Opposition Testimony: CO SB 21-175 to establish a Prescription Drug Affordability Review Board

Senate Health and Human Services Committee, March 17, 2021

Link to hearing:

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Dr. Kelly Greene: Pulmonologist, ICU Co-Director at Littleton Adventist Hospital (5:40:30)

- *[Begin presentation by Dr. Kelly Greene, Pulmonologist, at audio counter 05:40:30]*
- ***DR. KELLY GREENE:*** *Thank you for having me, this evening now, I guess.*
- ***CHAIRMAN:*** *It is.*
- ***DR. KELLY GREENE:*** *I am a pulmonary critical care doc. I work for a large health care system, although I'm here representing myself and other colleagues. I'm the medical director of an ICU at the hospital I'm at. I also am the medical director on the Pharmacy and Therapeutics Committee at the hospital, and I am a co-owner of our pulmonary clinic.*
- *So I'm here in opposition of the bill primarily for two reasons, two big reasons, which is the upper limit spending as well as the board. The concerns that I bring have already really been brought up by many other people. So I'll keep I brief, but my major concern is that this bill, although we all in this room understand and appreciate that patients need better access to medicines, I can give you thousands of stories that have already been shared, patients coming and can't get them.*
- *I am a firm believer this bill is not going to fix it, and the reason I have concerns is that not only am I concerned that it's not going to fix that problem, but also that it's going to limit access to these very important medications. So the concern of the upper-limit pricing is that it doesn't—it assumes that pharmaceutical companies are going to adhere to that. So many large health care systems purchase their medications, and it is very complicated, but they purchase them from out of state. So they will purchase them at a certain price, and then if there is upper-price limiting, that cost will go to the hospital or it will go to a pharmacy, which has already been—[digital interference]—it will go to a physician's office.*
- *I don't—we don't infuse any medications at our office, so that's not the issue from an outpatient standpoint, but in an ICU, some patients—and it's really only a few, but it is just the way diseases are—they need these very important high-cost medications, and they cost a lot for a reason, right? There's a lot of R&D that goes behind these medications. We can't change that. It's critical. It needs pharma support. We need that R&D, and so some of these medications are critically critical to some of these patients. And just because they're expensive doesn't mean that they should be limited.*
- *And the concern is if there is—if this bill goes through, there is no doubt in my mind, access to these medications will be changed to our patients. I have severe asthma patients who despite the inhalers that are awesome for many patients, it's not working for them. They need a biologic, and I can promise you that if this bill goes through and the upper-price limiting happens that affects pharmacies, pharmacies will make decisions about what medications they will have access to. So my patients, in addition to not being able to afford their medications, now are going to lose access to some very critical medications.*

- *So although we all want to fix this, we need to fix this—I will be the first one to support anything that I think can fix this—I am concerned that we're going to make a bigger problem for our patients rather than helping them. That's for the upper-price limit.*
- *Regarding the board, again, I sit on P&T. I'm the head of it. Boards are awesome, and they can also be very scary to those of us who are on the front lines. So the concern on this five-member board is it is a political board. They are members appointed by a governor, which means it is a political board. The conflict of interest is very concerning because it means that people who should be sitting on that board can't.*
- *I have a conflict of interest. Pharmacy has a conflict of interest. Pharma has a conflict of interest. All of those people should be on the board because they're the experts, and although it does have the 14-member advisory committee, they're not dictating it. And so that makes me very, very concerned.*
- *So, for those reasons, I oppose the bill.*

Dr. Alan Miller: Head of Rocky Mountain Oncology Society, Chief Medical Director of Oncology; Associate Chief Medical Director of Clinical Research, SCL Health Cancer Center of Colorado (8:48:44)

- *Dr. Miller: Good evening, Madam Chair and members of the committee, thank you for your perseverance, I am president of the state oncology society. The Rocky mountain oncology society. I also currently serve as Chief Medical Director of oncology for SCL health. I've been a medical oncologist for over 35 years and have seen an incredible change in cancer care, and the ability to treat and cure patients over time. I believe that all agree that we need to reduce the medical, financial burden on our patients. This bill, as currently constructed, however well intentioned may do so at the cost of worse clinical outcomes with greater toxicity and less access to care. We've seen a 29% decline in deaths from cancer over the last 26 years, advances in cancer treatments have allowed this to occur while providing options that are less toxic and which can lower the overall cost of care by decreasing adverse events and hospitalization. Many of these new medical newer medications can be delivered in the outpatient setting, rather than requiring or resulting in hospitalization with its costs. Some of the most dramatic increases in cancer survival have been seen in malignant melanoma, where the advent of immunotherapy drugs including Pertuzumab and targeted therapies like Venrafamib have made a huge impact. When I did my oncology fellowship in the mid 1980s The same two drug combination for the treatment of acute myeloblastic leukemia was used, that we still use as the main option until the last few years. This treatment requires two to three weeks of hospitalization and was not offered to older adults due to high toxicity including death. We can now prescribe less toxic treatments that can include older adults with drugs like Vanetaclax. One unintended consequence of upper payment limit is that oncologists and other providers might have to default to using older, less expensive alternatives that are less effective, with greater toxicity, hospitalization and costs of managing the toxicity. Dr. Green mentioned lung cancer, advanced lung cancer can now be treated with non chemotherapy, immunotherapy. With the addition of drugs like Nivolumab, survival from advanced lung cancer is increased from between eight and 12 months to now living between three and five years> If it was your loved one, would you want to be deprived that additional two to three years of having them with you? Another potential unintended consequences is that smaller independent oncology practices might not be able to afford to stay in business. Many of these practices are already strained by the impact of COVID. These independent practices tend to be in the rural and underserved portions of the state where they may provide the only local oncology care. I spoke to an oncologist, the other day from New Mexico who*

was planning on opening an oncology practice in an underserved oncology area of southern Colorado, but is unsure if he can do this, if this legislation is enacted. This would result in patients needing to travel long distances to receive cancer care, or not receiving it at all. There are additional costs to providers, besides the acquisition of the medication. Many of the most effective drugs are administered intravenously. This requires the operation of infusion centers, with specially trained oncology infusion nurses, physician supervision and administration and fluids and co-medications to prevent side effects. Despite the provisions on page 22 this may not be able to meet those needs. To summarize, the burden of this legislation appears to fall disproportionately on the providers. As described this could result in patients having decreased access to the most promising treatments, having to travel long distances to receive them, if at all, and hurting most, the population that you're intending to help. Thank you for your time.

- *Madam Chair: Thank you for your testimony, Dr. Miller. Are there any questions for this witness Yes, Senator Hakas Lewis.*

- *Senator Hakas Lewis: Thank you Madam Chair. This question is for Dr. Miller, I'd like to know, , what do you do when your patients can afford oncology meds and have 1000s of dollars of coinsurance per month, as their copay, coinsurance?*

- *Dr. Miller: We have members of our staff, usually social workers and financial counselors who look for all the different mechanisms possible to help those patients with those costs. I definitely agree that we have to do something to help patients whether they're cancer patients or other patients with the cost of their medications. Unfortunately, Senator Hakas Lewis, and you are my senator from Erie, I don't think this bill achieves that without having more serious unintended consequences.*

- *Madam Chair: Are there more questions for Dr. Miller? We really appreciate your testimony and thank you for hanging in there with us, to testify tonight. Thank you.*

Joshua Ewing: Vice President, Colorado Hospital Association (8:59:45)

- *Josh Ewing: Good evening everyone, it's good to see you on the screen. I wish I could be there in person hopefully very soon. I am Josh Ewing and I am here on behalf of the Colorado Hospital Association representing 100+, hospitals and health systems across the state of Colorado. I'm here in an amending position today, but I want to be very clear the problems the sponsors are trying to address with this bill are very real. They're doing quite a bit about the impact of individuals and families. But it's also important to note that rising drug prices can disrupt patient care, and certain hospital budgets and operations as well. Our Hospitals and Health Systems purchase a high volume of drugs used to treat patients in both the inpatient and outpatient settings, even when the prices rise these community institutions are significantly impacted. Just as an example for the committee in the inpatient setting, hospitals typically receive a bundled payment, either a per diem or what's called a DRG payment to cover the entire cost of admission, including all services and all drugs for a given stay. These bundled payments, do not immediately adjust for increases in input costs like drugs, and as such, managing prescription drug cost becomes a heightened focus for us to maintain the financial viability of our facilities, and a 2019 national survey two thirds of community hospitals nationwide reported that changes in drug prices had a moderate or severe impact on their budgets. Now for a number of years*

