because they're stupid.' This is Dunn's Razor: When somebody does something that's bad, sometimes it's because they're evil, and sometimes their apparent ignorance is because of the fact that they're paid off."

'Legal and Financial Peril'

The Texas case could have a long reach, says Quentin Brogdon, a personal injury trial attorney at Crain Brogdon, LLP in Dallas, Texas.

"If the Texas Attorney General's allegations are true, it shows a long-standing pattern of bad behavior that is exactly the kind of behavior the TMFPA was enacted to address," said Brogdon. "It's also important because it may begin a process by which other attorneys general jump into the fray. Collectively, multiple states and the federal government could create real legal and financial peril for Pfizer."

'A Fairly Stout Statute'

Paxton's case appears to be modeled on the federal qui tam law instituted during the Civil War to address war profiteering and war fraud, says Brogdon. The law punishes fraud committed by knowingly making or causing a false statement to be made, knowingly concealing or failing to disclose a false statement, or knowingly applying for or receiving a benefit or payment in violation of the law.

"If found guilty, you are subject to not just the amount that you wrongfully billed the government but potentially for court costs, attorney fees, witness fees, deposition fees, and interest and additional penalties, including but not limited to two times the amount of the payment or the value of the benefit," said Brogdon.

"The trier of fact, or the jury, can consider certain enumerated factors in determining the amount of that penalty, including whether you previously violated the statute, the seriousness of the act, the health and safety of the public to the extent to which they were jeopardized, your bad faith, and then the amount necessary to deter future unlawful acts. It is a fairly stout statute aimed to deter fraud, deemed to empower whistleblowers to come forward, and even to prosecute the case if the state AG does not elect to step in," said Brogdon.

'Very Real Jeopardy'

Pfizer and Tris Pharma face allegations they manipulated quality control testing to obtain passing results from tests. At issue is whether Quillivant, an extended-release drug, failed to dissolve as it was intended, which would affect the drug's ability to control ADHD symptoms, says Brogdon.

In 2017, the FDA warned Tris, which supplied Quillivant to Pfizer Manufacturing Labs, says Brogdon.

"Paxton's case is alleging that these manufacturing labs knowingly were rendering the product not consistent in its quality control testing," said Brogdon. "And if those things are true, then these actions fall squarely under the Texas act, and these companies then face the very real jeopardy of the penalties under the act."

Expects a Settlement

Pfizer was subpoenaed in 2022 by federal prosecutors in the Southern District of New York over its relationship with Tris, says Brogdon.

"Since it's in the Southern District of New York, it's possibly related to security issues and potential security fraud," said Brogdon. "But if you as a company know of information that could potentially impact the value of your shares and you don't make that public or you conceal it, then you may have violated federal securities laws and regulations."

Brogdon says he doubts the case will go to trial.

"I would imagine that Pfizer would try and work out some sort of civil penalty settlement involving repayment of money to the State of Texas," said Brogdon. "That's how this would get resolved—it would never actually, in all probability, go to any trial or adjudicatory proceeding."

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

INTERNET INFO

The State of Texas, *ex rel.* [UNDER SEAL] v. [UNDER SEAL] Defendants, Cause No. 23-1031, U.S. District Court, 71st Judicial District, Harrison County, Texas: **https://www.texasattorneygeneral.gov/sites/default/files/images/press/Pfizer%2C%20Tris%2C%20Mehta%20File%20Stamped.pdf**

COMMENTARY

A Pocket of Care Excellence for Low-Income Moms-to-Be

By John C. Goodman

Parkland Hospital in Dallas delivers almost 13,000 babies every year. It is one of the largest baby delivery centers in the country.

Almost all the mothers are low-income and minority. More than three-fourths are Hispanic, and I suspect a great many of those are undocumented.

This is a group researchers call "at risk." Yet among those who go through the prenatal program, infant mortality is half what it is for similar populations elsewhere.

The Parkland baby delivery program has been underway for several decades. (I wrote about it in my book *Priceless*.) It involves extensive prenatal and postnatal care provided by nurses. Most deliveries are done by midwives, not obstetricians.

Although the hospital does not release the figures, I suspect that this nonprofit institution actually makes a "profit" on the delivery of babies by piecing together various sources of government funding, minimizing the cost of personnel, and avoiding costly complications that lead to infant and maternal death.

Parkland's baby delivery program is an example of what Harvard University Professor Regina Herzlinger calls a "focused factory." These are places where the providers become really good at providing high-quality, efficient care. There would be a lot more Parklands around if we changed the way the health care safety net operates. (See related article, opposite page.)

