Pharm 543 Problem Description

**Group Title**

| 1 Reschedule pseudoephedrine – C-V "Meth Busters"  |
| 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 Intern Hours                                   |
| 12 Extension for CII partial fill completion     |

**Group 12: Extension for CII partial fill completion**

**Group Members:** Ashley Bean, Amy Chang, Morgan Hutchings, Ricki Schreffler, Kati Thornton, Kelli Watari, Jeff White

1. **Describe the problem**

This description of the empirical situation should be as precise and complete as you can make it. The values underlying your description of the problem should described - what is your perspective, a pharmacist, a pharmacy owner, pharmacist employee, patient, payer, etc. If you have documentation supporting your problem, please include the references as a footnote.

The 21 Code of Federal Regulations 1306.13a states “the partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72 hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.”¹

This is a problem for all parties involved. As a pharmacist, lack of stock is always a frustrating situation. The pharmacy owner cannot always stock medications in abundance to alleviate possibility of running out due to increased costs, as well as changes in supply and demand. Non-schedule medications can be borrowed or delivered within a 24 hour period at most locations, however schedule medication orders take at least 3 days to come once ordered. In an emergency situation, when a pharmacist runs out of stock and sends a patient away with only a partial of the schedule prescription, it is extremely difficult get sufficient supply in to provide to the patient so that they do not have to forfeit the remainder of their prescription and visit the doctor again. This is a problem for the patient as they have no control to take the prescription

¹ 21 FR 1306.13 a pg 249 Pharmacy Lawbook 2003 Washington State Department of Health Board of Pharmacy
elsewhere once it has been partially filled, and refusing partial fill at their regular pharmacy sends them into a new pharmacy where the pharmacist has no information of the patient’s other meds, current conditions, past medical history, etc. If the completion of the fill takes place after 72 hours, the physician has to be contacted and a new prescription obtained. This is inconvenient for both the patient, who must pick up the script, as well as the provider, who does not have time to redo his work.

2. **Delineate the boundaries of the problem**
   How long has the problem existed? What are its historical antecedents? Is your problem linked to some other, larger problem? Is the problem a local one, statewide, national, etc.? What changed to produce the problem?

   **How long has the problem existed?**
   This law was finalized in 1971 as a result of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

   **What are its historical antecedents?**
   §1306.13 started out as §306.13. The earliest final ruling on section a of §306.13 was Apr. 24, 1971. It came about as a result of the Comprehensive Drug Abuse Prevention and Control Act of 1970 which consolidated several different laws and placed all drugs into the five schedule system. The exact wording of §1306.13 part a has remained the same since §306.13 was put into effect under this act. §306.13 started as only part a and was later re-designated to §1306.13 when the powers of the Bureau of Narcotics and Dangerous Drugs was transferred over to the DEA. Further amendments added the additional sections of §1306.13 and changed the wording of those other sections slightly.

   **Is the problem linked to some other, larger problem?**
   I don’t think there is a larger problem beyond what we are trying to change. If anyone else disagrees please add what you think the larger problem would be.

   **Is the problem a local one, statewide, national, etc.?**
   The problem is a national one. This is a federal regulation and affects everyone.

   **What changed to produce the problem?**
   At the very least, the need for anti-drug laws of the 1970’s to be consolidated and President Nixon’s crack down on illegal drugs kicked off the Act mentioned above. However, this section has been alluded to being in existence since before this Act, so what propagated that change is unknown with seeing the notice of proposed rule making for the preceding regulation.

3. **Develop a fact base**
   Describe the sort of evidence that will be necessary to persuade others (e.g., a legislator) of the existence and severity of your problem. Identify suitable resources for you evidence.

   There are several ways to represent, through evidence, the problem that exists, to the legislation. For starters, we can get a petition out to local pharmacists who see that there is a problem with the current 72hr limit. Second, we can have testimonials and anecdotes from both pharmacists and patients. This problem goes both ways to the patient and to the Prescribers who will have to be notified if the patient does not receive the remainder of the prescription within the allotted 72 hours. They might have to prematurely write another
prescription. Information needs to be gathered whether the person is for it, against it, or does not care. Along with that a why would be very important also. It could be that there is a compelling argument out there for the given time limit. We can also pose questions getting to the significant part, why 72 hours.

Summary
Resources for information-
Pharmacists
Physicians
Patients

Types of information-
Petition (one sided because any one for it will be excluded)
Testimonials/anecdotes
Questionnaires

4. Describe your goals and objectives for resolving the problem, and how you might measure change.
For instance, if the problem is medication errors, the goal would probably be to reduce medication errors, the objective is to reduce medication errors reported to Board of Pharmacy by 20% in two years, and the measurement is a count of the reports of a specified type (e.g., medication errors where the patient actually took/was administered an incorrect drug/dose/strength).

5. Identify the policy envelope
What variables can be measured regarding the problem? For instance, is staffing an issue with medication errors? Who are the stakeholders (persons or organizations with an interest in or are at risk because of the problem)?

The stakeholders involved in this problem are the patients with the prescriptions for the Schedule II medications as well as the pharmacist and staff that order the medication and fill the prescription. If the pharmacy cannot complete a fill of a C-II within the 72 hour time limit, then the patient may have to go to another pharmacy to get the medication as was outlined in section 1. Another alternative for the patient is to go back to the doctor's office to get another prescription for the rest of their medication after receiving a partial fill. Not only is this inconvenient for the patient, it is time consuming for the doctor to write another prescription. A variable that could be measured might be how often C-II partial fills are completed at a particular pharmacy compared to how often they are left incomplete because of ordering delays.

6. What are the potential costs and benefits to resolving the problem? (Optional)
Note: identifying costs and benefits is an important part of policy analysis, but is beyond the scope of this course. If you have some ideas, please express them, but this is not required.

Benefits: An amendment to this law would make it possible to not interrupt the continuity of care we provide to patients. It would also decrease inconveniences, paperwork, and contact time for the pharmacist, patient, and provider and indirectly driving down health care costs. It would make it easier for pharmacists to adhere to the pharmacy laws. It would be beneficial for the one who orders and does the inventory for the pharmacy, as
they would not have to try and predict schedule II narcotics orders and take into account weekends, holidays, etc. The pharmacy would not have to stock all schedule II narcotics and risk having outdates to hassle with.

Costs:
This potentially could create extra trips to the pharmacy by the patient. The only issue we might run into is that this is a federal law, so it might be more difficult to petition.

Comment [DM1]: This looks like an interesting project. As noted, this rule has been around forever but times have changed. Have you thought about what time period might work better? Could the remaining stock be dispensed in partial quantities? Where is the line between eliminating 72 hours and refilling schedule II prescriptions?

Group 1: Meth Busters
Group Members: Etegenet Assefa, Louisa Chu, Dennis Go, Marshall Heaster, Marcie Hume, Kristen Kai, Robert Lambert, Jill Mack

1. The manufacture and use of methamphetamine has escalated drastically using pseudoephedrine and ephedrine (P/E) as a major precursor. In order to control this problem, we are attempting to make the following changes:

RCW 69.43.110
Ephedrine, pseudoephedrine, phenylpropanolamine -- Sales restrictions -- Penalty. (Effective January 1, 2006.)

