Continuing Education
Analysis of the Movement of Prescription Drugs to Over-the-Counter Status

Learning Objectives
Upon completion of this program, the participant will be able to:
1. List 4 reasons to explain the increase in over-the-counter drug sales in the last 10 years.
2. Describe the evolution of the regulatory changes that promoted the over-the-counter status in the United States.
3. Cite the 2 methods by which products are approved for OTC use in the United States.
4. List the 4 requirements for switching products from prescription drug status to OTC status in the United States.
5. Recognize at least 3 examples of successful prescription-to-OTC drug switches.
6. Recall and describe why some attempts to move prescription drugs to OTC status have failed.
7. Explain the role managed care has played in switching products from prescription status to OTC status in the United States, and explain the managed care economic and health care issues for offering OTC coverage to beneficiaries.

Self-Assessment Questions
Please indicate the correct answers on the Record of Completion.

1. Which one of the following is a false statement?
   a. OTC sales have quadrupled in the last 10 years and have surpassed the increase in prescription drug sales.
   b. Approximately 600 OTC products available today were not available 20 years ago.
   c. OTC drugs are the number one choice for consumers in treating minor ailments.
   d. More than 60% of OTC sales are from products that were recently switched from prescription-only status to OTC status.
   e. More than one of the above

2. Which one of the following is a reason for the recent increase in OTC sales?
   a. Emphasis on self-care and patient autonomy
   b. Recent trend to contain drug costs by health care organizations
   c. Profit interest of pharmaceutical manufacturers
   d. Steady increase in number of prescription-to-OTC product switches
   e. All of the above

3. Which of the following statements is false?
   a. OTC sales only represent 2% of the total health care costs in the United States.
   b. The Food and Drug Cosmetic Act of 1938 established the OTC category of drug products.
   c. The 1962 Kefauver-Harris Amendment established that OTC products must be effective when used without supervision by a health care practitioner.
   d. Manufacturers can receive an additional 3 years of patent protection if clinical trials are conducted for switching a product from prescription to OTC status.
   e. The 1951 Durham Humphrey Amendment states that the same drug at the same dosage and same indication cannot simultaneously be a prescription drug and an OTC drug.

4. Which one of the following is not considered to be a requirement when considering a product for the switch from prescription to OTC status?
   a. Is the drug effective as an OTC product?
   b. Is the condition for the OTC product self-diagnosable?
   c. Will the OTC product save the public money?
   d. Is the product safe when used as directed?
   e. Is the product label readable and understandable to the lay public?

5. Which one of the following products received a rejection from the FDA for the application of switching the product status from prescription drug to OTC?
   a. Lovastatin
   b. Ranitidine
   c. Loratadine
   d. Omeprazole
   e. More than one of the above

6. Which one of the following organizations is permitted to submit an application to the FDA for switching a prescription drug to OTC status?
   a. Only the manufacturer holding the patent can initiate the switch.
   b. FDA can initiate the switch.
   c. A health care organization (managed care firm, insurance company) can initiate a switch application.
   d. All of the above

7. Which of the following statements is false?
   a. The pioneer drug companies use the strategy of switching their product to OTC status in response to generic drug competition.
   b. Because of product elasticity, OTC drug products are more profitable than the same product as a prescription drug.
   c. It is in the best interest of the pioneer drug company to keep its products as prescription drugs for as long as possible because it is more profitable.
   d. Pioneer drug companies will usually wait to submit an application to move one of its products to OTC status until the patent is close to expiration.
   e. For many products, managed care benefits from the prescription-to-OTC switch because drug costs are shifted from the plan to the patient.

8. Regarding the 2 methods used by the FDA to approve drugs for OTC status, which one of the following statements is not true?
   a. The manufacturer can specify in the new-drug application that the drug is for OTC use.
   b. Manufacturers must submit labeling information and must conduct studies on readability and comprehension of the proposed OTC labeling.
   c. Manufacturers must conduct “actual use studies” as an OTC product.
   d. If the drug product has been used previously as an OTC product in a different country, it is an easier task for the approval process.
   e. No regulations exist specifying who may petition the FDA for switching a drug from prescription to OTC status.