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

Is Avoiding Medigap, Medicare Part D a Crazy Idea?

By AnneMarie Schieber

Medicare enrollees are wondering whether there might be a third option beyond traditional fee-for-service Medicare and Medicare Advantage.

Shawn McGuyer, a retiree from Texas, is trying to determine whether it would be financially advantageous to opt out of Medigap and Medicare Part D and self-fund those benefits throughout retirement. McGuyer, however, is unable to find estimated expenses for an individual or couple who wants to consider such an option.

"All the analyses I find online *assume* one is paying for Parts A, B, Medigap, and D," said McGuyer in an email to *Health Care News*. "However, without seeing the economic impact for those retirees that choose only Parts A and B, one cannot begin to compare estimated lifetime out-of-pocket, cash-costs (self-pay) expenses, or total economic impact, to any other scenario. In other words, these reported analyses are woefully incomplete."

"Is Medicare perfect? No. Are the rules crazy? Yes. But it's a fool's errand, in my view, to try to predict what one's out-of-pocket costs may be over their retirement without coverage."

ROBERT KLEIN
RETIREMENT HEALTH CARE ADVISOR
ARDMORE GROUP

Need to Know

Having that information would allow an enrollee to make an educated guess whether to buy the coverage or forgo the expense and invest the savings for a lifetime "self-fund."

Medigap is supplemental insurance enrollees purchase from private insurers to cover out-of-pocket costs in Original Medicare. Enrollees have six months to purchase such a policy when they first enroll without denial due to a preexisting condition. Costs can range from $1,224.28 to $2,854.20 a year. Medicare Part D covers drug costs; premiums vary but can add up to $2,341.20 a year.

'Could Be a Fool's Errand'

McGuyer found one analysis by Health-view Services that modeled lifetime retiree health care costs from $156,208 to $499,290, but he says he's unsure whether it included Medigap and Medicare Part D coverage.

"The 'No-Medigap' *and* 'No-Part D' scenarios *must* be modeled for total out-of-pocket costs, lest all the financial scenario comparisons be viewed as a type of smokescreen or incomplete analysis," said McGuyer.

"This could be a fool's errand and very dangerous," said Robert Klein, a retirement health care advisor with the Ardmore Group and policy advisor to The Heartland Institute, which co-publishes *Health Care News*.

"First, you would lose coverage for the Part A hospital deductible and the copays," said Klein. "Keep in mind, Medicare is not an annual deductible for Part A. It's for benefit periods of 60 days. That means one could trigger the deductible and copays multiple times in a given year. You would need a crystal ball, or a very large amount of money, to plan to invest around that."

Big Risks Involved

Klein points out Medicare Part B has a 20 percent coinsurance with no cap.

"So, if you ring up $100,000 in doctor fees and outpatient services, you will likely owe $20,000," said Klein.

Part D has a penalty for late enrollment—1 percent of the average Part D policy premium, per month.

"This penalty stays with you forever and will be deducted from Social Security retirement benefits," said Klein.

Also, if you decline Medigap in the first six months of enrollment, you could lose your chance to acquire a Medigap policy or have to pay stiff premiums later when you start.

'Crazy' Medicare Rules

Klein points out it is important to keep in mind Medicare uses multiple codes for health care treatment. With every code, there is a cost. Medicare reimburses around 40 percent, and the rest gets picked up by the Medigap policy.

"Is Medicare perfect? asks Klein. "No. Are the rules crazy? Yes. But it's a fool's errand, in my view, to try to predict what one's out-of-pocket costs may be over their retirement without coverage.

"We can tell you with a high level of accuracy, based on income projections, what Medicare, supplemental [gap], and Part D will cost over retirement," said Klein. "But asking to model specific costs without coverage? Oh boy, that's tough."

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

COMMENTARY

Mending Our Tattered Safety Net

By John C. Goodman

Here's the good news. Only 1 percent of Americans are (1) lawful U.S. residents, (2) uninsured, and (3) lack access to subsidized health insurance. That fact comes from health economist Brian Blase, based on a recent Congressional Budget Office (CBO) report.

Currently, 24.3 million individuals in the United States are uninsured. But aside from those who are here illegally, virtually everyone else is eligible for enrollment in Medicaid, Medicare, or private plans, such as those offered in the Obamacare exchanges or by employers.