(1) It is unlawful for a pharmacy licensed by, or shopkeeper or itinerant vendor registered with, the department of health under chapter 18.64 RCW, or an employee thereof, or a practitioner as defined in RCW 18.64.011, knowingly to sell, transfer, or to otherwise furnish, in a single transaction:

(a) More than two packages of one or more products that he or she knows to contain ephedrine, pseudoephedrine, or phenylpropanolamine, their salts, isomers, or salts of isomers; or

(b) A single package of any product that he or she knows to contain more than three grams of ephedrine, pseudoephedrine, or phenylpropanolamine, their salts, isomers, or salts of isomers, or a combination of any of these substances.

(2) It is unlawful for a person who is not a manufacturer, wholesaler, pharmacy, practitioner, shopkeeper, or itinerant vendor licensed by or registered with the department of health under chapter 18.64 RCW to purchase or acquire, in any twenty-four hour period, more than the quantities of the substances specified in subsection (1) of this section.

(3) It is unlawful for any person to sell or distribute any of the substances specified in subsection (1) of this section unless the person is licensed by or registered with the department of health under chapter 18.64 RCW, or is a
practitioner as defined in RCW 18.64.011.

(4) A violation of this section is a gross misdemeanor.

Section 1(b) of RCW 69.43.110 is amended by striking “three grams” and inserting “1.2 grams”.

Section 2 of RCW 69.43.110 is amended by adding after “of this section” “further, no pharmacist or pharmacy shall sell to any person, nor shall any person obtain more than twice the maximum quantity set forth in (1)(a) and (1)(b) above in any 60 day period”.

Our perspective is that of that of a pharmacist or pharmacy employee, the issue of methamphetamine use is a growing problem, and selling p/e products to customers that do not show symptoms that necessitate the product feels like we are propagating the problem instead of limiting it.

2. Use of p/e for domestic manufacture of methamphetamine has existed ~ 14 yrs.

Methamphetamine use is a worldwide problem. The use of the internet has greatly spread the ability to access directions on how to make methamphetamine.

3. Methamphetamine production and use leads to multiple crimes such as: child neglect, child and spousal abuse, assault, theft/robbery, homicide, ID fraud, mail theft, environmental problems. P/e is now a major culprit in the domestic production of methamphetamine. In law enforcement raids of methamphetamine laboratories p/e in tablet and powder form is commonly found in large quantities as a direct ingredient for the production of methamphetamine. Reducing the number of p/e sales has proven to significantly reduce the number of active domestic methamphetamine labs. Suitable resources: US Department of Justice, US Attorney’s Methamphetamine Working Group, Local and State Law Enforcement statistics and crime information.
4. Our goal is to reduce the number of domestic active methamphetamine labs through the restriction of p/e sales. In one year we would like to reduce the number of active labs in Washington State by fifty percent. The effect of the restriction of p/e sales on the production of methamphetamine shall be measured by law enforcement reports of methamphetamine production and crimes associated with its use.

5. We can measure the amount of p/e that is distributed to the public and compare the data with previous years. The amount of methamphetamine production halted by law enforcement with p/e as a main precursor as well as methamphetamine-associated crimes can be measured.

Stakeholders:

Drug Manufacturers, Drug Wholesalers, Prescribers, Pharmacists/Pharmacy employees, patients and family members, law enforcement, Shopkeepers without a license to sell p/e, Legislative bodies (BOP)

Group #6 <Indication for Use>
Members: Jens Frisvold, Erin Dennis, Hieu Le, Steve Hasslinger, Julia Coolman, Kellie Nakamura, Anne Mock, Nazleila Hojjati

1.) Describe the problem

Currently, Washington state law does not require prescribers to write an intended use on the prescription. This is a problem because oftentimes we, as pharmacists, are unaware of the condition for which the person is being treated. Being left in the dark does not allow us to perform our jobs to the fullest extent. Knowing exactly why a person is getting a particular medication would greatly aid us in the process of counseling. We will be able to tell them what to expect from the medication regarding their particular problems. Further, if we know why a certain medication is being used, we may be able to make better recommendations to physicians when they are prescribing a product that is sub-optimal for...
its intended use. For example, if a doctor prescribes an antibiotic for gonorrhea that is not indicated for treatment of a gonorrhea infection, we would be able to suggest a better option. This would improve patient care because the patient’s infection would clear up faster, and they would not have to go through an extra round of unnecessary antibiotic treatment. Clearly requiring prescribers to identify an intended use on the label would result in an improvement of the quality of patient care.

2.) Delineate the boundaries of the problem

-We suppose this issue has existed for as long as pharmacy has been around, since there has never been any law that says Dr’s must write Dx on Rx’s.

-Historical antecedents: California has tried to get this done before, and it never passed b/c of confidentiality. However, there is at least one state that has this law in effect: Texas(since 1993)

-The problem does link to some other, larger problem, possibly 3-fold. Patients may feel a violation of HIPPA, but if we must advocate that we are also health care professionals and their info would be confidential. (I am suggesting that the patient may ask to not have the Dx written on the bottle. But it would be on the original Rx for pharmacist to know.) The other reason is that if we have the indication for use, then it may give us a better idea on how to counsel. Thirdly, it may be helpful in identifying look-alike, sound-alike names. This will aid pharmacists in decreasing medication errors.

-The problem is a national one, because it can occur in all the states.

-What changed to produce the problem? Pharmacists want to be seen as healthcare providers and this would help us to take an active role in the patient’s care. This will help us to move beyond the dispensing role into a provider role.

3. Develop a fact base

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The main reason that the indication for a medicine should be placed on the signature is so that a trained health care professional (pharmacists) will have the information they need to ensure that the medication that they are dispensing is appropriate, efficacious and safe for that patient. In order to convince the legislators that this is a wise move, it is necessary to have them respect pharmacists as qualified healthcare providers who are motivated to accept greater responsibility in order to promote the best interests of patients. In addition, it is necessary to show that this would improve patient care with some well documented numbers and statistics concerning medication errors that could be prevented with this measure. Some suitable resources for this would be scientific studies concerning medication errors and their impact. These studies can be found in a wide variety of medical journals and government sponsored research as well as in the field of pharmacoconomics. It would also be important to gather citizen support to place a personal feel on this argument. An alliance of patients who have been harmed by medication errors that could have been prevented by such a law would likely be a very inspirational and persuasive spokes group.

Besides describing the benefits with scientific there are really several key issues that must be addressed in order to assure the interested parties that patients will be protected. The paramount issue that must be overcome is assuring prescribers, legislators and patients that their confidentiality will not be violated, abused, or used for detrimental purposes such as marketing. There should also be foresight into the implications that this could have on whether insurance companies will cover the cost of medications if they are not used for a designated indication.

4.) Describe your goals and objectives for resolving the problem, & how you might measure change.