9. Which one of the following switched products could be considered a “surprise move” due to its characteristic of being an addictive product?
   a. Monistat 3
   b. Rogaine
   c. Lamasil
   d. Nicorette
   e. Vagisil-1

10. Which of the following statements is false?
    a. The vast majority of managed care firms cover most OTC drugs in their plans.
    b. Some in managed care view the switch from prescription to OTC status as an opportunity to shift cost to consumers; this is reflected in the finding that only 31% of the managed care plans continued coverage of products that were switched from prescription status to OTC status.
    c. Network-model HMOs covered more “switched products” than IPA-model HMOs.
    d. Raising copayments for prescription drug products may be an incentive for beneficiaries to use the switched OTC product, especially if the copayment is greater than the cost of the OTC product.
    e. Medicaid program have the most liberal coverage of OTC products.
Continuing Education
Analysis of the Movement of Prescription Drugs to Over-the-Counter Status

Date: __________________________

In order to receive CE credit for this program, you must complete this form and the Program Evaluation form in addition to completing the post-test with a score of at least 70% (forms may be photocopied). Please mail all materials to the Academy of Managed Care Pharmacy, 100 N. Pitt Street, Suite 400, Alexandria, VA 22314. To receive credit, these forms must reach the Academy of Managed Care Pharmacy by December 1, 2005. CE certificates will be mailed to your address (below) as soon as possible after receipt of the Record of Completion and Program Evaluation forms and the post-test is graded and successful completion is determined.

All information will be kept confidential; it is used only for the processing and mailing of your CE certificate. You must complete and sign this form in order to receive CE credit for attending this program.

☐ I verify that I have completed the program and post-test for “Analysis of the Movement of Prescription Drugs to Over-the-Counter Status.”

Signature: __________________________________________

Please print your name as you would like it to appear on the CE certificate:

Last name: ___________________________________ First name: ________________________________

Company: ______________________________ State & License No: ________________________________

Address: __________________________________________________________

City: __________________________ State: __________________________ ZIP: ______________

Daytime phone: __________________________ Social security #: __________________________

Fax number: __________________________ E-mail: __________________________

Member Type:  ☐ Active   ☐ Supporting Associate   ☐ Student   ☐ Nonmember

The Academy of Managed Care Pharmacy is approved by the American Council on Pharmaceutical Education (ACPE) as a provider of pharmaceutical education. A total of 1 CEUs (1 contact hour) will be awarded to pharmacists for successful completion of this continuing education program. Successful completion is defined as receiving a minimum score of 70% on the post-test questions and completion of the Program Evaluation form. Continuing education certificates will be mailed to pharmacists within 8 weeks of receipt of the post-test questions and Program Evaluation form. Universal Program No. 233-000-02-005-H04 (Expiration date: 12/1/05)
Continuing Education
Analysis of the Movement of Prescription Drugs to Over-the-Counter Status

Participant's name: _____________________________ Date: ________________

Your assistance in the evaluation process is greatly appreciated. Please return this form with the post-test answers.

**Program Evaluation**

**Scale For Questions 1–8**

1 = Not at all  
2 = Not very well  
3 = Somewhat well  
4 = Well  
5 = Very well

**Scale For Questions 9–16**

1 = Poor  
2 = Fair  
3 = Good  
4 = Very good  
5 = Excellent

Using the scale above for Questions 1–8, please rate how well you will be able to accomplish the following objectives based upon successful completion of the program.

**Objectives:**

1. List 4 reasons to explain the increase in over-the-counter drug sales in the last 10 years. __________

2. Describe the evolution of the regulatory changes that promoted the over-the-counter drug status in the United States. __________

3. Cite the 2 methods by which products are approved for OTC use in the United States. __________

4. List the 4 requirements for switching products from prescription drug status to OTC status in the United States. __________

5. Recognize at least 3 examples of successful prescription-to-OTC drug switches. __________

6. Recall and describe why some attempts to move prescription drugs to OTC status have failed. __________

7. Explain the role managed care has played in switching products from prescription status to OTC status in the United States. __________

8. Explain the managed care economic and health care issues for offering OTC coverage to beneficiaries. __________

Using the scale above for Questions 9–16, please indicate the number that best expresses your opinion.

9. What is your overall rating of this program? __________

10. How would you rate the pertinence of the program materials to your practice? __________

11. Please rate each of the following program aspects:
   a. Content __________
   b. Clarity __________
   c. Knowledge gained __________

12. To what degree do you anticipate changes in patient care as a result of the material presented? (circle one)
   1 No Change 2 3 4 5 Significant change

13. Please indicate the length of time it took to complete this program: (Circle selection)
   Hours: 1 2 3
   Minutes: 0 15 30 45

14. Please rate the difficulty factor for completing this CE program: (Circle selection) Easy Moderate Difficult

15. Please rate your willingness to recommend this program to colleagues: (Circle selection)
   Very willing Willing Not willing

16. Please indicate which venue you prefer for obtaining continuing education: (Circle selection)
   Written monograph Slides Videos Internet-based

Live sessions Other: _____________________________