

TEACHERS' TOPICS

A Collaborative Student Project to Evaluate Switching Prescription Medications to Nonprescription Status

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Ongoing changes in the status of medications from prescription to nonprescription have reinforced the need for pharmacists and pharmacy students to be competent in their knowledge of nonprescription drugs and in their communication skills. The process by which the Food and Drug Administration (FDA) changes the status of a prescription medication involves close scrutiny of the literature and evidence related to a medication's safety, efficacy, and ability to be used appropriately without a prescriber's direction. An assignment that requires students to take on the "role" of an FDA taskforce member helps them to better understand the prescription (Rx) to "over-the-counter" (OTC) switch process, apply skills in drug information retrieval and literature evaluation, and develop teamwork and critical thinking skills. This paper describes a collaborative teaching project between faculty members at Washington State University and Oregon State University.

Keywords: prescription drugs, nonprescription drugs, Food and Drug Administration, student projects, drug regulation, drug reclassification

INTRODUCTION

The FDA process of evaluating prescription drugs for reclassification as nonprescription drugs is a thorough and somewhat daunting process. Committees of experts are assigned to examine reports and data to determine whether a change in prescribing status would be in the best interest of the public. From original consideration to the final recommendation, a committee may spend many years evaluating and re-evaluating research, literature, data, and evidence to ensure safety, efficacy, and appropriate use if the product were to become available without a prescription.¹

Over the past 20 years, more than 70 medications or products have been switched from prescription to nonprescription status.² Driving forces behind the changes have included manufacturers, insurance companies, and public health organizations. The process can be expensive as well as time consuming.

Always looking for opportunities to promote active independent learning and include practical subjects in the curriculum, faculty members at Washington State University and Oregon State University developed the idea of an "Rx to OTC Switch Project." In a truly collaborative manner, instructors determined that this project would be implemented at both campuses. Instructions to students,

objectives, assessment forms, examples of students' work, and lessons learned would be shared between instructors with the intent of continuously improving the way this project would promote learning at both universities.

The Rx to OTC Switch Project assigned students to 4- or 5-member "committees" to evaluate literature and make a recommendation for or against the status of a medication being changed from prescription to nonprescription. Although the projects on the different campuses differed in some aspects, the learning objectives were the same in both programs:

1. Describe the FDA process of switching a drug from prescription to nonprescription status;
2. Apply drug information and literature evaluation skills;
3. Develop collaboration and teamwork skills;
4. Analyze and synthesize information to make a professional recommendation;
5. Present and defend a drug use and safety recommendation;
6. Create a thorough understanding of a particular medication.

DESIGN

Washington State University

Washington State University students enrolled in the *Nonprescription Product Therapeutics* course were first assigned the Rx to OTC Switch Project in the spring of

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Table 1. Drugs Selected for Student Group Projects Evaluating the Process for Switching Prescription Medications to Nonprescription Status

celecoxib	montelukast	tolterodine	lovastatin
oxaprozin	azelastine	alendronate	pravastatin
diclofenac	cetirazine	oxybutinin	atorvastatin
valdecoxib	fexofenadine	clopidogrel	fluvastatin
etodolac	acyclovir	residronate	simvastatin

2004. This project provided an opportunity for third-year pharmacy students to think critically about a topic that would be relevant to their future pharmacy careers, regardless of practice setting.

Students were divided into working groups of 4 within their pharmaceutical care laboratory sections. Each group selected a prescription medication for consideration to be switched to nonprescription status. The assignment included both a written paper and a Microsoft *PowerPoint* presentation. Medications considered for status switching included lovastatin, pravastatin, fexofenadine, promethazine, hydroxyzine, fluticasone nasal spray, triamcinolone cream, rofecoxib, celecoxib, diclofenac, and oxybutynin.

The focus of the written report was to develop a foundation of understanding of the FDA process by which a prescription ingredient or product becomes available for nonprescription use. Groups were required to investigate and describe 3 primary Rx to OTC avenues: the FDA nonprescription drug review; the switch regulation; and processes related to the new drug application (NDA). The report also included a description of both a partial switch and a complete switch from prescription to nonprescription status. Finally, students were required to investigate and describe the factors considered in making decisions about prescribing status.

Each group was required to create 2 Microsoft *PowerPoint* presentations. One presentation outlined and defended the recommendation for the assigned medication to become available without a prescription. The second presentation outlined and defended the preservation of the medication as a prescription only product. Students were unaware of which recommendation would be the topic of their presentation until the day of their laboratory.

The instructors for both the nonprescription course and the *Pharmaceutical Care Laboratory* course evaluated all of the presentations. In addition, students in the laboratory were randomly chosen to evaluate each presentation. Areas of evaluation included introduction, recommendation, summary, style, and format. The evaluation tool used by both faculty members and students is available in Appendix 1.

Oregon State University

First-year PharmD students at Oregon State University take *Information Science* and *Pharmacy Practice I* courses concurrently. Instructors from the courses collaborated to develop the project, which integrated concepts from each class. The completed written project report was designed and submitted in the *Information Science* course, while the oral presentation of the final recommendation took place in the *Pharmacy Practice* laboratory. Eighty-three students, (20 committees) participated in the Rx to OTC Switch Project. Student teams were assigned within their laboratory period. Faculty members assigned a medication to each group to allow for some consistency between different laboratories. Consideration was also given to the availability and currency of primary literature for the project. Assigned medications for each laboratory day are listed in Table 1. Unlike the Washington State University project, students received an introductory lecture on the FDA process prior to beginning their project.

