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FDA Biosimilars Naming Rule
A new guideline requiring a suffix on the names of generic versions of biologic drugs is getting pushback from consumer groups, who say it is unnecessary and will slow market acceptance.  
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Judge Rules Against Association Health Plans
By Emma Kaden

A federal judge struck down the U.S. Department of Labor’s (DOL) 2018 rule that loosened regulations on association health plans (AHP), which are temporary group health insurance plans for small businesses and associations that are not subject to the same requirements as individual plans under the Affordable Care Act (ACA).

The DOL rule expanded eligibility for small employers and other groups, such as trade associations, to offer AHPs to employees and members.


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Proposed FDA Rule on Biosimilar Suffix Sparks Industry Concerns

By AnneMarie Schieber

The biosimilar drug industry and consumer, taxpayer, and health care groups are crying foul over the U.S. Food and Drug Administration’s (FDA) newly released guidelines requiring a four-letter suffix on biosimilar drug names, which would distinguish them from their brand-name biologic counterparts.

“The suffix matters because it acts as a significant, artificial barrier to biosimilars that is misaligned with the agency’s and the administration’s commitment to lowering drug prices for America’s patients,” Christine Simon, executive director of the Biosimilars Council and vice president at the Association for Accessible Medicines (AAM), wrote in an article posted on the Center for Biosimilars website.

The FDA published the revised guidelines, titled “Nonproprietary Naming of Biological Products: Update; Draft Guidance for Industry; Availability” in March, opening up a 60-day comment period to end May 7. The guidance calls for adding the suffix to the names of all biosimilars regardless of whether they’ve been approved to treat the same disease as their biologic counterparts.

The proposal would have a critical effect on the success of biosimilars, says AAM, because it would affect what happens at the pharmacy counter.

“A product may be on the market and not automatically substitutable during the pharmacy dispensing process, and then later gain the interchangeable designation allowing for automatic substitution,” stated a letter to FDA signed by 29 “stakeholder” groups such as the American Association of Retired Persons. “These types of scenarios could introduce unnecessary barriers and will require re-education of healthcare professionals for specific products.”

Doing No Harm?

In a March 7 statement, the FDA’s then-Commissioner Scott Gottlieb said although the agency is aware of the biosimilar industry’s concerns, he did not think the rule would harm the industry.

“We strongly believe in the ability of biosimilars to promote competition, lower prices and foster greater access,” Gottlieb wrote in the statement. “And we’re fully committed to the suite of announced and upcoming policies to help advance the goal of a robust, high-quality, competitive market for biosimilar products. But I do not believe that the naming convention should be used to advance these goals if it could come at the expense of the ability to ensure patient safety. Nor do I believe the inclusion of a suffix will frustrate the broader aim of inspiring strong biosimilar competition.”

Letters signed by AAM, industry stakeholders, and seven tax and consumer groups to Acting FDA Commissioner Norman Sharpless urge the agency to change course. The stakeholders’ letter says the suffix will cause confusion for patients, pharmacies, and providers without providing any added safety benefit, and FDA approval in and of itself recognizes there is “no clinically meaningful difference” between the drugs.

The tax and consumer groups’ letter notes the suffix policy deviates from the globally recognized International Nonproprietary Name (INN) system. Japan and the United States are the only countries that require biosimilars to carry the suffix. In the European Union, where the names are the same for biologics and biosimilars, consumers have experienced double-digit price decreases, the letter states.

Biosimilar drugs are the generic equivalent of these biological medicines and were first approved by the FDA in 2015. According to the AAM, biologics and biosimilars now account for 46.5 percent of total spending on medicines though comprising only 2 percent of all prescriptions. AAM reports biosimilars have on average a 47 percent lower list price than their brand-name counterparts.

Unpredictable Effects

The disagreement between the biosimilar trade industry and the FDA is a matter of drug industry economics, says David Hyman, a law professor at the Georgetown Law Center, adjunct scholar at the Cato Institute, and coauthor of Overcharged: Why Americans Pay Too Much for Health Care.

“Nobody welcomes low-cost competition,” said Hyman. “We don’t know enough to know what impact this will have. We also don’t know if it will cause consumer confusion. Either biosimilars are identical or similar, and how similar, if similar is enough, [are they] that we would want to disclose it to people?”

Hyman says when pharmacies began substituting generic drugs for brand-name versions, the law didn’t require a special naming convention for generics.

“Pharmacists will automatically swap generics for brand names, but I’m not sure how this would work for biosimilars,” said Hyman. “Branded companies don’t advertise drugs when they go generic.”

The FDA’s new draft rule on the proposed suffixes is expected by May 31.

AnneMarie Schieber (amschieber@heartland.org) is managing editor of Health Care News.
In an effort to encourage expansion of consumer-driven health care provider models, a growing number of states are moving to exempt direct primary care (DPC) from insurance regulations.

Classifying DPC as not being insurance means these providers are not subject to insurance regulations that drive up the cost of health care.

Direct primary care practices charge a flat fee for unlimited service. The providers can offer lower prices because bypassing the insurance system reduces administrative costs substantially. Members often supplement their care by buying insurance coverage through health-care sharing ministry programs which cover hospitalization and specialty care at a fraction of the price of traditional insurance plans.

This year, insurance definition bills emerged in Arizona, Georgia, Hawaii, Maryland, Minnesota, New Hampshire, South Carolina, and Wisconsin. In April, Arizona Gov. Doug Ducey signed into law S.B. 1105, which addressed ambiguity in previous law by specifically stating DPC plans are not insurance.

Georgia became the 26th state to define DPC as not being insurance, with the passage of S.B. 18 this year.

**Trying It Out**

States are also looking at other ways to boost the DPC movement, such as allowing DPC practices to dispense medication or launching DPC pilot programs for government workers or for people enrolled in Medicaid.

Adam Habig, cofounder and president of Freedom Healthworks, says the legislative action shows increasing acceptance of DPC as a viable option for consumers.

“Mostly these laws provide certainty that insurance regulators will not interfere with DPC practices, as was threatened by insurance officials in several states, like New York, early in the DPC movement,” said Habig. “We now have Georgia, which will put DPC beyond the point where the majority of states will have enacted such legislation.”

By distinguishing DPC from insurance, states allow the industry to be tested in the marketplace, says Habig.

“Doctors and patients win, since they can interact free from fear of violating insurance regulations,” said Habig.

Philip Eskew, a physician, attorney, and founder of DPC Frontier, says he is encouraged by the state action this year.

“States need to lower legal barriers or risk to market entry so new DPC practices are more likely to launch,” said Eskew.

**Cutting Costs**

These reforms reduce costs for states and providers alike, says Eskew.

“Both the practices and the state insurance commissioner’s office benefit because now there is less guessing work, and contract audits, if needed, can happen in a streamlined and predictable manner,” said Eskew.

“Attorneys that like to draft agreements from scratch in areas with much uncertainty lose the ability to rack up legal fees.”

DPC Frontier offers model legislation on its website with language that defines DPC as not being insurance.

Jake Grant (jakeg42294@gmail.com) writes from Alexandria, Virginia.
Bills Before Congress Would Allow Use of HSAs for Direct Primary Care Dues

By Jake Grant

Congress is considering legislation that would modify the federal tax code to allow the use of pretax health savings accounts (HSAs) to pay for the noninsurance payment model of direct primary care (DPCs).

An HSA is a type of savings account that allows people to set aside money before taxes to pay for qualified medical expenses such as deductibles, copayments, and coinsurance. Some in Congress want to extend those qualified medical expenses to include dues that members pay to direct primary care practices. Because DPCs don’t accept insurance or payment from third-party payers, they can offer unlimited primary care for typically less than $100 per month.

Bills Would Broaden HSAs

Sen. Marco Rubio (R-FL) introduced S. 12, the Health Savings Act of 2019. Cosponsored by Sen. Lisa Murkowski (R-AK), the legislation would expand the use of HSAs to pay for fixed-fee primary care and services.

In the U.S. House, Rep. Mike Gallagher (R-WI) has introduced H.R. 603, the Health Savings Account Expansion Act, which would increase the maximum contribution limits for HSAs and allow the accounts to pay for fixed-fee primary care services and fitness center memberships. It also allows for a medical care tax deduction for fixed-fee primary care and services.

Game-Changer for DPC

Philip Eskew, a family physician, attorney, and founder of DPC Frontier, says the bills would make DPC much easier to access.

“Federal clarification that DPC fees are not health plan fees as defined by current law under 223(c) and are a qualified medical expense under 213(d) would allow patients and their employers to comfortably use DPC plans without any tax uncertainty through HSAs, HRAs, and FSAs,” said Eskew.

Eskew says those who oppose the bills are typically proponents of socialized medicine. “Most of the opponents are confused,” said Eskew. “The small number that oppose DPC after understanding the concept generally seem to want to prohibit all forms of private medicine. DPC has broad, bipartisan support across red and blue states. Employers and patients benefit because now they can use pretax dollars to pay for DPC, just like most of their other health expenditures.”

Empowering Consumers

HSAs allow market forces to help keep health care costs down, says Sarah Anderson, federal affairs manager at FreedomWorks. “It’s abundantly clear that there is widespread support for HSA expansion from all corners of the Senate Republican conference,” said Anderson. “While disagreements may continue in other areas of health care reform, Republican leadership should capitalize on this rare area of consensus and work to use HSAs as a means to put Americans in charge of their health care dollars and slow the growth of costs.”

