

## Alabama Pharmacists' Attitudes Regarding a Third Class of Drugs

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### Abstract

**Objective:** To assess the attitudes of Alabama pharmacists regarding the concept of a third class of drugs described as pharmacist-prescribed.

**Methods:** An attitudinal survey of Alabama pharmacists attending continuing educational programs was conducted in spring of 2005. Using anonymous responses based on a Likert-type scale, the pharmacists completed a self-administered questionnaire designed to achieve the research objectives.

**Results:** A total of 249 surveys was collected and analyzed. Most pharmacists (77.8%) agreed that there is a need for a pharmacist-prescribed class of medications and 83.9% agreed that patients would benefit from having access to medications that are pharmacist-prescribed. A majority of respondents (63.7%) indicated that their respective workplace settings could accommodate this service to their patients. An encouraging number of pharmacists (91.1%) indicated that they were willing to take the necessary steps (i.e., continuing education, reviewing current literature, etc.) to safely and effectively provide this service to patients. Pharmacists agreed that some over-the-counter and prescription medications should be included in a pharmacist-prescribed third class of drugs.

**Conclusion:** The majority of respondents expressed positive attitudes regarding the need for and benefits of a third class of drugs.

**Key words:** Pharmacy class, pharmacist prescribed, third class of drugs

### Introduction

Pharmacists serve an important triage function in our health care system. They often facilitate self-care by the patient or referral to a physician's care. In recent years, many products that were formerly available by prescription have been switched to over-the-counter (OTC) status.<sup>1</sup> There are advantages and disadvantages to the patient when a product has been released from prescription only status. Possible advantages include increased access to medications and decreased time and money spent on physicians' visits.<sup>2</sup> Possible disadvantages include delaying or masking a diagnosis of a serious illness, increased drug interactions and adverse reactions, self treatment being undertaken instead of medical treatment, potential misuse and abuse of medications, and increased direct drug cost to the patient.<sup>3-6</sup>

Currently the United States (US) has 2 classes of drugs: prescription and OTC medications. Other countries such as the United Kingdom have three classes. In the United Kingdom, there are Prescription Only Medications (POM), General Sales List (GSL), and Pharmacy Medicines (PM). Medications in the PM class can only be sold in pharmacies under the supervision of a pharmacist. In the US, the issue of a third class of drugs that is either pharmacist prescribed or sold only in pharmacies has been debated for many years.<sup>7,8</sup> This issue has received more attention recently due to a number of factors. One of these factors is the increasing number of products that are undergoing a switch from prescription to OTC status. A third class of drugs would provide a mechanism for former prescription-only products to be accessible to patients in a manner that could address some of the disadvantages associated with switching a product from the prescription to OTC classification. In November 2004, the results of the consumer use study of OTC lovastatin (CUSTOM) trial were published in the *American Journal of Cardiology*.<sup>9</sup> The study evaluated the ability of patients to correctly select, seek out appropriate professional advice, and achieve overall improvement in their lipid concentrations. The results of this 26-week observational study found that of 848 people who completed the study, 62% achieved LDL target goals of 130mg/dL and 2%

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demonstrated behavior that created potential for suboptimal safety. Overall, the study concluded that use of OTC lovastatin results in patient interaction with health care professionals to make appropriate decisions to manage elevated levels of LDL cholesterol, with minimal safety risk.<sup>9</sup> However, a survey commissioned by the National Lipid Association revealed that both pharmacists and physicians have concerns about OTC lovastatin use.<sup>10</sup> These concerns included fear that the patient would discontinue prescription lipid lowering therapy in favor of the OTC product, potential drug interactions and side effects with OTC statins, and patient ability to self-manage OTC statin usage through lipid testing, and remaining compliant to therapy.<sup>10</sup>