now Colorado hospitals and health systems have been have been focusing efforts to reduce the total cost of care in our health system, meaning all costs across all payers for all Coloradans. But if we are to be successful in that as a state, we must be able to better identify the cost drivers and our impacts on other sectors, not to mention the patient. We do believe that the data collection and affordability review functions of this bill, Senate Bill 175, will bring much needed transparency to an otherwise opaque process and will help us to continue to improve the affordability across our healthcare system, and most importantly for our patients. Unfortunately, I'm not here in a position to fully support the bill and it has to do with the way that our hospitals and health systems purchase their drugs. The majority of Colorado hospitals are members of a group purchasing organizations, GPOs, where hospital bands and together and realize savings through economies of scale across the nation on everything from prescription drugs to PPE to cleaning supplies. The report I just referenced found that 75% of hospitals nationwide are members of GPOs. We haven't been able to survey our members, but we believe that number to be at least 75 maybe higher here in the state of Colorado. However, given that these multi state GPOs are not based in Colorado, we do worry about the state of Colorado, the ability to impact our purchase price through those national organizations. Senator Smallwood, I actually missed the Unlawful Acts provision in my read through the bill. So I'm going to maybe set that aside, it sounds like a really good question that frankly we have a lot of unanswered questions around the upper payment limit and this bill, but I don't think it changes my ask of the committee tonight. My analysis is based on the assumption that Colorado hospitals and health systems could actually find themselves in a situation where the purchase price is remains unchanged for drugs but our reimbursement is significantly reduced. The numbers that executive director Ben Stafford?? throughout referencing other countries for instance: if we're reducing our reimbursement by 70%, that's going to have significant financial consequences for our community hospitals here in Colorado. That puts hospitals and providers in a really difficult position of either taking a loss on the purchase price of finding alternative treatments if they're available. And as you've heard time and again tonight, potentially discontinuing these treatments altogether. If the financial penalty their impact is too severe.

- *Madam Chair: Are there any questions for Mr. Ewing. Yes, Senator Smallwood.*

- *Senator Smallwood: Thank you Madam Chair and thank you Mr. Ewing for staying up somewhat late to testify. I wanted to know if your organization has done any research around the fines that hospitals would be subject to. So, as I read the bill, it's very clear. If one of your member hospitals purchases a single medication that is on the upper payment limit list and over that amount that, your member organizations would be subject to a fine of $1,000 for each violation, and I wanted to know based on your professional experience is that violation for each day that you did that for each and every medication that you purchased for each individual script? How many 1000s of dollars would your organization be subject to, if you stayed in this GPO and purchased any medication on that list over the UPL in the state of Colorado?*

- *Josh Ewing: Thank you Senator for the question. You know, I know this bill has been worked on for a couple of years now. But hospitals were only brought into the conversation a few weeks ago, I believe after I made a comment on in a meeting just expressing some concern over rumors I heard about the bill. Despite the significant amount of prescription drugs purchased by hospitals. So we have not done any analysis around the fines. I can tell you that hospitals are going to do what's right for their patients. And if it means getting fined, I guess, so be it, but I just I do worry that because we're*

purchasing our drugs to GPOs outside of the state of Colorado, whether, whether we're fined of being unlawful or just reimbursed lower either way that adversely impact our hospitals pretty significantly.