HSAs empower consumers, says Jonathan Byddal, founder and president of the Coalition to Reduce Spending. “HSAs are an essential piece of the puzzle that is solving the country’s growing health care crisis and are a foil to the government-centric efforts like Medicare for All or even some Republican-led plans that would create new entitlements for paid family leave,” said Byddal. “By contrast, expanding HSAs allows people to save for what they want, such as Rep. Andy Biggs’ recently filed Freedom for Families Act, without burdening an already strained system with more mandates.”

HSAs allow consumers to save pretax money in tax-free interest-bearing accounts. Consumers, however, have had a hard time using the accounts for savings because they are restricted to certain high-cost expenses such as insurance deductibles, premiums, and insurance copays. A recent survey by the Kaiser Family Foundation and the Los Angeles Times found less than 22 percent of those with incomes under $75,000 have more than $2,000 in an HSA.

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The Trump administration is appealing the decision.

**ACA vs. AHPs**

Under the ACA, health insurance plans must include "essential benefits," a set of 10 forms of coverage. Included among those mandates are services for mental and behavioral health treatment and maternity care. For small businesses and trade associations, AHPs offer a more affordable and less comprehensive alternative to plans that follow the rigid ACA guidelines.

Tim Benson, a policy analyst at The Heartland Institute, which publishes Health Care News, says AHPs benefit people by providing more choices of affordable health insurance.

“AHPs give people many more options and a better chance to find a reasonably priced plan that best suits the needs of their family,” said Benson.

With AHPs, employers can assess which benefits their employees need most and provide health insurance plans that meet those needs. AHPs are more flexible and affordable than most other health insurance plans because they do not have to meet all the Obamacare requirements and they can create larger risk pools by consolidating many individuals and organizations into their plans.

Since the Trump administration took office, about 30 AHPs have been formed. Before the ruling, approximately four million Americans were expected to enroll in AHPs by 2023, according to the Congressional Budget Office. That number includes roughly 400,000 Americans who would be uninsured if AHPs were not available.

Many groups support the AHP regulatory reform. Thomas Donohue, president and CEO of the U.S. Chamber of Commerce, wrote that the new rules were “a major step in the right direction for small businesses and the millions of Americans who will now be able to buy lower-cost health insurance plans.”

**Question of Intent**

In the court decision, Bates stated the Trump administration had not followed the law.

“The final rule was intended and designed to end run the requirements of the ACA, but it does so only by ignoring the language and purpose of both ERISA and the ACA,” Bates wrote in his ruling.

Bates claimed the Trump administration’s intent behind the AHP rule was to defy the will of Congress, and he said Trump’s negative public comments on the ACA are evidence of that.

Benson says the ruling will be most detrimental to small businesses and other people who don’t receive health insurance from large employers.

“This is an unfortunate ruling that is going to hurt many small businesses and families,” Benson said. “AHPs are great because they allow consumers to purchase insurance at lower rates thanks to the increased negotiating power larger groups naturally have with insurance companies, and these larger groups also help spread out costs.”

**Raises Concerns**

The ruling against AHPs could have a big impact on the nation’s health insurance industry. Shortly after the case was filed, the U.S. Chamber of Commerce and the Society for Human Resource Management filed an amicus brief supporting the rule.

“This case raises an issue of significant importance to amici’s members and to all of America’s small businesses—the availability of real opportunities for small employers to access quality, affordable health insurance coverage for their employees,” the brief states. “Amici are intimately familiar with the problems small businesses encounter when attempting to secure such coverage and have a strong interest in seeing the Labor Department’s Final Rule go into effect.”

Josh Archambault, a senior fellow for the Foundation for Government Accountability, says despite the ruling, states should pass legislation to ensure small businesses and trade associations have the freedom to offer AHPs that best meet the needs of their employees and members.

“It is not yet clear what the full effect of this ruling will be, ... so states should proceed with updating their laws in order to empower small businesses to take full advantage of association health plans and new federal flexibility,” Archambault said. “In doing so, states can ensure that small businesses and entrepreneurs have the same access to affordable health insurance as large employers.”

**Legislation Offered**

Less than two weeks after the ruling, Republicans in the U.S. House of Representatives introduced the Association Health Plans Act, which would make it easier for small businesses across the country to offer affordable AHPs. Companion legislation was introduced in the U.S. Senate.

According to bill sponsor Sen. Mike Enzi (R-WY), the legislation would guarantee small businesses the ability to offer AHPs without facing the strict restrictions imposed by the ACA.

“As a former small-business owner, I understand firsthand the difficulties that employers face when trying to provide health insurance for their employees,” Enzi stated in a news release. “Association Health Plans work for small businesses. They provide coverage to people who would not otherwise have it, and they provide comprehensive health benefits at an affordable price the same way larger employers do—the same way most folks get insurance.”

“One family shoe store probably cannot get an insurance company to play ball, but 1,000 family shoe stores probably could,” said Enzi.

Emma Kaden (ekaden@heartlandgmail.com) is an assistant editor at The Heartland Institute.
Florida Legislature Approves International Drug Purchasing

By Rocco Cimino

Florida has joined Colorado, Missouri, Utah, Vermont, and West Virginia in attempting to save money on prescription drugs by importing them from another country. The Florida House and Senate have approved House Bill 19, which would authorize the creation of two programs. One would import drugs from Canada and would focus on the purchase of drugs for state-run programs, such as the prison system and Medicaid. The other, with a focus on the consumer market, would operate under the Department of Business and Professional Regulation and import drugs not just from Canada but other countries as well.

The plans are meeting stiff resistance from the drug industry and pro-taxpayer and conservative groups.

Gov. Ron DeSantis strongly supports the bill, which remained pending on his desk at press time. However, even if DeSantis chooses to sign the bills, the federal government must approve any drug importation program, and it has yet to give the go-ahead to similar programs in other states.

The proposed Florida programs would include the purchase of all prescription drugs except controlled substances, biological products, injectable drugs, and drugs inhaled during surgery.

Prices of prescription drugs in Canada and other countries can be more affordable because their governments control the prices. It is not clear whether Canada is willing or would have enough drugs or the right kind of drugs to supply Florida.

Reduced Availability

Although legislators are attracted to Canada’s lower drug prices, prescription drugs in other countries cost less because the governments force the prices down, which would reduce access if tried here, says Ed Hudgins, research director at The Heartland Institute, which publishes Health Care News.

“Prices in other countries are usually determined or manipulated by governments,” said Hudgins. “They are not market prices.”

These below-market prices ultimately decrease people’s access to drugs, says Hudgins.

“As artificially low-priced drugs come into the U.S. market, American drug developers will find it more difficult to recover their investments,” Hudgins said. “Importation undermines the incentive to innovate.”

Other problems arise from the complexities of the U.S drug market caused by government policies.

“There are patent protection issues involved,” said Hudgins. “Also, importation does not get to the root causes of high or really distorted prices in the United States, most notably the spaghetti-tangle of U.S. government pricing regulations, such as through Medicare, insurance regulations that leave out consumer choice, and the high price of drug certification because of antiquated FDA certification regulations.”

Safety Questions

Importing drugs from a foreign country raises questions about safety and oversight, says Merrill Matthews, a resident scholar with the Institute for Policy Innovation.

“The FDA is, by law, charged with ensuring the safety of drugs in the United States,” said Matthews. “There has been a law on the books for years that if the FDA commissioner could certify that importation was safe, then it would be allowed. No FDA commissioner, Republican or Democrat, has been willing to do that.”

Matthews says allowing importation of drugs carries big political risks.

“That sense of let-the-buyer-beware would be quickly abandoned if there were widespread injuries due to an outbreak of fake or compromised drugs,” Matthews said. “From a political standpoint, it is foolish to push importation. If deaths occur, the politicians who promoted it will take the blame.”

Matthews says it might not be realistic for states to provide their own safety inspections.

“State-mandated inspections might help, if citizens could depend on the state to do the job thoroughly,” Matthews said. “But they can’t. The FDA is overwhelmed, and the states would soon be also. The tendency would be to provide limited funding for inspections and claim that the state has addressed the issue when it hasn’t.”

Failed Tests

Several states and cities have set up drug importation programs over the past 15 years, but they have failed to gain traction, Matthews says.

“Several states and cities have set up importation programs over the past 15 years or so, and they have failed for lack of use,” Matthews said.

“State-sponsored importation schemes are all about politics and not about medical necessity,” Matthews said.

There is also the concern of an expanding black market for prescription drugs as cheaper drugs are brought into the country.

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Merrill Matthews
Resident Scholar
Institute for Policy Innovation

“A black market for drugs already exists, though it is mostly focused on opioids and similar substances,” said Matthews. “What importation does is provide a veneer of legitimacy to the notion that people can buy drugs located in another country, often claiming to be in Canada, and it’s perfectly safe.

“In other words, it makes the existing black market appear to be safer than it is,” Matthews said.

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Florida Removes Certificate of Need Laws

Continued from Page 1

laws, but Senate support for the idea proved insufficient. A modified version, Senate Bill 1712, met resistance from reformers and opponents alike.

Ultimately, lawmakers agreed to eliminate CON for new general hospitals and tertiary services such as organ transplants, but nursing homes, hospice programs, and “boutique” facilities such as cancer care and orthopedic hospitals will still require CON approval.

The final bill passed overwhelmingly in the Florida House, and Gov. Ron DeSantis is expected to sign the bill, which would go into effect July 1.

Bills to eliminate CON have been introduced before in Florida, especially over the past few years, but never gained traction until now.

“Rolling back Florida’s certificate of need laws is a tremendous accomplishment for the Florida legislature,” said Matthew Glans, a senior policy analyst with The Heartland Institute, which publishes Health Care News. “CON laws are an outdated mechanism which far too often devolve into crony capitalism and indulge certain providers with special treatment over the good of the market.”