Our goal is to provide better, more personalized and condition-specific care to our patients; our proposed measure for its achievement is through the addition of an indication for the medication on the prescription by the prescriber. Change could be measured as the percent of new prescriptions having an indication for the current year less the percent new prescriptions having an indication from the previous year. Data from the same month of consecutive years could provide a useful proxy for early years, if the burden of retroactive data-collection is too onerous.

5. Identify the policy envelope

Variables to be measured are statistics on medication errors after 3 Years of passing the “intent of use” law. This is to see if there is a decreasing trend in the amount of medication errors caused by the prescriber. Pharmacists can also be polled after 1 year to see if they feel the “intent of use”
law is helping to verify that a script is free of medication errors. Any patient filling a prescription at a pharmacy is at risk for this problem. The wrong drug therapy prescribed for a medical condition is a common problem, as well as the wrong dose given to treat a patient’s condition. Pharmacists can better catch these medication errors with the “intent of use” written clearly on the prescription. The other party affected by this law would be prescribers. Although they would need to take one further step and write “intent of use” on the prescription, we need to stress the value to the patient and how much it could help. The other side of this is that for places using computerized order entry, there would need to be an alteration in the program to allow a space to input the "intent of use."

I think it's also important to note that having "intent of use" written on the prescription also makes it a lot faster for pharmacists when dealing with DSHS and other sorts of claims where a diagnosis code is necessary. This not only decreases strain on pharmacists but also on doctor's offices having to receive calls from the pharmacy and decreases the wait time for patients.

6.) What are the potential costs and benefits to resolving the problem?

If this law gets passed, there is a potential that insurance companies put some restrictions over certain indications. They might put some limits on less vital indications. For instance they cover the drug "singular" if it is indicated for asthma but not for allergies. This could cause some problems for both physicians and patients. On the other hand, stating the indicated use could help pharmacists to counsel patients more productively and appropriately. This improvement in drug therapy could be cost effective in the long term.

Group 7 Label Requirements- description and picture

Madeline Lorraine Fry, Caroline Kim, Casey D. Lirot, Suejin Park, Catherine Dela Cruz Ulep, Dimay Wang, Caroline Yuan-Chi Wu, Chris B. Yocom

1. Describe the problem.

Medication errors are one of the leading causes of preventable harm to patients “errors involving prescription medications kill up to 7,000 Americans a year.” ¹ Product labeling is
considered one of the contributing factors to medication errors. We, as pharmacists, are in a position to help in decreasing this number. By placing a description that includes the shape, color, and imprint of the drug on the prescription label, many medication errors and patient confusion could be avoided. Also, some patients are not compliant when their medication looks different, which leads to lower positive therapeutic outcomes. These mandatory descriptions will not only add a quick and efficient check-point for the pharmacist, but it will also enable the patient to determine that they are receiving and taking the correct medication.

2. Delineate the boundaries of the Problem.

The problem of medication errors has been around since the beginning of use of pharmaceutical products and most likely will increase as the usage of prescription medication rises. As pharmaceutical manufacturers produce more generic medications, a single drug exhibits more physical variations. This can lead to dispensing and patient confusion. Also, some patients are not compliant when their medication looks different, which leads to lower positive therapeutic outcomes. As patient advocates, we can implement mandatory medication description on labels at a state level and as it proves beneficial, we can then pursue changes at the national level.

3. Develop a fact base.

We will illuminate numbers and facts that express the severity and frequency of medication errors. There are numerous resources that reflect this situation. There are the two references from above, the FDA, the BOP, and numerous others. We can also use statistics that measure the number of positive therapeutic outcomes.
4. Describe your goals and objectives for resolving the problem, and how you might measure change.

Our goal is to reduce medication errors and to increase patient compliance and patient confidence in correct medication dispensing. For the reduction of medication errors we would monitor the number of errors reported to the BOP. For patient compliance we would need to survey health care providers and patients. The matter of confidence could be monitored through anonymous survey as patients pick up prescriptions.

5. Identify the policy envelope.

Some of the variables that could be measured are prescription volume, changes of manufacturers, and satisfaction of patient knowledge and confidence.

The stakeholders would include manufacturers, independent pharmacist, retail pharmacist and their employer’s, insurance companies, and out-patient pharmacies. We also think that the patient should be included as they are at a great risk.

Group 10 –Generic Substitution
Frances McGaugh, Michael Fallon, Whitney Stoffel, Jasmine Chase, Thu Dang, Ching Chow

1. Describe the problem

This description of the empirical situation should be as precise and complete as you can make it. The values underlying your description of the problem should described - what is your perspective, a pharmacist, a pharmacy owner, pharmacist employee, patient, payer, etc. If you have documentation supporting your problem, please include the references as a footnote.

According to Revised Code of Washington (RCW) 69.41.120, prescribers can dispense either brand or generic drugs to their patients by signing on one of two lines at the bottom of the prescription to indicate their choice. In Washington, the right side is designated as “dispense as written” and the left side is designated as “substitution permitted”. However, in other states, such as Alaska, the lines are switched. Since most
legal documents are signed on the bottom right, prescribers have a tendency to sign “dispense as written” line.

Under Federal Drug Administration’s therapeutic equivalence standards for drugs, generic medications can substitute brand name drugs if there is AB rating for bioequivalence. Currently, when patient’s insurance does not cover the brand medication and the practitioner signed under “dispense as written”, pharmacists must call their physicians for approval to substitute for the generic product. Pharmacists often spend many hours with insurance claims and communicating changes with doctors. Dr. Hazlet cited a NACDS study which shows that about 27% of a pharmacist’s time is spent on dealing with insurance claims. RCW 69.41.150 absolves pharmacist from any responsibility or risk as long as the prescription is filled exactly as it was written. With the extensive clinical knowledge provided in Pharm D. programs, pharmacists can assume a more active role in therapeutically helping patients choose appropriate medications.

As Medicaid and Medicare cost continue to rise, as well as private health care premiums, many patients cannot afford their medications. In a study published in June 7, 2005 issue of *Annals of Internal Medicine*, it cited that “generic substitution... could save consumers nearly $9 billion a year”. Data acquired by the Agency for Healthcare Research and Quality shows that “56 percent of all prescription medications have a generic substitute”, thus there is great potential for patients to save money. Currently, if the patient wants generic drugs, but the doctor wrote for a brand prescription drug, pharmacists have to call the provider to get the medications switched. The patient’s autonomy to use brand or generic drugs and right to choose their healthcare is hindered when the practitioners sign on the “dispense as written” line.

With the current laws in place, hospitals and pharmacy owners struggle to keep an updated inventory of all the brand name drugs that practitioners write for. If deemed therapeutically appropriate by the Pharmacist, automatic substitution for generic products...
could save a lot of money on stocking an adequate inventory and throwing away outdated drugs.

For insurance companies, auditing prescriptions can be very cumbersome when refills do not have “dispensed as written” explicitly written on each refill authorized by the doctor. The insurance company must take all money back for the prescription and the pharmacy has to accept the cost for their mistake. This is a huge loss of money and time for both pharmacists and insurance companies.

