


Firefighters relieved as Board of Pharmacy delays vote on promising medication it tried to ban

After seven hours of discussion and public comment, the state Board of Pharmacy decided not to decide and will take up the matter again on Sept. 12. |  1



SLIDE 1 OF 3

Volunteer Fire Foundation founder Jacquie Jorgeson, center, with Integrative Healers Action Network co-founders Jenny Harrow-Keeler, left, and Dr. Jen Riegler during a health and wellness event hosted by the two organizations for volunteer firefighters at Gold Ridge Fire District station in Sebastopol, Calif. on Friday, April 9, 2021. (Photo: Erik Castro/for The Press Democrat)

AUSTIN MURPHY

THE PRESS DEMOCRAT
August 1, 2024, 5:39PM

In the end, after nearly seven hours, they punted.

The California State Board of Pharmacy met Wednesday in Sacramento to take “possible action” on new regulations to restrict a group of drugs known as Category 1 sterile compounded substances, including one that firefighters say has the potential to prevent cancer.

The controversial new rules, if adopted, would make it much more difficult for Californians to get medications they’ve long used for relief from such ailments as cancer, long COVID, cystic fibrosis, Lyme disease and many others.

One of the substances the Board seeks to regulate further is glutathione, an antioxidant made in the liver and other tissues of the human body.

In compounded form — as a number of Sonoma County firefighters and their advocates testified during the meeting’s several comment periods — it has shown promise in lowering levels of toxins often found in high concentrations in the bodies of some firefighters.

But instead of rubber-stamping the latest version of the regulations and proceeding to a 15-day comment period that would keep the new rules on track for passage, the Board decided, after a lengthy back and forth that it would take no action.

Members decided to “press pause,” as one put it, and pick up the discussion at its next meeting, on Sept. 12.

That pause pleased board critics who regard the proposed rules as looming disaster for patients who rely on those compounded products.

The Press Democrat

Breaking News Alerts

First and factual. Get the details you need from the PD newsroom team.

Sign me up

“I took some encouragement from that,” said Tenille Davis, chief advocacy officer for the Alliance for Pharmacy Compounding, a trade group representing the country’s compounding pharmacies.

Compounding is the pharmaceutical process of combining ingredients to create medications tailored to the needs of individual patients — medicine not available in a regular CVS or Walgreens.

Sterile compounding, which takes place in specially licensed facilities, is the method of preparing those medications in a sterile environment to prevent contamination.

Glutathione and methylcobalamin, a form of vitamin B12, are currently on the Food and Drug Administration’s “interim bulk list,” Category 1. That means compounding pharmacies have the green light to dispense it.

That applies in all but one of the United States.

Even though it’s had no laws on the books with regard to compounding those Category 1 substances, California “has deemed that compounding inappropriate,” said Davis.

“It’s never been against the law in California, but the California Board of Pharmacy has taken the stance that it was.

“It took several pharmacies” — eight, actually — “to the Administrative Law Judge, and lost those cases. But the California Board has the authority to overturn that judge’s decision. They overturned the (judge’s) decisions and disciplined those pharmacies anyway.”

Emails sent to six Board members and executive director Anne Sodergren in July were not returned.

The Board’s previous proposed regulation, unveiled in June, outlawed compounding with items from the FDA’s interim Category — including glutathione.

That proposal was met with intense criticism. In this latest iteration, the Board provided a carve-out, allowing compounding with glutathione and methylcobalamin.

But that carve-out that comes with a number of requirements so onerous, critics say, that they’ll make the cost of compounding prohibitive.

Pharmacies can make glutathione and methylcobalamin — but only as a Category 3 sterile compound, said Davis, who ran a compounding pharmacy for 16 years, “which means they have to be made to the highest standard of any type of sterile compounding.

“The board is treating them as inherently more dangerous than other drugs, even though they’re essentially supplements — antioxidants, B vitamins.”

Scott Brunner, CEO of the Alliance for Pharmacy Compounding, said the California Board has proposed regulations that “go well beyond national standards from the U.S. Pharmacopeia” — the highly respected, widely recognized gold standard in this field — “but has failed to demonstrate how the excessive regulation makes patients safer.