- *Senator Smallwood: Thank you Mr. Ewing So coincidentally, you're the second person working with hospitals who said basically exactly that, that if we're fined so be it, we're going to do what's right for our patients. So I guess I misunderstood part of this so when do you attended the stakeholder meeting or meetings regarding this as hospitals are, I'm assuming, other than pharmacies, the second largest purchaser of prescription drugs in the state. How was this particular issue described to you?*

- *Josh Ewing: Thank you Senator. I have not participated in these stakeholder meetings, I'm not aware of any stakeholder meetings have been held on this bill. If there were, I don't believe I've received an invite. So, the best answers I've received to date. I've received two responses based on my assumption, having missed the unlawful acts provision of the bill that we would be reimbursed, lower. The first response was, "Well, just change who you purchase drugs from" which I don't think is reflective of how the real world works. The second answer I got was, "Well, when other states, see what we're doing in Colorado, prices will come down." which means to me, you'll be on the hook for that Delta, the difference between your purchase price and the reimbursement rate until other states pass this law set up affordability boards, and an act similar rates.*

- *Senator Smallwood: Thank you. Thank you Mr. Ewing, I just want to make sure I heard that part correctly the Colorado Hospital Association did not participate in any stakeholder process any stakeholder meetings regarding this bill this year.*

- *Josh Ewing: That is correct.*

- *Senator Hakas Lewis: Josh, I know you and I talked at the town hall that we had. So and I know you had a chance to ask me some questions and I told you how the upper payment limit would work and we have a very nice dialogue. I am also being told that you did have some meetings with some of our folks but my question for you is, you know, if GPOs are exclusive, meaning that hospitals are restricted to using a GPO, you know what if there's a better cost out there for a drug availability. What do you do in that case?*

- *Josh Ewing: Thank you Senator Hakas Lewis, And I should clarify, I have had conversations around the bill since I found out about it. I have not participated in any broad stakeholder meetings on the legislation. I don't believe hospitals are restricted to the use of GPOs. However, as I mentioned earlier we purchase more than just prescription drugs through these GPOs and in some cases 1000s of hospitals banding together to use that, those economies of scale, to leverage better rates. And so, going out on our own, assuming that there is someone willing to sell us prescription drugs here in the state of Colorado subject to the upper payment limit could potentially benefit hospitals. But there are a lot of Ifs in that statement and I do worry I don't know how this works. And so, I'm not in a position yet to say that that's an okay path.*

- *Senator Hakas Lewis: Josh, I know this is very complicated, so I appreciate you saying you don't know exactly how this works. As I understand it, really hospitals can have a choice where they buy their medication so if you find one that's $50,000 or one that's $250,000, you could take the $50,000 one and pass along the savings is it is there something I'm missing from that?*

- *Josh Ewing: I think, my understanding is, they're kind of two primary GPO representing about 70% of the purchasing market, in the hospital space. I don't know how those contracts are structured. But I think that had we had more time to work on this, had we engaged earlier, I would probably have better answers to these questions for you. Unfortunately, as I mentioned, we've only known about this bill for a few weeks now. So, doing our best to catch up. I think that the reason we use GPOs. And the reason why so many hospitals band together is because it is the cheapest price. It is what we can leverage with across the country. And so, I'm not saying that this 100% will not work, but I struggle to see how it will function for us at this point so our ask for you, for the committee is: Let's keep the transparency measures. Those are vital, and will help us improve affordability and the system, but our ask for the committee tonight, which is why we're in an amending position is to simply remove this UPL language until we can better understand how it will impact all parts of the healthcare system.*

- *Senator Smallwood: Thank you again, Mr. Ewing so in case any of this is vague. I'm going to read part of the bill to you to make positively sure that you remember organizations understand this, which is on page 27 starting on line 12 under "unlawful acts". On or after January 1 2022 it is unlawful for any person to purchase a prescription drug for which the board has established an upper payment limit, pursuant to 10 -16 -1307. at an amount that exceeds the upper payment limit, established by the board for that prescription drug, regardless of whether the prescription drug is dispensed, or distributed in person, by mail or other means. I'll skip two and go to three, a person who violates subsection one, which I just read, or two of the section, may be subject to a fine of $1,000 per each violation. Now what I don't understand is a violation, one prescription. One pill, one batch of pills that part is, is the bill silent around, but I would encourage you, if you're purchasing prescription drugs, if your member organizations are purchasing it, there does not appear to be any ambiguity at all, in the way this bill is written. If you do this, you are committing an unlawful act, and subject to a penalty of $1,000 for each violation and I think your member hospitals as significant purchasers of prescription drugs need to know this.*

