USING INNOVATIVE TECHNOLOGIES TO INCREASE PATIENT ACCESS TO MEDICATIONS

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BACKGROUND

• Limited access to prescription medications due to the time and cost associated with a pharmacist 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”.
• This hearing repopulated 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”.
• 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.
• 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 profile patient’s condition about the safety of the drugs for use.
• 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.

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pharmacists would have time to assist patients in selecting the most appropriate “new paradigm” drug</td>
<td>6.40%</td>
<td>45.84%</td>
<td>35.18%</td>
<td>12.58%</td>
</tr>
<tr>
<td>2. Pharmacists would have time to assist patients in selecting the most appropriate “new paradigm” drug</td>
<td>6.43%</td>
<td>44.80%</td>
<td>35.18%</td>
<td>12.58%</td>
</tr>
<tr>
<td>3. Pharmacists would have time to assist patients in selecting the most appropriate “new paradigm” drug</td>
<td>6.43%</td>
<td>44.80%</td>
<td>35.18%</td>
<td>12.58%</td>
</tr>
</tbody>
</table>

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

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 of concern if a new third class of drugs is not properly implemented.

REFERENCES


ACKNOWLEDGEMENTS

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