5543 Stakeholders

Overall Comments:

• recall that there are prescribers other than MDs in WA
• when you make assertions (i.e., “our scheme is proven to reduce substance abuse by 50%”), provide citations

| 1. Restriction on sales of pseudoephedrine – C-V “Meth Busters”  |
| 2 Prescription-Only Pseudoephedrine                     |
| 3 Show and Tell at Dispensing                           |
| 4 Expiration of Schedule II Prescriptions              |
| 5 Black Box Warnings for Benzodiazepines               |
| 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 #1 Meth Busters

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

Stakeholders to be contacted are: Drug manufacturers/Drug wholesalers, Washington State Medical Association, Pharmacists/Pharmacy management, Law enforcement, Fire fighters, Washington State Board of Pharmacy, Washington State Pharmacy Association, and the Department of ecology.

Degree of political influence of each stakeholder group.
Law enforcement: Police officers are not generally going to change their job dramatically based on politics. Law enforcement officers are government officials however, and may be influenced by “higher ups” in government that are pushing a certain agenda.
Manufacturer/Wholesaler: Finding out about campaign contributions is certainly one way I will try to assess the degree of political influence, however with a company like Pfizer, it’s likely that they contribute to whichever side looks strongest (or both sides). The same approach can be taken with wholesalers. One other possible method is to try to determine how many (if any) government contracts have been awarded to a particular company.
Fire Fighters: Politically, the Fire fighters union has a great deal of influence on public opinion of the drug restrictions due to the fact that they often must put their own lives on the line in order to put out fires of ‘cookhouses’. Therefore they can directly influence public awareness of the issue in a bipartisan manner.
Department of Ecology: To assess the degree of political influence the Washington Department of Energy has it would be useful to determine the stance Washington State Representatives have on the environment. If they have strong views for or against that would give a better idea of the amount of weight their support carries.
Washington State Pharmacy Association: Rod Schafer: Being the Chief Executive Officer for the Washington State Pharmacy Association (WSPA), a legitimate guess is that Rod Shafer does have somewhat of an influence as a stakeholder since he is representing our state’s pharmacy association. As a stakeholder group, the WSPA is probably more concerned about how the proposed restrictions regarding pseudoephedrine will affect the practice of pharmacy within the state.

Washington State Board of Pharmacy Member: Board of Pharmacy members ensure that regulations are followed according to the RCW. They have the ability to revoke licenses and impose punishments against offenders. Their influence lies heavily on health care professionals (especially pharmacists), pseudoephedrine retailers, and the drug manufacturing industry.

Washington State Medical Association (WSMA): This medical community has historically had a large influence on legislation affecting their practice and health care in general. Support from the WSMA and other associations affiliated with prescribers would be critical for this piece of legislation to pass.

Pharmacy Manager: This individual sits on the Washington Legislative Regulatory Hearing Commission and may be influenced by inside knowledge or prior experience.

Assessment of the position of the stakeholder.

Law enforcement: Law enforcement officers are going to be in favor of something that helps them do their job without creating more hassle and “red tape.” I believe that most law enforcement officers would be in favor of this bill, as it would reduce domestic methamphetamine production even though meth use would probably remain constant due to an increase in foreign importation.

Manufacturer/Wholesaler: Assessing the position of the stakeholder can be done in a few ways. Looking into how ballot measures were endorsed is one way. Another is to go through past industry publications to see if a position has been stated. Finally, asking the stakeholder (and hoping for a sincere response) is the most direct way to assess their position.

Fire Fighters: Fire fighters would be FOR the proposed change to increase regulation of pseudoephedrine sales because of the possible benefits that would come from less meth production. With this regulation there could possibly be a decrease in the number of cookhouses that would be a safer work environment for the fire fighters due to the fact that they would not have to fight dangerous chemical fires.

Department of Ecology: By doing a search on the website of Washington's Department of Ecology (DOE), and reading publications they have published on the subject of methamphetamine use and production we can gauge their reaction to our suggested law. Our proposal, to limit the sales of psuedoephedrine to a therapeutic dose and to a set number of purchases within a two month period, which we believe, would limit the availability of the key ingredient in methamphetamine production. Such an action would decrease the number of homegrown methamphetamine labs found and requiring clean-up, as well as reduce the amount of toxic byproducts made and dumped, which would be favorable to the Washington DOE.
Washington State Pharmacy Association: Rod Schafer: To determine what position the WSPA would take; a possibility is to search through their publications and research what positions they have taken (if any) in the past regarding pseudoephedrine.

Washington State Board of Pharmacy Member: Position can be determined in two ways. The simplest way is to contact a BoP member. With only 7 members on the board, a general consensus can be found. The other way is to look at the history of current pseudoephedrine regulations and determine if there have been previous changes based on similar conditions in the past. The Board of Pharmacy would probably be in favor of further limiting the amount of pseudoephedrine per transaction. As mostly pharmacists on the board, they would understand the amount of drug necessary for proper treatment of a condition as compared to the amounts found in OTC packages.