- *Senator Hakas Lewis: And since we're in the reading mode right now, I just want to point out, on page 27 line 25, MAY be subject to a fine. Thank you.*

- *Senator Kirkmeier: So, still on page 27. It says, again, "unlawful for any person." So does it it's not speaking to the energy entity. So it might be just fine and dandy that the health plan people or the hospitals, think they want to take it on the chin but actually this is directed at a person. I'm thinking that means your purchasing agent is on the hook maybe for the violation. It says, The Attorney General is authorized to enforce. I'm not so sure they'd want to take it on a chin. So, I don't know if you have the bill in front of you but how are you actually reading that to where it would be the hospital that performing then lawful Act, or your purchasing agent?*

- *Josh Ewing: I am not an attorney. So there's a big asterisk, that comes with this next statement person under state statute has a broad definition that also includes entities, such as hospitals, in other parts of statute, I am assuming, I have not had an attorney review this for me yet, but I am assuming that that broad definition would apply in this case and so if the hospital was the purchaser the hospital would be the one committed the unlawful act.*

- *Madam Chair: Thank you Mr. Ewing, other further questions of Mr. Ewing. If not, thank you so much for hanging in there with us tonight. Thank you all.*

Dr. Ashely Mains Espinoza: Colorado Pharmacists Society, Administrator of Pharmacy Business Services and Practicing Pharmacists- SCL Health (6:04:22)

DR. ASHLEY MAINS ESPINOSA: Madam Chair, thank you, and thank you. I'm Ashley Mains Espinosa, a third-generation pharmacist representing Colorado Pharmacists Society. Colorado Pharmacists Society is a professional association representing pharmacy professionals, including pharmacists, technicians, and interns as health care providers in all practice settings, community, hospital, clinics, and specialty pharmacy across the state.

I'm also a practicing pharmacist at SCL Health, and my role is an administrator of Pharmacy Business Services. So it is with that background that I give this feedback on this bill related to these pieces.

First, we are thankful for the sponsor's efforts surrounding drug transparency and finding novel ways to try to help our patients afford their medications. I'm personally obsessed with learning about what drives pricing, and indeed, it is so complicated. We hope to be here today to voice our concerns about parts of this bill and to lend our perspective to the overall conversation for this bill with an ultimate recommendation to amend.

I'd like to highlight one primary focus of our concerns shared by some other folks who shared testimony is that upper payment limit piece, where prices for drugs are set for payers and purchasers but not manufacturers. The theoretical worry for pharmacy, both hospitals and community, is that we may not reasonably maintain access to important medications for our patients.

Pharmacies could be financially underwater. As another testimony stated, we're not assured an outcome on dispensing medications in health systems or outpatient pharmacies. The other concern about access is the assurances about what a drug manufacturer may choose to do because of the new rules that we'd be operating under. This is something that I think is different than others have shared already. Today this occurs in my practice where a drug manufacturer may lean on limited distribution rules that they create in essence to not sell my health system the drug.

We all want to ensure patients have access to cost-effective, appropriate medications when they are needed. However, this bill doesn't appear to address the actual issue of drug cost and access and has the potential unintended consequence instead of decreasing access to potentially life-saving treatments across the state. The cost controls described in this bill appear to fall disproportionately on the care provider, potentially, and pharmacies and has the potential to create situations where providers and pharmacies may simply be forced to other therapies or otherwise create an unsustainable model for us to continue.

Let me clarify that it doesn't matter if this is one drug, and handful of drugs, or every drug under the sun. Any drug under this bill as proposed could put us in that unsustainable situation to continue offering that drug. If unsustainable, providers and pharmacies would leave the market, and this would contribute to additional access issue for patients, especially in rural and underserved areas.