Medicaid enrollment is free, Obamacare insurance is heavily subsidized, and almost all employer-provided insurance is required to be "affordable." So arguably, we have achieved "universal coverage," or something very close to it.

Here's the bad news. Almost all the increase in health insurance coverage under Obamacare has been the result of an expansion of Medicaid. When Obamacare was being debated, its advocates never said they planned to insure the uninsured with Medicaid. But that is what happened. What's wrong with that?

Medicaid Merry-Go-Round

First, since Medicaid pays the lowest provider fees, Medicaid enrollees are the last patients doctors want to see. Almost a third of doctors won't take any new Medicaid patients at all. Second, since eligibility for Medicaid is determined by income, people find they are enrolled and disenrolled frequently over the space of a few years.

Families at the bottom of the income ladder find that as their income goes up and down and as their job opportunities ebb and flow, they bounce back and forth among eligibility for Medicaid, eligibility for subsidized insurance in the Obamacare exchanges, eligibility for employer-provided coverage, and sometimes eligibility for none of the above. No continuity of health insurance usually means no continuity of medical care.

Net Zero Effect

Going by the raw numbers, the CBO tells us the number of people with private insurance has increased by 1.6 million over the last decade. But remember, Obamacare came into being as America was recovering from the Great Recession. So, even without any change in health policy, we would expect that as more people found jobs, more people would become privately insured.

On balance, there is little reason to think Obamacare has increased the number of people with private coverage at all.

There has been a major change in the kind of private insurance people have, however. An increase in the number of people with coverage purchased in the Obamacare exchanges (where the average government subsidy is about $6,000), has been offset by a decrease in employer-provided coverage (where the average subsidy is $2,170).

Aside from needlessly adding to the federal deficit, what's wrong with that? Several things.

High Deductibles, Low Access

First, the typical plan offered in the exchanges pays provider rates that are not much more than what Medicaid pays. As a result, these plans look like Medicaid with a high deductible. Additionally, the deductibles are really high. In Dallas, Texas, for example, an average-income family of four getting insurance in the exchange pays no premium at all. But if a family member gets sick, the out-of-pocket exposure is $9,100. If two family members get sick, the exposure is $18,200. And that's every year.

Next, at lower income levels, the children may qualify for Medicaid and the adults may qualify for subsidies that reduce their out-of-pocket costs. But these freebies from government are far from "free." The benefits phase out quickly as income rises. So, if the family earns an additional $1,000 in wages, they can lose several times that amount through higher health care costs.

Another problem is that enrollees in Obamacare exchange plans often lack access to the best doctors and hospitals. Our Dallas family, for example, has no access to the city's Baylor Medical Center or UT Southwestern Medical Center, nor to the MD Anderson Cancer Center in Houston.

Poor Results, Low Satisfaction

There are numerous papers demonstrating that despite the appearance of universal coverage, we are doing a very poor job of providing care to those at the bottom of the income ladder. Careful studies have determined Medicaid itself is a poor health insurance plan.

In the most meticulous study ever done of the matter, researchers discovered Medicaid in Oregon had no effect on the physical health of enrollees, and after enrollment, emergency room traffic actually increased. A subsequent study found Medicaid enrollees value their participation in Medicaid at as little as 20 cents on the dollar.

Failed Rescue Attempt

It's not clear that Obamacare's exchange insurance is much better. One reason Congress in recent years added on an extra tier of subsidies for higher-income families is that the unsubsidized part of the individual market was in a death spiral. It seems very few people are willing to pay the market price for what Obamacare has to offer.

That said, there are pockets of excellence, and they exist within the safety net. (See related article, opposite page.)

Boston University economist Laurence Kotlikoff and I have advocated replacing Medicaid, the Obamacare exchanges, and other safety net programs with a system that functions like Medicare Advantage. Risk-adjusted payments would be made to competing organizations. The ones that succeed in producing high-quality, efficient care would be financially rewarded. Those that fail in this regard would be penalized with financial losses.

The first step toward that goal would be for the health policy community to recognize the achievement of near-universal health insurance coverage has not created anything resembling universal access to high-quality care.

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

"Boston University economist Laurence Kotlikoff and I have advocated replacing Medicaid, the Obamacare exchanges, and other safety net programs with a system that functions like Medicare Advantage. Risk-adjusted payments would be made to competing organizations. The ones that succeed in producing high-quality, efficient care would be financially rewarded."