Most States Impose Restrictions

Florida is one of 35 states with CON laws. This year, Alaska, Georgia, Missouri, South Carolina, and Tennessee were among those considering CON reform.

Repeal can be challenging. Several high-profile projects in Florida had been thwarted by the state’s CON board, including two hospitals requesting permission to perform pediatric heart transplants. Currently, two hospitals are trying to establish adult bone marrow transplant programs. CON laws require facilities to demonstrate an unmet need before expanding or entering new markets, thus thwarting improvement of services and expansion of access.

The U.S. Department of Health and Human Services has encouraged states to eliminate CON laws, which came into existence in 1974 when the federal government required them in return for federal funding. Over the years, opinion on CON has changed, with presidents from both parties favoring repeal.

“Eliminating these unnecessary barriers would unleash competition, thus producing myriad choices and innovations that will benefit all health care consumers,” said Glans. “Without CON laws, more medical facilities will be built and additional procedures will be offered in Florida, allowing for new and existing patient services to be met in a convenient, reliable, affordable, and timely manner.”

Non-Physician Practitioner Bill Stopped in Florida Senate

By Ashley Herzog

Lawmakers are not giving up the fight to expand the role of non-physician health care practitioners in Florida after a bill that would have allowed practitioners to work independently of doctors was voted down.

House Bill 821 failed to clear the Florida State Senate, but supporters are not giving up.

“We’ll try again for the 2020 legislative session,” said Brandon Miller, legislative assistant to the bill’s sponsor, State Rep. Cary Pigman (R-55).

Proponents say Florida’s health care challenges remain formidable.

“Presently, the State of Florida ranks 41st in the nation for health care access and affordability, with the highest Medicare readmission rates in the country,” said Arlene Wright, president of the Florida Nurse Practitioner Network.

“The data demonstrating cost-effective quality care by nurse practitioners has been evident and proven in the 22 states that have full practice authority,” said Wright. “In those states that operate with practice expansion, there has been a significant decline in the number of people lacking a primary care provider.”

The American Association of Nurse Practitioners defines “full-practice authority” as evaluating patients; diagnosing, ordering, and interpreting diagnostic tests; initiating and managing treatments; and prescribing medicine.

State Faces Provider Shortage

The bill is a cost-effective measure to meet the state’s increasing demand for health care services, especially among Florida’s elderly population, rural residents, and the poor, says Wright.

“Modernizing antiquated health care statutes gives patients accessibility and choice,” said Wright. “It also decreases preventable delays in care, especially for the outlying, underserved areas.”

Preventative health care provided by nurse practitioners allows people to avoid needing much more expensive care later on, Wright says. When people cannot get the preventative health care that is routinely provided by nurse practitioners in many other states, they often end up making costly trips to the emergency room.

“The cost savings are reflected in the decreased utilization of emergency services for nonemergency health care issues and unnecessary referrals,” said Wright. “Ensuring that the population has access to preventative health care services will decrease hospitalization rates and reduce length of stays.”

The bill would have significantly increased access to health care services, says Wright.

“It would have opened up the door for access and provided an avenue of choice, particularly among the most vulnerable of populations and those that would otherwise not have care,” said Wright.

Clarifying the Roles

Opposition to the bill arises largely from misinformation about what nurse practitioners do, says Wright.

“As House Speaker Oliva mentioned in his comments post-session, the majority of the opposition arises from perception,” said Wright. “There are many misconceptions that non-physician providers would be practicing outside their scope, which is erroneous.”

The state should allow medical professionals to provide all the services they are capable of performing successfully, Wright says.

“The goal is that all providers be provided with the opportunity to practice to the full extent of their training, education, and licensure and work towards a common ground to unlock the doors for the citizens of Florida to receive quality, accessible, timely care.”

Arlene Wright, President, Florida Nurse Practitioner Network

AnneMarie Schieber (aminschieber@heartland.org) is managing editor of Health Care News.
Maryland Legislature Passes Clampdown on Prescription Drug Costs

By AnneMarie Schieber

A bill to create a Prescription Drug Affordability Board cleared the Maryland General Assembly and has been sent to Gov. Larry Hogan for his signature.

Maryland House Bill 768 and its Senate counterpart Senate Bill 759 call for establishing a panel with authority to review prices and set caps on prices of drugs exceeding $30,000 for a single course of treatment or within a year’s time.

Lawmakers scaled back the bill from the original version to limit the board’s authority to public health care plans only.

Maryland would be the first state in the nation to create such a panel.

The governor has until the end of May to sign the bill, veto it, or allow it to become law without his signature.

Availability Questions

The pricing board could reduce drug availability, says David Hyman, M.D., a Georgetown University Law Center professor, adjunct scholar at the Cato Institute, and coauthor of Overcharged—Why Americans Pay Too Much for Health Care.

“For state employees, they have a right to say, ‘This is what we’re going to cover, and this is what we’re not,’ and that is not unreasonable, because they’re footing the bill,” said Hyman. “Medicaid is a different kind of problem. The cost is shared with the federal government, and it involves a population that is not set up to fend for itself in this context. Drug companies can refuse to sell a product for a lower price.”

State Medicaid programs have used other measures to control drug costs, such as limiting patients to a certain number of prescriptions per month. Much of the variability of drug prices is made possible because third parties, not consumers directly, foot the bill, Hyman says.

“If these were individuals making the decisions, we’d have no difficulty how they decide,” said Hyman. “When you’re deciding what car to buy, you get to set the ceiling, and when it doesn’t meet your parameters, you don’t buy the car. Nobody thinks there is anything problematic about it.”

Tried Before

The current legislation is not Maryland’s first attempt to control drug prices.

In 2017, state lawmakers gave the state’s attorney general power to review and regulate prices of generic drugs. The Association for Affordable Medicine (AAM) challenged the law in court, arguing it violated the Dormant Commerce Clause of the U.S. Constitution. The U.S. Court of Appeals for the Fourth Circuit sided with AAM, and the U.S. Supreme Court declined to take up the case, thus invalidating the law.

AnneMarie Schieber (amschieber@heartland.org) is managing editor of Health Care News.
ALS Patient Runs for National ‘Free to Choose Medicine’ Reforms

By Andrew Whitney

A n experimental treatment that enabled a man with amyotrophic lateral sclerosis (ALS) to run around the room while testifying before a U.S. Food and Drug Administration (FDA) panel has cast new attention on the agency's process for approving life-improving treatment.

Video of Mark Bedwell's dramatic demonstration has been circulated widely on the internet and on television newscasts. Bedwell was making the case for FDA reforms championed by the “free to choose” and “right to try” (RTT) movements to speed up the agency's drug approval process, which can take longer than many patients are expected to live. The panel applauded after Bedwell stood up and did his lap around the conference tables.

"It worked," a tearful Bedwell told the panel. "It was hard for me to walk, hard for me to talk. I'm very emotional about it. It works. I'll run around the building with you."

The experimental treatment Bedwell has been using is called NurOwn, by Brainstorm Therapeutics. NurOwn is a targeted cellular therapy designed to slow down the progression of ALS. It completed three Phase 2 FDA trials involving 70 patients and is now beginning Phase 3 trials with 200 patients. Bedwell participated in one of the completed trials.

Says FDA Excludes Too Many

Annie Swarts, an ALS activist, says FDA's drug approval process is outdated and excludes too many patients.

"The guidance documents are so archaic," said Swarts. "They're from the 1950s. They rule out a lot of people, right off the bat."

Guidance documents are intended to encourage and guide prescription drug makers through trials. Swarts says the ALS community is being ill-served by the FDA.

"The FDA doesn't have a point person for ALS," said Swarts. "We've been failed on a lot of levels."

‘Right to Try’ Limits

ALS patients have been trying to convince regulators that NurOwn should fall under RTT legislation President Trump signed into law in May 2018. The Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 created a uniform system for terminally ill patients who have exhausted treatment options and cannot get into clinical trials. The FDA has given such permission under its "expanded access" clause and other parallel programs, but many patients fail outside the eligibility requirements. RTT drugs are generally in an earlier stage of development than the FDA's access framework allows.

Christina Herrin, campaign manager for the Free to Choose Medicine initiative at The Heartland Institute, which publishes Health Care News, says there is good reason for ALS patients' frustration.

"Twelve years is simply too long to get a drug approved," said Herrin. "Instead of having the FDA pore over hypotheticals, we need to be helping these people."

Government Obstacles to Drug Access

The FDA process is intended to ensure patient safety and efficacy for new drugs, which leads to long trial times and extensive periods of review. Experimental access is granted for drugs that have already passed safety trials.

The average cost for getting a new drug to market is $2.6 billion, according to a recent study by the Tufts Center for the Study of Drug Development. The cost may make some companies wary of the FDA process, as they are unsure their costs can be recuperated should early access disprove efficacy projections, or should the FDA refuse to approve the drug.

Bartley Madden, author of Free to Choose Medicine and a policy advisor to The Heartland Institute, writes how expanded access would work.

Free to Choose Medicine "sets up a competing system that would allow manufacturers to market new drugs after completion of the FDA's Phase I testing and at least one round of Phase II testing, contingent upon certification of a FTCM Committee that the drug successfully completed that testing," Madden proposes in his book. Patients could make drug treatment decisions based on their individual circumstances, and their experience would provide real-life data so drugs could get to market faster if they prove safe and effective, writes Madden.

Public Supports Faster Access

A poll by The Heartland Institute found 92.8 percent of active voters support implementing a faster FDA process for getting prescription drugs to market.