To provide one example—but there are many—there are newer expensive therapies, especially—these are specialty drugs like we talked about before—that have changed the way that we treat sever asthma, allowing patients relief and improved outcomes instead of puffing on an inhaler multiple times a day. This bill could potentially prevent this from being available to patients.

Pharmacies are under significant pressure due to unfair insurance and pharmacy benefit manager, or PBM, tactics. These are too many to name, but we can look to the state of Ohio, their state Medicaid agency, and what they have suffered, fought, and accomplished over time with the payer industry and pharmaceuticals.

Financial pressures have put many independent pharmacies in Colorado out of business and may continue to do that. You may have seen a new story just last night talking about the crisis in chain pharmacies due to these pressures.

Lastly, addressing points that were talked about before testimony, I also share the concern about clear guidance in the makeup of the board, assurances thereto. We don't have much detail on that, but just that bullet point, and then second, regarding the drug HUMIRA, biosimilars will be available soon, and we recommend the legislature advance support for those biosimilars as a solution instead of creating an uncertain committee with vague and potentially harmful objectives in scope.

Thanks for your time. Thanks for your service to our state. Thanks for any questions you may have for me.

Amanda Massey: Executive Director, Colorado Association of Health Plans (8:54:46)

Ms. Massey: Thank you, Good Evening Madame Chair, my name is Amanda Massey and I am the Executive Director at the Colorado Association of Health Plans. As many of you know, together our members provide health coverage to more than 3.5 million Coloradans. I want to be clear, health plans are very much committed to making sure that our members have access to affordable, high quality health care, including prescription drugs and affordable prescription drugs. Prescription drugs make up almost 22% of every premium dollar and the cost of drugs do impact access to care for our members. We are fully supportive of finding workable solutions to help reduce the cost of drugs for Coloradians. That said, um, SB 175 as drafted is not the solution. As drafted, this bill would create the Upper Payment Limit which I know you've heard others speaking about this evening. That would force carriers to decide whether or not to cover the drug, per pay the $1,000 per prescription fine for reimbursing over the upper payment limit and we would be doing that in order to be able to provide the drug on our formularies that we are legally required to fill for our members. So in effect, this bill creates additional cost-shifting to consumers by penalizing payers for providing access to life saving medications for those consumers. So rather than reducing premiums, which, I know is the intended goal, we are concerned that this bill could actually increase them. Um, we would suggest that the upper payment limit should not be mandatory. If affordability is the goal, then payers and purchasers should be able to opt-in when it would actually help consumers and not be penalized when it doesn't. Additionally, as mentioned by some um uh previous testimony the reporting for carriers is burdensome and is duplicative. So much of the information that SB 175 asks carriers to report to the commissioner is already reported to and captured by the all payer claims database. So this is exactly the type of reporting requirement that would drive unnecessary administrative costs for carriers. We also have serious concerns about allowing the Commissioner to determine what is and what is not proprietary as these determinations could violate confidentiality provisions we have in contracts with manufacturers. So I ask for you to reconsider these issues in SB 175 or to vote against the bill this evening. I do not believe that the bill, as drafted, will help consumers as promised. Thank you.

Chair: Thank you Ms. Massey, are there any questions for this witness? Yes, Senator Kirkmeyer

Senator Kirkmeyer: Thank You Madame Chair, I'm sorry I couldn't quite catch everything you said regarding how this bill would cos-shift to consumers, could you just explain that again please?

Ms. Massey: Thank you Senator, um yes, so basically under this bill, what would happen is that if a carrier were to reimburse above the upper payment limit, so to a Hospital, for example or to a pharmacy. We would also be fined $1,000 per violation, per prescription. And that money we would have to pay out would have to be built back into premiums, because as carriers we have to have actuarially sound premiums. So there would be a cost shift there. We are also concerned about that fact that, for example: say there is a payer, a hospital perhaps, that purchases this drug outside of upper payment limit and can only be reimbursed at the upper payment limit and is therefore losing the difference will have to find ways to make up that difference and will likely cost shift that to payers.