Washington State Medical Association (WSMA): In general, the WSMA does not support legislation that is considered micromanagement or that does not make the administrative aspect of medical practice simpler. However, they do support legislation that promotes the health and welfare of patients and a healthy lifestyle.

Pharmacy Manager: This individual believes that our proposal attacks the wrong people and that the benefit of this proposal is almost non-existent. He feels like this problem should be addressed at Federal level, mainly by dealing with the external sources of meth precursor drugs. He also sits in the Washington Legislative Regulatory Hearing Commission and he said that the current laws are a compromise to what was proposed by law enforcement agencies and that he is ok with it for now.

Questions to ask the stakeholders:
- Does your organization feel that the current legislation is appropriate and/or strong enough to control methamphetamine abuse in the US?
- What drawbacks and advantages does your organization see in the current legislation?
- What drawbacks and advantages does your organization see in this proposed legislation?
- What would your organization like to see added to or removed from this legislation?
- Would your organization support these proposed changes to legislation?
- Do you think that the methamphetamine problem is something that can be controlled on a state level? Can it be changed or improved on a state level?
- Do you feel stronger restrictions will have any impact on costs associated with closing methamphetamine labs, decreasing the number of “mom and pop” methamphetamine labs, or decreasing general methamphetamine traffic?
Do you think that all forms of pseudoephedrine should be limited or the tablet form only?

What would you (as an organization) have to do, or change, to make this law take effect?

Have any other stakeholders/interest groups addressed your organization in response to the methamphetamine problem?

Have any loopholes in current legislation been observed that make this a difficult topic to enforce?

Is there an intermediate step between the current sales limitations and the final manufacturing of meth that exacerbates or alleviates the drug abuse problem?

Have we overlooked any important steps in this process of illegal drug production?

**Group 2: Prescription Only Pseudoephedrine**
Leigh Brown, Shawn Hancey, Angela Hitt, Vu Hoang, Jared Judd, Young Mi Kim, Karyn Moretsky, Elyse Tung

Stakeholder types:
- Washington State Department of Ecology
- Pseudoephedrine manufacturer: Pfizer
- Non-pharmacy retail groups (gas stations, smaller grocery stores)
- Pharmacists
- Professional organization - Washington State Pharmacy Association
- Drug addicts
- Law enforcement agency - police
- DSHS - Washington State Child Protective Services -

How we will assess the degree of political influence of each stakeholder group?
Each stakeholder listed above has some political influence. At a bare minimum each individual has a single voting voice during the general elections. The most influential groups represent a collective voice. Also the more influential groups are part of an administrative agency with law and rule making power. We will investigate these characteristics to evaluate their political influence.

How will we assess the position (against, neutral, or for) of the stakeholders?
We will assess their position on our new proposed law by investigating if they have already published their own viewpoint on pseudoephedrine and methamphetamines prior to the interview. We will also investigate how much of a financial tie they have with pseudoephedrine. The more money they make from the pseudoephedrine, the more they are opposed to our stricter guidelines.

Questions:
1. How are you connected to pseudoephedrine?
2. Do you have any financial investment with pseudoephedrine?
3. Do you think pseudoephedrine should be prescription only?
4. What do you know about the methamphetamine abuse in our country? (Social, health, environmental, financial, etc.)

5. How will the new law impact your life/job?

6. Do you think what we are proposing will impact the production of methamphetamine and why?

7. Do you think what we are proposing will impact the use of methamphetamine and why?

8. Do you think what we are proposing will be more of a burden or an improvement?

Group 3 (Show and tell group)-Stakeholders
Joe Johnson, Helen Song, Connor Christy, Olga Shvartsur, Zachary Beard, Aaron Chin, Lydia Zou, Tina Ngo

Assessing political impact:
1. size of the organization, number of members
2. political contributions, how active it is in lobbying
3. ability to promulgate laws
4. public perception of the organization

Assessing the position:
1. Check for published materials and position papers online.
2. Consider the nature of the organization and how its workflow will be impacted.
3. Find contact in organization to get an opinion on the proposed law.

List of potential questions to assess position on proposal:
1. What is your organization’s goal with respect to medication errors?
2. Do you think “show & tell dispensing” represents a best practice?
3. Would you favor a law requiring this procedure in your pharmacy?
4. What concerns and objections do you have the proposed modification of the law?
5. Do you think “show & tell dispensing” would have a significant impact on the problem of medication dispensing errors?
6. What are some alternate approaches you would suggest for dealing with medication errors?
7. How do you think your particular organization would be impacted?