"This is a bipartisan issue," said Herrin. "Comprehensive reform is being demanded by the American people, with almost 95 percent of Americans supporting patients and their doctors making the decisions regarding their health care, not the government."

Swarts says a faster process is critical for those with terminal diseases such as ALS.

"We need options, and if we keep waiting for that magic bullet, we're never going to get any options," said Swarts. "The concern about safety doesn't always matter when you have a terminal disease. It will either work or it won't."

Getting drugs to patients faster has an added benefit, says Herrin.

"The goal of the Free to Choose Medicine solution is to make drugs fail faster and succeed sooner. The current drug approval process is convoluted, lengthy, and extremely expensive. In a country that prides itself on individual freedom, no American should be forced to die because government regulations can't keep up with the medical advancements of the private sector."

Andrew Whitney (agwhitney97@gmail.com) writes from Lansing, Michigan.

INTERNET INFO

“Arkansas man with ALS runs in front of FDA staff,” ALS News Now, April 9, 2019: https://www.youtube.com/watch?v=4uOjo7xhOQ


Free to Choose Medicine: http://freetochoosemedicine.com
By Ashley Herzog

With bipartisan support, Congress is moving forward with the Creating and Restoring Equal Access to Equivalent Samples (CREATE) Act to expand market opportunities for generic drugs.

The legislation addresses existing laws that make it more difficult for generics to enter the market, says Rachel Schwartz, communications director of the Association for Accessible Medicines, a generic drug industry trade group.

“In about 2007, Congress passed a law that required certain FDA-approved drugs to be more closely monitored to make sure the benefits outweighed the risks,” said Schwartz.

The U.S. Food and Drug Administration (FDA) then created the Risk Evaluation and Mitigation Strategy (REMS), a drug safety program that the FDA can require for certain medications.

Safety or Monopoly Protection?
The REMS program was developed for drugs judged to have serious or potentially fatal side effects. One example is Zyprexa, a medication used to treat schizophrenia in adults. The drug was linked to delirium and coma in a small number of patients. The FDA said the cause of the deaths was inconclusive, but because it could not rule out the drug, it issued guidelines in 2015 under REMS, restricting administration to certified health care facilities where patients can be observed after receiving the drug, among other mandates.

Although REMS can protect patient safety, it can also be misused, says Schwartz.

“Our industry supported these programs,” said Schwartz. “Unfortunately, after 2007, some brand-name drug manufacturers realized they could take advantage of a loophole to keep generics from being tested and proven to be just as safe and effective as the brand-name drug.”

Brand-name manufacturers refused to sell samples of the medications to competitors so they could test them and create a generic, says Schwartz.

“The higher the risk of the drug, [the more it] gave the brand-name companies an opportunity to say, ‘We can’t sell you these drugs; they’re too dangerous,’” said Schwartz. “It made no sense. This obviously wasn’t a safety issue—they just didn’t want the competition—they were exploiting a loophole to prevent generics from coming to the market.

“The FDA sent letters to the drug companies telling them to stop this practice so that generics could be developed, but unfortunately, those letters had no legal weight behind them,” said Schwartz.

Big Savings
The proposed legislation would change that, says Schwartz.

“The CREATE Act gives generics companies some recourse against the brand-name manufacturers so they can purchase these drugs, test them, and bring generics to market,” said Schwartz.

Schwartz says the legislation would help bring down drug prices.

“As we all know, generic prescription medications are 85–90 percent cheaper than their brand-name counterparts,” said Schwartz. “If the CREATE Act passes, patients will have access to more generics, earlier.”

An increase in availability of generics would also lower taxpayer costs of government health care programs, says Schwartz.


Fear of Litigation
The prominent taxpayer advocacy group Americans for Tax Reform (ATR) opposes the CREATE Act, arguing it will create endless litigation and suppress innovation.

“The CREATE Act modifies the FDA’s Risk Evaluation and Mitigation Strategies (REMS), a regulatory structure that applies to roughly 40 highly advanced, yet potentially dangerous drugs,” Alexander Henrie of ATR wrote in a blog post on the organization’s website in January. “REMS has been carefully enshrined in law to balance safety, innovation, and access to medicines.”

Henrie says the CREATE Act would end up reducing the availability of prescription drugs.

“It would set a precedent that undermines innovation and the safe development of medicines in favor of a system that promotes reckless litigation and grants generic manufacturers the right over an innovator’s creation under threat of lawsuit,” Henrie said. “In turn, this would undermine intellectual property protections, open the door to unjustified litigation, endanger patient and researcher safety, and suppress innovation.”

‘Addressing Patent Abuses’
Schwartz says the bill merely removes an opportunity a few companies have used to create artificial monopolies.

“Nothing here undermines innovation,” said Schwartz. “Right now, patent law allows innovators a 20-year monopoly. The reward is there. What this bill is really about is addressing patent abuses that artificially extend the monopoly,” said Schwartz. “The brand-name companies have had these drugs on the market for 15 years and have recouped the cost of investment. Unfortunately, not every company is as good at innovating. For many, they have one product bringing in revenue, and want to protect that monopoly. Even President Obama’s HHS Secretary called this ‘gaming the system,’ and it needs to end.”

Sees Simpler Solution
David Hyman, M.D., a Georgetown University law professor, adjunct scholar at the Cato Institute, and coauthor of Overcharged: Why Americans Pay Too Much for Health Care says CREATE may not get to the heart of the problem.

“You could fix abuse of the REMS system more simply than having one company sue another,” said Hyman.

“Maybe we say to the brand companies, ‘REMS requires you to provide access to samples automatically to anyone who asks,’” Hyman said. “If companies were providing the samples, it is a bit much for them to complain about the possibility of being sued. Reminds me of the definition of ‘chutzpah.’”

Ashley Herzog (aebristow85@gmail.com) writes from Avon Lake, Ohio.
Lawmakers Fight for Certificate of Need Reform in Missouri and Tennessee

Editor’s Note: With legislative sessions winding down in Missouri and Tennessee, three state lawmakers are hopeful their bills have opened the door to reform and eventual repeal of their states’ certificate of need (CON) laws. In Missouri, H.B. 433, sponsored by state Rep. Jason Chipman (R-Steelville), passed through one committee but never reached the House floor. Tennessee is considering two CON reform bills. H.B. 1085, sponsored by state Rep. Martin Daniel (R-Knoxville), would eliminate the state’s CON laws over a five-year period, with the exception of nursing homes, and H.B. 0075, sponsored by state Rep. Cameron Sexton, would address CON in distressed, rural areas. The three lawmakers discussed with Health Care News the challenges they are facing.

By AnneMarie Schieber

Schieber: Rep. Chipman, do you think your bill opened the door for CON repeal in the future?

Chipman: It is a massive change from the status quo, and what it did do was to get the nursing home industry and the hospital industry to finally come to the table and talk about some much-needed reforms.

The bill was hung up in one of the committees, and the chairman was not inclined to move on it even though it passed out of another committee. The vote might have been unanimous. I will introduce it again next year. My bill eliminates whole sections of the statutes.

For a constitutional conservative, it’s kind of fun. I want to keep driving the narrative that this program is inefficient, ineffective, and not needed. There is no guarantee baby step reforms will pass, and until the committee reforms itself out of business, I’m going to continue to file this every year. For something this big, it will take a while to get everyone used to the idea. I’m hoping that is what the reforms will do, but I still want to drive the whole thing into the ground.

Schieber: Rep. Daniel, how did your bill for repeal do this time around?

Daniel: Very well. My bill got out of the House Government Operations Committee [Daniel is chair] and now it’s in the finance committee. It did not move in the Senate, because there is a little bit of resistance over there.

I think we’ll see some reform in 2020. There were at least four bills filed this year that would have reformed the CON process. I think the Senate is starting to realize the people in Tennessee have an appetite for change here. State Sen. Bo Watson will be organizing several study sessions over the summer and fall, and hopefully we can make the case that it is time for reform.

Schieber: Rep. Sexton, your bill would reform CON in distressed areas. How would it improve access to health care?

Sexton: We have 15 economically distressed counties in Tennessee. In those counties, if there is not an emergency room or a surgical center or a particular outpatient diagnostic service, then you can bypass the CON process [if the bill passes]. We think this is a first step. Both bills are parked in committees to hold them for next year so we can tighten down the timeline to get them to the floor as we negotiate.

I think an all-out repeal is harder to do. One of the things Rep. Daniel and I have come to realize is as you start looking at things to do, then you bring more people to the table and they start offering things up. Opponents to CON reform have painted a doom and gloom scenario, and legislators can be sensitive to that. So, you have to show them that is not the case, and it may take one, two, or three steps, but in the end, I think you can get there because you’re systematically showing them that competition will work.

Schieber: Rep. Chipman, during the hearing on your bill you said opponents were actually making a case for repeal. How so?

Chipman: A banker who finances nursing homes told the committee that his industry scrutinizes projects more closely in states without CON laws. He was there to oppose repeal, but he made the argument that the free market takes care of the problem. The hospital industry stated that CON laws help them negotiate better prices on equipment because CON does not apply under a certain price threshold. Why should a government system be set up to do their bargaining?

Schieber: How do you think CON is holding back health care improvements in your state?

Daniel: We relaxed the laws a few years ago, but certainly if we want to be friendly to business and promote capital investment and access to health care, we need to do more. The hospitals and providers present a scenario of chaos and mass confusion and elderly people being tossed out onto the street, and some of the legislators are very attached to these providers, so they listen to them. But it is something we have to overcome and present a free market that will benefit everybody.

