

543 Project – Project Title

<b>Group</b>	<b>Title</b>
1	Reschedule pseudoephedrine – C-V
2	Prescription-Only Pseudoephedrine
3	Show and Tell at Dispensing
4	Expiration of Schedule II Prescriptions
5	Rescheduling of Clonazepam
6	Stating the “indicated use” on the prescription
7	Label Requirements – description and picture
8	Allow spacers to be dispensed without a prescription
9	Reschedule tramadol
10	Generic substitution at the discretion of the pharmacist
11	
12	Extension for CII partial fill completion

Pharm 543 Project Topic and Brief Description

Group 9 Rescheduling of Tramadol

Group Members: Holly Dirks, Michael King, Amy Little, Adam McCown, Pavel Mitin, Robert Siegfried, Gigi Wong

Comment: As I mentioned in class, we need to assemble the criteria for regulatory change. I try to get a copy and post it.

Also, I'd like to approach the Board and let them know what's coming down the pike – looks like rescheduling for 4 drugs – 2 for pseudoephedrine, tramadol, and clonazepam

/Tom

Due to its potential addictive properties, we would like to reschedule Tramadol as a controlled substance.

Pharm 543 Project Title

Group10

Group Members: Jasmine Chase, Ching Yeung Chow, Thu Oanh Thi Dang, Michael

Fallon, Frances McGaugh, Whitney Stoffel, Melvin Wang.

A very interesting project!

/Tom

Our group wants to allow generic substitution at the discretion of the pharmacist. This is going to require changing two laws. First, RCW 69.41.120, to change the requirements for a prescription away from the 'two-line system'. And then second, RCW 69.41.150, to afford pharmacists the legal responsibility for the substitution. What we are proposing is that ALL prescriptions are assumed to be 'substitution permitted' unless the doctor states 'dispense as written'. This would mean we only have one signature line. The reasons for this are mostly economical. Money cost to patients, insurance companies, and money in the form of wasted time with us pharmacists and prescribers. Also, pharmacists run the risk of insurance audits and the resulting lost revenue if any prescriptions were not explicitly marked 'dispense as written' or 'substitution permitted'. Besides the economic concern, there is also the increase in patient autonomy that changing the law would provide. Patients would be allowed to say they only want generics, even if there doctor forgot to ask them in the office. Also, pharmacists ARE the drug experts. Who better to hold the responsibility for such choices? Liability should be held to a minimum if we stick to the Orange Book's AB rated system.

Pharm 543 Topic & Brief Description

Group 12: Extension for CII partial fill completion

Group Members: Ashley Bean, Amy Chang, Morgan Hutchings, Rachel Schreffler, Kathleen Thornton, Kelli Watari, Jeffrey Brandon

We would like to extend the length of time allowed for a pharmacist to complete a partially filled CII from 72 hours to 7 regular days. This would allow adequate time for ordering the medications along with any complications that may arise, without causing patient suffering due to lack of necessary medications due to the pharmacy being out of stock.

Comment for Groups 4 and 12

Group 4 – you are addressing issue that could be changed in WA law, as was addressed thoroughly by two projects last year. I'd like to see what the BOP would like you to do that would add on to last year's projects.

Group 12 – you are addressing an issue that would need to be changed in federal law. So, a petition to the DEA.

21CFR Sec. 1306.13 Partial filling of prescriptions.

This was last changed in 1997, so you will want to review the Final Rule, and any previous Proposed Rules covering this section in the Federal Register.

Pharm 543 Project Title

Group 2

Group Members: Leigh Brown, Shawn Hancey, Angela Hitt, Vu Hoang, Jared Judd, Young Mi Kim, Karyn Moretsky, Elyse Tung

Project Title: Prescription-Only Pseudoephedrine

Comment: As I mentioned in class, we need to assemble the criteria for regulatory change. I try to get a copy and post it.

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I'm pretty sure that there is either rule-making or legislation afoot re pseudoephedrine, so you want to be sure you aren't working at cross-purposes.

/Tom

1. We propose that products containing pseudoephedrine be made available by only by prescription.

This would be an amendment to RCW 69.43.110.