2. **Delineate the boundaries of the problem**

How long has the problem existed? What are its historical antecedents? Is your problem linked to some other, larger problem? Is the problem a local one, statewide, national, etc.?

What changed to produce the problem?

States began to pass “generic substitution” laws starting in the 1970’s. Prior to this many states had protections barring dispensing generic products, dubbed “anti-substitution laws”, which were supported by the APhA up to 1970.¹ These products were notorious for being fraudulent in the 1940’s and 50’s, the age of “miracle drugs”. The poor quality stemmed in part from the fact that many of the “miracle drugs” were still on patent and thus not easily replicated. The Kefauver-Harris Amendment of 1962 mandating drug efficacy aimed in part at solving this problem.

By the 1970’s many of the earlier drugs patent lives had run out and even large pharmaceutical firms were producing generic products. The fact that by the early 1980’s eighty percent of generics were being produced by large “brand name” firms largely debunked the pharmaceutical industries widely pushed claim that generics were unsafe.² The NY Legislature provided a list of 2000 generic substitution products deemed equal in strength and purity to brand name products. This list was endorsed be the FDA in 1978.³ Brand name products, then as now, commanded a premium price. Legislative hearings floated figures like “300-700%” higher costs.⁴ Consumer protection on this cost front, not the safety front, was the driving force for legislation.
Pharma and medical groups were largely opposed. Consumer protection and senior advocacy groups were largely for the proposal. Pharmacy interests were split, leaning slightly towards favoring. APhA backed the proposal on the grounds of a larger role for the profession. In opposition, at least one group of pharmacist brought suit claiming decreased “brand name” sales were hurting their practice. Additionally a NY study showed that pharmacists given generic substitution scripts only filled with an available generic 68% of the time. Doctors only prescribed generic if available 58% of the time.

Analyzing laws across states proved helpful in determining how the various stakeholders were satisfied. In the case of NY (and I believe much of the country but I’m not positive on this one yet) laws started with the 2-line format and evolved towards formats that favored greater generic substitution. NY changed its 2-line script law of 1977 to the current 1-line script in 1981. The new script requires a box that has written underneath “THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PRESCRIBER WRITES ’d a w’ IN THE BOX BELOW”. Many states went further by mandating 1-line Rx forms with generic substitution by default unless the prescriber handwrites “No Drug Product Selection,” “Dispense as Written,” “Brand Medically Necessary,” “No Generic Substitution,” or something else to that effect. Interestingly, out of 45 states surveyed, an incredible 35 already operate under the law our group is proposing. Four others have the NY style box system, while the remaining 6 use Washington’s 2-line system. (Please see attached “Generic Substitution Laws by state” spreadsheet)

Additional protections were put in place. The following is a partial list with at least one state that utilizes:

1. Specific lists of narrow therapeutic range drugs not to be substituted. (MN)
2. The patient must be informed that a generic is being dispensed. (most)
3. Mandated generic fill must be given when available. (PA, NY)
4. Mandated sign posting in pharmacy that says something to the effect that “generics can save you $$.” (MN, CT, FL)
5. Pharmacist is liable for substitution, not the prescriber.* (CA)
6. Pharmacist is liable but not if following FDA or State guidelines.(KY, MD, IL)
7. Rx forms with small font instructions for how "d.a.w." is assigned.** (DE, ME)
8. Consumer choice of brand name product allowed at additional cost. (most)

* This law seemed to place the most liability on pharmacists
** These did not seem to be very common

References:

3) Develop a fact base
Describe the sort of evidence that will be necessary to persuade others (e.g. a legislator) of the existence and severity of your problem. Identify suitable resources for your evidence.

Pharmacists are medication specialists. We have the most training and knowledge of therapeutics in comparison to other healthcare providers. Thus, pharmacists dispensing therapeutic equivalent generic medication for all applicable prescriptions should not only be authorized, it should be required by law. However, Washington's current law, RCW 69.41.120, inhibits pharmacists from expanding our specialized area of knowledge. Thus, pharmacists have a wealth of knowledge that has not been used towards maximizing
patients' benefits. With the existence of the FDA tight regulation, the Orange Book, and the pharmacist’s knowledge of evidence base medicine, we can augment our standard of patient care by enhancing the aspect of economically favorable pharmaceutical care. We all know that generic medications cost less and it works as well or better than brand name product if it has an AB rating. So why not discard the DAW way of dispensing and leave it up to the pharmacists and the patients to decide. That way it will maximizes patient's autonomy and the pharmacist's therapeutic knowledge. Additionally, practitioners are released from having to decide what is the best therapeutic category for the patients, which means one less decision to make and one less thing for them to worry about.

There is a small part in RCW 69.41.120 that allows pharmacists limited ability to do therapeutic equivalent generic drug substitution. It says " in case of prescription issued by a practitioner in another state that uses a one-line prescription form ... pharmacist may substitute a therapeutically equivalent generic drug ....".

If this is already part of the law, why not expand it to authorize pharmacists to make substitutions for all of the medications that have AB rated generics. The potential benefits of granting pharmacists that right are numerous. In addition to what I have mentioned above, pharmacists and practitioners don't have to waste time in communicating generic substitutions per patients' request. Wasted time is wasted money. But most importantly, time is limited, so it should be dedicated to patient care, not asking or authorizing whether we can dispense generic or not.

4.) Describe your goals and objectives for solving this problem. How will you measure change?

The intent of this legislation is to simplify the prescription process to guarantee patients are receiving the most cost effective therapeutic treatments. All patients should have the right to know about and choose equivalently safe and effective generic medications, which can be purchased at a much lower price than brand name products.
This legislation also empowers Pharmacists by increasing their responsibility of medication management. Since Pharmacists are medication experts, it should be their role to properly select cost effective generic substitutions based upon FDA regulations. Pharmacists are also the best healthcare professionals for knowing what generic products are currently available, as it is their duty to remain knowledgeable about the pharmaceutical marketplace.

Implementing this change will also streamline the prescription filling process and eliminate confusion over the lack of unified regulations. Pharmacists will be able to use their professional judgment for generic substitution, which will save time from calling providers or insurance companies to authorize changes. One unified system will also save money pharmacies lose to insurance company audits by eliminating confusion over medication substitution and the quagmire of necessary documentation.

Once this plan is implemented change will be apparent in several ways. The first is the financial impact of mandating generic substitution (unless explicitly written DAW by the physician or requested by the patient). Almost every player in the health care industry stands to save money through mandatory generic substitution (except of course brand name pharmaceutical manufacturers.) Patients, pharmacies, taxpayers, the government, and insurance companies will all see savings from the switch to mandatory substitution.

Other areas of progress which may be measured are the time and money saved by Pharmacists who have the power to automatically dispense generics. This change will save thousands of hours a year spent on the phone clarifying substitutions with prescribers and insurance payers. With this simplified filling process, Pharmacists will be able to spend less time coordinating dispenses and more of their time educating patients.