Sexton: You have to spend massive amounts of money just to get into the market, and the problem with CON is it doesn’t allow innovation without government say. We rolled back some of these laws a few years ago, and we have seen great growth and not the doom and gloom the hospitals said we would see. “You have to spend massive amounts of money just to get into the market, and the problem with CON is it doesn’t allow innovation without government say. We rolled back some of these laws a few years ago, and we have seen great growth and not the doom and gloom the hospitals said we would see.”

Cameron Sexton
TENNESSEE STATE REPRESENTATIVE

AnneMarie Schieber (amschieber@heartland.org) is managing editor of Health Care News.
Texas Senate Passes Legislation to Combat Surprise Medical Bills

By Bonner R. Cohen

By an overwhelming 29–2 vote, the Texas Senate approved legislation designed to prevent patients from being subjected to surprise medical bills.

Patients receiving surprise medical bills typically have been recently released from emergency rooms. They are often unaware the treatment they received may be from a physician or other medical practitioner outside of their health insurance network. Upon receiving bills for these services, patients learn they fall outside negotiated rates with their insurance provider and therefore might need to pay a much steeper deductible. The bills spark endless wrangling with health care providers and disgruntled patients.

Surprise billing is closely related to balance billing (the two terms are often used interchangeably), in which physicians or facilities charge patients for the portion of medical expenses not covered by the patient’s insurance, beyond the usual charges such as copays. These additional charges tend to arrive as a surprise to patients.

‘To Protect the Patients’

Senate Bill 1264, introduced by Texas state Sen. Kelly Hancock (R-North Richland Hills), would create an arbitration process that removes the patient from the billing dispute.

“The whole premise of this bill is to protect the patients,” Hancock said in a news conference after the vote. “We take them out of the process of balance billing, where they don’t have to initiate it.”

“Today’s vote means we are one big step closer to ending surprise billing for good,” Hancock told the press. “With health care costs skyrocketing, this relief can’t come soon enough.”

Under the bill, which the state Senate passed on April 16, patients would still be responsible for copayments, cost sharing, and deductibles.

A Decade in the Making

Hancock’s bill builds on legislation and corresponding steps by Texas authorities going back a decade. In 2009, Hancock, then a state representative, sponsored a bill to establish a mediation process for patients who had received surprise balance bills of more than $1,000. The next year, the Texas Department of Insurance (TDI) began accepting requests for mediation and experienced a gradual increase in such requests as more patients and providers became aware of the program.

In 2015, Texas enacted legislation lowering the dispute claim threshold from $1,000 to $500 and added assistant surgeons to the list of providers subject to mediation. The list also includes facility-based radiologists, anesthesiologists, pathologists, emergency room physicians, and neonatologists. The law increases the required notifications to patients that mediation is available to resolve billing disputes. Providers are also responsible for notifying patients that mediation is available to them on the balance bill.

Savings to Patients

According to TDI data, surprise bill mediation has saved Texas patients more than $32.8 million in health care costs since 2015, including $8 million in 2018 alone.

A medical doctor and fellow Republican opposes Hancock’s legislation.

“Senate Bill 1264 is a step in the wrong direction,” said Sen. Donna Campbell (R-New Braunfels), an emergency room physician, in a statement. “This bill moves our state closer to single payer medicine and further away from doctors and hospitals being able to operate in a free market.

“The state cannot simply wave a magic wand and make the real costs of providing health care disappear,” Campbell stated. “These costs have to be made up somewhere, either by reducing access to care or through insurance companies raising their premiums. Neither is a decent outcome for patients. Surprise medical bills do exist, not because of greedy doctors but because health insurers who charge thousands of dollars in premiums surprisingly don’t pay for health care when families need it.”

Opt-In Passed

The Senate also passed Hancock’s S.B. 1530, a companion bill which would allow federally regulated self-funding health benefit plans to opt in to the existing TDI surprise billing mediation system. Both bills have been sent to the House, where they are awaiting action.

“It’s naïve simply to argue surprise medical bills are the result of stingy insurance companies,” said Devon Herrick, Ph.D., a policy advisor for The Heartland Institute, which publishes Health Care News. “If you look at where surprise bills originate, it’s those providers patients personally do not choose or even meet prior to care. These include emergency room physicians, anesthesiologists, radiologists, pathologists, and assistant surgeons.

“These aren’t the trusted physicians with whom patients have established a trusting relationship,” Herrick said.

“Especially in the ER, patients have little discretion to go elsewhere. Thus, patients are stuck with balance billing from doctors they cannot choose or reject.”

DEVON HERRICK, PH.D.
POLICY ADVISOR
THE HEARTLAND INSTITUTE

“It’s naïve simply to argue surprise medical bills are the result of stingy insurance companies. If you look at where surprise bills originate, it’s those providers patients personally do not choose or even meet prior to care. These include emergency room physicians, anesthesiologists, radiologists, pathologists, and assistant surgeons. These aren’t the trusted physicians with whom patients have established a trusting relationship. Especially in the ER, patients have little discretion to go elsewhere. Thus, patients are stuck with balance billing from doctors they cannot choose or reject.”

Bonner R. Cohen, Ph.D., (bcohen@nationalcenter.org) is a senior fellow at the National Center for Public Policy Research and a senior policy analyst with the Committee for a Constructive Tomorrow.

Official Connections:
The 13TH INTERNATIONAL CONFERENCE ON CLIMATE CHANGE (ICCC-13) will take place on Thursday, July 25, 2019, at Trump International Hotel in Washington, DC.

The event will feature the courageous men and women who spoke the truth about climate change during the height of the global warming scare. Now, many of them are advising the new administration or joining it in senior positions.

Climate realists have established beyond a reasonable doubt that the human impact on climate is likely to be very small and beneficial, rather than harmful. Realists have proven most scientists now share this opinion, except those who have made careers out of finding a human impact and exaggerating it.

Speakers at ICCC-13 will summarize the best available climate science and recommend which policy changes are needed for America to lead a post-alarmist world in climate realism. ICCC-13 will also feature timely, in-depth, expert discussions about the “Green New Deal” and the benefits of ending the Democrats’ war on fossil fuels.

Space is very limited, so reserve your conference pass and hotel room now. Admission is $129. To register or learn more about ICCC-13, visit heartland.org or call 312/377-4000.
TN General Assembly Passes ‘Right to Shop’ Price Transparency Bill

The Tennessee General Assembly passed a “Right to Shop” bill intended to help consumers find out the true cost of the medical services they receive.

The bill, sponsored by state Rep. Robin Smith (R-Hixon), is part of the Republican-backed CARE plan, which stands for increasing consumerism, expanding access, improving rural health systems, and empowering patients.

“This bill will create a statewide database that makes the prices of services public,” Smith told Health Care News. “Right now, insured people belong to a network from which they can choose doctors and providers. But we would create a portal where people can shop for the best prices within their own network.”

The bill was awaiting the governor’s signature at press time.

Opponents of Transparency
The CARE plan, including the Right to Shop bill, has faced fierce opposition from some lobbyists, says Devon Herrick, a policy advisor to The Heartland Institute, which publishes Health Care News.

“The insurance industry considers its negotiated discounts to be proprietary,” Herrick said. “For enrollees to shop around for the best prices, they have to know what the prices are. Insurers are loath to reveal what they pay, afraid their competitors will ask for the same discounts.”

Part of the problem is that the insurers manage plans for employers, Herrick said. “Plan administrators may worry their clients—larger employers—will wonder why they reimburse expensive services when cheaper ones exist nearby,” Herrick said.

Smith says forcing insurance companies to compete with one another offers consumers the greatest benefit.

“The insurance industry has perverted market forces,” Smith said. “Many people, especially in rural areas, are discovering that increased access to health insurance does not necessarily improve access to health care. It also doesn’t improve the quality or affordability of care. Obamacare resulted in more people having insurance, but prices and availability didn’t improve because of it. We’re working to take back the idea of health care.”

Incentives to Cut Prices
When prices are transparent, insurance companies have more incentive to offer the best prices, Smith said.

“We are hoping insurers will develop their own incentive plans,” Smith said.

The CARE plan would also reform the state’s certificate of need (CON) laws, which require new medical facilities and practices to prove to the government there’s a need for their services in the community. This decreases innovation and access to services and drives up prices because of a lack of competition.

“The push for certificate of need reform is ongoing,” Smith said. “Our CON reform bill is moving through the House. In 2016, we passed a series of CON exemptions for facilities that provide medical imaging services, such as CT scans, x-rays, and MRIs. However, there’s still more that needs to be accomplished on that front.”

Smith says CON laws do particular harm to rural communities, where a dearth of providers and medical facilities makes it difficult for residents to shop around for better prices.

“We want people to be able to shop,” Smith said. “Especially in rural areas, having the opportunity to compare prices and choose the best deal empowers patients.”

Unleashing Consumer Power
Price transparency enables consumers to place pressure on providers to decrease costs, Herrick says.

“Consumers benefit from transparency by being able to shop smarter for medical care,” Herrick said. “For example, when consumers know a radiology clinic is hundreds of dollars cheaper than a similar clinic, over time providers have an incentive to lower prices.”

Herrick says the benefits of transparency compound over time.

“Consumers who are cost-savvy and know how to shop for the best deals will encourage insurance companies to lower prices,” Herrick said. “Consumers also benefit from prudent behavior, which sends a message to the suppliers of services that they have to compete for business.”

Ashley Herzog (aebristow85@gmail.com) writes from Avon Lake, Ohio.

Texas House Bill Pushes ER Insurance Network Transparency

The Texas State Legislature is considering a bill that would require freestanding emergency rooms (ERs), those separated from hospitals, to post notice of the health benefit plans for which the facility is an in-network provider.