Leah Lindahl: Healthcare Distribution Alliance (9:17:32)

- *Leah Lindahl: Leah Lindahl with the Healthcare distribution Alliance similar the hospital associations we are here in more of an amend position to the bill. The healthcare distribution Alliance is the national trade association for primary health care wholesale distributors, and we serve in a really unique role actually, we're not really engaged in the pay side of health sensitive requests are really safe for the patient, or pharmacy counter. Pur members provide a link in the system so we purchase product from the manufacturer and then sell it to the pharmacy. in turn we charge manufacturers service fee. So it's a fee for service that our companies operate under. Our concerns come in again on the upper payment limit, and how that would impact our pharmacy customers including hospitals, clinics, nursing homes, and pharmacies that are trying to purchase these products and should they be under some type of limitation on how they are reimbursed or able to be compensated for the delivery or administration of those products to a patient, then they could potentially not be able to purchase those products or to administer those products to patients. So really our concerns echoed by some of the physician for today are around those pieces. The other side is for the Advisory Council. We request the ability to serve our role on the Advisory Council. There's a statement in the bill that the supply chain needs to be fully represented on the Advisory Council and we're a missing piece. We think that in order for the advisory council to really have a thorough viewpoint coming to any recommendation or issues that come up to the Committee that the wholesale industry should be on the committee to offer a perspective of the supply chain. So with that, we did submit written testimony, so you have that available to you as well but I'll keep it short and sweet.*

- *Senator Smallwood: Thank you for your testimony. Did you say you provided written testimony, because I'm not sure I've seen that.*

- *Leah Lindahl: Yes, I submitted it last night through the system.*

- *Senator Smallwodd: Thank you very much, we'll make sure that gets distributed to the committee, thank you. Madam chair may we get a printed copy of that?*

Mark Spiecker: President, STAQ Pharma (08:15:55)

MARK SPIECKER: Thank you, Madam Chair and members of the committee. My name is Mark Spiecker. I'm the president and founder of STAQ Pharma. STAQ is a 503(b) pharmaceutical manufacturing facility in Denver, Colorado, that makes compounded medications in prefilled syringes for surgical procedures.

We responded to the pandemic more recently by ramping up supply of critical medications for hospitals across the state of Colorado to assist in ventilation of COVID patients as a result of worldwide shortages. We employed pharmacists, and we commend the work that I heard earlier today that you all did for pharmacists here in the state of Colorado.

I'm here today in opposition to Senate Bill 175. Throughout my career, I've been involved in the health care sector, and I've had the privilege to be part of Colorado's growing biosciences community. As former chair of the Colorado Bioscience Association and as an entrepreneur starting in funding for companies here in Colorado, most recently Sharklet Technologies, where we used textures from the skin of sharks to control microorganisms on surfaces to reduce infections.

While I commend the bill's sponsors and the goal to improve the affordability of medicines, I'm concerned that capping reimbursement for prescription drugs in the state of Colorado could have downstream effects on the early and development-stage companies in our ecosystem and the availability of new medicines for people of Colorado.

Back in 2007 and 2010, it was nearly impossible to raise money for anything bioscience-related due to concerns over FDA approvals. No significant investor wanted to invest due to regulatory uncertainty, severely constraining growth in bioscience and causing many companies to die on the vine. This was resolved, but even still, once we do get a drug or a device approved, we then have to work with CMS on reimbursement. We then negotiate with insurance companies, GPOs, PBMs, distributors, IDNs, and a host of others for reimbursement, eventually receiving about half of what the consumer actually pays for that medication.

If Colorado imposes price constraints on top of all that work that's already been done, it will create regulatory uncertainty for investors, and it will devastate our ability to raise money to begin these ventures in the first place.

These are the same ventures that you just invested another $10 million into to the Advanced Industries Grant Program, and while we're grateful for that, the next set of investors are going to be asked to invest in something that you're not sure they're going to be able to get reimbursed for at a rate that's going to recover that investment, and these investors just aren't going to invest in these companies.

We're living in a time right now with the pandemic that more than ever, investments in science and research have yielded unprecedented results in a vaccine. New therapies that cure, not just treat, genetic disorders are coming out over the next decades and are even more striking, providing opportunities for countless patients to not only survive, but thrive as productive members of society.

