



AMERICAN ASSOCIATION
OF COLLEGES OF PHARMACY

Food and Drug Administration [Docket No. 2007N-0356]
Behind the Counter Availability of Certain Drugs

The American Association of Colleges of Pharmacy (AACP) is pleased to respond to the Food and Drug Administration's request for comments as published on October 4, 2007. AACP is the national organization that represents the interests of academic pharmacy. We are grateful to the members of our Self Care SIG for their thoughtful response to the FDA request. The Special Interest Group (SIG) in Self Care and Nonprescription Medications is comprised of faculty whom specifically are responsible for the delivery of these education related topics. AACP would also like to express its appreciation to many of our members that acted as reviewers of the SIG comments and to those pharmacy faculty that submitted comments on their own or on behalf of other organizations.

General Comments:

Prior to addressing the issues set forth for comment, we would first like to request the FDA consider alternative terminology for "behind-the-counter" (BTC) medications, such as "pharmacist-only" or "pharmacist-assisted". BTC terminology may imply that these medications are available behind any counter in a retail setting and not specifically recognize the critical role the pharmacist plays in appropriate use of these medications. Other countries, such as Australia and the United Kingdom, have adapted similar terms.

In the future, as the FDA contemplates moving "chronic, long-term medicines," e.g., statins for cholesterol lowering, to over-the-counter status (OTC), it will be important to have a learned intermediary to safeguard and monitor the patient. This monitoring aspect of patient care is well-suited for the pharmacist. Further, the pharmacist will have the opportunity to intercede for the patient with his/her primary care provider. Establishing this "pharmacist-only" category will facilitate continuity of care and enhance collaborative interdisciplinary health care. In addition, it would be predicted that the cost of health care would diminish with this approach.

General

1. Should there be BTC of certain drug products? If so why? If not why?

The following conditions contain medication classes identified as potential candidates for BTC status:

Allergies

Seasonal and perennial allergies are currently assessed by pharmacists on a routine basis as they recommend lifestyle changes and over-the-counter (OTC) products. Currently one medication in the non-sedating antihistamine class, loratidine, is OTC, the rest are prescription (Rx). Rx ocular antihistamines can also be included here.

Intranasal steroids are also currently Rx. These medications have proven safety and efficacy profiles; pharmacists can provide additional counseling on proper administration and adherence.

Topical and oral decongestants should also be considered for BTC status due to potential of misuse and diversion. Pseudoephedrine products are presently placed here as a result of The Combat Methamphetamine Epidemic Act of 2005.ⁱ

Gastroesophageal Reflux Disorder (GERD)

Several H₂-antagonists (at previously Rx strengths) and one proton-pump inhibitor are available OTC. There is precedent to consider increased access to Rx proton-pump inhibitors. Safety profiles have been established in these medications when properly administered. A pharmacist can assess patient symptoms, triage severe cases to physicians for further evaluation, provide advice on non-drug measures, and counsel on proper use.

Smoking cessation

Patients are twice as likely to quit smoking if they receive clinician assistance. Providing nicotine replacement products through a pharmacist will ensure proper use of these medications and will give the pharmacist an opportunity to provide behavioral advice and counseling to achieve cessation. Varenicline (Chantix®) may also be considered here as post-marketing surveillance data becomes available.

Analgesics

Though many are currently OTC, there has been growing concern about potential dangers of NSAIDs and acetaminophen regarding stomach bleeds and liver toxicity, prompting new labeling.ⁱⁱ Pharmacists dispensing these medications can help ensure proper use, administration, identification of side effects, and misuse.

Blood Pressure (Uncomplicated Stage 1)

Pharmacists are trained to take blood pressure measurements, assess staging, and recommend non-drug measures. Adding first-line medications with favorable safety profiles, such as hydrochlorothiazide, would offer initial options for patients with Stage 1 hypertension without coexisting disease states. Pharmacists have the ability to monitor efficacy on a routine basis as a patient visits the pharmacy, assess side effects, and monitor laboratory parameters such as potassium and uric acid. They can also reinforce non-drug lifestyle changes set forth by the JNC 7.ⁱⁱⁱ As hypertension progresses, pharmacists can triage patients to their primary providers.

Cholesterol

Statins have been considered for OTC status in the past, and will be examined once again by the FDA this December.^{iv} In 2005, OTC status was denied based upon concerns of the inability to self select, citing the medication could not be approved for safe and effective use in a self-management situation.^v These issues may be addressed with BTC status.

Other medications that could be considered are ezetimibe (Zetia®) and omega-3 fatty acids (Lovaza™). They both have good safety profiles and efficacy with proper cholesterol monitoring.

