Dear members of the Criminal Justice and Public Safety Committee,

The following correspondence is in regard to LD 663. First of all, I would like to thank all of you for allowing me to participate in these important hearings and for taking the time to consider my statements.

If there is one thing I've learned through my work in addiction medicine, as well as emergency medicine, it is that medicine is not a "one size fits all" practice. I truly believe that one of my most important duties as a physician is to listen to my patients and use my knowledge and experience to determine what is best for them as an individual. Determining what is "best" must include discussions on all of the treatment options available as well as the risks and benefits of said treatments. Patients who are welcomed into the decision making process with regard to their health and wellness do better.

At its heart, LD 663 is about best practices and informed consent. The American Medical Association discusses the importance of informed consent:

"Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making".

Below I will discuss the medications that are FDA approved for opioid use disorder (OUD) and alcohol use disorder (AUD). These are medications that, as an addiction medicine physician, I use on a daily basis. It is my hope that I have provided an adequate amount of information on each and clearly represented the similarities, differences, and specific use cases for these medications. Treating substance use disorder can be complex and requires careful consideration of a patient's specific needs, abilities, and substance use history. Luckily, we have an array of effective medications that are FDA approved and supported by data.

There are three FDA approved medications for the treatment of opioid use disorder:

1) Buprenorphine-naloxone (suboxone), buprenorphine (subutex), Sublocade (long acting injectable): Buprenorphine is an opioid called a partial agonist. It binds to opioid receptors, like other opioids, but only partially stimulates them. In doing so, it helps decrease cravings and urges to use and also relieves withdrawal symptoms.

Pros: Great at controlling cravings, urges, and relieving withdrawal symptoms. It is very safe for those with opioid tolerance.

Cons: It is an opioid so patients develop a physical dependence on the medication and need to be weaned off from it slowly. It also requires a special license to prescribe making follow up and access to care sometimes more difficult.

In regard to **sublocade**: This is the long acting, injectable form of buprenorphine. Because buprenorphine is an opioid, it does have some misuse potential. Patients who either 1) cannot tolerate the taste of oral buprenorphine, 2) have compliance issues ie forgetting doses, taking more or less than prescribed and 3) patients with whom you are concerned about medication diversion are ideal for this medication provided they have been on oral buprenorphine for at least 7 days, are taking a daily dose between 8-24 mgs, and buprenorphine is effective for them.

2) **Methadone**: A full agonist opioid that binds to a patients opioid receptors and fully stimulates them. This helps to decrease cravings and urges to use and prevents withdrawal symptoms.

Pros: because of the strict regulations for methadone, this medication requires patients to go to the clinic to receive their dose every day. Some patients who are struggling, have not been successful on other regimens, or do not want to use other regimens, can benefit from this structure. Methadone is also very good at controlling cravings and withdrawal symptoms.

Cons: Methadone has an extremely long half-life and therefore sticks around in the body for a long time. Because of this, there is a greater risk of overdose than with buprenorphine. Methadone also has a more significant side effect profile than buprenorphine and has greater potential to interact with other medications. Methadone prescribing for opioid use disorder also requires additional licensing.

Naltrexone: Opioid antagonist that binds to, and blocks, a patients opioid receptors.

Pros: non-opioid, non-narcotic, not habit forming, no physical dependence and no misuse potential.

Cons: It is not as effective as the other medications at controlling cravings and urges and does not prevent withdrawal symptoms. It can also cause significant withdrawal symptoms if taken too soon after a patient has been using opioids.

Vivitrol is the long acting, injectable version of naltrexone. It's mechanism is the same as listed above but, for patients who may have medication compliance issues (forget to take the dose, take more or less than is prescribed, or for those who don't want to take pills every day) this medication is ideal provided they have been on oral naltrexone for at least one week and it is effective for them. Naltrexone does not have any misuse potential so this is not a consideration when switching to Vivitrol

Examples of patients who would specifically benefit from each of these medications:

- 1) **Buprenorphine**: This medication is very effective for patients struggling with opioid cravings, urges, and withdrawal symptoms. It can be used for patients who are early on in their recovery but is also a great maintenance medication
 - a. **Sublocade**: As above I would recommend sublocade for patients who cannot tolerate oral buprenorphine (sometimes it's the taste, sometimes people get oral sores from taking it but this is rare), patients who have compliance problems (ie taking too much, too little, forgetting doses, etc) and patients with whom I am concerned about buprenorphine diversion.
- 2) **Methadone**: This medication can be used in the same situation as above (for buprenorphine). In addition, some patients require a full-agonist opioid, like methadone, to control their cravings and urges when buprenorphine does not work for them. Some patients also prefer methadone for multiple reasons for some patients, methadone is more effective. Other patients may benefit from the structure provided by methadone dosing as they have to check in at the clinic every day.
- 3) Naltrexone: Because this is a non-opioid, an example of an ideal patient for this medication would be someone who has been opioid-free for an extended period of time and does not want to start using opioids again. Just because a patient has opioid use disorder doesn't mean that restarting an opioid is the best thing for them. Many of my patients report naltrexone as a "security blanket" as they are fairly stable in their recovery but appreciate the fact that their opioid receptors are blocked and if they were to use, wouldn't get the same euphoria. This medication does not control cravings to use like buprenorphine and methadone and therefore would not be my first choice for someone who is struggling and/or early on in their recovery. Naltrexone is typically my first recommendation to patients who were recently incarcerated, have OUD, and have not had opioids for an extended period of time.
 - a. **Vivitrol**: as above. I would recommend this medication for patients with compliance issues (ie forget to take their dose, take too much or too little, etc) or patients who do not want to take pills every day.