The written report primarily focused on drug information. Students were required to describe their search strategy for primary literature sources to support their findings. In addition, the report included an evidence table, a drug monograph concentrating on safety and efficacy of the assigned drug, and a professionally written recommendation for or against the change from prescription to nonprescription status. Within each group, half the students focused their research on defending the switch to nonprescription status while the other half focused on preserving the prescription status of the drug. Then, collectively, the group decided on a recommendation based on the identified criteria for prescribing status.

The *PowerPoint* presentation was presented during the laboratory. The presentation provided background information on the medication and the condition for which it is indicated to treat. Each group evaluated information and defended their recommendation either for or against nonprescription availability. In addition, each group created a drug facts label for the assigned medication as if it were available without a prescription. An evaluation (Appendix 2) of each group's presentation was completed by two instructors and several students in the laboratory.

ASSESSMENT

The faculty members involved in the Rx to OTC Switch Projects on both campuses felt that the students achieved the learning objectives stated. Particularly impressive was the level of professionalism that was demonstrated by students in their presentations.

Questions posed by instructors at the end of each presentation elicited confident answers, often including citation and explanation of studies to support their answers. Requiring students to make a recommendation based on their findings stimulated higher-level thinking skills.

Formal surveys of students' impressions of the assignment were not conducted; however, informal conversations with students provided generally positive feedback. Students were impressed with the level of knowledge they gained from the project. They valued the experience of researching, developing a recommendation, and presenting a persuasive argument about whether or not the prescribing status of a drug should be changed. Presenting this argument in front of the class highlighted the importance of choosing words and communication styles carefully. The group that did their presentation on acyclovir mentioned that they had initially thought their medication should be available without a prescription, but as they gathered more information they changed their recommendation.

Negative feedback about the project was minimal, yet typical for this type of assignment. A few groups had trouble scheduling meetings, and a few students were frustrated with unequal distribution of workload within their group. Some groups mentioned they wished they had more time. These concerns came as no surprise to anyone who has ever served on a committee.

The relevance of this project is reinforced as manufacturers continue to pursue nonprescription status for current prescription medications. Two weeks after OSU students completed their project, Bristol Meyers Squibb announced its pursuit of nonprescription status for Pravachol, one of the medications investigated by stu-

dents in the course. Early in 2005, the FDA considered moving to nonprescription status some topical corticosteroids, which was a class also considered by WSU students for the project in the spring of 2004.

CONCLUSIONS

The Rx to OTC committee project stimulated PharmD students to develop a comprehensive understanding of the FDA nonprescription drug approval process, apply skills learned in drug information courses, and evaluate literature to make a recommendation with patient safety in mind. Faculty members involved in the project considered it a successful use of class and students' time. The project will continue to be implemented at both campuses. Adjustments may be made in evaluation tools to assess specific course and curricular objectives.

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Appendix 1. Evaluation form for Rx-to-OTC Project at Washington State University

Evaluation Form

Powerpoint® Presentation Evaluation Rx-to-OTC Switch

Score

Comments

Section 4

Committee D

Content

X

Introduction (5 points)

- Outline what this presentation will cover
- Describe medication being considered for Rx-to-OTC switch

Present and defend the group's decision about whether or not an Rx medication should be switched to OTC status (15 points)

- Outline the group's viewpoint
- Refute the opposition's point of view
- Describe the safety considerations associated with the drug
- Describe the efficacy issues associated with the drug
- Describe any monitoring considerations
- Demonstrate why the public can or cannot use this medication properly

Summary (5 points)

- Reiterate main points
- Substantiate use of appropriate research/sources
- Convince audience that the group's point of view is valid and should be instituted

Presentation

X

Style (15 points)

- Verbal attributes
 - Audible
 - Understandable
 - Professional language
- Appearance: professional dress
- Audience interaction
 - Eye contact
 - Conversational vs reading word-for-word
- Questions
 - Answered appropriately, not defensively

Format (10 points)

- Time frame (8-10 minutes)
- Slides: Professional, readable, correct spelling, grammatically correct

Total Score (50 points possible)

Appendix 2. Evaluation form for Rx-to-OTC Project at Oregon State University

Presentation Evaluation	Score	Comments
Stage Presence (5 points) <ul style="list-style-type: none">• Fluent delivery• Eye contact, volume, tone• Pronunciation, grammar• Nonverbal• Keeping within the time limit		
Depth of knowledge (5 points) <ul style="list-style-type: none">• Medication• Condition(s) indicated to treat• Comparison with other medications• Safety issues		
<i>Total points for stage & depth (Phar 729 score)</i>		
Slides (5 points) <ul style="list-style-type: none">• Professional, legible• Correct spelling and grammar• Referenced appropriately		
OTC Label (5 points) <ul style="list-style-type: none">• Complete and accurate information• Compliant with FDA guidelines• Understandable language for consumers		
<i>Total points for slides & label (Phar 720 score)</i>		
<i>Other comments:</i>		

Evaluator initials:
