USING INNOVATIVE TECHNOLOGIES TO INCREASE PATIENT ACCESS TO MEDICATIONS

Ruchitbhai Shah, M.S., Erin R. Holmes, Ph.D.

Department of Pharmacy Administration, University of Mississippi

THE UNIVERSITY OF MISSISSIPPI Department of Pharmacy Administration

THE UNIVERSITY OF MISSISSIPPI Center for Pharmaceutical Marketing and Management

BACKGROUND

- Limited access to prescription medications due to the time and cost associated with a physician visit and safety issues associated with prescription-to-over-the-counter (Rx-to-OTC) switches continues to be a cause for concern.
- Consequently, the FDA has considered creating a third class of drugs which would not require a prescription, but require a pharmacist's consultation upon purchase.
- Recently the FDA held a hearing entitled "Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription"[1].
- This hearing repositioned a third class of drugs "as a 'new paradigm' under which certain drugs, that would otherwise require a prescription, would be approved for nonprescription use . . . under conditions of safe use"[1].
- These conditions of safe use would be specific to the drug product and might require sale in certain pre-defined health care settings, such as a pharmacy[1].
- In order for such a system of patient-directed self-care to work efficiently, the FDA would set up kiosks at pharmacies, computer algorithms or questionnaires on the Internet, which would help the patient to self-diagnose correctly.
- Alternatively, pharmacists could recommend the appropriate drug based on the patient's medical records and inform the patient about the conditions for the safe use of the drug[1].
- Several aspects of the new paradigm such as establishing conditions for safe use and using innovative technologies appear novel approaches to addressing a third class of drugs[2].

STUDY OBJECTIVES

- To measure community pharmacists' attitudes toward the new paradigm.
- To determine which drugs, community pharmacists believe, are acceptable additions to this proposed drug class.

METHODS

- This study was conducted by means of a self-administered web-based survey which was distributed to a national convenience sample of community pharmacists.
- The survey items were developed after considering several aspects of the "new paradigm" on which the FDA is seeking feedback from the key stakeholders by the end of this year.
- Respondent attitudes to these items were measured using a 7-point linear numeric agreement scale.
- This scale and study data were subject to qualitative validity checks, pretesting, principal components analysis (PCA), reliability analysis, and non-response bias assessment.
- The survey also included a list of current "prescription-only" drugs which may be potential candidates for the "new paradigm" based on criteria outlined by the FDA during the hearing.
- Respondents were asked to indicate whether the particular drug should be marketed as a prescription drug, nonprescription drug under the "new paradigm" or an OTC drug.

RESULTS

- Respondents were generally positive about the provision of patient care under the new paradigm but were skeptical about reimbursement, professional liability, significant workflow changes, and increased workload.