5. What variables can be measured regarding the problem? Who are the stakeholders?

There are many variables that may be considered when striking out the DAW line. In order for this to be successfully implicated, it will require that all prescribers obtain the newly designed Rx pad AND actually use it. If they do not comply, then time and money
may be spent again on correcting the nuances. Additionally, all pharmacists must agree and make wise decisions when completing a substitution. If he/she has any hesitation to substitute the medication, he/she must consult with physician before making any final decision in the choice of therapy for the patient.

Who’s at stake here? Everyone. Manufacturers are the major stakeholders here. The pushing of generic medications poses a big loss in potential profit; they are the most likely opponents of this measure. Conversely, insurance companies are likely to be supporters of this cause because this means that they will not have to include the expensive, brand-name medications in their formularies. Pharmacists themselves too, are another major stakeholder. If they do not demonstrate that they can effectively make the ideal decision for the patient, they will be highly criticized. And of course, patients too will need to be considered. All these changes are ultimately made in order to benefit the patient’s well-being thus they play a big role in the issue.

Group 4 Expiration of Schedule II Rx
Linh Mai, Andrea Eberly, Quyen Nguyen, Jeff Loor, Geoff Meer, Jennifer Law, Nick Wyatt, Sareh G.

1. Describe the problem

This description of the empirical situation should be as precise and complete as you can make it. The values underlying your description of the problem should described - what is your perspective, a pharmacist, a pharmacy owner, pharmacist employee, patient, payer, etc. If you have documentation supporting your problem, please include the references as a footnote.

The Washington State Board of Pharmacy finds that all schedule II substances listed under WAC 246-887-140 have a high potential for abuse. Although these substances are currently accepted as medical treatment for severe pain and mental disorders, they may lead to serious physiological and psychological dependence if abused. Because of its addictive potential, it is not recommended to have a schedule II prescription last a year after the date the prescription was written. The argument has been made that seeing a physician is expensive, time consuming and bothersome, and the fact that there are no refills on CII prescriptions puts an undue burden on patients. Therefore prescribers have got around this by issuing multiple prescriptions on the same day to the patient with the idea that the patient will then get the prescriptions filled each month until they see the physician again. As the prescriptions do not expire for one year, the patient could in theory not revisit the physician for a year! In effect, refills CAN be written. But is this good medicine? We think not, however we also understand the perspective that patients may not need to see the physician every month (like in the case of amphetamine salts,
methylphenidate) and recommend limiting the validity to 90 days. Additionally, it is not logical for a schedule II prescription to have a longer expiration date than schedule III and IV, which have a six month expiration date since the potential for abuse is less in the latter examples. Medical conditions which require schedule II substances for therapy need to be monitored carefully. If patients can legally pickup a schedule II prescription after a year of the written date, they are obviously not under strict supervision of a provider. As health care provider, one should always look out for the best interest of the patients. Schedule II prescriptions should only last for 90 days to increase the need for closer supervision to ensure patients’ safety.

2. Delineate the boundaries of the problem

How long has the problem existed? What are its historical antecedents? Is your problem linked to some other, larger problem? Is the problem a local one, statewide, national, etc.? What changed to produce the problem?

Schedule II substances are considered as legend drugs. According to WAC 246-869-100, no prescription may be refilled for a period longer than one year from the date of the original prescription. Section RCW 69.04.560 limit schedule III and IV substances to be filled or refilled for no more than 6 months after the written date, unless renewed by a practitioner. Schedule II was excluded from this limitation. Although schedule II substances have a one year expiration date, a prescription can not be refilled.

This is both a national and state level problem. In essence the problem has existed as long since the Harrison Narcotic Act and was not fixed in the 1970 Controlled Substances Act. CIII and CIV were tackled and regulated, but CII prescription expiration was ignored in the final law. [(a) Schedule II substances. Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 USCS 301 et seq.], may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 USCS Section 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 307 of this title [21 USCS Section 827]. No prescription for a controlled substance in schedule II may be refilled.] Nothing particularly changed to cause the problem so much as the problem or potential for abuse was largely ignored.

3. Develop a fact base

Describe the sort of evidence that will be necessary to persuade others (e.g., a legislator) of the existence and severity of your problem. Identify suitable resources for you evidence.

One would need evidence showing that patients are somehow receiving better care and closer monitoring. We will search in the law library to find old arguments for and against having CII prescriptions limited to 72 hours of validity. Other facts could be statistics on CII abuse and also facts regarding best treatment of patients who require CIIs in terms of physician visits, monitoring, etc in order to demonstrate that one year is really too long for these prescriptions to be valid when they see their providers more frequently for assessment of their condition. We can also look to other states’ regulations regarding this matter. For instance, Oklahoma requires the schedule II prescriptions to be filled within 5 days of the written date. Similarly, California restricted schedule II prescriptions to be
filled within 14 days in the past and Massachusetts regulations limit schedule II prescriptions to be filled within 30 days.

4. Describe your goals and objectives for resolving the problem, and how you might measure change. For instance, if the problem is medication errors, the goal would probably be to reduce medication errors, the objective is to reduce medication errors reported to Board of Pharmacy by 20% in two years, and the measurement is a count of the reports of a specified type (e.g., medication errors where the patient actually took/was administered an incorrect drug/dose/strength).

Our goal is to change the expiration date of schedule II substances from one year to three months to ensure patient safety and less potential for abuse. Change could be measured in the reduction of schedule II prescriptions filled. Perhaps after an assessment, a schedule II prescription is not necessary to treat the condition.

5. Identify the policy envelope
What variables can be measured regarding the problem? For instance, is staffing an issue with medication errors? Who are the stakeholders (persons or organizations with an interest in or at risk because of the problem)?

Stakeholders include everyone who handles CII prescriptions, such as pharmacists, physicians, patients, dentists, and potentially associations. Patients are vague and cannot be contacted, however pharmacists, physicians and Dentists can be. As far as variable---length of time the prescription is valid. Bearing in mind that federal law says that there can be no refills.

The key variable to measure is the average length of time between acquisition of a CII prescription and the dispensation of the medication. This average length of time would be the most important measure of how long the lifetime of such a prescription should be. Shorter timeframe was bothersome to physicians who found they had to rewrite prescriptions for controlled substances if their patients failed to have them filled in 14 or five days. The longer timeframe makes abuse by patients more feasible, and that increases the workload for DEA agents. A more moderate timeframe would be beneficial to all stakeholders.

Group 5 Rescheduling of Clonazepam
Group Members: Osama Saleh, BJ Gleason, Rachel Nowak, Kevin Hiroo, Vivian Villanueva, Hae Young Zhang, Benjamin Davis, Carolyn Sear

1. Problem Description
As stated below, Clonazepam (Klonipin®) has been categorized under the Revised Code of Washington as a Schedule IV controlled substance. 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:

\[^{3}\text{RCW 69.50.210 (b) (9)}\]

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:
with administration of Clonazepam may be excessively disregarded in comparison to similar Schedule III narcotics. Furthermore, the chances for access to and use as a recreational drug or “street-drug” are greater under the Schedule IV status as regulations upon suppliers of Clonazepam such as extended health care facilities, hospitals, and pharmacies are less stringent. Unwarranted and over prescribing of Clonazepam by medical authorities has been shown to be indicative of increased illicit use, and as national data has shown a marked increased in overall Clonazepam prescriptions, it is apparent that the legal and clinical awareness of the prescriber may be inadequate due to the less significant current scheduling of this narcotic. As a pharmacist and healthcare professional, we feel it is obligatory to ensure the best possible health outcomes for our community, but as a Schedule IV narcotic, it is currently impossible to maintain that expectation for the safe and effective dispensing of Clonazepam.