The bill attempts to address consumer complaints that providers fail to answer questions about network status and prices because they are prohibited from doing so under the federal Emergency Medical Treatment and Active Labor Act (EMTALA). Congress passed the act in 1986 to require emergency services to treat patients regardless of their ability to pay. One complaint is facilities may tell consumers they accept insurance but not disclose the networks in which patients are covered.

In 2009, Texas passed legislation allowing the formation of independent, licensed, freestanding ERs. These facilities differ from urgent care in offering much more comprehensive service, such as trauma care, and they are staffed around the clock by ER physicians. The option was created as a partial solution to the lack of hospital ERs in remote areas.

H.B. 2041 would require these freestanding ERs to place signs regarding insurance networks throughout the facility and offer each patient written documentation of facility and observation fees and notice that treatment may not be covered as an in-network provider.

“The ERs say it violates federal law,” said Herrick. “On the other hand, I don’t know why Texas cannot regulate medical providers within its borders. A few years ago, the Texas Department of Insurance did not agree EMTALA prevented ERs from answering questions about price, if asked.”

H.B. 2041 was placed on the general state calendar April 29. The 2019 legislative session ends May 27.

—Staff reports

Official Connections:
Texas state Rep. Tom Oliverson (R-Cypress): https://house.texas.gov/members/member-page/?district=130
North Carolina Senate Rejects Medicaid Expansion

By Bonner R. Cohen

A rarely used state Senate rule and growing concerns over the potential cost of providing health care to tens of thousands of additional low-income residents in North Carolina stymied efforts to enact Medicaid expansion in this year’s legislative session.

The state Senate, by a 38–8 vote in March, approved bipartisan legislation allowing small businesses to band together and buy cheaper health insurance, after defeating efforts by Democrats to add a multibillion-dollar Medicaid expansion to the bill.

Expanding Medicaid has been a top priority for Gov. Roy Cooper and his fellow Democrats in the legislature. Senate Republicans, who hold a majority, tabled a Medicaid expansion amendment to the small-business insurance-pool bill. Under a North Carolina Senate rule, once a bill or amendment has been tabled, it cannot be brought back up in the session in progress.

Expansion Debate Could Continue

Medicaid expansion could resurface in the larger budget debate later this year.

Statehouse observers speculate Cooper might veto any budget that doesn’t include Medicaid expansion. As a result of last November’s midterm election, Republicans no longer have veto-proof supermajorities in the legislature.

Under the 2012 U.S. Supreme Court ruling on the Patient Protection and Affordable Care Act, commonly known as Obamacare, states may expand Medicaid coverage to people earning up to 138 percent of the federal poverty level, which is $16,642 per year for individuals or $33,984 for a family of four. North Carolina is one of 18 states that have not done so.

Trouble in Other States

A study by the North Carolina-based John Locke Foundation found states that have opted for Medicaid expansion have been saddled with spiraling costs that have severely strained their budgets.

In Arizona, which expanded Medicaid in 2002, “the expanded population (mostly childless adults) ended up costing two to four times the cost of covering low-income parents,” the study states. “Similar outcomes occurred in other expansion states, including Oregon, Delaware, Maine, Washington, D.C., Utah, and Vermont.”

“Medicaid expansion would cost North Carolina an estimated $6 billion between 2020 and 2039,” the study states. “To pay for the expansion, the North Carolina General Assembly would need to reduce provider payments, divert resources from other important parts of the budget such as education or transportation, or greatly increase taxes.”

“Our Medicaid program already covers over two million of the state’s children, disabled, elderly, and low-income mothers. Legislators should leave the program for the intended population rather than adding an estimated 500,000 individuals, the majority of whom are able-bodied, working-age, childless adults.”

JORDAN ROBERTS, HEALTH CARE ANALYST, JOHN LOCKE FOUNDATION

Bonner R. Cohen, Ph.D., (bcohen@nationalcenter.org) is a senior fellow at the National Center for Public Policy Research and a senior policy analyst with the Committee for a Constructive Tomorrow.

Family Planning Pilot Program Wants No Government Funding

By Ashley Bateman

The organization behind a program to provide free health care to underserved women says it has no interest in federal grant money because it wants to deliver its family planning message without government intrusion.

Healthy Tomorrows is a collaboration between a group of Michigan-based pregnancy centers and Christian Healthcare Centers (CHC), a Grand Rapids, Michigan-based direct primary care practice. The program is raising private money to provide free health care services to women as an alternative to organizations such as Planned Parenthood that refer women for abortions.

“It’s women’s health, it’s maternity care, it’s prenatal care, it’s postpartum, well-child, and ongoing care,” said Mark Blocher, CEO of Christian Healthcare Centers and organizer of Healthy Tomorrows. “Pregnancy care centers do a wonderful job at what they do, but the abortion issue has changed, the way you reach abortion-vulnerable women has changed, and we need to change with it.”

Widening Access

Healthy Tomorrows, currently in the pilot stage, provides care at the pregnancy centers and at CHC locations using CHC doctors and staff. The program will serve uninsured women ineligible for Medicaid, and Medicaid-eligible women lacking access to a primary care provider.

Blocher says he’s not concerned about other organizations’ funding.

“I’m tired of people talking about defunding Planned Parenthood,” said Blocher. “I just want to take their business away from them.”

Patients will enroll in the program through the pregnancy centers.

“One of the challenges has been creating and developing relationships with patients, and this is a start,” said Blocher.

Freedom to Practice Beliefs

Healthy Tomorrows is nonprofit and funds itself through private contributions and community grants. Because it does not promote abortion or have any connection to abortion services, it could qualify for federal grant money under the new rules for Title X family planning funding.

Blocher says he’s rejecting involvement with the government because there is nothing to say a different presidential administration wouldn’t change the rules again.

“Healthy Tomorrows wants to avoid entanglement with the inevitable government red tape that accompanies government funding,” said Blocher. “Healthy Tomorrows is an outreach from the life-affirming Christian community to pregnant women in need, and government funding introduces a third-party funding source that has the potential to undermine that message.”

Blocher says he is hopeful donors who share the organization’s beliefs will come forward to support the program.

“At the end of the day, we have the ability to take our pro-life commitment and strategically use it to change the lives of women and change the language of abortion,” said Blocher.

Ashley Bateman (bateman.ae@googlemail.com) writes from Alexandria, Virginia.
Medicaid Expansion in Kansas Fails

By Bonner R. Cohen

The Kansas State Legislature adjourned for the year after deciding not to expand Medicaid coverage to as many as 150,000 additional residents in the state.

The effort stalled at the eleventh hour, when pro-expansion Republicans in the Senate backed off by not agreeing with Democrats to a procedural vote that would have moved the bill this calendar year. The motion fell one vote short, with Senate Majority Leader Jim Denning (R-Olathe) choosing to “pass.”

“I’m not saying no,” Denning told reporters. “I’m saying this policy isn’t ready.”

Medicaid expansion seemed to be a strong possibility this year, with the support of Gov. Laura Kelly, a Democrat, and her party controlling the state legislature. Lawmakers threatened to hold up passage of the state’s budget to get action on expansion, but then a wing in the Senate fought back with a plan to reduce the size of the budget.

After legislation stalled, Denning told reporters, “it is not a question of if, but rather when and how.”

Still Debating

In its 2012 ruling upholding most of the Affordable Care Act, the U.S. Supreme Court allowed states to opt out of the law’s expansion of Medicaid, leaving each to decide whether to participate. Some states have opted for expansion, others have not, and some, like Kansas, are still debating the issue.

“None of us have any idea how this is going to move forward at this point, but this is one of the governor’s and the majority of the legislature’s, ... both of their priorities,” Sen. Barbara Bollier, a Mission Hill Democrat and supporter of Medicaid expansion, told the Wichita Eagle on March 24.

For Senate Republicans, the stumbling block is the enormous cost of the program, which they say they fear will wreak havoc on the state’s budget. There is also concern that once Kansas applies for expansion, it will be up to the federal government to determine the details of the program.

“You don’t come back and fix it next year,” Denning said. “She’s [Gov. Kelly] going to have to tell me where she’s heading.”

Free Money Is Not Free

According to the Kansas Health Institute, Medicaid expansion would cost the state $520.8 million over 10 years. Of particular worry is the federal government’s long-term commitment to cover 90 percent of the cost, with the state picking up the remaining 10 percent. Already more than $22 trillion in debt, the federal government could decide to scale back its share, leaving Kansas and other states on the hook for the rest.

Kansas House Democrats were able to use parliamentary maneuvers to ease passage in the lower chamber, but in the Senate, Republicans have the power to keep almost any bill from coming up for a vote.

Lennie Jarratt, a state government relations manager at The Heartland Institute, which publishes Health Care News, says Medicaid expansion is a bad deal for any state.

“Despite the claims of its supporters, Medicaid expansion is not ‘free money’ from Washington,” Jarratt said. “It would cost Kansas millions.”

Bonner R. Cohen, Ph.D., (bcohen@nationalcenter.org) is a senior fellow at the National Center for Public Policy Research and a senior policy analyst with the Committee for a Constructive Tomorrow.

HHS Changes Family Planning Grant Rules to Allow More Providers

By Ashley Bateman

The U.S. Department of Health and Human Services (HHS) made revisions to the rules on Title X funding to give low-income women more options for health care and family planning services.

The new rules prohibit grants to agencies that “perform, promote, refer for, or support abortion as a method of family planning,” and although agencies can give “non-directive” counseling on abortion, the new rules do not require it, which opens the door to providers that do not want to discuss that option.