2. We care about this issue because pseudoephedrine can be used to create methamphetamine, a growing problem in Washington State. We feel that making pseudoephedrine a prescription-only drug (as Oregon has) would make it much more difficult for people in this state to make methamphetamine, therefore reducing addiction and laboratory-produced toxic waste. It might be helpful if some pharmacists had the authority to prescribe pseudoephedrine for legitimate reasons as well as the legal right to refuse to dispense it.

Pharm 543 Project Topic

Group 3:

Group Members: Zackary Wade, Aaron Chin, Connor Christy, Joseph Craig, Tina Ngo, Olga Svartsur, Helen Song, Lydia Zou

Comment: 246-869-220 is presently under review by BOP so you should contact them (suggest Andy Mecca or Lisa Salmi) to find out where things are. I'd note that the Board went to great lengths with their last revision to NOT be "prescriptive", so this represents a change in direction. Not that that should influence you.

/Tom

We want to add an amendment to WAC 246-869-220 requiring patient counseling to include the showing of the medication (opening the actual bottles) to the patient for all prescriptions filled.

We think this is a necessary part of counseling because we want to make sure the patient verbally and visually understands what they are receiving. The issues of dispensing the medication to the wrong patient, dispensing a different medication to the correct patient, or other misunderstandings (same drug, different manufacturer) have unfortunately been not uncommon in the pharmacies that we've worked in. In the pharmacies that have implemented mandatory showing of medication, this problem has been greatly reduced or nearly eliminated by this simple procedure. We just think that it's an easy and efficient additional check to ensure patient safety and that pharmacists should incorporate this into their counseling routines.

#### Pharm543 Expiration of Schedule II Prescriptions

Group 4

Group Members:

Andrea Eberly, Sareh Ghazafarpour, Jennifer Law, Jeff Loor, Linh Mai, Quyen Nguyen, Nick Wyatt, Geoff Meer

Comment: as mentioned there were two of these last year.

From our experience in pharmacy, we believe that CII prescription should expire earlier (we recommend prescriptions being valid for no longer than a maximum of three months) because CIIs are generally used for pain management, mental disorders, and other indications that should be monitored regularly. It seems unlikely that a patient one year following receipt of prescription will be in the same state that had originally necessitated prescription writing in the first place.

According to WAC 246-869-100 d)

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#### PHARM 543 Project Title

##### Group 5 *Rescheduling of Clonazepam*

Group Members: Osama Saleh, BJ Gleason, Rachel Nowak, Kevin Hiroo,  
Vivian Villanueva, Hae Young Zhang, Benjamin Davis, Carolyn Sear

Comment: As I mentioned in class, we need to assemble the criteria for regulatory change. I try to get a copy and post it.

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/Tom

As stated below, Clonazepam (Klonopin) has been categorized under the Revised Code of Washington as a Schedule IV controlled substance.<sup>1</sup> Under this schedule, dependence risks associated with administration of clonazepam may be excessively disregarded resulting in adverse events including withdrawal syndrome due to excessive use and duration of clonazepam administration.<sup>2</sup> To improve awareness of this risk by health-professionals and to decrease over-dispensing of this CNS depressant, clonazepam should be recategorized as a schedule III narcotic. To illustrate the lack of awareness regarding clonazepam as a habit-forming agent, it is a common occurrence in pharmacy to receive a prescription for clonazepam that has been authorized for PRN refills or greater than 5 refills--which indicates that either the prescriber is unaware that clonazepam is a schedule IV controlled substance or that the prescriber is unaware that schedule IV controlled substances are only allowed 5 refills and expire after 6 months under Washington State law.<sup>3</sup>

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<sup>1</sup>RCW 69.50.210 (b) (9)

**Schedule IV.** Unless specifically excepted by state or federal law or regulation or more specifically included in another schedule, the following controlled substances are listed in Schedule IV:

(b) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances having a depressant effect on the central nervous system, including their salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation: **(9) Clonazepam.**

<sup>2</sup>Benzodiazepines. Facts & Comparison 4.0.