2. Boundaries of the Problem
The potential for abuse of benzodiazepines has been recognized since its introduction into the market over 30 years ago as a C-IV narcotic. Benzodiazepines have since then replaced older sedatives and hypnotics and are now widely used. Four types of benzodiazepines: Alprazolam (Xanax), Clonazepam (Klonopin), Diazepam (Valium), and Lorazepam (Ativan) are among the top 100 prescribed medications. Data show that abuse rates of benzodiazepines have decreased since the 1970s and a national sample in 1992 showed that one to three percent reported non-medical use within the past year. However, these statistics become more significant when considering the wide use and availability of benzodiazepines. Another concern is the abuse of benzodiazepines among poly-drug addicts—it is estimated that 80% of benzodiazepine abuse is associated with poly-drug abuse. Members of this class of drug are rarely abused solely or the preferred drug of abuse, but have multiple uses including: to enhance the effects of opioids, relieve withdrawal symptoms, and augment effects of consumed alcohol. Given the wide use of

(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.
benzodiazepines, along with the link to other forms of substance abuse, there is a clear indication of the necessity to address this national problem.

3. **Fact Base**

The evidence necessary to validate our point includes statistics involving Clonazepam and negative consequences associated with the drug. These statistics include, but are not limited to: the percentage of people addicted to clonazepam, adverse events associated with clonazepam, current use frequencies of clonazepam, and a measure of lack of awareness by health professionals (including physicians, pharmacists, nurses, caretakers, etc.) on the current schedule status of clonazepam and the legal implications of this classification. In addition, it will also be necessary to have evidence that shows the chemistry behind the drug and its effects on the human body, and why it can be dangerous. Furthermore, it is pertinent to prove why addiction or substance abuse is a problem with clonazepam and if specific patient populations are targeted.

4. **Goals and Objectives for Resolving the Problem**

The objective of our project is to change clonazepam from Schedule IV narcotic to a Schedule III narcotic. By this action, our goals are then: to increase prescriber awareness of the potential for abuse and addiction associated with Clonazepam so as to decrease unnecessary and over prescribing; to increase awareness by pharmacists so as to decrease the dispensing of Clonazepam by illegitimate or forged prescriptions; to increase the general awareness of health care professionals who dispense and have direct access to supplies of Clonazepam so as to decrease theft and illegal removal and distribution of this drug; and to ultimately decrease abuse and addiction of Clonazepam in the State of Washington and primarily outside of the clinical setting where Clonazepam is used as a popular “street-drug.” Success could be measured by monitoring the number of new prescriptions written for Clonazepam and the number of refills given on new prescriptions. Overdose and addiction intervention rates could also be monitored to gauge the effectiveness of this rescheduling. The rescheduling itself could also be a measure of success since it is an objective of this project.

5. **Policy Envelope**

There is a wide policy envelope regarding the rescheduling of Clonazepam from C-IV to C-III. The measured variables surrounding this issue include, but are not limited to: practitioners’ prescribing habits.
in regard to Clonazepam, the number of individuals who are currently using and abusing Clonazepam, and the burden placed on medical services by individuals who abuse clonazepam. The stakeholders involved in this rescheduling issue would include practitioners (basically all involved in the health care system, since individuals who abuse medications put extra strain on an already taxed health care system), pharmacists (who will be faced with the day-to-day ramifications of this rescheduling), manufacturers, chemical dependency specialists, individuals addicted to Clonazepam, as well as those who could potentially become addicted in the future.

6. Potential Costs and Benefits of Resolving the Problem

One possible cost is increased financial costs due to requirement of daily counts and record keeping associated with Schedule III narcotics. Another cost related to rescheduling Clonazepam may be that the drug is stigmatized as addictive thus decreasing its use as a therapeutic agent. Benefits would include the increased awareness of potential for physical or psychological dependence and more stringent controls on inventory counts and records to prevent diversion.

Comment [DW18]: Which requirements for daily counts and more stringent controls are you describing?

Group 3: Show and Tell During Dispensing

Group Members: Aaron Chin, Tina Ngo, Lydia Zou, Helen Song, Connor Christy, Olga Shvartsur, Zachary Beard, and Joe Johnson

1. Delineate the Problem  According to the Institute of Medicine’s 1999 report, To Err is Human: Building a Safer Health System, nearly 100,000 people die each year due to medical errors. A national observational study on prescription dispensing accuracy published in 2003 estimates that 51 million dispensing errors occur annually, while an APhA report estimates that drug misuse costs the economy more than $177 billion each year. From the pharmacist and staff perspective, dispensing errors are a liability issue that can result in reprimand and revocation of license to practice. From the patient’s perspective medication errors are dangerous and could result in serious adverse effects, and even death. On a smaller level, the individual pharmacies may
choose to keep their own documentation of these errors, but on a formal level, we still need to research the process of submitting medication errors.

2. Delineate the Boundaries of the Problem Although this problem occurs worldwide, we will limit ourselves to dealing with the issue in our own state of Washington for the time being. This problem has existed for as long as drugs have been dispensed, but the trend of increasing prescription volume and pharmacist workloads is likely to exacerbate the problem during the decades ahead.

3. Develop a fact base Studies on error rates and testimonies from patients that have experienced adverse reactions from dispensing errors would be needed to persuade pharmacies to implement visually showing the medication during the counseling process. Testimonies from pharmacists about the errors they’ve made and the economic impact on their practice could convince pharmacy owners to require visually showing the medication to patients.

4. Describe your goals and objectives for resolving the problem, and how you might measure change. Our goal is to prevent wrong medications from being dispensed to a patient. In this effort, we propose adding an amendment to WAC 246-869-220 regarding patient counseling. “The pharmacist shall present each medication individually to the patient for a visual inspection upon dispensing of said medication, with the exception that a patient may opt to forgo such inspection at his/her own risk.” We will gather more information before deciding on the time frame and percentage of medication errors we want to reduce reported to the BOP.
5. **Identify the policy envelope.** The variables that can be measured are the feasibility of incorporating visual inspection of the medication within the pharmacy workflow and organization. Prescription volume and staffing would be considered as variables that contribute to medication errors. Estimates have been offered for the number of medication errors that occur. Adverse reaction reports are made through the FDA’s MedWatch. Some stakeholders include pharmacy owners, pharmacists involved in dispensing medications, the patients being served, and public health groups.

6. **What are the potential costs and benefits to resolving the problem?** It will require more time to dispense medications which may force some pharmacies to hire additional staff. While this law is relatively easily applied in an ambulatory care setting, special situations like mail order, long term care facilities, and hospital inpatient dispensing must be addressed.