Stakeholders
Independent Pharmacy Owner
Retail Chain Pharmacy
Hospital or Institutional Pharmacy
Board of Pharmacy / NABP
Federal Agencies – CMS (patient safety)
Medical & Consumer Safety Organizations (NCCMERP)
Closed Door & Mail Order Pharmacy
National Pharmacy Associations (NCPA, APhA, etc)
State Pharmacy Associations (WSPA)
Group 4: Expiration and Refills of Schedule II prescriptions
Group Members: Quyen Nguyen, Linh Mai, Andrea Eberly, Jeff Loor, Geoff Meer,
Jennifer Law, Nick Wyatt, Sareh Ghazanfarpoor

Expiration of schedule II prescriptions can be changed to expire within 90 days. However, refills are allowed within this time frame (maximum of 2 refills). This allows prescribers to see patients more often for monitoring and decreases the hassle of patients having to obtain several prescriptions. This is a Federal issue as this addresses changing current federal regulations.

STAKEHOLDERS:
1. Patients
2. Prescribers (this includes dentists, ANRPs, PAs, etc—however we mainly look at physicians because they are so much more numerous with real political clout)
3. Pharmacists
4. American Medical Association (AMA)
5. NCPA
6. APhA
7. Drug Manufacturers

Assessing the degree of political influence of each group:

We are basing our assessment of political influence coming from a couple of sources:
• The amount of money donated to various political units, such as political parties or candidates.
• The scale of lobbying activity at a national level
• Degree of public influence the stakeholders have—indirectly causing the stance of the stakeholder to reverberate through the Congress and Senate such as that due to grassroots advocacy (letters, phone calls, etc to representatives) (think social power)

As for the first three stakeholders, Patients, Prescribers, Pharmacists, it is difficult to accurately evaluate their political influence because they are ultimately individuals.

For each stakeholder group, we will assess their stance on this issue by interviewing a small sample of representatives. (Refer to the questions below) We will also access their websites to see if they have any existing resolution that would lead us to believe that they may or may not support our proposal.

Patients:
While one patient who needs CII prescriptions may vote one way and donate money accordingly, another may be a polar opposite. More than likely, their stance as one who utilizes CII drugs is unlikely to unite them to other CII drug users politically. That being said, it is possible they may have passing interest on the
issue if they have had significant experience with filling CII prescriptions on a long
term or chronic basis. Patients requiring a CII for acute conditions are likely filling
the prescription within a day or two, and as a refill was not necessary, are unlikely
to be aware of the current statute that forbids refills.

We would rate them a neutral body with no uniting political influence. Also, as they
are not likely to be united in political view, while they are a stakeholder, asking
them their stance, short of asking large quantities of patients in some sort of poll, is
unlikely to be beneficial in the analysis of the fitness of our proposed change to
federal legislation.

Questions to ask:

1. How do you feel about the new DEA statement that reads:

   For a physician to prepare
   multiple prescriptions [for a schedule II
   controlled substance] on the same day
   with instructions to fill on different
dates is tantamount to writing a
   prescription authorizing refills of a
   schedule II controlled substance." To do
   so conflicts with the provision of the
   CSA which provides: "No prescription
   for a controlled substance in schedule II
   may be refilled."
   From: Federal Register / Vol. 70, No. 165 / Friday, August 26, 2005 / Notices

2. In your position, would you support a change in regulation that changes the
   expiration date of CII prescriptions to 90 days, but allows for 2 refills versus the old
   statute that allows for prescriptions to never expire, but no refills, especially in light
   of the above DEA statement?

3. Do you think it would be possible to change the law as we suggest?

4. What do you think the ramifications of such a change would be?

5. How would it affect your life or the lives of your family members?

6. Do you think this change would benefit you and/or your family? Why?

7. Do you think this would be better than reinstituting the practice of writing
   multiple prescriptions with different fill on dates?

Prescribers:
Prescribers have large and well organized state and national associations and their
political clout is like to source from these groups. It is likely that strong support at
the physician level would also prompt the AMA to be supportive of our proposed
change. Therefore we feel that by asking a couple of physicians/pharmacists for
their opinions on the matter, we will hopefully get a feel for the feasibility of our changes.

Questions to ask:

1. How do you feel about the new DEA statement that reads:

   For a physician to prepare multiple prescriptions [for a schedule II controlled substance] on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance.” To do so conflicts with the provision of the CSA which provides: “No prescription for a controlled substance in schedule II may be refilled.”
   From: Federal Register / Vol. 70, No. 165 / Friday, August 26, 2005 / Notices

2. In your position, would you support a change in regulation that changes the expiration date of CII prescriptions to 90 days, but allows for 2 refills versus the old statute that allows for prescriptions to never expire, but no refills, especially in light of the above DEA statement?

3. Do you think it would be possible to change the law as we suggest?

4. What do you think the ramifications of such a change would be?

5. How would it affect your patients?

6. Do you think this change would benefit patients and why?

7. How do you think your colleagues and patients would feel about this change?

Pharmacists:
Similar to physicians, strong consensus from the pharmacist level will prompt support from state and federal pharmacist associations.

Questions to ask:
1. Are you aware of current regulations regarding CII prescription expiration?
2. Are you aware of the new statement from the DEA that reads:

   For a physician to prepare multiple prescriptions [for a schedule II controlled substance] on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a
schedule II controlled substance.” To do so conflicts with the provision of the CSA which provides: “No prescription for a controlled substance in schedule II may be refilled.”

From: Federal Register / Vol. 70, No. 165 / Friday, August 26, 2005 / Notices

3. In your position, would you support a change in regulation that changes the expiration date of CII prescriptions to 90 days, but allows for 2 refills versus the old statute that allows for prescriptions to never expire, but no refills?

4. How much time do you spend on your patients with their prescriber for an issue relating to schedule II prescriptions?

5. Do you think it would be possible to change the law as we suggest?

6. What do you think the ramifications of such a change would be? How would it affect you? Would it affect patient safety, public health, drug diversion, abuse...?

7. How do you think your colleague in health care would feel about this change?

AMA:
This group has a high level of political influence. This organization is the voice of practicing physicians, of which there are roughly 800,000 in the United States. They spent more than 18 million dollars in lobbying efforts. For our legislation to pass, it would be vital to gain the support of this organization. They would like support our legislation:
“support interpreting federal law and regulation to allow physicians to continue the well-established clinical practice of writing multiple prescriptions for controlled agents on the date of a face-to-face examination with the actual date the prescriptions were issued, but also written directions for dispensing supplies of medication on future specified dates”
As our legislation in many way mirrors the intent of their statement.

Questions to ask:

1. How do you feel about the new DEA statement that reads:

   For a physician to prepare multiple prescriptions [for a schedule II controlled substance] on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance.” To do so conflicts with the provision of the CSA which provides: “No prescription
for a controlled substance in schedule II
may be refilled.”
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2. In your position, would you support a change in regulation that changes the expiration date of CII prescriptions to 90 days, but allows for 2 refills versus the old statute that allows for prescriptions to never expire, but no refills, especially in light of the above DEA statement?

3. Do you think it would be possible to change the law as we suggest?

4. What do you think the ramifications of such a change would be?
5. How would it affect your members?

6. Do you think this change would benefit patients and why?

7. Do you think this would be better than reinstituting the practice of writing multiple prescriptions with different fill on dates?


http://www.ama-assn.org/apps/pf_new/pf_online?f_n=resultLink&doc=policyfiles/DIR/D-120.979.HTM&s_t=schedule+II&catg=AMA/HnE&catg=AMA/BnGnC&catg=AMA/DIR&&nth=1&&st_p=0&nth=10&


APhA and NCPA:
There are about 200,000 pharmacists in the United States currently. As they have vast social networks, they can be seen as a somewhat politically influential group, though not as much as physicians due to numbers and moneys donated to associations that lobby on behalf of the profession. APhA only donated 476,602 in 2004 compared to over 18 million by the AMA. Some influence, but not much. NCPA-PAC is more active, though not as large, having spent over 100,000 dollars in the 2006 election cycle and about 40,000 dollars for lobbying efforts. Members of the NCPA also will individually meet with Congress and Senate members during yearly legislative conference to express views.

Questions to ask APhA/NCPA:

1. Are you aware of current regulations regarding CII prescription expiration?
2. Are you aware of the new statement from the DEA that reads:

For a physician to prepare
multiple prescriptions [for a schedule II
controlled substance] on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance.” To do so conflicts with the provision of the CSA which provides: “No prescription for a controlled substance in schedule II may be refilled.”

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3. In your position, would you support a change in regulation that changes the expiration date of CII prescriptions to 90 days, but allows for 2 refills versus the old statute that allows for prescriptions to never expire, but no refills?

4. How much time do you think pharmacists spend dealing with issue related to CII that take away from patient care?

5. Do you think it would be possible to change the law as we suggest? Do you think the AMA would also support this?

6. What do you think the ramifications of such a change would be?

7. How would it affect patient care?


http://www.hhs.gov/pharmacy/php pharmacist/howmany.html

Pharmaceutical Industry
This group is ranked 10th in the country for moneys spent on lobbying efforts, having spent in 2004 $15,520,000. This is a powerful industry. It donated nearly a 100,000,000 dollars last year to political causes, as compared to just 50,000,000 by all health professions combined. They will likely support any legislation that makes the dispensing of drugs less problematic.
Questions to ask:

1. Are you aware of current regulations regarding CII prescription expiration?
2. Are you aware of the new statement from the DEA that reads:

   For a physician to prepare multiple prescriptions [for a schedule II controlled substance] on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance.” To do so conflicts with the provision of the CSA which provides: “No prescription for a controlled substance in schedule II may be refilled.”