Planned Parenthood states it has received a large portion of Title X funding over the years, although it doesn’t specify an exact amount. For each year since 2015, the federal government has distributed $286,479,000 in Title X funding grants, according to HHS.

Opening Up New Options

HHS announced on March 29 the Obria Group will receive $5.1 million in Title X Family Planning Funding over the next three years. The nonprofit provider oversees seven clinic partners in four California counties, offering pregnancy testing and counseling; prenatal care through delivery; HIV/AIDS testing; pregnancy ultrasound; breast, and cervical cancer testing; well-woman care and pap smears; STD testing and treatment; sexual risk avoidance education; fertility education; natural family planning; adoption referrals, and post-abortion support.

“The new Title X regulations have opened the door for the Obria Group to offer women and their families healthy, comprehensive, and life-affirming care without having to offer abortion,” said Kathleen Eato Bravo, Obria Group founder and CEO. “The [Trump] administration has opened up a new avenue of health care choices for low-income and underserved women and their families.”

Funding may be less certain for other states on the hook for the rest.

For more information, see the HHS notice.

Head to Court

At least 20 states, the District of Columbia, and the American Medical Association have filed legal challenges against HHS’s Title X rule revisions. If an injunction halts Title X funds, Obria will continue to provide care, independent of government dollars, Bravo says.

“Obria clinics are fully licensed and staffed by full-time medical staff, allowing us to address a full spectrum of medical care in addition to crisis pregnancy support,” Bravo said. “Obria is transforming health care by providing compassionate, comprehensive, life-affirming, and affordable care to men and women across the United States.”

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

“The [Trump] administration has opened up a new avenue of health care choices for low-income and underserved women and their families.”

KATHLEEN EATO BRAVO
FOUNDER AND CEO
OBRIA GROUP

INTERNET INFO

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Stenping enrollment in ObamaCare’s Medicaid expansion would protect valuable resources for the truly needy.

Find out more about freezing ObamaCare expansion enrollment at TheFGA.org.
Upcoming Medicare Insolvency Poses Big Challenges for Government, Individuals

By Kelsey E. Hackem

Medicare’s assets will be depleted by 2026, the 2019 Medicare Board of Trustees Annual Report states.

In 2018, expenditures for Medicare Part A exceeded income by $1.6 billion, and the Annual Report projects deficits for all future years until the trust fund becomes insolvent in 2026. Annual growth in Medicare Part A expenditures is projected to reach 7 percent for the next five years, rising from an annual expenditure increase of 3 percent from 2013 to 2018. The Medicare Part A trust fund “has not met the trustees’ formal test of short-range financial adequacy since 2003,” the report states.

This year’s report forecasts the same year of projected insolvency as the 2018 Annual Report found.

Cutting into Social Security

Related to the issue of Medicare insolven-cy is the connection between retirees’ Social Security benefits and Medicare, says Robert Klein, a retirement health care advisor and policy advisor to The Heartland Institute, which publishes Health Care News. Retirees will have to fund rising Medicare costs out of their Social Security checks, says Klein.

“Medicare has become a way to save Social Security,” said Klein. “You just won’t get as much Social Security. I think Medicare is wonderful if you follow the rules, but you also have to understand that it’s not free; it’s going to cut into your Social Security check, it’s going to cut into your monthly and therefore annual income, it’s going to take a huge bite out of your retirement.”

“And if it’s to work as designed, you have to have private insurance,” said Klein. “Original Medicare does not fully cover you.”

Sees Trouble Ahead

The Annual Report is 243 pages long, with a copious amount of information on the fiscal condition of Medicare.

Klein says consumers will have to read between the lines to see how the fiscal limits will impact their wallets.

“Part B must be deducted from Social Security once someone accepts Social Security and enrolls in Medicare,” said Klein. “Look at the jump as a percentage, not in dollar terms. I suspect Social Security won’t have a 6.5 percent or more cost of living allowance in 2020 to offset the increase should Medicare Part B go up to $8.80 a month. A few years ago, Social Security trustees were forecasting a COLA to never be more than 2.8 percent in the near future.”

“Those with modified adjusted gross income under $85,000 or $170,000, single or joint [filing, respectively], will be held harmless, and their Social Security check will remain mostly the same,” said Klein. “Those with higher incomes will pay more.”

According to Jane Orient, M.D., executive director of the Association of American Physicians and a policy advisor to The Heartland Institute, entitlement programs do not have enough workers contributing in order to support the current and upcoming amount of retirees.

“There is no way a retiree can be supported by only two working people,” said Orient. “Nor can the government borrow or print or tax enough to keep the promises.”

Klein says he warns prospective retirees not to count on Medicare.

“The financial services industry is not preparing their clients for this,” said Klein. “Too many see Social Security as the foundation for a financial plan. That’s a dangerous plan if you don’t factor in Medicare.”

Tax Hikes or Benefit Cuts?

The trustees’ Annual Report says without legislation to address the revenue shortfall, the trust fund assets will cover expenditures only until 2026. To illustrate how serious the deficit is, the Annual Report on page 28 states that to remain solvent during the 75-year period, the trustees use to project solvency, the standard 2.90 percent payroll tax would have to be increased immediately to 3.81 percent. If no changes are made to Medicare by 2026, the required payroll tax increase will have to be 1.02 percentage points.

Another potential solution to the lack of Medicare funds is a 19 percent cut in Medicare spending, the report states.

If the government fails to implement a solution to the Medicare funding shortfalls, affected institutions and individuals will have to adjust their behavior and expectations regarding the program. The trustees’ report recommends “that Congress and the executive branch work together with a sense of urgency to address” the Medicare challenges.

Problematic Economic Consequences

Orient says any solution will have far-reaching consequences.

“Cutting benefits or raising taxes or some combination will significantly affect the economy,” said Orient. “Draining resources from the private, the productive sector, will, of course, reduce productivity and investment. It always has.”

Orient says there is a way for prospective retirees to protect themselves.

“Social Security was never supposed to be enough to support you [fully] in retirement,” said Orient. “People will have to delay retirement, work part-time, or find other sources of income. The last is harder and harder with effectively zero or negative interest rates. Everybody who can, needs to decline Medicare and become independent of Social Security income—increasingly by continuing to work.”

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Kelsey E. Hackem (khackem@gmail.com) writes from the State of Washington.
Comparison of U.S., Canadian Systems Shows Single-Payer Is a Bad Deal

By Bonner R. Cohen

Widespread reports this spring that elderly patients in the United Kingdom were facing significant delays getting routine cataract operations coincided with the news that British rock music legend Mick Jagger underwent a transcatheter aortic valve replacement (TAVR). Jagger hasn’t said why he chose to have the risky operation in New York instead of in London, but if cataract operations are hard to come by in the United Kingdom, the advantages of having a procedure as complicated as a TAVR undertaken where it is readily available would be clear.

Distinctive Access to Quality Care
Access to high-quality health care distinguishes the pluralistic, public-private U.S. system from traditional singer-payer systems such as those in the United Kingdom and Canada, writes Brett J. Skinner, founder and CEO of the Canadian Health Policy Institute (CHPI) and editor of CHPI’s online journal Canadian Health Policy, in a Fraser Institute blog post titled “Single-payer Health Care Warning for the U.S.” Americans spend more money on health care on average “but get faster access to more and better medical resources in return for the money spent,” writes Skinner.

Health care only appears to cost less in Canada than in the United States partly because Canadian government health insurance does not cover any advanced medical treatments and technologies that are commonly available to Americans,” writes Skinner. “If Canadians had the same access to the quality and quantity of health care resources that American patients enjoy, the government health insurance monopoly in Canada would cost a lot more than it currently does.” Americans spend 55 percent more than Canadians do on health care as a percentage of their national income, yet the United States has 327 percent more MRI units and 183 percent more CT scanners per capita than Canada does, Skinner writes. The United States also performs twice as many inpatient surgical procedures per capita as Canada.

“Plus, American patients do not wait as long as Canadians for medical care,” writes Skinner. “The U.S. has 14 percent more physicians and 19 percent more nurses per population than Canada; U.S. hospitals are newer and better equipped than Canadian hospitals; and Americans have access to more new medicines than Canadians,” writes Skinner.

Universal in Name Only
A standard criticism of the U.S. system is that it doesn’t provide universal health insurance coverage. Skinner argues the definition of “universal” may be in the eye of the beholder. He cites data from Statistics Canada showing an estimated 1.7 million Canadians aged 12 or older had no access to a regular family physician in 2007.

“Without access to a family doctor, a person can’t obtain regular primary care or referrals for elective specialty medical services,” writes Skinner.

“When Canadians can’t get access to health care because they can’t find a physician or wait so long that they are effectively uninsured, they are no better off than uninsured Americans,” writes Skinner. “Access to a waiting list is not the same thing as access to health care.”

Research shows the actual number of “effectively” uninsured Americans is significantly less than the 47 million reported and that being uninsured is only a temporary condition, says Skinner.

“The point of this comparison is not to advocate for an American-style health care system,” writes Skinner. “The point is to show that all of the costs of a single-payer health care system are not as obvious as the dollars spent.”

BRETT J. SKINNER
FOUNDER AND CEO
CANADIAN HEALTH POLICY INSTITUTE

Georgia Pares Back CON Laws
By Andrew Whitney

After some back-and-forth in the Georgia General Assembly, Gov. Brian Kemp signed into law significant reforms to the state’s certificate of need (CON) process.