[talk to Donna Dockter at Sandpoint Pharmacy for more info about medication errors; Mondays and Fridays are busy]

Testimony of Michael R. Cohen, MS, RPh
President, Institute for Safe Medication Practices
Testimony Before the Committee on Ways and Means
Subcommittee on Health, Congress of the United States
House of Representatives
Hearing on
Medicare Reform: Laying the Groundwork for a Prescription Drug Benefit
March 27, 2001
A new study released in the American Pharmaceutical Association's (APhA) March/April Journal of the American Pharmaceutical Association (JAPhA) has updated an analysis of prescription drug use problems in the United States. It estimates that drug misuse costs the economy more than $177 billion each year. The estimated number of patient deaths has increased from 198,000 in 1995 to 218,000 in 2000. [due to error?]


MAIN OUTCOME MEASURE: Dispensing errors on new and refill prescriptions. RESULTS: Data were collected between July 2000 and April 2001. The overall dispensing accuracy rate was 98.3% (77 errors among 4,481 prescriptions; range, 87.2%-100.0%; 95.0% confidence interval, +/- 0.4%). Accuracy rates did not differ significantly by pharmacy type or city. Of the 77 identified errors, 5 (6.5%) were judged to be clinically important. CONCLUSION: Dispensing errors are a problem on a national level, at a rate of about 4 errors per day in a pharmacy filling 250 prescriptions daily. An estimated 51.5 million errors occur during the filling of 3 billion prescriptions each year.


BACKGROUND: Medical errors have received national attention in the past few years, largely due to the Institute of Medicine's (IOM) 1999 report, which found that over one million
injuries and nearly 100,000 deaths occur annually in the US as a result of medical
errors.

Bond CA, Raehl CL. Pharmacists' assessment of dispensing errors: risk factors, practice

Certain demographic, practice, staffing, and pharmacist satisfaction variables may
contribute to dispensing errors. A survey was randomly mailed to 7298 (50%) Texas
pharmacists, of which 2862 were returned (39% response rate). Responders were 2437
pharmacists who indicated that they were in practice. Of these, 535 (23%) reported no risk
to patients for dispensing errors and 793 (34%) reported at least one patient/week was at
risk for such an error. There was a positive relationship between number of prescription
orders filled/hour and the estimated risk of dispensing errors ($r$=0.285, $p<0.001$).
Pharmacists practicing in mail service pharmacies (risk score = 1.85 +/- 1.32), traditional
chain store pharmacies (1.66 +/- 1.18), and hospital pharmacies (1.61 +/- 1.09) reported a
higher risk than other groups. Pharmacists practicing in independent community pharmacies
(0.75 +/- 0.84), home health care (0.83 +/- 0.99), grocery chain store pharmacies (1.30
+/− 0.96), and mass merchandise chain store pharmacies (1.30 +/- 1.08) reported a lower
risk ($H=260$, df=8, $p<0.001$). Nine job satisfaction variables were strongly associated with
the risk of dispensing errors ($r$ = between -0.3 and -0.422, $p<0.001$), as were
prescription volume, practice site, staffing, training, pharmacist functions, and professional
organization membership. The results of this survey should help pharmacists and
management develop specific plans for reducing the risks of dispensing errors. These data
should be useful for more in-depth study of such errors.
Australian study

RESULTS: Completed questionnaires were received from 209 pharmacists (50% response rate). Most pharmacists (82%) believed that the risk of dispensing errors is increasing. The principal contributing factors nominated were: high prescription volumes, pharmacist fatigue, pharmacist overwork, interruptions to dispensing, and similar or confusing drug names. The main factors identified as being important in reducing the risk of dispensing errors were: having mechanisms for checking dispensing procedures, having a systematic dispensing workflow, checking the original prescription (duplicate) when dispensing repeats, improving the packaging and labelling of drug products, having drug names that are distinctive, counselling patients at the time of supply, keeping one's knowledge of drugs up-to-date, avoiding interruptions, reducing workloads on pharmacists, improving doctors' handwriting, and privacy when counselling patients. Most pharmacists (72%) stated that they were aware of dispensing errors that had left the pharmacy undetected, in their place of practice during the past 6 months. The median number of such dispensing errors that they were aware of was three. A median of 150 was nominated as the maximum number of prescription items that can be safely dispensed per 9-h day (i.e. 17 items per hour) by or in the presence of one pharmacist. Most pharmacists (58%) stated that there should be a regulatory guideline for the safe dispensing load in Australia. CONCLUSION: Dispensing errors are occurring in numbers well above reports to regulatory authorities or professional indemnity insurance companies, and seem to be accepted as part of practice. High prescription volumes, pharmacist fatigue and overwork appear to be important factors. The profession needs to be proactive and standards must be set appropriately high (i.e. zero error tolerance).

Group #2: Prescription Only Pseudoephedrine
I. Describe the Problem

Pseudoephedrine is a decongestant found in many over the counter drugs. In recent years illicit drug users have found a way to easily turn pseudoephedrine into methamphetamine by the chemical removal of a single hydroxyl group. The manufacturing of methamphetamine form pseudoephedrine is a major contributing factor to Washington States significant methamphetamine problem. Methamphetamine is a potent CNS stimulant with a high abuse potential. It is well documented that Abuse of this drug leads to a very destructive addiction and is a significant risk to public health. Based on the high potential for abuse and addiction it is a schedule II drug. Given the ease of methamphetamine synthesis from pseudoephedrine and the nature of the addiction it is imperative that drugs containing pseudoephedrine be taken off of the shelves and made available as prescription only products. It is our belief that the authority to take steps to control pseudoephedrine-containing products is established in WAC 246-887-090, and in RCW 69.50.201. We believe that the steps the state is currently taking, along with the additional measures that go into effect in January will be insufficient to stop the illegal synthesis of methamphetamine.

II. Delineate the boundaries of the Problem.

While the use and abuse of methamphetamine has existed for at least eighty years, the production of this drug from the precursor chemical pseudoephedrine is a more recent development. Methamphetamine production in Washington State, as well as throughout the country, has increased rapidly in the past few years. The number of domestic meth labs has grown quickly as people learned that they

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5 Pharmacy Lawbook. Washington State Department of Health; 2003. 69,206
could make methamphetamine relatively easily from over the counter pseudoephedrine-containing products. The problem of methamphetamine production is linked to the larger problem of methamphetamine abuse, which often leads to drug-related violence and crime. Toxic waste produced by meth labs is also a growing environmental hazard.

III. Develop a fact base.

The evidence necessary to persuade others will include facts and statistics supporting the problem. A few examples collected from government offices would include the following:

- In 2004, 1339 methamphetamine labs were seized in Washington state with nearly half (551) labs residing in Pierce county.6
- In 2002, 17,696 emergency room visits in the nation were due to methamphetamine.7
- For every pound of methamphetamine produced, up to 5 pounds of toxic waste is created.8
- Toxic chemicals found in clandestine labs include acetone, methanol, ammonia, benzene, ether, Freon, hydriodic acid, hydrochloric acid, iodine crystals, lithium metal, muriatic acid, phosphine gas, red phosphorous, sodium hydroxide, sulfuric acid, and toluene.9
- Indiana saw a drop of from 153 meth lab busts to 113 busts the following year after stricter regulations of pseudoephedrine were enacted.10

We would use these facts, plus others, to indicate the severity of methamphetamine problem in WA state. Suitable resources of evidence include WA state DOH, Department of Ecology, US

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VI. Describe your goals and objectives for resolving the problem and how you might measure change.

