State board foiled, for now, in quest to limit access to treatments believed to extend firefighters' lives

New rules proposed by the California Board of Pharmacy threaten to limit access to glutathione, which has shown great promise in lowering toxin levels in firefighters.

AUSTIN MURPHY
THE PRESS DEMOCRAT
September 24, 2024, 5:09PM | Updated 17 hours ago

Amy Segui spent Sept. 11 in Sacramento. In full turnout gear, along with several hundred fellow firefighters, the Petaluma assistant fire marshal climbed 110 flights of stairs. Each climber carried the nameplate of a firefighter lost 23 years earlier in Manhattan's Twin Towers.

Segui stuck around Sacramento the next day. She had more work to do, this time in the service of colleagues “still on the line,” as she put it.

At a meeting of the California Board of Pharmacy, she reminded its 13 members of their mission “to protect the health, safety and welfare of the public.”

Segui and scores of others attended that meeting, in person and remotely, to let the board know it was failing in that mission, in their view, by working to pass regulations that would severely restrict access to treatments believed to extend firefighters’ lives.

After providing a primer on the benefits of glutathione — “a powerful antioxidant that detoxifies the body, protects cells from damage and enhances immune function” — Segui pleaded with board members to “send these regulations back to committee.”

Pushing in the opposite direction was board chair Maria Serpa, a pharmacist from Elk Grove and champion of new rules that will make it more difficult for Californians to access Category 1 sterile compounded substances. Serpa and her allies contend that, to be completely safe, these already regulated substances must be regulated further.

Among the treatments under discussion was glutathione (glue-tuh-THIGH-own), which has shown great promise in lowering the levels of toxins found in the bodies of firefighters, whose work puts them at greater risk of cancer than the general population.

The new rules will also likely limit access to methylcobalimin (meth-ul-kuh-BAL — uh-min), a form of vitamin B12, which, along with other treatments on the FDA’s Category 1 list, provide relief to tens of thousands of Californians with such ailments as autism, cancer, long COVID, cystic fibrosis, Lyme disease, chronic fatigue syndrome and others.

At the Sept. 12 meeting, Serpa repeated her concerns that merely following U.S. Pharmacopoeia (USP) standards in the preparation of those bulk substances holds too high a risk of contamination.

Critics of the new regulations pointed out that most other states abide by USP standards, considered the gold standard in their field, and that incidents of contamination have been

vanishingly rare — all but impossible, if USP guidelines are followed.

The board, they noted, had presented little scientific evidence that its proposed regulations would make anyone safer. Adding layers of testing and retesting, the critics predict, will jack up the cost of treatments, putting them out of reach for many Californians.

The board has justified its hard line against pharmacies that compound bulk substances such as glutathione and methylcobalamin, by pointing out that those substances lack a USP "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 California's compounding pharmacists have pointed out, both federal law and California law allow them to work with glutathione and methylcobalamin, even without the monograph. Those substances enjoy an exemption — that's why they're on the FDA's Category 1 list, making them lawful to compound.

That hasn't stopped the board from aggressively disciplining pharmacies that compound those substances, as it presses ahead with its proposed new rules.

"I'm hopeful we will reach a consensus and be able to take action today," Serpa said on Sept. 12.

There was consensus, just not the kind she was hoping for. For the second time in as many meetings on the topic, the board was deluged with hours of public comments overwhelmingly critical of the proposed regulations. In the end, a divided board took no action, other than to announce that the matter would taken up at its Nov. 6 meeting.

"It's a bit disappointing, to not pass a motion to go back to committee, or to adopt USP standards," said Segui, afterward. "But hopefully, we'll get there."

Coalition of critics

Lining up against the proposed rules was a broad coalition of critics, including groups representing hundreds of pharmacies and hospitals up and down the state such as Kaiser Permanente, with its 9 million patients in California. Also in opposition were pharmaceutical giants CVS and Walgreens, along with individual pharmacists, veterinarians and naturopathic doctors whose treatment options will be limited by the new regulations.
The most powerful testimony came from patients who believe their suffering will be increased by the rule changes, and firefighters who say their careers, and lives, could be shortened.

Segui, with the Petaluma Fire Department, was part of a robust Sonoma County contingent at the meeting. That cohort included Gabe Stirnus, a paramedic and fire captain with Sonoma Valley Fire District. Stirnus told the board how his 26 years as a firefighter exposed him to toxic substances that left him with a chronic cough.

That cough was treated successfully, he said, with a regimen of nebulized (inhaled) glutathione — a treatment that's no longer available because "this board has intimidated pharmacists in California to the point where they're scared to compound this medication for us."

After long weeks this summer "in a wildland fire environment," and with no alternative treatment for his lungs, Stirnus told the board, "unsurprisingly, the cough has returned."

Another Sonoma County firefighter, who gave his name as Justin, had spent three weeks working one of California's wildfires this summer.

"I had been coughing up all kinds of black junk out of my lungs," he told the board. "My lungs felt tight. I had been wheezing."

A regimen of nebulized glutathione "relieved a lot of the symptoms I was feeling."