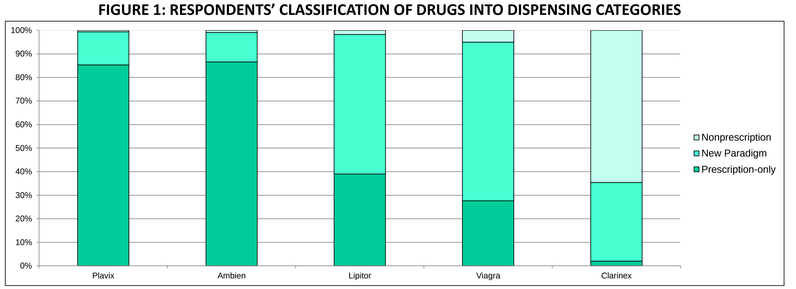
TABLE 1: RESPONDENT ATTITUDES TOWARD AN EXPANDED NONPRESCRIPTION DRUG CLASS

Assuming the implementation of an expanded nonprescription drug class under the FDA's proposed "new paradigm", please indicate your level of agreement with each statement using a scale from 1-7 where 1 = "strongly disagree" and 7 = "strongly agree"	Overall mean
PATIENT CARE 1. Pharmacists would have time to assist patients in selecting the most appropriate "new paradigm" drug 2. Pharmacist-authorized refills following a physician's initial prescription should be permitted under the new paradigm 3. Pharmacists would be comfortable enough to order diagnostic/lab tests before dispensing certain "new paradigm" medications 4. Pharmacists are capable enough to order diagnostic/lab tests before dispensing certain "new paradigm" medications 5. Pharmacists have the ability to make appropriate treatment recommendations 6. The "new paradigm" would allow for more patient-directed care 7. I support the institution of the "new paradigm" in pharmacy practice. 8. Patient medication adherence would improve 9. Patients would be accepting of pharmacists monitoring their treatment	5.17
WORKFLOW 1. Significant structural changes would have to be made in pharmacies to incorporate extra space for patient consulting rooms 2. Significant structural changes would have to be made in pharmacies to incorporate extra space for an expanded nonprescription drug section under the "new paradigm" 3. The number of personnel in pharmacies would have to be increased if the "new paradigm" were instituted 4. Significant changes in workflow of the pharmacy would have to be made 5. It would be difficult to implement the "new paradigm" in a typical community pharmacy setting 6. The installation of innovative technologies such as kiosks and online questionnaires in pharmacies would be problematic	5.18
PATIENT SAFETY 1. When in doubt, pharmacists should refer patients to a physician before dispensing a "new paradigm" medication 2. Pharmacists should alert a physician if there are problems with "new paradigm" medications that a patient is taking 3. Patient counseling by pharmacists for "new paradigm" medications should be mandatory 4. Pharmacists should document the "new paradigm" medication history of a patient 5. Pharmacists should have access to patient medical records to dispense "new paradigm" medications	6.43
NON-PHARMACIST PROVIDERS 1. Physician workload would be reduced 2. Primary care physician shortages would be reduced 3. The burden on emergency rooms would be reduced	4.49
PHARMACIST BURDEN 1. Pharmacists should be reimbursed for the time they spend diagnosing and counseling a patient for "new paradigm" medications 2. The professional liability of a pharmacist would increase 3. Pharmacist workload would increase	6.64
ACCESS 1. Pharmacy shopping among patients would increase 2. Patients would have increased access to medications 3. There would be an increase in out-of-pocket drug expenditures for insured patients under the "new paradigm"	4.91

RESULTS

- Respondents were skeptical about the switching Plavix® and Ambien® to the new paradigm, but affirmative about switching Lipitor ® and Viagra ® to this proposed class.

FIGURE 1: RESPONDENTS' CLASSIFICATION OF DRUGS INTO DISPENSING CATEGORIES



IMPLICATIONS FOR KEY STAKEHOLDERS

IMPLICATIONS FOR THE INDUSTRY

- Such a drug class can impact strategies adopted for drugs nearing patent expiration.
- Changes to pricing and reimbursement, labeling, packaging, marketing, and promotion requirements for "new paradigm" drugs would have to be considered.

IMPLICATIONS FOR PHARMACY PRACTICE

- Professional liability and time commitments of community pharmacists may increase however it can also be argued the role of the pharmacist in providing patient-directed care would increase, while at the same time reducing physician workload.

IMPLICATIONS FOR THE PATIENT

- There is a potential for increase in patient medication access and patient safety may also be a concern if a new third class of drugs is not properly implemented.

REFERENCES

1. *Karst, K.R. On-again off-again third category of drugs is on again at FDA; Simultaneous Rx and OTC marketing also up for debate. FDA Law Blog. 2012. Retrieved 8/8/2012, from* http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/02/on-again-off-again-third-category-of-drugs-is-on-again-at-fda-simultaneous-rx-and-otc-marketing-also.html
2. *Food and Drug Administration. Behind the counter availability of certain drugs: public meeting. 2012c. Retrieved 3/11/2012, from* www.federalregister.gov/articles/2007/11/27/E7-23026/behind-the-counter-availability-of-certain-drugs-public-meeting-comment-period-clarification

ACKNOWLEDGEMENTS

The authors would like to express their appreciation to Delta Marketing Dynamics who provided the national panel of community pharmacists used for this study at no cost.

Poster presented at The Seventh Annual Meeting of the PMRG Institute, October 20-22, 2013; Hyatt Regency Jersey City.