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3. In your position, would you support a change in regulation that changes the expiration date of CII prescriptions to 90 days, but allows for 2 refills versus the old statute that allows for prescriptions to never expire, but no refills?

4. DO you think the current regulations cause access issues for patients?

5. Do you think it would be possible to change the law as we suggest?

6. What do you think the ramifications of such a change would be? Especially regarding drug abuse potential?

7. How do you think the AMA would stand on this issue?

**Group 5** Rescheduling of the Benzodiazepines or something

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

Background:

Benzodiazepines are a family of depressants which are controlled as Schedule IV narcotics. Members of this class include short acting Benzodiazepines such as temazepam and long acting forms such as alprazolam, diazepam, lorazepam, and clonazepam. With various indications for use as hypnotics, anxiolytics, and sedatives, Benzodiazepines are among the most widely prescribed classes of drugs. Our research has identified an increasing trend in misuse and illicit abuse of Benzodiazepines among special populations. While this risk factor was originally acknowledged, little has been done to address the increasing trends of improper Benzodiazepine use, and thus it is pertinent to take further measures in reducing
this growing problem. We believe that the implementation of “Black Box Warnings” on all Benzodiazepine packaging and the use of “Dear Doctor Letters” will be an effective tool in reaching prescribers and other health care professionals and will result in an increased level of awareness on a national level. Through these actions, it is intended that inappropriate prescribing, misuse, and illicit abuse of Benzodiazepines will be minimized.

1. How do Benzodiazepines impact your practice/profession? Please consider both licit and illicit drug use in your evaluation.

2. In your practice/profession, have you observed misuse (including improper prescribing, overuse, addiction and abuse) of Benzodiazepines? If so, approximately what fraction of Benzodiazepine use in your opinion would be considered misuse?

3. Are there any special populations in which the use of Benzodiazepines would be considered inappropriate?

4. Have Black Box Warnings affected your practice/profession? If so, how?

5. Do you think that a Black Box Warning, indicating the increased abuse potential of Benzodiazepines in populations with histories of prior drug/alcohol abuse problems, would be an effective step towards increasing awareness of the addiction potential of this drug class? Please elaborate if possible.

6. Would you support the implementation of a Black Box Warning on Benzodiazepines?
   □ YES  □ NO
   □ If Yes, what outcomes (both positive and negative) do you anticipate from this action?

Comment [t6]: incremental?
Comment [t7]: BE sure that your answers can't be answered from the literature.
Comment [t8]: are these questions really different?
If No, what alternatives could be used to increase awareness towards the addiction potential of Benzodiazepines in the aforementioned populations?

7. What other ways might be more effective in disseminating this information to people of your practice/profession (i.e. rescheduling narcotic status, Continuing Education Sessions, etc.)?

Identified Stakeholders:
- Evergreen Treatment Center:
  - Micki Kedzierski
- Ron Jackson
- Washington State Board of Pharmacy:
  - Don Williams
  - Dick Morrison (also former FBI agent)
- Washington State Pharmacy Association:
  - Rod Shafer
- Emergency Room of Valley Medical Center:
  - Kris Tiernan
  - Young Kim
- Washington State Department of Public Health:
  - Susan Kingston
- Savon Pharmacy:
  - Angela Norman
- Kwawachee Counseling Center:
  - Saidee Whitehorn
- Adult Medicine Clinic of Harborview Medical Center:
  - Jeff Chin
- UW School of Pharmacy:
  - Jackie Gardner
- DEA:
- FDA:
- White House:

Assessment Plan for Degree of Political Influence
Factors to be considered in measuring the degree of political influence by a stakeholder include:
- What financial power (i.e. how much access to funds and what magnitude of funds) does the entity have;
- How much monetary support does the entity provide (i.e. lobbying) to legislators for legislation related to Benzodiazepines, controlled substances, and general pharmaceuticals;
- How much general lobbying does the entity participate in;

Comment [9]: the "yes-no" question doesn't really add to the process.

Comment [10]: who did you have in mind?
How long has the entity been in existence and what is their general reputation (subjective).

Assessment Plan for Position of Stakeholders Relative to Topic
Factors to be considered in determining what the stance of a stakeholder is for or against our proposal include:
- Mission statement of representative organization;
- Relevant petitions to legislators and involvement in policy making related to Benzodiazepines, controlled substances, etc.;
- Any other action taken related to substance abuse, controlled substances, etc;
- What other groups, organizations, or events does the entity sponsor.

**Group 6: Stakeholders Assignment**

Questions for the Stakeholders

1) If the stakeholders do not agree with our idea, perhaps we can ask them what they feel would be an appropriate alternative &/or why they feel this idea would not work.
2) Can you think of any negative aspects that may appear if this law comes into affect?
3) Can you think of any positive aspects that may appear if this law comes into affect?
4) Do you think that this is a conceivable plan that the legislature and the public would support?
5) If this law goes into effect, do you think that MD’s who do not follow should have consequences? If so, how harsh?
6) What do you think the patients reaction will be to this law and what can we do to inform the patient (and the MD) that it is in their best interest to do this?
7) Do you think this proposal decreases or compromises patient privacy?
8) What do you think is a reasonable timeline to implement this proposal if it were to pass?

