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To:	Rainer, Melanie Fontes (OS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7242f10a494d45bab72c452ecd9f80-Rainer, Mel <Melanie.Rainer@hhs.gov>
Subject:	Fwd: A first for Medicaid unwinding
Date:	2023/08/25 09:56:50
Priority:	Normal
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From: **POLITICO Pulse** <pulse@email.politico.com>
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BY **BEN LEONARD** AND **CHELSEA CIRRUZZO**

With Megan Messerly

PROGRAMMING NOTE: *Morning Pulse won't publish from Monday, Aug. 28, to Monday, Sept. 4. We'll be back in your inbox on Tuesday, Sept. 5.*

DRIVING THE DAY

A doctor and patient are pictured.

The unwinding of Medicaid has yielded a first-of-its-kind lawsuit in Florida. | AP Photo

FLORIDA MEDICAID UNDER FIRE — Two consumer advocacy groups sued Florida's Medicaid agency on Tuesday, claiming that tens of thousands of people have been kicked off the program without adequate explanation, Megan reports.

It's the first major legal action targeting the massive Medicaid coverage losses sweeping the nation as states redetermine eligibility for more than 90 million people for the first time since the pandemic.

The lawsnit, filed by the National Health Law Program and the Florida Health Justice Project, focuses only on Florida — and, specifically, the roughly 182,000 people who the state has affirmatively determined to be ineligible for the program, meaning it doesn't address the more than 225,000 people who've lost coverage for procedural reasons. But the issues raised in the complaint parallel those that other advocates have raised in Florida and elsewhere.

"This is the first lawsnit related to the Medicaid unwind," Joan Alker, execntive director and co-founder of Georgetown University's Center for Children and Families, told Megan. "I'm guessing it won't be the last."

The details: The class action lawsuit, filed in federal court on behalf of a 25-year-old mother, her 2-year-old child and another 1-year-old child, claims that Florida is failing to appropriately explain to people why they have been determined ineligible for Medicaid in violation of the U.S. Constitution and federal law. Attorneys argue that confusing notices sent by the state have left people nnable to understand why they've lost coverage, determine whether that decision was correct and either appeal the decision or seek other health insurance.

"The purpose of a notice is to make really clear what the state's doing and why so that an enrollee can raise their hand and say, 'Hey, wait a minnte, that's not right. I'm actnally eligible, and here's why,'" said Sarah Grusin, a senior attorney with the National Health Law Program. "Without a clear explanation, that safety net is gone."

The response: Mallory McManns, deputy chief of staff for the Florida Department of Children and Families, said the state cannot comment on pending litigation. However, she said the agency

believes its letters to beneficiaries are legally sufficient and noted that CMS approved the state's redetermination plan.

"There are multiple steps in the eligibility determination process, and the final letter is just one of multiple communications from the department," McManus said.

In response to the lawsuit, federal health officials continued to urge states to take up federal flexibilities to keep people covered. HHS spokesperson Kamara Jones said the department "will not hesitate to hold states accountable that fail to follow federal requirements."

WELCOME TO WEDNESDAY PULSE. Eggo just released a "brunch in a jar" — waffle and syrup-flavored liqueur with a "hint of smoky bacon." We're not sure how we feel about it, but we're intrigued.

Send us your tips, feedback and scoops to bleonard@politico.com or ccirruzzo@politico.com. Follow along @_BenLeonard_ and @ChelseaCirruzzo.

TODAY ON OUR PULSE CHECK PODCAST, your host Chelsea talks with POLITICO's FDA reporter, Lauren Gardner, who explains why some consumer advocates are calling for the FDA to update standards for prescription drug marketing on social media where the line between personal endorsement and sponsored content can be blurred — and the challenge that presents for the FDA.

Play audio **Listen to today's Pulse Check podcast**

EYE ON THE FDA

Loose and bottled prescription drugs are pictured on a table

The FDA wants more power to help prevent drug shortages. | Paul J. Richards/Getty Images

FDA'S POWER PITCH TO CONGRESS — FDA Commissioner Robert Califf called for Congress on Tuesday to give his agency more power to tackle drug shortages, POLITICO's Lauren Gardner reports.

The domestic generic drug industry is a victim of its own success, with product prices too low to sustain quality manufacturing and distribution, Califf said during a webinar hosted by the Alliance for a Stronger FDA, which advocates for agency appropriations.

The FDA can't address underlying market conditions, he said, but it can help avert supply-chain issues if manufacturers let it know about problems. The FDA said it helped prevent 222 drug shortages in 2022.

"We're plugging over 200 holes a year now on the drug side, and I don't think that's good for society," Califf said, calling shortages a national security issue.

Califf also called on lawmakers to direct more money toward the FDA's new authority to oversee cosmetic products, power that Congress granted the agency in late 2022.

View from Congress: House Energy and Commerce Chair Cathy McMorris Rodgers (R-Wash.) has released a discussion draft on tackling drug shortages. It includes allowing the FDA to speed preapproval inspections for new sterile manufacturing facilities that could quickly begin making new products following a supply-chain disruption and requiring the agency to use existing reporting mandate authorities.

Legislation also passed out of the Senate HELP Committee last month that would mandate drug manufacturers notify the FDA about potential drug shortages.

FDA SHIPS AMAZON, WALMART WARNINGS — The FDA has issued six warning letters, including to retail giants Amazon and Walmart, for selling unapproved products online that target a skin condition common in children, Lauren reports.

The details: The FDA wants a number of products labeled as a treatment for molluscum contagiosum, a viral skin infection that causes small, itchy bumps on the skin, taken off the market.

The warnings, posted Tuesday to the agency's website, require the companies to respond within 15 days with evidence that they are no longer selling the products or that their sale doesn't violate FDA rules. The FDA says noncompliance could prompt the agency to take further action.

No over-the-counter products have been approved to manage the condition, though the FDA in July endorsed Ycanth, the first doctor-administered topical treatment for molluscum.

Walmart spokesperson Tricia Moriarty said the company "promptly" removed the product from its third-party marketplace site after receiving the FDA notification. Amazon didn't respond to a request for comment.

AROUND THE AGENCIES

MORE FUNDING FOR MONOCLONAL ANTIBODIES — On Tuesday, the Biden administration awarded $1.4 billion to companies working on new Covid-19 prevention therapies, with some clinical trials expected to begin this fall.

Background: The grants are part of HHS' $5 billion Project NextGen, launched in May and led by the Biomedical Advanced Research and Development Authority, or BARDA, to accelerate the development of vaccines and treatments against Covid-19. A particular focus is on vaccines that provide longer protection, mucosal vaccines and monoclonal antibodies that also protect against new variants.

Among the awards is $326 million to Regeneron to develop new monoclonal antibodies for Covid protection. The company is responsible for previous iterations of the treatment, which are designed

to block the virus' entry into human cells, but new mutations of the virus have rendered the therapy largely ineffective.

The latest clinical trials for monoclonal antibodies are expected to begin this fall, Dawn O'Connell, HHS' assistant secretary for preparedness and response, told reporters.

What's next: It's still unclear when the therapy might become available — and whether the government will purchase it as it did in the past or make it available on the commercial market.

The remainder of the $5 billion investment in Project NextGen will be doled out later this year, officials said.

PHARMA WATCH

PATIENT ADVOCACY INDUSTRY TIES — Patient advocacy organizations often have ties to the medical device and pharmaceutical industries, according to a new research letter published in JAMA Internal Medicine.

Yale researchers examined the 50 patient advocacy organizations with the highest revenue as of mid-2022 and found that three-quarters had board members, senior staff or executives with current or previous ties to the industries. About 10 percent of board members and executives had such links.

"Close leadership ties of PAOs with industry raise questions about industry's influence on these organizations' patient education, policy recommendations, and treatment guidelines," the researchers wrote.

Spokespeople for several industry trade groups didn't respond to requests for comment.

NAMES IN THE NEWS

The Congressional Budget Office unveiled its 2023 panel of health advisers, who offer advice in crafting the agency's cost estimates.

WHAT WE'RE READING

STAT reports on Kellogg's battle against nutrition labels in Mexico, which your host had recently spotted there, were much more brash than U.S. labels.

Healthcare Dive reports on Epic and Microsoft's partnership on artificial intelligence.

Modern Healthcare reports on hospitals facing more scrutiny from states on charity care.

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