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

NC's Medicaid Expansion Enrolls 270,000 on First Day

By Victor Skinner

A new Medicaid expansion dashboard that will track enrollments monthly in North Carolina shows more than 270,000 people gained coverage on Day One.

The majority of the 272,937 enrolled by Medicaid expansion on December 1 were part of the family planning population automatically moved to full coverage.

The platform, an addition to the state Department of Health and Human Services' existing Medicaid Enrollment dashboard, breaks down enrollment based on plan type, location, age, race, ethnicity, and other demographics. It will be updated monthly.

"Hundreds of people each day are gaining health care coverage and getting the care they need," said North Carolina Health and Human Services Secretary Kody Kinsley in a statement. "Our work continues with state and community partners to support enrollment efforts to ensure as many people as possible can get covered."

Early Enthusiasm

Seventy-five percent (205,847) of those newly enrolled in North Carolina Medicaid live in urban areas, and 25 percent (67,090) live in rural areas.

The data shows the counties with the highest percentages of adults enrolled include Anson, Edgecombe, Richmond, and Robeson. The state health department reports an additional 84,000 people applied through December 15.

"The work of the department, community partners and county DSS [Disability Determination Services] offices is resulting in thousands and thousands of people checking to see if they're eligible" for Medicaid, said Jay Ludlam, state Medicaid deputy secretary, in a statement. "We encourage everyone to share materials, volunteer and take other opportunities to help spread the word about Medicaid expansion to family members, friends, neighbors and other members of their communities."

Other States' Enrollment Declining

North Carolina's expansion is expected to affect roughly 600,000 eligible residents. Despite the additions, a nonpartisan health policy research group is forecasting a nosedive in enrollments nationally in 2024.

KFF, an independent nonprofit research, polling, and journalism entity, released an analysis in November that projected steep enrollment declines and rising state spending on the government insurance program as pandemic policies expire.

Post-Pandemic Disenrollment

Federal Medicaid rules that threatened to cut pandemic funding to punish states for removing people from Medicaid added 23 million people to the program in recent years, while the enhanced federal funding cut state spending on Medicaid to pre-pandemic levels. The continuous enrollment provision expired in April, and states are now working through eligibility redeterminations, a process known as "unwinding."

A KFF survey of Medicaid directors in 48 states and Washington, D.C. forecasts an 8.6 percent decline in enrollments nationally for the 2024 fiscal year. That would be the largest annual decline since the foundation began collecting data in 1998.

In North Carolina, the unwinding has resulted in 184,375 North Carolinians being determined ineligible or having coverage ended for procedural reasons through November, according to the NC Medicaid Continuous Coverage Unwinding Dashboard. About 2.8 million North Carolinians are enrolled in Medicaid.

Victor Skinner (**think@heartland.org**) *is a contributing writer for* The Center Square. *An earlier version of this article was published by The Center Square. Republished with permission.*

COMMENTARY

The Cure for U.S. Physician Burnout

By Deane Waldman, M.D.

The United States has a critical shortage of health care professionals: nurses, mental health therapists, and especially physicians.

Burnout among these clinicians is the proximate cause of the shortage. Maximum wait times to see a primary care doctor can exceed four months, resulting in death by queue.

"Death by queue" was coined for Great Britain's vaunted National Health Service (NHS), where Britons die waiting for lifesaving medical care. As in the United States, the NHS is experiencing an exodus of burned-out physicians, especially senior ones, with catastrophic consequences. In addition to worse delays in caring for current patients, where will we get experienced physicians to teach the next generation of doctors how to care for future patients?

Solutions Off the Mark

Proposed solutions for burnout include AI-assisted documentation, immigration of caregivers, virtual caregivers, online toolkits, and recommendations to rest/eat well/exercise/ask for help. As these solutions do not address the causes of burnout, such fixes will fail and could make things worse.

A review of the common causes of burnout unveils a common theme.

Physicians cannot exercise their best judgment when making care recommendations to patients. They must follow clinical guidelines, crisis standards of care, pharmacy benefits managers' drug limitations, federal advisories, CDC mandates, and FDA prohibitions.

All these cases of advice and guidance are effectively orders. They seem designed to protect the patient from the doctor, replacing the physician's judgment with government authoritarianism. Doctors feel the weight of responsibility for the patient but are denied the appropriate authority. Physicians always get the blame but rarely any praise.

Missing 'Psychic Reward'

Clinical caregivers endure years of school and training along with long hours and great emotional and physical stress for one reason above all others: the psychic reward. The psychologist Abraham Maslow described it as the highest of human needs—self-actualization, discovering the meaning of one's life and achieving it.