Another factor drawing attention to the third class of drugs debate is the consideration of moving ethically controversial items out of prescription-only classification. Plan B (Levonorgestrel) is a drug that until recently was classified as prescription only, but was dispensed by pharmacists without a prescription in seven states (Alaska, California, Hawaii, Maine, New Mexico, New Hampshire, Washington).<sup>11</sup> Each of these states had different guidelines for pharmacist-prescribing of Plan B.<sup>12</sup> Another factor fueling the third class of drugs debate is substance abuse. Many states are addressing the issue of using OTC products as precursors in the manufacture of illicit substances by restricting public access to these products. According to the National District Attorney's Association, in the 2005 legislative session, 29 states enacted legislation that addressed this issue. Public access was limited by restricting the sales quantity or location of ephedrine and/or pseudoephedrine-containing products and mandating the purchase procedure for these types of OTC medications.<sup>13</sup> Although some would argue that the limited examples of Plan B and pseudoephedrine constitute an established third class of drugs in the United States, this is far from true. Duramed Pharmaceuticals filed an application to switch Plan B from prescription to OTC that would voluntarily commit the product to limited distribution. The application filed by the company directed that consumers over the age of 18 can purchase the product without a prescription, but consumers under the age of 18 must obtain a prescription. The approval letter and accompanying memos issued in August 2006 from Federal Drug Administration (FDA) officials regarding Plan B did not state that the FDA's policy position has changed regarding the U.S. two-class drug system. The case of pseudoephedrine also represents limited distribution that does not constitute a true third class of drugs. New federal law restricts placement of pseudoephedrine (PSE) containing OTC medicines under the authority of the Drug Enforcement Administration (DEA) but does not change the product's classification in the FDA system. The FDA maintains that PSE-containing products are safe and effective for OTC use. DEA's position reflects the opinion that these substances can be used with criminal intent and should therefore have restricted distribution. The federal law effectively requires pharmacists to assist in law enforcement. Neither of these examples addresses a true third class of drugs designated by the FDA as a class of products that require additional health information or monitoring by a pharmacist to ensure appropriate use but do not require a prescription.<sup>14</sup> These examples of restricted distribution draw attention to the third class of drugs debate and may be used to pave the way to an established third class of drugs recognized by the FDA. Although the FDA has historically been opposed to creation of a third class of drugs, the issue has recently become a current area of interest to the FDA. In March 2007 at the Consumer Healthcare Product Association's Annual Executive Conference, FDA Commissioner Andrew von Eschenback, MD, announced FDA plans to begin working with stakeholders in considering the issue of whether existing regulations allow for the development of a third class of drugs or whether additional legislation is necessary to accomplish its creation.<sup>15</sup> Dr. Eschenback fielded questions on his projected timeline for creation of a third class of drugs by responding "The process is timely, so it should begin now."<sup>16</sup> Also in March 2007, Dr. Ilisa Bernstein, FDA Director of Pharmacy Affairs, announced at the American Pharmacists Association Annual Meeting that the FDA believes a new behind the counter (BTC) class of drugs could translate into greater access for patients and provide additional safeguards encouraging appropriate medication use. The goal as stated by the FDA for this BTC class of drugs is to increase access to drugs rather than restrict distribution.<sup>17</sup>

The American Pharmacists Association (APhA) issued a report in 2004 defining a new category of OTC medications called Pharmacy Care OTCs, which constitutes nonprescription medications available in retail establishments that have a pharmacy onsite. The goal of this new category defined by APhA is to

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facilitate interactions between consumers and pharmacists. APhA believes that Pharmacy Care OTCs would expand consumer access to medications that may be used for chronic, asymptomatic conditions such as high cholesterol or osteoporosis or other conditions where consumers would benefit from additional interaction with their pharmacist. In January 2005, APhA released its recommendations for creating this class noting that such a shift would require additional thought and planning on the part of the manufacturers, pharmacists and facility staff. The task force issued guiding principles for implementation including training and personnel issues.<sup>18</sup> With the current debate concerning a third class of drugs ongoing, it is important to ask the question of whether or not pharmacists are ready, willing, and able to provide the necessary services to support a third classification of drugs to be distributed by a licensed pharmacist without the requirement of physician prescribing.