A veteran of six years as a firefighter, he speculated, "You know, I may not make it another 20 to 30 years. I may not make it to retirement," then strongly encouraged the board to "reconsider" its position on Category 1 substances.

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.

In June, the board proposed banning outright the compounding of Category 1 substances. That plan provoked such a fierce backlash that the board backtracked. A little. Before its last two meetings, the board has unveiled revised regulations that allow for such compounding.

Even the revised regulations, said Tenille Davis, chief advocacy officer of the Alliance for Pharmacy Compounding, "will dramatically increase costs, potentially to the point where some preparations become prohibitive to produce or access."

Access already an issue

Serpa and board president Seung Oh, a pharmacist from San Diego, gave assurances during the meeting that preserving patient access to compounded preparations was a high priority.

But that access, noted Crystal Frost during public comment, has already been severely curtailed — the result of aggressive discipline by the board's enforcement arm.

Frost, a composer and writer in Southern California, depends on weekly glutathione infusions to manage her Lyme disease. She is the founder of StoptheBOP.com, and also started a Change.org petition to preserve access to sterile compounds that now has nearly 5,000 signatures.

"Members of the public who are listening should know that nebulized glutathione is already unavailable" throughout California, she said.

That's the case at Wild Oak Medicine in Santa Rosa, a naturopathic practice run by Dr. Jen Riegle and her husband, Dr. Chris Holder.

Starting in 2023, Riegle directed a pair of glutathione-centered pilot studies, measuring the effectiveness of glutathione treatments in reducing the levels of toxins in two small groups area firefighters.

She described the results of the studies, conducted in partnership with the Integrative Healers Action Network and another Santa Rosa-based nonprofit, the Volunteer Fire Foundation, as "incredibly encouraging."

In addition to administering it to firefighters, Riegle has prescribed nebulized glutathione for patients with certain lung conditions — asthma, chronic coughs due to long COVID, and coughs "due to conditions where they've been exposed to some sort of chemical — miners, even construction workers."

But nebulized glutathione hasn't been available to her practice since July of 2023, when her office got its final shipment from Koshland Pharmacy in San Francisco, which was being sued by the Board of Pharmacy.

At the end of that nine-day trial, Administrative Law Judge Michael Starkey found that Koshland had committed some minor violations, which he described as "predominantly technical" in nature.

As for the board's most serious accusation, Starkey ruled that it had failed to prove that "any specific aspects of the ingredients used was impermissibly dangerous," or that Koshland's "preparations of methylcobalamin and glutathione were adulterated."

In a follow-up brief to the board, Koshland attorney Derek Davis, who is also a registered pharmacist, invited its members to review the expert testimony given during the trial on his client's behalf, "to better understand how Board Staff has repeatedly mischaracterized category 1 substances compounding as 'unsafe' when, in fact, the FDA Guidance and USP analyses demonstrate safety on multiple levels."

Confusion around enforcement

In that brief he also noted the disconnect between the board's assurances in public meetings that pharmacists are still allowed to compound category 1 substances, even as it aggressively pursued discipline against compounders who took them at their word.

Davis cited minutes from meetings of the board's Compounding and Enforcement Committee in April 2021:

- Supervising inspector Christine Acosta “stated there is nothing wrong with compounding methylcobalamin.”
- “Dr. Serpa advised this has been discussed in depth at committee level and the Board has not stopped any pharmacy from using methylcobalamin specifically.”
- “Chairperson Serpa noted because of the complexity and intricacies, it is important to know the Board’s approach is education with enforcement discretion to ensure access [to the treatments] is maintained.”

This was news to Koshland Pharmacy, which had stopped compounding methylcobalimin, at the board’s direction, eight months earlier. A month or so before the April 2021 meeting, Koshland had learned it was being sued by the board, which sought to revoke its license.

Koshland was one of many sterile compounders confused about where the board’s “education” ended and its enforcement began.

Critics claim that the board’s current push to pass regulations is an effort to retroactively justify the enforcement actions it has taken against compounders of Category 1 substances since 2019.

“You guys have spent years enforcing regulations that don’t exist yet,” said Frost, “ensuring that these very treatments are not available to patients.”

Out to lunch

Just over three hours into the Sept. 12 meeting, the board finally voted on a motion to proceed to a 15-day comment period “for additional modified text.” It failed, 6-3.

Trevor Chandler, one of the board’s newer members — he’s also running for the Board of Supervisors in San Francisco — offered a motion to send the rules package “back to committee,” meaning, basically, back to the drawing board.

When no one stepped up to second that motion, Serpa made a motion to proceed to a 30-day comment period. After it failed, by the same margin, the board went to lunch.

Upon returning, Oh announced that the board would return to this issue at its Nov. 6 meeting.

Frost was philosophical afterward. Despite her disappointment that the rules package hadn't been sent back to committee, she was encouraged, she said, to see some board members finding their voices, "starting to catch on, and recognizing" that the proposed rules are "not in the best interest of the public. I'm relieved that they seem to be noticing that now."

You can reach Staff Writer Austin Murphy at austin.murphy@pressdemocrat.com or on Twitter @ausmurph88.