In addition to crippling our ability to fund Colorado life science companies and speaking as a patient that takes medications, Senate Bill 175 can also stimulate a flurry of patients fleeing to other states to seek coverage where the states did not limit their ability to get necessary medicines, similar to the days of

people moving to states without limits on preexisting conditions, so that they can get treatment before the days of the Affordable Care Act.

Additionally, you just passed a bill today giving pharmacists more control over the medications that they can provide to patients. This bill could take that ability away, restricting the patient's ability to get those medications.

I remain strongly opposed to Senate Bill 175 and request that you reconsider taking this drastic action that will result in unintended consequences to patients and potentially destroying the chances of our Colorado life science community to fund our companies and continue the development and commercialization of life-saving therapies.

I also just, based on testimony that I've heard recently, would let you know that I am part of the 720 bioscience companies, and of the four companies that I've been involved in, every one of them has looked at affordability and has built a cost model on the affordability of these medications compared to what life would be like without assertive therapies or without these medications.

Thank you so much for the opportunity to testify, and I'd be happy to answer any questions.

Trey Rogers, Shareholder, Recht Kornfield (7:30:33)

Mr Rogers: Thank you Madame Chair, Committee members, my name is Trey Rogers I am a lawyer with the Recht Kornfield firm here in Colorado and my work focuses on public policy an litigation and often includes analysis of legal issues raised by bills pending before the General Assembly. I'm here on behalf of the Pharmaceutical Researchers and Manufacturers of America or PhRMA a trade association representing leading biopharmaceutical research companies, and I'd like to address two concerns with SB 21175. The bill will create a review board that will be tasked with establishing upper payment limits, or UPL, for certain prescription drugs, and as you've heard from a number of other witnesses tonight, setting prices within the drug supply chain could restrict access to medicines in a variety of ways and that leads to the first issue I'd like to address. If the UPL results in restricted access to medicines, the state may become the target of litigation for violating a PRISONER'S constitutional rights, I'll bet you didn't see that coming. The 8th amendment to the US Constitution and Article 2 Section 20 of the state constitution prohibit cruel and unusual punishment. Our Federal courts have repeatedly recognized that depriving inmates of lifesaving or life enhancing medications violates the 8th amendment. This is not a hypothetical issue in Colorado, a few years ago the ACLU brought suit against the Colorado Department of Corrections challenging it's denial of treatment to more than 2,200 prisoners suffering from chronic Hepatitis C. The DOC settled the case through an agreement which required the state to eliminate policies that prevented inmates from receiving necessary drugs. The DOC also agreed to spend $41 million over 2 years to provide treatment to all prisoners infected with Hep C and agreed to pay $175,000 in plaintiff's costs and attorney's fees. If SB 175 becomes law, if access to medicines is limited, and if successful 8th amendment litigation follows, the state will be left in a very difficult situation. To violate state law by paying more than the UPL or violate a court order to provide necessary medication to inmates. I believe Senator Smallwood referred to a situation like this as being whipsawed when referring to a similar scenario. Even more troubling, if the state is required to provide medications to inmates, despite the UPL, then inmates will have access to medications not available to the general public, and

that raises interesting questions of public policy. The solution to these problems are to eliminate the mandatory UPL provisions of SB 175. The second issue I'd like to address is that the bill conflicts with Federal patent law and thus the doctrine of Federal preemption may be invalidated. As with the 8th amendment issue, this was is not purely hypothetical. In 2007, the Federal circuit held that the District of Columbia's Prescription Drug Excessive Pricing Act of 2005 was preempted by Federal patent law because " underlying determination about the proper balance between innovators profit and consumer access to medication is exclusively one for Congress to make." And because the FeDC Act stood as an " obstacle to the Federal patent law's balance and objectives" the law was invalidated. If SD 175 becomes law in it's current form it will likely face the same fate: invalidation by Federal courts on preemption grounds. Again, the solution is to invalidate the mandatory UPL provision of SB 175. Thank you for the opportunity to address you today and for your attention and I am happy to answer any questions you might have.