## **Objectives**

The goal of this study was to assess the attitudes of Alabama pharmacists regarding the creation of a third class of drugs described as “pharmacist-prescribed.”

## **Methods**

Data collection in the form of a survey (see Appendix A) was obtained from Alabama pharmacists attending continuing education (CE) programs at Samford University, Birmingham, AL. Participation was voluntary and did not affect the CE credit granted. Surveys were excluded if the location of practice was outside Alabama. At the end of the survey, space was provided for voluntary comments on the issue. Approval for the study was obtained from Samford University Institutional Review Board prior to data collection. Data were analyzed via Excel spreadsheet.<sup>19</sup>

## **Results**

A total of 249 surveys were collected from two separate CE programs (Table 1). Results are provided based on total responses for each question. More than one-half of respondents (55%) were 25-45 years of age.

Pharmacists overall agreed (77.8%) that a need for a third class of pharmacist prescribed drugs exists (Table 2). A large majority of pharmacists surveyed (83.9%) believe patients would benefit from having access to medications that are pharmacist-prescribed (Table 2). Most pharmacists surveyed (88.3%) agreed they have the education and knowledge base needed to provide services associated with this class (Table 2). More than three-quarters (78.4%) of Alabama pharmacists agreed there are medications over-the-counter that should be restricted to pharmacist-prescribed (Table 2).

Table 3 summarizes responses of agree or strongly agree based on area of practice. Pharmacists who practice in independent retail pharmacies are strongly (90%) supportive of the concept of a third class of drugs (Table 3). Concerning knowledge base, education, and commitment to necessary continuing education, those pharmacists who listed education as an area of practice had an agreeable response rate of 100%. Ironically, only a third of these pharmacists (33.3%) agreed that their practice area can accommodate third class drug services. Pharmacists who practice as staff in a hospital pharmacy also indicated a high willingness to receive additional training but a lack of opportunity to provide this type of service. All areas of practice had a majority agree that there are both prescription and OTC medications that should be pharmacist prescribed.

## **Discussion**

Attitudes of Alabama pharmacists are favorable toward a third class of drugs in the U.S. Pharmacists overall agreed (77.8%) that a need for this class exists and independent pharmacists (90%) in particular are supportive of the concept (Table 3). Concern about use of OTC agents that are currently also available as prescription drugs, or that have recently been switched from prescription status, is one likely

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reason pharmacists agree there is a need for the additional classification. Literature has documented the patient belief that only safe medications are sold without a prescription and that OTC medicines do not usually have serious side effects.<sup>5</sup> McKenney and colleagues surveyed consumers, physicians, and pharmacists regarding the issue of OTC statins. One of the findings was that patients who are at high

**Table 1.** Demographics of survey participants

| <b>Gender</b>                | <b>Number<br/>(n=249)</b>                     | <b>Percentage<br/>Respondents</b> |
|------------------------------|---|-----------------------------------|
| Male                         | 112   | 44.9%                             |
| Female                       | 89  | 35.7%                             |
| No response                  | 48  | 19.3%                             |
| <b>Years in<br/>Practice</b> | <b>Number</b>                                 | <b>Percentage<br/>Respondents</b> |
| 0-5                          | 40  | 16                                |
| 6-10                         | 41  | 16.4                              |
| 11-15                        | 29  | 11.6                              |
| 16-20                        | 25  | 10                                |
| 21-25                        | 25  | 10                                |
| 26+                          | 64  | 25.7                              |
| No answer                    | 25  | 10                                |
| <b>Area of<br/>Practice</b>  | <b>Percentage<br/>Respondents<sup>a</sup></b> |                                   |
| Retail chain                 | 38.9  |                                   |
| Retail independent           | 24.1  |                                   |
| Hospital staff               | 12.5  |                                   |
| Hospital-clinical specialist | 8.4   |                                   |
| Pharmacy administration      | 4.4   |                                   |
| Educational institution      | 4   |                                   |
| Managed care                 | 1.6   |                                   |
| Mail-order pharmacy          | 2   |                                   |
| No answer                    | 14.4  |                                   |

<sup>a</sup> % >100 since some participants listed multiple areas of practice.

cardiovascular risk or currently on prescription lipid lowering agents (and therefore not appropriate candidates for nonprescription statin therapy) would still purchase and use over-the-counter lovastatin.

