

Firefighters say this medicine could save their lives. Why does California want to restrict it?

Some Sonoma County firefighters are angry that the Board of Pharmacy seems determined to cut off access to a drug that could extend their careers — and lives. | 



SLIDE 1 OF 8

Santa Rosa Firefighters exit a home on the southeast side of Humboldt and Seventh St., in downtown Santa Rosa, after dousing a blaze on the top floor of a home, Tuesday, July 30, 2024. (Kent Porter / The Press Democrat)

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THE PRESS DEMOCRAT
July 31, 2024, 6:57AM

Among the 6,300 firefighting personnel swarming the massive Park Fire north of Chico this week was Bob Molesworth, an engineer with the Sonoma Valley Fire District.

That's remarkable in its own right: Molesworth, who's been fighting fires for 22 years, was diagnosed with bladder cancer two years ago.

Doctors performed a transurethral resection, and injected chemotherapy into his bladder. "It was like it marinated in there for an hour," he recalled.

After two procedures, Molesworth went into remission. Earlier this year he took part in a pilot research study, a 12-week treatment that dramatically lowered the levels of harmful toxins and PFAS "forever chemicals" in his body.

That study was centered on a compounded substance called glutathione (glue-tuh-THIGH-own), an antioxidant that has shown great promise in lowering the levels of toxins found in the bodies of firefighters, whose line of work puts them at greater risk of cancer than the general population.

It was ironic to some and infuriating to others that while Molesworth and thousands of his firefighters were battling the Park blaze on Wednesday, the California State Board of Pharmacy was meeting in Sacramento, 100 or so miles south, with the express purpose of severely restricting Californians' access to Category 1 sterile compounded substances — including glutathione.

After a contentious, seven-hour meeting punctuated with numerous scathing public comments, the Board decided to press "pause," as one member put it.

Instead of proceeding to a 15-day comment period that would have kept the new rules on a fast track to passage, the Board read the room, then tapped the brakes, deciding it would take no action. It will resume discussion at its next meeting, on September 12.

The delay was good news not just for firefighters and their advocates. The controversial new rules, if adopted, would make it more difficult for Californians to get the "Category 1"

compounded medications that give them relief from such ailments as cancer, long COVID, cystic fibrosis, Lyme disease, chronic fatigue syndrome and many others.

“Incredibly encouraging” study results

Jen Riegler is a licensed naturopathic doctor who, along with her husband, Dr. Chris Holder, runs Wild Oak Medicine in Santa Rosa. Riegler, who directed those glutathione-centered pilot studies, invited the Board during Wednesday’s public comment period to inspect her data. She assured members that she’d been using compounded glutathione for years and that it is “incredibly safe and efficacious.”

To conduct those studies, using a small number of area firefighters, she partnered with the Integrative Healers Action Network and another Santa Rosa-based nonprofit, the Volunteer Fire Foundation,

The results, she said, have been “incredibly encouraging.”

The first round, in 2023, included firefighters from three local agencies. They were tested before treatment, halfway through, and just after completion. The total number of high-range (95th percentile) toxins across all participants decreased 72.5%. Among the top three most prevalent toxins was glyphosate, with many participants initially showing levels two to three times the 95th percentile. By the end of treatment, glyphosate levels decreased 93%.

In the second round, earlier this year, the total number of high-range toxins across all 11 firefighters decreased 81.4%. Perhaps the most exciting result was that the total number of high-range PFAs, or “forever chemicals,” decreased by 80%.

“It’s a small sample size,” allowed Jacqui Jorgeson, founder of the Volunteer Fire Foundation. “But we feel the ripple effects of this study can’t be overstated for the fire service at large.”

Their hope is to get enough data to persuade firms or other entities to cover the costs of the tests — around \$5,500 per firefighter — so the departments don’t have to dip into their own budgets “to pay for their own salvation,” as she put it.

But that research now stands to be kneecapped by the Board of Pharmacy, which is poised to effectively cut off access to compounded glutathione. That, said Riegler, “would be a major, major loss for our patients.”

She has no answers, Riegler informed the Board during her public comment on Wednesday, why it is restricting these medicines.

“I am absolutely confused as to (why) this is going forward.”

Hard line against compounding pharmacies

The reasons for the Board’s actions are unclear.

It did not respond to a list of questions The Press Democrat emailed on July 17 to its executive director, Anne Sodergren. (A public information officer with the Board acknowledged receipt of the questions the next day.) Emails to six Board members went unanswered.

Compounding is the pharmaceutical process of combining ingredients to create a medication tailored to the needs of an individual patient — 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.

In the past, the Board has justified its hard line against pharmacies that compound sterile drug products using bulk substances such as glutathione and or methylcobalamin, a form of vitamin B12, by pointing out that those substances lack a United States Pharmacopeia drug “monograph.”

According to the USP website, a monograph outlines the quality expectations for a medicine and describes the tests for validating that the medicine and its ingredients meet those standards.

But, as lawyers for compounding pharmacies sued by California’s Board of Pharmacy have pointed out, both federal law and California law allow their clients to use glutathione in their compounded sterile drug products even without the monograph. Both substances appear on the FDA’s Category 1 list, making them lawful to compound.

The Board has declared compounded sterile drug products “adulterated” if they contain “nonpharmaceutical grade” drug components such as glutathione or methylcobalamin.

However, as Amy Summers, a doctor of pharmacy and a consultant for compounding pharmacies, has pointed out, “the board’s standards of ‘pharmaceutical grade’ and ‘nonpharmaceutical grade’ are not even defined terms under California law, federal law, or elsewhere in the compounding industry.”

The Board members “aren’t legislators,” said Jorgeson. “They don’t have the jurisdiction to make a medicine illegal. So they’re taking this path. They’re essentially shadow-banning these legal substances.”