Act 41 changes the capital expenditure threshold for any health care facility requiring CON from $2.5 million to $10 million and from $1 million to $3 million on diagnostic equipment. The new law limits the geographic boundaries of entities that can object to a CON application to a 35-mile radius, and it allows private doctor groups to operate imaging facilities without CON as long as the applicant physician is present 75 percent of the time. It also stops hospitals from using “medical use rights” to block competition.

Act 41 is a modified version of House Bill 198, which failed to make it out of the House. The Senate reworked the bill to make less sweeping changes. The new law does not allow hospitals to establish standalone emergency rooms or cardiology ambulatory surgery centers, for example.

Unleashing Innovation
This reform should allow more health care innovation in the state, says Matt Glans, a senior policy analyst for The Heartland Institute, which publishes Health Care News.

“Like all industries, when the U.S. health care sector has improved, it’s been from competition and innovation born in the free market, not because of government regulation,” said Glans.

In theory, CON laws allow a critical assessment of demographic needs and curb unnecessary spending, but they have had adverse effects, says Glans.

“One of the big problems with CON laws is the inappropriate influence given to competitors during the vetoing process,” said Glans.

“When a provider applies to enter a new market, competitors often use the CON process to protest potential competition, which is currently allowed in many states. Repealing CON laws ends a burdensome and unnecessary regulation that stifles state health care markets.”

Andrew Whitney (agwhitney97@gmail.com) writes from Lansing, Michigan.

“Warning for the U.S.”

“When Canadians can’t get access to health care because they can’t find a physician or wait so long that they are effectively uninsured, they are no better off than uninsured Americans. Access to a waiting list is not the same thing as access to health care.”

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“Single-payer Health Care Warning for the U.S.”

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Tightly Controlling Access
“If you look around the world, single-payer systems all suffer from rationing, bureaucracy, shortages, and excess demand,” said Devon Herrick, Ph.D., a health care policy advisor for The Heartland Institute.

“In tax-funded systems, medicine becomes political,” Herrick said. “There are more votes to be gained by pleasing the majority of the people who are not sick. Thus, systems like those in Canada and the U.K. ration by placing emphasis on primary care but tightly controlling access to specialty care.”

Bonner R. Cohen, Ph.D., (bcohen@nationalcenter.org) is a senior fellow at the National Center for Public Policy Research and a senior policy analyst with the Committee for a Constructive Tomorrow.
Central Planning Destroys Health Care Innovation

By Chad Savage, M.D.

Direct primary care (DPC) doctors have found ways to improve health care access, include telemedicine, and offer deeply discounted rates on medications, labs, and imaging for a low-cost monthly membership, similar in design and value to Costco. Matched with appropriate insurance coverage, DPC can save patients thousands of dollars per year compared to the current broken, highly inefficient system.

DPC is one of the most innovative areas of health care for one reason: It is not part of the centrally controlled (socialized), government-managed system. DPC doctors offer fantastic care, and they do so without the artificial restrictions imposed by governments and insurance companies, who exert significant power over the practice of medicine.

DPC doctors, along with free-market entrepreneurs, are competing to find solutions to the problems facing our health care system in ways the government/insurance-controlled system can’t or won’t.

This doesn’t mean free enterprise is easy. As a direct primary care physician, building my practice from the ground up was hard, risky, and stressful. I had to save money to cover my expenses until the new practice grew to the point it could be successful and self-sustaining. I also had to create a business plan, rent space, hire staff, market my new practice model, and jump through countless government-imposed hoops. And even after all the hard days and long nights of work, there was never any guarantee of success.

Government’s Bureaucratic Obstacles

Taking part in creating a new type of medical practice is unquestionably a difficult endeavor, but as challenging as it has been, I can’t help but think how utterly impossible it would have been to accomplish it under a socialized system. In such a system, a doctor who wants to develop a new practice, innovative service, or fancy new widget that can help patients cannot do so by relying on passion, talent, and hard work alone. In a socialized system, innovation exists only if permission can be secured from that system’s army of slow-moving, often uninterested government bureaucrats and central planners, because individuals do not own the means of production in socialist systems.

Nothing about central planners makes them prescient, of course, and history is full of examples of government agents failing to innovate even when a solution was obvious.

Bureaucrats’ inability to grasp a new idea is never proof of its likelihood of failure. Numerous culture-changing innovations were initially rejected by others. For examples, see FedEx’s Frederick Smith and Apple’s Steve Jobs. On this point, Jobs once said, “Our job is to figure out what they’re [the public] going to want before they do,” adding, “People don’t know what they want until you show it to them.”

Neither Practitioners nor Customers

One of the biggest problems with socialized systems is that the government agents making the decisions often have no knowledge of the industry they are regulating, and even when they do, they typically aren’t the customers. They don’t know if a new gadget would make a farmer more productive, a TV thinner, or blood draws less painful. How could they? They would have to possess near-omniscience to perceive all potential applications—applications that the end user, the customer, often readily grasps.

How many existing innovative products and ideas would have died at the hands of bureaucrats, had they been in charge? How many great ideas have already been snuffed out by regulators the world over? How do you measure the loss of innovation that never occurred?

Because of bureaucratic hurdles and the risks of challenging them, countless great ideas have likely died on the lips of innovators in socialist countries with the defeated whisper, “Why bother?” and we are all likely worse off because of it.

Imagine where our world would be if the creative potential of the hundreds of millions of people who toiled under socialist regimes in the twentieth century had been unleashed instead of being crushed. Embracing the way of innovation, entrepreneurship, and free enterprise isn’t always easy, but give me the opportunity to improve the world while improving myself and I’ll take that any day of the week.

Chad Savage, M.D. (info@d4pcfoundation.org) is a policy fellow at the Docs 4 Patient Care Foundation, a policy advisor at The Heartland Institute, and the founder of the DPC practice YourChoice Direct Care in Brighton, Michigan. A revised version of this article was also published at The American Thinker.
COMMENTARY

Panic Over Measles Leads to More Government Intrusion

By Jane M. Orient, M.D.

In general, it is not a good idea to panic about anything. The panic itself often causes more harm than the original threat.

Crisis situations, real or contrived, lead to new, intrusive laws the public would never accept otherwise. We supposedly cherish freedom, but if we believe the world will end if we don’t act now, we may clamor for the government to save us. Cynical politicians bent on increasing their power never let a crisis go to waste.

Something like the Green New Deal—the end of our comfortable, prosperous lifestyle—requires a truly apocalyptic threat. But to eliminate our freedom to decline a medical treatment, the threat that “millions will die” of the original threat.

Itate all but very narrow exemptions to the 60 shots now mandated for school attendance.

Vaccine Police

In New York City, people are receiving summonses based on Mayor Bill de Blasio’s emergency order. Everybody, adult or child, who lives in one of four ZIP code areas must get a mumps, measles, and rubella shot, prove immunity, or face the prospect of a $1,000 fine ($2,000 if you don’t appear as ordered). Your religious exemption is overridden. The threat of six months in prison and the prospect of forcible vaccination were removed before a hearing on a lawsuit brought by five mothers. The judge dismissed the case.

New York City Health Commissioner Oxiris Barbot said the purpose of the fines is not to punish but to encourage more people to proclaim the message that vaccines are safe and effective. Get it? If you say something to avoid a fine, that makes it true.

It’s about the need for herd immunity, they say. We need a 95 percent vaccination rate to achieve herd immunity to measles. With only 91 percent or so, we are having outbreaks! If we could just vaccinate another 4 or 5 percent!

Mayor de Blasio has a point about vaccinating everyone. Adults are getting measles because their shots have worn off. It is likely that we have survived for decades with a large part of the adult population vaccinated but not immune. So where do the mandates stop?

False Outbreak Alarms

Outbreaks have occurred in populations with a near 100 percent vaccination rate. Was it vaccine failure? Or was the vaccine not refrigerated properly? Or was a claimed outbreak not real?

Alarm over an outbreak in Ann Arbor, Michigan was called off when a special test, a reverse transcriptase polymerase chain reaction, showed a strain related to a vaccine rather than a wild-strain measles virus. Some 5 percent of people vaccinated may get an illness that looks like measles, but it is just a “vaccine reaction,” which appears to have been the case in Ann Arbor.

Can vaccinated people shed live virus? Yes. Should you keep your immunocompromised child away from recently vaccinated people? Just asking.

Safe and Effective?

Like all medical treatments, vaccines are neither 100 percent effective nor 100 percent safe. Read the FDA-required, FDA-approved package inserts. Arizona legislators failed to move on a bill that would have required making these available to parents in obtaining informed consent. (You can get them on the internet.)

There are tradeoffs with vaccines: risks and benefits. But in the panic about measles, the right to give or withhold informed consent—fundamental in medical ethics as well as U.S. and international law—is being sacrificed. And so is freedom of speech.

The threat of infectious diseases is real and increasing. We need more robust public health measures, better vaccines, and improved public knowledge and awareness. Deploying vaccine police and shutting down debate will erode trust in health authorities and physicians, although more people may get their shots.

Such heavy-handed measures will not defeat the real enemy: measles and worse diseases.

“The threat of infectious diseases is real and increasing. We need more robust public health measures, better vaccines, and improved public knowledge and awareness. Deploying vaccine police and shutting down debate will erode trust in health authorities and physicians, although more people may get their shots. Such heavy-handed measures will not defeat the real enemy: measles and worse diseases.”

A project of the Galen Institute, ObamaCareWatch is your go-to online destination for credible, substantive news about the health overhaul law plus the most cogent commentary and analysis from free-market health policy experts.

Jane Orient, M.D. (jane@apsonline.org) is an internist and executive director of the Association of American Physicians and Surgeons (AAPS). This article is excerpted from a paper published on the AAPS website and is reprinted with permission.
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