Another finding of the McKenney survey is that pharmacists are concerned about potential drug interactions and adverse effects associated with OTC therapy and are also concerned about the patient's ability to self-manage OTC statin therapy.<sup>10</sup> These concerns for patient safety likely contributed to this study's finding that a large majority (78%) of the pharmacists surveyed agree certain OTC products should be restricted as pharmacist prescribed (Table 2).

**Table 2.** Attitudes of Alabama pharmacists regarding the creation of a third class of drugs described as “pharmacist-prescribed”

| Survey item  | % Strongly Disagree | % Disagree | % No opinion | % Agree | % Strongly Agree |
|--|---------------------|------------|--------------|---------|------------------|
| As a pharmacist, I feel there is a NEED for a pharmacist-prescribed class of medications. (n=248)  | 3.2                 | 10.5       | 8.5          | 50.8    | 27               |
| As a pharmacist, I feel patients would BENEFIT from having access to medications that are pharmacist-prescribed. (n=248)   | 2.8                 | 6.9        | 6.5          | 58.1    | 25.8             |
| As a pharmacist, I feel I have the education and knowledge base needed to provide this type of service to my patients. (n=248)   | 1.6                 | 3.2        | 6.9          | 52      | 36.3             |
| As a pharmacist, I would be willing to take the necessary steps (i.e., continuing education, reviewing current literature, etc) to safely and effectively provide such a service to my patients. (n=248) | 1.6                 | 3.2        | 4            | 53.2    | 37.9             |
| My workplace setting could accommodate providing this service to patients. (n=245)   | 7.8                 | 14.7       | 13.9         | 42.9    | 20.8             |
| There are medications OTC that I feel should be restricted to pharmacist-prescribed.(n=226)  | 3.5                 | 10.2       | 8            | 49.6    | 28.8             |
| There are prescription medications that I feel should be allowed to be pharmacist-prescribed. (n=225)  | 1.8                 | 8.4        | 7.1          | 54.7    | 28               |

Most pharmacists surveyed (83.9%) believed patients would benefit from having access to medications that are pharmacist-prescribed. A 2004 study sponsored by the National Lipid Association indicated that 68% of pharmacists were interested in supporting a patient interested in taking an OTC statin. A strong majority of consumers who participated in this survey indicated that they would talk with their physician or other health care provider before purchasing an OTC statin.<sup>10</sup> One of the benefits of a pharmacist-prescribed class of drugs is the ability for the pharmacist to address the issue of concurrent use of prescription and nonprescription products that has been documented in the literature.<sup>20</sup>

A high degree of training and skill is required for practitioners to provide services associated with a third class of drugs. Arguably, some pharmacists may require additional training to be competent when providing these services. Less than 10% of the Alabama pharmacists surveyed indicated they were not willing to take the necessary steps (i.e., continuing education, reviewing current literature, etc) to safely and effectively provide such a service to patients. Most pharmacists surveyed (88.3%) agreed they have the education and knowledge base needed to provide services associated with a third class of drugs (Table 2). In contrast, in a recent survey sponsored by the National Lipid Association,<sup>10</sup> 68% of pharmacists agreed that they would need to learn more about National Cholesterol Education Panel ATP III guidelines to effectively advise patients about OTC statins.