Losing access to this medication, she said, means “losing the most promising method doctors have to protect firefighters from cancer.”

“Good news for firefighters”

The leading cause of death for firefighters is not fire. In 2023, according to the 348,000-member International Association of Fire Fighters, 72% of its line-of-duty deaths were from occupational cancer.

That’s alarming but not surprising to Molesworth, who told his urologist after undergoing his second transurethral resection in two years, “You’re a really nice guy, but I don’t want to keep coming back here annually to do this same procedure.”

Before beginning Riegle’s glutathione protocol, Molesworth had 16 toxins identified in his body that registered in the “high” range. After a 12-week course, only two of those toxins were still in that range. In all, tests revealed elevated levels of 33 different toxins in his body. After the study, 20 of those toxins had returned to normal range.

Starting his treatment, Molesworth had elevated levels of 12 different PFA “forever chemicals” (per- and polyfluoroalkyl substances) in his body — nine high, three moderate. After treatment, all had decreased, with six returning to normal levels.

Joe Neeley, a retired geologist and volunteer at the Sonoma Valley Fire District, has been a firefighter for three decades. A prime candidate for Riegler’s first pilot study, he was also a skeptic.

After a meeting where the program was explained in detail, he told Jorgeson that “any new, untested scientific claim” prompted him to “put on my skeptic hat and say, ‘OK, you’ve gotta prove it to me.’”

When the halfway test results came in, and he saw his toxin levels dipping, Neeley said, “OK, we’ve got something here.”

Upon seeing his final numbers, he remembers thinking, “This is good news for firefighters.”

Another participant in that study was Steve Akre, chief of the Sonoma Valley Fire District, now in his 37th year as a firefighter.

“I had 12 categories that were above the 75th percentile, and every single one of them went down as a result of the program,” he said. “My liver function improved, I had a lot more energy, I slept better. Overall I just felt a whole lot better.”

Akre, who has added his name to a petition [calling on Gov. Gavin Newsom to “Stop the BoP”](#) from eliminating access to these Category 1 substances, is a member of the Cal Chiefs Executive Board and president of a statewide joint powers authority providing workers' compensation and benefits to over 200 fire agencies.

At every board meeting, he said, “we go in and provide approval for settlement authority for firefighters and their families effected by cancer.”

Such discussions are “heart-wrenching, on a personal level,” he said. “But it’s also incredibly expensive, what we pay out for cancer treatments and death benefits from cancer.”

It makes no sense, he said, “to take away a tool from doctors that can be helping us on the preventive side of things.”

Addressing the Board in person at its June 18 meeting, he spoke of three close friends, all firefighters, who died of cancer at the ages of 35, 50 and 57. He mentioned the three members of his department diagnosed with cancer in the last two years.

He expressed appreciation that 10 members of his department had gone through Wild Oak’s glutathione-based detoxification program.

“We have seen how this program has greatly reduced the amount of cancer-causing toxins in our bodies.

“We need to expand the tools and resources available to our doctors, not limit them.”

Akre was covering some of that same ground when called in to make a public comment during Wednesday’s meeting. Then he went “off script a little bit,” as he put it.

“ I’m incredibly frustrated with this. Throughout this process, we have still not been told the WHY of all of this. Why is the Board proposing to take these unnecessary actions? Where’s the data and the case studies to support this?

“If you approve this, you’re telling us essentially you want us to fight the fires here in the state. But in order to get cancer prevention treatments, we’re have to go out of state. We’ll have to Nevada or Arizona or Oregon or any of the other 49 states to get this treatment. How utterly ridiculous is that?”

Testing, testing

Compounding Category 1 substances like glutathione and methylcobalamin has never been against the law in California, said Tenille Davis, chief advocacy officer for the Alliance for Pharmacy Compounding.

“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.”

At that June meeting, the Board of Pharmacy proposed a regulation that banned compounding with items from the FDA's interim category — including glutathione.

But that proposal was met with such intense criticism that the Board backed off. Sort of. In this latest iteration of the rules, discussed during Wednesday's marathon session, the Board provided a carve-out, allowing for compounding with glutathione and methylcobalamin.

But that carve-out came with a set of requirements so onerous and expensive, critics said, that they'll make the cost of compounding prohibitive.

Under the new rule pharmacies could compound glutathione and methylcobalamin — but only as Category 3 sterile compounds, said Davis, “which means they have to be made to the highest standard of any type of sterile compounding.”

Before compounding any substances, under this proposed rule, pharmacies would be required to send those products out for independent testing, “even though it comes with a certificate of analysis saying it's already gone through those tests,” said Davis.

Once compounded, it would need to be sent out for “stability testing, sterility testing, endotoxin testing, particulate testing, container enclosure integrity testing, and antimicrobial effectiveness testing,” said Davis.

The Board, she pointed out, is treating glutathione and methylcobalamin “as inherently more dangerous than other drugs, even though they're essentially supplements — antioxidants, B vitamins.”

Those added layers of regulation will make the process much more expensive, causing many pharmacies to close their doors, critics said.

Scott Brunner, CEO of the Alliance for Pharmacy Compounding, expressed deep frustration at the Board's failure to demonstrate how “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.”

In the penultimate round of public comment — by now it was getting dark outside — 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.

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

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

Something shifted in the room. Board member Nicole Tibeau spoke of her own experience with chronic fatigue syndrome, which she treated with compounded medications.

Board member Jeff Hughes, a longtime firefighter and former Fire Captain from Orange County, mentioned 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 make my vote.”

And so, after nearly seven hours, the decision was made. The Board would punt, and return to the drawing board in September.

Then they stood, free at last to return to their homes and hotels.

No such luck for the men and women on the fireline north of Chico, where the marauding Park Fire burned into the night.

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