<http://online.factsandcomparisons.com/MonoDisp.aspx?book=DFC&id=483454&searched=clonazepam|clonazepam%20odt|klonopin|klonopin%20wafer&#warnings>.

<sup>3</sup>RCW 69.50.308 (c) (d)

Group #6

Stating the “indicated use” on the prescription by the primary health care provider can be very helpful for pharmacists to provide the most appropriate and relevant information to the patients when counseling. As a result, we would like to offer a state law that would require physicians to make this piece of information available to pharmacists. The indicated use as well as other personal information (of the patients) stay confidential within the pharmacy and as a result would not interfere with the patients privacy right.

Comment: Note that the privacy stuff isn’t an issue. It is covered in HIPAA and RCW70.02.

I’d like for you to contact WSPA very early to engage them. I think it might also be worthwhile to schedule a meeting with Steve Saxe and his equivalent with the Medical Board once you’ve got your arguments formulated.

/Tom

Pharm 543 Label Requirements

Group 7

Group Members: Casey Lirot, Chris Yocum, Dimay Wang, Caroline Wu, Suejin Park, Catherine Ulep, Caroline Kimani, Madeleine Fry

As I mentioned, this is a frequent project candidate. I’d like to suggest trying some new things this year, such as

- Contacting WSPA very early – like this week – and figuring out the political barriers, which “fights” are worth it, etc.
- Lets discuss the possibility of your meeting with the Medical Board’s executive director, as well as Steve Saxe (BOP ED) to present your story ... after you’ve had a chance to frame your argument.

√Tom

We would like the requirements on a prescription label<sup>1</sup> to include a description and picture of the medication being prescribed to prevent medication mistakes. This allows the patient to make sure they do not take the wrong medication.

We are also considering adding that patient education material on the prescribed medication be required. We are not sure which law this could be amended to, or if it is already part of a law.

Allow spacers to be dispensed without a prescription

Group 8

Group Members: Alesya Vlasenko, Reilly Benz, Holly Warner, Brian Seike, Heidi Colpitts, Viet Lam

Spacers should be dispensed without a prescription with intent to improve therapeutic outcomes when using orally administered inhalers and also to optimize the efficiency of workflow within the pharmacy. Spacers should be accessible to patients when they feel like they need one.

Comment: Because the nature of this project has to do with the medical devices and their regulation, we are unable at the moment to provide a citation of the offending law. We are planning to consult with Don Downing regarding the topic of our project.

Comment:

The first technical issue is how spacers are classified federally. If they are prescription under federal classification, you cannot seek a less restrictive classification in WA. I believe that spacers are classified as

### Product Classification Database

<b>Device</b>	spacer, direct patient interface
<b>Regulation Description</b>	Nebulizer.
<b>Regulation Medical Specialty</b>	Anesthesiology
<b>Review Panel</b>	Anesthesiology
<b>Product Code</b>	NVO
<b>Submission Type</b>	510(k)
<b>Regulation Number</b>	<a href="#">868.5630</a>
<b>Device Class</b>	2
<b>GMP Exempt?</b>	No
<b>Third Party Review</b>	Not Third Party Eligible

<http://www.fda.gov/cdrh/ode/784.pdf>

One of the issues with prescription status is that the “adequate directions for use” are changed to “professional labeling”. So, assuming that the devices are indeed prescription (I’ve not been able to determine this yet), you may be blocked in taking them OTC because their present labeling is written for professionals. Note, Wellpoint (Southern California) petitioned FDA to take non-sedating antihistamines OTC a few years back, so do feel constrained.

Anyway, this is a complicated issue. I've already spoken to one device expert, who didn't know where to find out about the prescription status stuff, suggested calling FDA in DC. I'll ask someone else on Tuesday.

**Pharm 543 Topic and Description**

**Group 1 Meth Busters**

**Group Members:** Etsegenet Assefa, Louisa Chu, Dennis Go, Marshall Heaster, Marcie Hume, Kristen Kai, Robert Lambert, Jill Mack

In order to better manage the use of pseudoephedrine, we are proposing to make the tablet form a schedule V, with pharmacists' ability to dispense with their discretion up to a "to be determined" amount. The focus of the project is at State Level.

See comments for Group 2.