**Table 3.** Summary of responses (agree or strongly agree) based on area of practice

|   | Retail chain<br>(n=97) | Independent Pharmacy<br>(n=60) | Hospital staff<br>(n=31) | Hospital-clinical specialist<br>(n=21) | Other Groups (Administration, nuclear, mail order, managed care)<br>(n=29) <sup>a</sup> |
|---|------------------------|--------------------------------|--------------------------|--|---|
| As a pharmacist, I feel there is a NEED for a pharmacist-prescribed class of medications.   | 66% <sup>b</sup>       | 90%                            | 83.9%                    | 95.3%                                  | 63.3%   |
| As a pharmacist, I feel patients would BENEFIT from having access to medications that are pharmacist-prescribed.  | 75.4%                  | 86.7%                          | 93.6%                    | 95.3%                                  | 76.6%   |
| As a pharmacist, I feel I have the education and knowledge base needed to provide this type of service to my patients.  | 85.5%                  | 83.3%                          | 93.5%                    | 95.3%                                  | 76.7%   |
| As a pharmacist, I would be willing to take the necessary steps (i.e. continuing education, reviewing current literature, etc) to safely and effectively provide such a service to my patients. (n=248) | 88.7%                  | 91.6%                          | 90.3%                    | 100%                                   | 86.7%   |
| My workplace setting could accommodate providing this service to patients   | 61.8%                  | 76.6%                          | 41.9%                    | 70%                                    | 43.3%   |
| There are medications OTC that I feel should be restricted to pharmacist-prescribed   | 73.2%                  | 80%                            | 83.8%                    | 95%                                    | 70%   |
| There are prescription medications that I feel should be allowed to be pharmacist-prescribed  | 78.3%                  | 86.6%                          | 87.1%                    | 89.4%                                  | 73.3%   |

<sup>a</sup>Total N=238, 11 did not indicate type of practice setting

<sup>b</sup>Row responses may be >100% since some participants listed multiple areas of practice

Three-quarters (78.4%) of Alabama pharmacists agreed there are over-the-counter medications that should be restricted to pharmacist-prescribed (Table 2). This may reflect pharmacists' concern about inappropriate use and abuse of nonprescription medications. In a recent survey of consumers, one-third of respondents reported encountering cases of inappropriate OTC drug use that they classified as abuse.<sup>21</sup> More than four-fifths of pharmacists surveyed (82.7%) felt there are prescription medications that should be allowed to be pharmacist-prescribed. This may be due to the perception that certain

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products offer an opportunity for pharmacists to expand their professional responsibilities. In a recent survey of pharmacists attitudes toward prescribing emergency contraceptives, three-quarters of respondents agreed that oral emergency contraceptive prescribing provides opportunities for pharmacists to be seen as health care providers. In a study by Borrego and colleagues, over one-third of the respondents indicated that they would like to be certified to prescribe oral emergency contraceptives.<sup>22</sup>

Concerning various subsets of pharmacists surveyed, there were some notable differences among various groups. Pharmacists must be adequately trained to provide services in a third class drug system. A degree of commitment to training and continuing education is necessary for appropriate professional practice in this context. The authors of the Alabama pharmacists' survey believe the present survey reflects a willingness on the part of pharmacists to maintain an appropriate level of training to provide the services. Concerning knowledge base, education, and commitment to necessary continuing education, those pharmacists who listed education as an area of practice had an agreeable response rate of 100%. Ironically, only one-third of these pharmacists (33.3%) agreed that their practice area can accommodate third class drug services. Pharmacists who practice as staff in a hospital pharmacy also indicated a high willingness to receive additional training but a lack of opportunity to provide this type of service. This finding does not necessarily suggest that it is difficult to provide third class of drugs services since presumably most of these services will need to be delivered in an ambulatory care environment. Approximately 90% of pharmacists who practice in retail (chain and independent) environments expressed a willingness to take necessary steps to safely and effectively provide pharmacists services within a third class of drugs system. A majority of pharmacists in all areas of practice agreed that there are both prescription and OTC medications that should be pharmacist-prescribed.