As one nurse described the psychic reward, "When my babies [her patients] do well, it feeds my soul."

The current health care system disconnects patients from physicians emotionally. The depersonalization patients rightly resent is felt equally by care providers. My former personal physician had an assigned list of more than 900 patients. Surgeons often first learn the patient's name from that day's operating schedule. The lack of psychic reward combined with overwork, especially from BARRCOME (explained below), leads to burnout.

Bureaucrats in Charge

When Washington regulates the health care system, guides care, and establishes insurance rules, it does so through bureaucracy, administration, rules, regulations, compliance, oversight, mandates, and enforcement (BARRCOME). BARRCOME manifests in health care as third-party decision-making by Washington directly through Medicare, Medicaid, and Tricare (171 million Americans) and indirectly through federal rules and regulations governing employer-supported private insurance (134 million Americans).

Third-party decision-making producing bureaucratic diversion and disconnection is the ultimate cause of physician burnout.

Bureaucratic diversion refers to inefficient health care spending that produces no medical care. In 2022, the United States expended $4.3 trillion on its health care system, an amount greater than the gross domestic product of Germany. Half of that spending was diverted from patient care to pay for BARRCOME, $2 trillion worth of care Washington denied people to pay itself.

As Medicare and Medicaid repeatedly lower allowable reimbursement schedules—aka payments to physicians—wait times get longer, patients die waiting, and physicians burn out, feeling frustrated and devalued (see related article, page 3).

Third-Party Disconnect

BARRCOME's third-party decision-making disconnects patients from their money, and doctors from their patients emotionally (along with financially).

Health care expenditures for the average American family of four were $31,065 in 2023. More than 80 percent will go to an insurance company where unaccountable, faceless bureaucrats decide how to spend family funds. As most families are healthy and have low medical expenses, they get no value from their share of the cost.

Disconnecting patients from their money promotes physician burnout. Patients see massive spending on health care, and intolerable wait times despite exorbitant physician charges (not payments, which are generally a small fraction of the charges), and direct their anger at physicians. Doctors quickly burn out if they get up at 3 a.m. to see a patient and are rewarded with disdain and physical violence.

A fiduciary connection is the key to a successful therapeutic relationship; it is also a preventative for burnout. In medicine, fiduciary means one person (the patient) gives up medical autonomy—control of body and/or mind—to another person (the physician) to be used exclusively for the benefit of the first person. This is an intimate, emotionally intense relationship between two people.

When the patient and physician are disconnected by the third party, there cannot be a true fiduciary relationship. Without such a connection, there is no trust and no psychic reward. The result is burnout.

The Answer: Direct Pay

The cure for physician burnout follows from the root cause. Eliminate third party and federal government decision-making from health care, and health and care will reconnect.

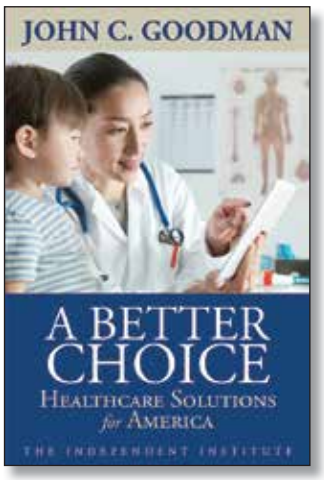
Reconnect the patient with his/her money, so the patient, not the third party, makes spending decisions.

Reconnect the patient directly with his/her chosen physician, with no third party making medical (or financial) decisions (see related article, page 14).

This reestablishes both medical freedom and the fiduciary relationship, which can cure the problem of physician burnout and the consequent shortage of doctors.

*Deane Waldman, M.D., MBA (***dw@deanewaldman.com***) is a prof*essor *emeritus of pediatrics, pathology, and decision science at the University of New Mexico; former director of the Center for Healthcare Policy at the Texas Public Policy Foundation; and former director of the New Mexico Health Insurance Exchange. An earlier version of this article appeared in* Real Clear Health. *Reprinted with permission.*

Prescription for Better Healthcare Choices



A Better Choice

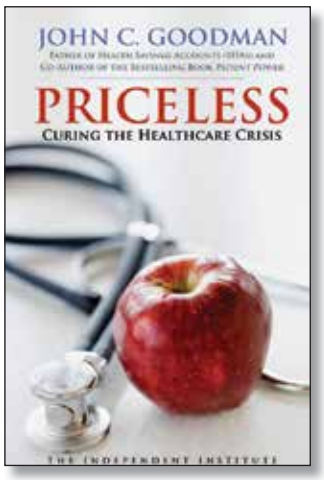
Healthcare Solutions for America

John C. Goodman

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

—**Bill Cassidy**, M.D., U.S. Senator

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



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Racial Quotas for State Medical Boards Under Fire

By AnneMarie Schieber

A nonprofit organization is challenging a 35-year-old Tennessee law that requires the governor to appoint members to state licensing boards based on race.