- Describe in two or three sentences how you will assess the degree of political influence of each stakeholder group. For instance, you could see if a stakeholder group contributes to a particular political party.

Does your organization contribute funds for any particular political party? Does your organizations support or belong to any group that promotes or lobbies for certain legislation?

- Describe in two or three sentences how you will assess the position (against, neutral, for) of the stakeholders. For instance, you might see what has been published about a stakeholder group, look up annual reports for corporations, etc.
An organization's history of endorsement or opposition to previous legislation is likely the best indicator for how they will view our legislation. We should therefore ask them what the best source for this data will be.

Alternative 1: Create an area on paper prescriptions to encourage the "indicated use" to be written by the prescriber. This is much like a designated area on paper prescriptions for "allergies" and helps pharmacists give better quality health care to their patients.

Outcome

1) The worst-case scenario for this alternative is that the doctors would just ignore this line and it would never be used. The MDs might complain that it will cost them more money to change their prescription pads and to throw out their old prescription pads. The best possible outcome would be the MDs embracing this and always writing the diagnosis on the prescription and therefore decreasing medication errors. In reality, the MDs will use the line when they feel like it. Some will probably like the idea and use it all the time while others will hate the idea and never use it. The majority will use it occasionally or at the patient’s discretion if it is not a required to fill the prescription.

2) Alternative 1 has the potential to decrease prescription writing errors by one half. In a small study conducted in 1993, first year residents were given training in prescription writing and prescriptions that included a diagnosis contained half the errors of those that did not. In addition, the diagnosis will provide benefits in the patient/pharmacist relation as well and provide a better evaluation of medication utilization and appropriateness.

3) A possible side-effect to this alternative is that prescribers would not follow it, since writing the "indicated use" on a prescription is still not mandatory. Prescribers would continue to write prescriptions as usual, and because it costs money to reprint/make new prescription pads and change software, many prescribers will opt to ignore this alternative completely. The only way to mitigate this side-effect and still keep the "indicated use" on the prescription is to encourage Alternative 2; to write the "indicated use" in the sig of the prescription. This would cut out new software and new prescription pad costs to prescribers and hospitals, which could result in a higher compliance with our law.

Alternative 2: Mandate the "indicated use" be written in the sig of the prescription; i.e. "take one tablet by mouth every morning for ___." This is for prescribers who do not want to/can’t afford to reprogram their computer system, or print new prescription pads.

Outcome
1) The worst possible outcome of requiring an indication in the sig of a prescription would be the provision of false indications by prescribers in an attempt to protect patients with disease of a socially sensitive nature. This would decrease interprofessional reliance and trust and exacerbate the existing, unacceptable situation of relying on the patient for information on patient disease states. Ideally, providing an indication on the prescription would improve pharmacy patient record-keeping and allow more personalized and appropriate counseling. Adding the indication in the sig specifically would provide a better opportunity for patient education, reminding patients at almost every dose of what the medication is for and why it is taken in the manner indicated. Realistically, requiring an indication may lead to prescribers using the most generic indication possible; eg, “for pain” rather than “for chronic neuropathic pain”, or “for infection” rather than “for UTI”; this is nevertheless an improvement over the existing situation in that pharmacists are provided with some information and patients receive their “indication reminder” on the label.

2. Range of resistance among prescribers would probably be highly dependent on practice subspecialties. Pain clinic providers are unlikely to withhold a “for pain” note in the sig, but urologists, OB/GYNs, and other specialists who provide services perceived as socially sensitive might be more likely to give a vague or absent indication, and this is most likely for drugs which have some uses considered “socially acceptable” and some not. Because of the heterogeneity of the prescribing population, a reliable estimate of compliance is not possible without survey data; nevertheless, given the number of non-socially-sensitive prescriptions processed by a typical average pharmacy, an initial compliance of at least 50% could be expected. Paradoxically, it is the prescriptions in question for which an indication would be most valuable to the pharmacist. Compliance with an indication requirement in the sig might be lower than compliance with an indication requirement on the prescription, because the indication will be visible on the label.

3) This alternative suggests incorporating the indication for use directly into the sig that the physician rights. This could pose a potential problem because it gives the physicians the opportunity to leave out the indication for use entirely. A better alternative would be to have an area on the prescription specifically designated for an indication for use. Leaving it entirely up to the physician to change the way he/she writes sigs is almost unreasonable. I could see using this alternative if absolutely necessary, but I think it would be best if we were to create new prescription pads that catered more toward our new law. This would reduce this particular side-effect by at least half and most definitely to an unobjectionable level.