Our goal is to reduce or eliminate the sale or diversion of pseudoephedrine obtained for the purpose of methamphetamine production in Washington state, while still making pseudoephedrine available for patients who need it. Our objective is to reduce the number of active methamphetamine labs in Washington state by an additional 25% two years after the new law takes affect. This goal/objective could be measured using state crime statistics showing the number of methamphetamine labs seized annually.

V. Identify the Policy Envelope

The over the counter availability of pseudoephedrine products creates easy access for those who produce methamphetamine. The law requiring the logging of pseudoephedrine sales does not go far enough to restrict the access of those people producing methamphetamine, especially in light of Oregon’s recently passed law making all products containing pseudoephedrine prescription only. Methamphetamine makers will likely come to Washington to purchase their main ingredient, potentially bringing their laboratories, social, and environmental hazards with them.

It is not unprecedented for methamphetamine makers to go to other states when their supply in their home state is eliminated. When Missouri made pseudoephedrine products Schedule V and requiring a log book of all sales on July 15, 2005, the number of methamphetamine labs seized by police decreased by more than 50 percent in August when
compared to August 2004. It was found that the methamphetamine producers began
driving to Illinois to obtain their main ingredient.\textsuperscript{11}

All community members are stakeholders in this law, especially those in rural areas where
the manufacturing of methamphetamine occurs more frequently. Methamphetamine
laboratories are a significant environmental hazard, one pound of methamphetamine can
have five to seven pound of toxic byproducts. Of county law enforcement officials
representing 45 states, 58 percent rank methamphetamine labs as their number one
problem.\textsuperscript{12} This is a significant drain on our law enforcement. Community members are also
patients requiring this common cold medication.

Pharmacies are also stakeholders, as the majority of the burden for policing this substance
will fall to them under the current regulations. Prescribers are also stakeholders, as the
prescription requirement will involve them more directly.

Group 9 Rescheduling of Tramadol
Group Members: Holly Dirks, Michael King, Amy Little, Adam McCown, Pavel Mitin, Robert
Siegfried, Gigi Wong

1. Describe the problem.

 We believe that there is a problem associated with tramadol abuse that can be resolved
by rescheduling it as a Schedule IV controlled substance. Although currently an
uncontrolled substance, tramadol has the potential to cause “psychic and physical
dependence”, as well as “craving, drug-seeking behavior and tolerance development.”\textsuperscript{13}
It also has the ability to cause a number of other adverse events in overuse, including
the lowering of the seizure threshold.\textsuperscript{1} Since 1995, The MedWatch program of the FDA
has received 766 case reports documenting tramadol abuse, as well as 482 cases

\textsuperscript{11} Hathaway, M. St Louis Post-Dispatch. Pill law gets credit for drop in meth raids But
from: ProQuest Accessed October 11, 2005

\textsuperscript{12} The Monitor’s View Washington Responds to ‘Meth’; But Congress, feds shouldn’t
overreact to this drug. Christian Science Monitor. July 26, 2005:08. Available from:
ProQuest Accessed October 11, 2005

\textsuperscript{13} Drugs and Chemicals of Concern (Tramadol) [Internet]: U.S. Department of Justice; c2004. [updated 2004 July;
demonstrating withdrawal associated with tramadol.\textsuperscript{14} In addition, The Drug Abuse Warning Network reported over 12,000 cases of tramadol-related emergency room visits from 1995-2002, with a total of 382 deaths due to tramadol from 1998 through 2002.\textsuperscript{1,2} We believe that health professionals are currently unaware of the abuse risk of tramadol due to its uncontrolled status. From the perspective of pharmacists and pharmacy employees, we would like to decrease the incidence of tramadol abuse for the safety of our patients, and would hence like to reschedule tramadol as a Schedule IV controlled substance.

2. Delineate the boundaries of the problem.

The problem has existed since tramadol was marketed in 1995. Originally claimed by its manufacturer to have only "very weak narcotic effects," it was prescribed to many known narcotic abusers by physicians who considered the drug to be safe. Following numerous reports of physical dependence, the labeling has since been modified to advise physicians not to prescribe tramadol for opioid-dependent patients, as the drug has been shown to be associated with "craving, drug-seeking behavior and tolerance development."\textsuperscript{15} The MedWatch and Drug Abuse Warning Network drug surveillance programs have received a multitude of case reports relating to tramadol abuse, and other countries have noted reports of adverse events relating to tramadol abuse as well. Although this problem exists nationally, we will look at it from the perspective of a statewide problem as the FDA is already aware of the problem and has it under review for possible control.

3. Develop a fact base.

The evidence that is necessary to persuade others of the existence and severity of our problem include reporting data demonstrating incidences of tramadol abuse, particularly data that indicates an increasing amount of tramadol abuse. Possible sources of this information include the MedWatch program of the FDA, as well as the Drug Abuse Warning Network. It would also be helpful for us to find evidence showing the addictive potential of tramadol, especially in regards to its effect on serotonin and opioid receptors. In addition, we would like to survey physicians and pharmacists to ask how they would rate the abuse risk of tramadol and if they would support the rescheduling of the drug.

4. Describe your goals and objectives for resolving the problem, and how you might measure change.

Our solution for resolving the problem would be to reschedule tramadol as a Schedule IV controlled substance by amending the Revised Code of Washington 69.50.210. Through the rescheduling of the drug, we could improve awareness of the abuse risk by health professionals, and decrease the incidences of tramadol abuse-related adverse events. Our goal could be measured through a follow up survey to pharmacies and physician’s offices to see if pharmacists and physicians believe the tramadol problem has improved with regulation of the drug. We could also look for a decrease in reports of adverse drug events due to tramadol if there is a reporting system for Washington State.

5. Identify the policy envelope.

\textsuperscript{14} McDiarmid T, Mackler L, Schneider DM. Clinical inquiries. What is the addiction risk associated with tramadol? J Fam Pract 2005;54:72-3.

\textsuperscript{15} Drugs and Chemicals of Concern (Tramadol) [Internet]; U.S. Department of Justice; c2004. [updated 2004 July; cited 2005 Oct 12]. http://www.deadiversion.usdoj.gov/drugs_concern/tramadol.htm
The variables that can be measured regarding the problem include the abuse potential of tramadol, as well as the adverse effects of tramadol. The stakeholders in this problem include patients, pharmacists, physicians, as well as insurance companies that may have to cover patients' hospital expenses as a result of adverse events that may occur from overuse of tramadol.

Comment [DW24]: The companies that manufacture this drug should be included as stakeholders.