The complaint from nonprofit organization Do No Harm in a lawsuit filed in the U.S. District Court for the Middle District of Tennessee, Nashville Division claims Tenn. Code 8-1-111 and 63-3-103 (b) violate the equal protection clause of the Fourteenth Amendment to the U.S. Constitution. The plaintiffs are seeking a declaratory judgment, a permanent injunction on the racial mandates, and reimbursement for legal fees.

"Using race to make appointments to government boards is not only demeaning and unconstitutional, but it undermines the distinctive spirit of the Volunteer State by precluding opportunities for Tennesseans to serve their local communities," said Laura D'Agostino, an attorney with the Pacific Legal Foundation (PLF) representing Do No Harm, in a press release.

"State medical boards are given important responsibilities to oversee the quality of care in their state and the safety of patients," said Stanley Goldfarb, M.D., chairman of Do No Harm, in the press release. "It is crucial that they be the most qualified physicians available. Like all aspects of healthcare, patient safety and patient concerns should be primary, not the skin color or the racial makeup of any oversight committee."

Racial Balancing Hangups

Eleven of the state's 70 licensing boards supervise health care professions in the state. Licensed podiatrists who are members of Do No Harm are seeking to fill two vacancies on Tennessee's six-member Board of Podiatric Medical Examiners. There are more than 200 practicing podiatrists in the state, according to the American Podiatric Medical Association.

INTERNET INFO

Do No Harm v. *William Lee*, U.S. District Court for the Middle District of Tennessee, Nashville Division, November 8, 2023: **https://pacificlegal.org/wp-content/uploads/2023/11/11.08.23-Do-No-Harm-v.-William-Lee-PLF-Complaint.pdf**

"Tennessee is one of several states nationwide that mandate the governor to engage in racial balancing when making appointments to public boards and commissions," D'Agostino told *Health Care News* in an email. "Apart from the Board of Podiatric Medical Examiners, the governor must ensure that he complies with a specific racial quota for nearly 70 other boards, including a catch-all statute that requires the governor to engage in racial balancing whenever making appointments to any public board or commission."

New Precedent on Quotas

Last summer, the U.S. Supreme Court ended racial preferences among college applicants in *Students for Fair Admissions v. University of North Carolina*. The same rationale applies in the Tennessee case, says D'Agostino.

"After Students for Fair Admissions, only two compelling interests justify race-based government action: (1) 'remediating specific, identified instances of past discrimination that violated the Constitution or a statute' or (2) avoiding imminent risk of riots in prison," said D'Agostino. "The government may try to argue that it is attempting to remediate past discrimination with its racial quotas, but the legislative record strongly indicates otherwise."

PLF reviewed the 1988 legislative recordings and discovered there were no discussions about any past discrimination.

"On the contrary, there were questions on whether these quotas were 'constitutional' or 'legal,'" said D'Agostino. "Unfortunately, these concerns did not halt the passage of these statutes, and countless people across the Volunteer State have been precluded from serving their local communities ever since. We hope to change that. The governor's office filed a motion to dismiss our complaint yesterday [January 8], and we are drafting our response."

Mandates Galore

According to a PLF report D'Agostino co-wrote, at least 25 states have race- or sex-conscious mandates for public licensing boards. In the medical field, those include boards that oversee chiropractors, dental hygienists, dentists, nurses, occupational therapists, optometrists, pharmacists, psychologists, physical therapists, physicians, podiatrists, social workers, and veterinarians.

Licensing boards interpret laws, rules, and regulations, investigate complaints, and have the authority to discipline licensed professionals.

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

"There were questions on whether these quotas were 'constitutional' or 'legal.' Unfortunately, these concerns did not halt the passage of these statutes, and countless people across the Volunteer State have been precluded from serving their local communities ever since. We hope to change that."

LAURA D'AGOSTINO
ATTORNEY
PACIFIC LEGAL FOUNDATION

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