Alternative 3: Do nothing regarding the indicated use on prescriptions.

Outcome

1) Writing the diagnosis on a separate line on the prescription gives the pharmacist a clear idea about the intended use. This leads to better pharmacist-patient communication and gives pharmacists a better chance to provide effective and
appropriate counseling. On the other hand, sometimes MDs may not want the pt to know too much about the real diagnosis or intended use. This can cause some problems in this regard.

2) The studies that have been performed regarding medication errors and their tremendous repercussions are sobering. It has been estimated that there are ~7000 unnecessary deaths per year and billions of dollars spent in the healthcare system due to due to medication errors. Writing the indication on a prescription is a positive step in addressing this issue. If nothing is done in this regard, then the costs in human life and healthcare dollars will continue to climb.

3) Undesired side effects can occur if we don’t do anything because this may keep leading to more medication errors such as look-alike, sound-alike drugs. This will lead to more possibilities of economic loss and even deaths. This can be mitigated because it also offers better indications while counseling the patient, which will lead to even more decreases in medication errors. In order to change something to lessen the side effects, we must try to make prescribers to follow this law and educate them on the benefits of this, which would lead to increased patient care.

1Howell RR Prescription-writing errors and markers: the value of knowing the diagnosis. Fam Med 1993 Feb;25(2):104-6

**Group 7.** Caroline Kimani, Catherine Ulep, Madeleine Fry, Casey Lirot, Suejin Park, Chris Yocom, Dimay Wang, Caroline Wu
Stake Holder Questions.

1. How would this idea help you improve your compliance to your medications?
2. What would be some disadvantages of our proposal?
3. Which alternative would be the best and why?
4. Do you think this law can be improved and would you add anything to it?
5. How do you feel about the feasibility of implementing the new system, taking into account issues of time, space, money, staff, etc?
6. Would it be difficult to comply to this law, why or why not?
7. How would this proposal improve patient care in the pharmacy?

**Group 8: Spacer Stakeholder Inquiries**
Reilly Benz, Heidi Colpitts, Viet Lam, Brian Seiki, Alesya Vlasenko, Holly Warner

**Questions?**
Stakeholder Categories

1. Manufacturers
2. Pharmacies and Pharmacists
3. Physicians

We asked The Washington State Medical Association if they thought that physicians would support or oppose the idea. Would they feel that we were infringing upon their rights to prescribe? Do pharmacists have the necessary judgement and education necessary to prescribe spacers?

4. Federal Regulatory Agencies

The CDRH is the FDA agency that regulates spacers, so we asked if this idea would change the way spacers were categorized or regulated.

5. Patient Representatives

Both The American Lung Association, and Asthma and Allergy Association of America were presented with the idea. We would like to know how patients would feel about having a spacer prescribed by a pharmacist rather than a physician and whether this change would play a role in improving their quality of life.

6. State Regulatory Agencies

Some members from The Washington State Board of Pharmacy were present during lecture this week and we were able to tell them about our idea to modify the part of RCW 18.64.011 which defines the practice of pharmacy by further saying that distribution of devices for administration of drugs shall be at pharmacists’ discretion, prescription or non-prescription (whichever is available at the pharmacy).
7. Insurance Companies

We contacted DSHS and Blue Cross and asked them what is covered in general as of now, and how this might affect future coverage of MDI devices.

Group 9, Stakeholders Assignment

Pavel Mitin, Gigi Wong, Amy Little, Michael King, Adam McCown, Holly Dirks, Brad Siegfried

1. Stakeholders:
   - Washington-based chain-Bartells pharmacy (Pavel), neutral or slightly opposing
   - National-based chain- Rite-Aid (Mike), neutral
   - WSPA (Amy), supportive
   - BoP (Gigi), supportive
   - Tramadol manufacturing company (Adam), strongly opposing
   - DSHS (Brad), neutral
   - Drug recovery center (Holly), supportive

All stakeholders have been contacted, all but two have replied as of 11/10/05.

2. Planning:
   - To assess a political influence of each stakeholder would be cumbersome, but one of the obvious one is financial contributions to its lobby and more direct relationship to enforcement. For example, a drug company has a large financial capability and hence a larger political lobby compared to BoP but BoP has more legal weight since they directly influence the shaping of RCW in terms of drug laws.
   - The predicted position of stakeholders will be estimated by their publications, statements and financial interests.
   - The actual position of stakeholders will be assessed using the following questionnaire:

Comment [t15]: be sure to assess the 8 thinks you'll need for rescheduling

1. In what way would scheduling Tramadol affect your org?
2. What kinds of things would you have to do or change if T was rescheduled to a CIV?
3. Would there be any financial benefit or cost to you?
4. How could this increase positive outcomes in your org?
5. How could this increase negative outcomes in your org?
6. Would your org support the statement that "It is in the patients best interest to reschedule T?"
7. Would your org support the re-sched of T?