“We’ve asked them multiple times to show us the science, show us their studies that support what they’ve proposed. Nothing but crickets in response.”

Wednesday’s meeting was prolonged by dozens of passionate, angry 3-minute comments from members of the public. Many made no attempt to disguise their indignation.

Amy Segui, an assistant fire marshal with the Petaluma Fire Department, told the Board how nebulized glutathione treatments had lowered the levels of toxins and PFAs — “forever chemicals,” that had built up in her body during her 7-year firefighting career.

After recalling the several colleagues she’d lost to cancer, she noted, “We all pay for the cancer rider on our [life] insurance because it feels like an inevitability.

“Firefighters risk their lives every day in the course of this job,” she declared. “They shouldn’t have to accept the inevitability of a death by cancer if we make it to retirement.”

“Every day we’re putting our lives on the line to save you and your loved ones, take you to hospital when you need it, save your home when it’s a risk,” she declared.

“It’s time for you to put yourself out there for us.

“What we’re asking for is a human right — a legal right to safe legal medication that could be the difference in us ending our career safely and getting to spend time with our loved ones.”

The Press Democrat

Daybreak newsletter

Kickstart your mornings with a roundup of the latest news, ensuring you step out the door fully informed. Arrives in your inbox at 8 a.m.

SIGN ME UP!

She pleaded with the Board to tap the brakes. “Just because there’s a motion on the table doesn’t mean you have to continue. You can make a new motion.”

Her suggestion took root. Board member Nicole Tibeau spoke of her own experience with chronic fatigue syndrome, which she treated with compounded medications.

“That shifted the tone and brought things to a more reflective place,” said Jacqui Jorgeson, founder of the Santa Rosa-based Volunteer Fire Foundation, who traveled to Sacramento to look Board members in the eye as she made her case.

Board member Jeff Hughes, a longtime firefighter and former Fire Captain from Orange County, then spoke of colleagues he’d lost. He needed to make sure that “firefighters and the people that need these medications” would not lose access to them.

"I have to know that, before I made my vote."

And so, after nearly seven hours, the decision was made. They would punt, and try again in September.

You can reach Staff Writer Austin Murphy at austin.murphy@pressdemocrat.com or on Twitter [@ausmurph88](https://twitter.com/ausmurph88).

The Press Democrat

In the Newsroom

Get the stories behind the headlines, plus other insights, from PD Executive Editor Chris Fusco. Delivered to your inbox every other Thursday.

SIGN ME UP!

SPONSORED CONTENT



 **Costco Shoppers Say This Wrinkle Cream Is "Actually Worth It" [↗](#)**

BY [BRUNCHESNCRUNCHES.COM](https://brunchesnocrunches.com)

Around the Web

REVCONTENT

Diabetes is Not From Sweets!
Meet the #1 Enemy of Diabetes
[Health-Review24](#)

Joint Pain? Doctor Says Do This
First Thing Each Morning
(Simple)
[WellnessGaze Joint Pain](#)

Heart Surgeon Begs Americans
Over 50: "Stop Eating This for
Breakfast"
[Gundry.MD](#)

Plastic Surgeon Tells: If You Have
Wrinkles, Do This Immediately
(It's Genius!)
[Beverly Hills MD](#)

Diabetes Is Not from Sweets! Meet
the Number One Enemy
[WellnessGuide](#)

Benefits Seniors Are Entitled To
In CA, But Often Forget To Claim
[Super Savings](#)

MD: If You Have Dark Spots, Do
This Immediately (It's Genius!)
GundryMD

Brain Scan Uncovers Real Cause
of Tinnitus and Its Remedy (It's
Genius)
WellnessGaze Tinnitus

Simple Method Can Restore Your
Vision Naturally (Watch)
WellnessGaze Vision

UPDATED: Please read and follow our commenting policy:

[Send a letter to the editor](#)

- *This is a family newspaper, please use a kind and respectful tone.*
 - *No profanity, hate speech or personal attacks. No off-topic remarks.*
 - *No disinformation about current events.*
 - *We will remove any comments — or commenters — that do not follow this commenting policy.*
-

Our Network