There are three FDA approved medications for the treatment of alcohol use disorder:

1) Naltrexone: See above for general description of naltrexone. Naltrexone is very effective at controlling cravings to use alcohol. The mechanism of action in alcohol use disorder is not greatly understood. It is thought that blocking the opioid receptors reduces stimulation of the "reward" and behavior reinforcement pathways in the brain associated with continued alcohol use.

Pros: Safe, non-addictive, non-habit forming, non-narcotic, not a controlled substance. In both the literature, and my anecdotal experience, this medication is very effective at decreasing cravings to use alcohol. In my practice, this is my "go to" medication for this purpose.

Cons: For myself, there are not any cons to at least trying this medication. It is well tolerated, effective, and does not have any misuse potential. There is some evidence that the use of naltrexone can cause liver injury but the data was gathered when using much higher doses of naltrexone than what is recommended for daily dosing. Checking liver function is recommended but should not delay treatment.

Vivitrol: as above. It is as effective as oral naltrexone in my experience but switching to long acting injectable can be beneficial for certain patients. It increases compliance and therefore, patients tend to be more successful if they were struggling to take their medications as prescribed.

2) Acamprosate: This medication acts to modulate several brain receptors and neurotransmitters thought to play a role in alcohol dependence and craving. It is non-narcotic, it is not a controlled substance, and has a relatively benign side effect profile. Acamprosate is effective and well tolerated by patients. This is typically my second line treatment method behind naltrexone if 1) naltrexone doesn't work or 2) the patient is taking opioids or is on buprenorphine as you cannot use naltrexone (opioid blocker) while using opioids.

Pros: safe and effective and can be used in patients on buprenorphine or those taking opioids

Cons: Not many. In my practice, however, Naltrexone has been more effective and is my #1 choice in appropriate patients.

3) **Disulfiram**: Non-narcotic, not a controlled substance. Disulfiram works by blocking an enzyme that helps to metabolize alcohol. When this enzyme is blocked, it leads to a buildup of a metabolite of alcohol that causes many, unpleasant symptoms. These include skin flushing, chills/sweats, nausea, vomiting, and diarrhea. Much like naltrexone for opioid use disorder, this medication provides a "security blanket" for patients as they know if they do drink, they are going to feel sick.

Pros: not a controlled substance and generally does not have any impact on the patient unless they consume ethanol. Due to the illness caused by drinking alcohol, some patients report a decreased craving to drink moving forward given this negative experience.

Cons: Patients tend to not take it when they know they are going to drink so in these situations, it is less effective. Also, patients need to be careful with the use of alcohol based hand sanitizers and mouthwash with alcohol in it.

Examples of patients with alcohol use disorder who would benefit from each specific medication

1) **Naltrexone**: As stated above, this is my #1 choice for patients with AUD who are not on opioids. It is very effective, safe, and non-habit forming.

Vivitrol: This is ideal for a patient with AUD who has difficulty remembering to take their medication, takes too much or too little, etc. Using a long acting injectable increases compliance and therefore, success.

- 2) **Acamprsoate**: This medication is ideal for a patient with AUD who is on buprenorphine or is known to/suspected of using opioids. Naltrexone will cause opioid withdrawal in those dependent on opioids and therefore cannot be used in these situations. Acamprosate helps to control cravings and urges to use alcohol and is well tolerated by patients.
- 3) **Disulfiram**: This medication can be used in patients who want an added layer of "security" in their recovery. This medication has no effect unless alcohol is consumed but this does provide some comfort to patients. In those who have consumed alcohol while using disulfiram, I frequently hear about negative thoughts concerning alcohol given the adverse reaction they experienced. This medication can be used in combination with the other two listed above. It is safe and well tolerated however, some patients tend to just skip their dose if they are going to drink. Also, I would not give this to anyone that I felt concerned about their ability to handle the adverse reaction (elderly patients, patients with significant comorbidities, etc).

As I hope was highlighted above, each medication has its own risks, benefits, and optimal use cases. Treatment of any medical condition requires careful consideration of all available treatment options and a thorough discussion with the patient. In doing so, we are able to care for our patients in a way that is most beneficial for them. This increases compliance, and ultimately, treatment success.

I am more than happy to speak to anyone and answer any que	stions/address any concerns
Sincerely,	
Dr. Nick Gallagher	
doctornickgallagher@gmail.com	(207) 213-5300