Group 10, Generic Substitution
Below are the groups we are contacting and how we believe they will feel about our proposal. The person responsible for contacting that group is in parentheses.

Stakeholder Groups:

<table>
<thead>
<tr>
<th>PRO</th>
<th>NEUTRAL</th>
<th>AGAINST</th>
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<tbody>
<tr>
<td>AARP (TD)</td>
<td>BoP (MW)</td>
<td>PhRMA (JC)</td>
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<tr>
<td>WSPA (FM)</td>
<td>Chain pharmacies (MW)</td>
<td>Doctors (MF)</td>
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<tr>
<td>Insurance Co.(CC)</td>
<td>Independent pharmacies (WS)</td>
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</tbody>
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To assess the degree of political influence that each group has, some research would need to be done in order to prepare to defend our proposal. As stated, we could see if a stakeholder group contributes to a political party. We could also see if any public figures belong to these groups. We could find reports of how much money was spent on advertisements or marketing, and to what audience, this would show what areas the stakeholders find important.

To determine what position the stakeholders would take regarding our proposal we could look up annual reports, research what has been published about the group, and find out what positions they have taken on past topics. By finding out what initiatives they have supported or opposed in the past and why they did may give insight into the stance they would take towards ours.

The following are questions that we would choose from to ask each stakeholder group in order to assess their position on our proposal. Which questions we would ask would depend on which group we are addressing.

1. What is your initial impression of our proposed changes?
2. Are you concerned about Pharmacist's abilities to make wise decisions?
3. How do you feel this will impact patients? Doctors? Healthcare costs?
4. What risks do you see? What benefits?
5. How do you feel about the increased autonomy of patients?
6. Is use of the Orange Book's AB rating system acceptable practice for Pharmacists to use when substituting?
7. Should we be willing to take on the extra liability legally?
8. How much liability and with what consequences?
9. Do you think it might be even more appropriate to give the final decision to substitute solely to the Pharmacist?
10. How do you predict the medical community will react to this, and why?
11. What additional changes would you propose, or do you propose to leave the system the way it is?
12. How do you predict the drug manufacturers will react to this, and why?

Group 11 Ensuring the quality of the internship experience
Stacie Chen, Rebecca Goodwin, Tuyen Huynh, Kelly Philopant, Christopher Rogge, Julie Sun, Amy Thomas
Potential Stakeholders
Jeff Rochon (WSPA) – support
Terri O’Sullivan (UWSOP Director of Experiential Learning) – support
Stan Weber (UWSOP Associate Dean of Professional Education) – support
Gail Caballe (Retail Preceptor from Bartell’s) – support, neutral
Hospital preceptors (Group Health) – support, neutral
Independent preceptors – support, neutral
UWSOP or WSU pharmacy students – support

To assess the degree of political influence of each stakeholder group, we will consider what organization each person is representing, the number of pharmacists this organization represents, and the organizations ability to influence legislation.

To assess the position of the stakeholders, we will look at the mission statement for each organization to determine if our proposal fits with their overall goals. We will also look at the logistical impact our proposal will potentially have on each group and their ability and willingness to adapt to these changes.

1. What in your opinion is the current state of the internship experience for students and preceptors?
2. Do you feel that the current law provides enough guidelines to provide interns a quality internship experience?
3. What is your position on changing the law to provide preceptors a set of guidelines to follow for internship programs?
4. As a retail pharmacist, what is your opinion on increasing the quality of the internship by providing monthly evaluation on your student and quarterly progress reports on the improvement of your students’ abilities?
5. Would providing additional CE credits for this increase in workload give incentive to continue on as a preceptor?
6. Does the hospital have enough “pharmacy power” to implement these guidelines or adhere?
7. What do (Jeff Rochon) think the responsibilities of preceptors are, currently, or should be, regarding internships?
8. Do you think it is realistic to ask interns to submit yearly progress reports? Does the BOP have the manpower or even the legislative power to enforce such changes/additions to the laws?
9. Does providing specific guidelines help make expectations of interns and preceptors clearer or is there another alternatives?

Group 12 – Extension of C-II Partial Fill Time Limit
Group Members: Ashley Bean, Amy Chang, Morgan Hutchings, Rachel Schreffler, Kathleen Thornton, Kelli Watari, Jeff White

1. Have you ever personally run into this issue in the pharmacy?
(e.g. Had to wait for new Rx from prescriber because partial fill could not be completed within 72 hrs)

2. How often, if ever, does it occur?

3. Can you think of any reason why a time extension would be inappropriate?

4. What problems, if any, would this change in the law pose for your pharmacy?

5. What benefits, if any, would it bring to your pharmacy?

6. Would you be for or against this change?

7. Do you think your colleagues would be for or against this change?

8. Our proposal is to change the time limit to 5 days. In your opinion, is there a more appropriate time period (i.e. 4 days, one week, no limit)