### **Limitations**

One limitation of this study may lie in the population of pharmacists surveyed. These were pharmacists attending live continuing education (CE) programs that presumably require more time and effort to complete than journal CE's. This may mean the pharmacists surveyed are more motivated and willing to learn than the average pharmacist. Also, because not all respondents listed their geographic location of practice, it is not certain that all respondents practiced in the state of Alabama. Some of the survey questions focused on willingness to perform certain things to enable pharmacists to provide services in a pharmacist-prescribed system such as obtain continuing education, review literature, etc. Although the pharmacists in this survey responded favorably to that commitment on paper, the survey does not record any evidence of pharmacists actually doing those things.

### **Conclusion**

Overall, Alabama pharmacists favored the creation of a pharmacist-prescribed category of drugs. Most indicated there was both a need and a benefit to such a category and that they have the knowledge base to provide this service to patients. Many expressed concerns regarding workplace settings that would accommodate this service. While there is no substitute for a physician's care, there are valuable services that pharmacists want to provide that can ultimately improve patient care without nullifying the role of the physician. Pharmacists play an increasing role in patient care. Creating a pharmacist-prescribed class of drugs may extend this role and may improve patient care overall. This study shows that interest in pharmacist-prescribing exists in the Alabama pharmacy community and demonstrates further need for exploration, perhaps on a national level.

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Appendix A  
Data Collection Form

Please answer the following questions concerning your attitude and opinion towards the creation of a 3<sup>rd</sup> class of drugs herein referred to as “pharmacist-prescribed”.

1. As a pharmacist, I feel there is a need for a pharmacist-prescribed class of medications.  
  - 1- Strongly Disagree
  - 2- Disagree
  - 3- No opinion
  - 4- Agree
  - 5- Strongly Agree
  
2. As a pharmacist, I feel patients would benefit from having access to medications that are “pharmacist-prescribed”.  
  - 1- Strongly Disagree
  - 2- Disagree
  - 3- No opinion
  - 4- Agree
  - 5- Strongly Agree
  
3. As a pharmacist, I feel I have the education and knowledge base needed to provide this type of service to my patients.  
  - 1- Strongly Disagree
  - 2- Disagree
  - 3- No opinion
  - 4- Agree
  - 5- Strongly Agree
  
4. As a pharmacist, I would be willing to take the necessary steps (i.e. continuing education, reviewing current literature, etc) to safely and effectively provide such a service to my patients.  
  - 1- Strongly Disagree
  - 2- Disagree
  - 3- No opinion
  - 4- Agree
  - 5- Strongly Agree
  
5. My workplace setting could accommodate providing this service to patients.  
  - 1- Strongly Disagree
  - 2- Disagree
  - 3- No opinion
  - 4- Agree
  - 5- Strongly Agree

6. There are medications over-the-counter that I feel should be restricted to “pharmacist-prescribed”.

- 1- Strongly Disagree
- 2- Disagree
- 3- No opinion
- 4- Agree
- 5- Strongly Agree

7. There are prescription medications that I feel should be allowed to be “pharmacist-prescribed”.

- 1- Strongly Disagree
- 2- Disagree
- 3- No opinion
- 4- Agree
- 5- Strongly Agree

Please provide some information about yourself and you practice background. (Circle responses where appropriate)

Location of practice (city, state) \_\_\_\_\_

Male                      Female

Age:                              <25    26-34    35-45    46-55    56-65    <65

Degree:                              PharmD    RPh

Years in practice:              0-5    6-10    11-15    16-20    21-25    26+

Area of Practice:

|                             |  |
|-----------------------------|--|
| Retail Chain                | Retail Independent Pharmacy            |
| Hospital-Staff              | Managed Care                           |
| Hospital- Clinic Specialist | Nuclear Pharmacy                       |
| Pharmacy Administration     | Mail-Order Pharmacy                    |
|                             | Educational Setting (i.e., University) |

In the space below, please provide any comments you may have on this issue as well as your thoughts on what medications you think could be classified as “pharmacist-prescribed” if such a class existed.