Acne (topical)

Topical medications such as tretinoin (Retin-A®), adapalene (Differin®), clindamycin/benzoyl peroxide (BenzaClin®), and other similar medications can be dispensed and safely administered with proper assessment and counseling. If improvement is not seen with these products, patients should be referred to a dermatologist for alternative therapies.

Otic analgesics

Otic A&B (antipyrine/benzocaine) could be considered here for short-term analgesic relief of earaches. This may be further supported by studies demonstrating the overuse of antibiotics for ear infections, adapting a “wait and see” approach.^{vi}

2. What might the impact of BTC be on patient access?

In one survey, 65% of Americans desired increased access to some of their Rx medications.^{vii} As the pharmacist is the most accessible healthcare professional to patients, BTC status is likely to increase patient’s access to former prescription medications, while ensuring proper administration. This is evident with moving emergency contraception (EC) to a nonprescription status.^{viii} Though it is “behind the counter” to assure only those over 18 has access, it has increased the ability for patients to receive the medication in a timely manner.

When these medications are moved from an OTC to BTC, it would limit access to medications consumers could once buy freely. This is demonstrated with The Combat Methamphetamine Epidemic Act of 2005, as pseudoephedrine is stored behind the counter limiting access only to those who seek it from the pharmacy.¹ Through limiting access, it has decreased drug diversion.

3. What might the impact of BTC be on patient compliance with drug therapy?

In one large study, an estimated 35% of prescriptions written and given to a patient are not dispensed.^{ix} The introduction of e-prescribing has reduced this number. Being assessed by a pharmacist for specified conditions and having the drug dispensed on-site may help increase patient compliance. Additionally, if BTC status decreases direct-cost for patients, this too will have a positive impact upon adherence.

4. What should the criteria or standards be for a drug to be treated as BTC?

- a. Drugs for certain uncomplicated, chronic conditions that have proven safety and efficacy if proper monitoring is performed. Examples include statins, non-sedating antihistamines, proton pump inhibitors, and H₂-antagonists.
- b. Drugs that need special counseling to assure that patients understand and are monitored for adherence to therapy. Examples include nicotine replacement products, varenicline, or intranasal steroids.
- c. Drugs that may have a potential for overuse, misuse, abuse, or diversion. Examples include pseudoephedrine or dextromethorphan.

5. Please comment on the following criteria for what roles a pharmacist or other health care professional might play, which are included below for discussion purposes. For example, a pharmacist or other practitioner licensed by law to dispense prescription drugs prior to sale might:

- a. **Review or conduct an initial screening for clinical laboratory test results, contraindications, or drug interactions;**
- b. **Counsel the patient on safe use;**
- c. **Monitor for continued safe or effective use.**

Pharmacists are medication experts. They receive an extensive education in pharmacology, pharmacotherapy, and pathophysiology. They are formally educated to assess appropriate drug therapy and monitor patient progress.. Currently, in many settings, pharmacist’s are providing medication therapy management (MTM) and recommending self care measures, including the use of nonprescription medications. When assisting patients with appropriate use of nonprescription medications, pharmacists must first assess criteria for self treatment. Specifically, is this self treatment appropriate for the patient. When it is, the pharmacist provides counseling inclusive of triaging the patient to appropriate healthcare providers when the patient is not a favorable candidate for self treatment. In the event that medications are shifted to a pharmacist-only category, pharmacists are educated to interpret baseline laboratory tests, know monitoring parameters, know contraindications to drug-therapies, and know drug-interactions. Pharmacists are skilled to counsel patients on the safe and effective use of medications, and are the only health professional to receive formal, in-depth training in nonprescription medicines.^x

6. Should BTC availability be used as a temporary or transitional status for drugs that move from prescription status to OTC versus permanent status?

BTC can be used as a temporary stop for prescription medications, pending evaluation of its impact on patient health and safety. BTC should also be a permanent placement for medications that would not be appropriate for open OTC sale based on safety and appropriate self selection of therapy.

7. Should there be criteria or standards for a drug to transition out of BTC status to OTC status? If so, what should these criteria or standards be?

Certain criteria should be considered when considering a drug switches from both Rx to BTC and OTC to BTC status:

- a. RX to pharmacist only – Products which demonstrate adequate safety data with use as prescription; products for chronic conditions, especially conditions where patient self care is an integral part of therapy; products for which the need for monitoring can be determined in large part by the onset of physical warning signs and/or is needed only at pre-determined intervals.
- b. OTC to pharmacist only – Products which demonstrate the need for appropriate patient counseling to ensure patient adherence or proper administration to achieve positive outcomes. Examples include orlistat (Alli®), and proton-pump inhibitors.

8. If safety concerns arise, should there be criteria or standards for a drug to transition out of BTC status to prescription status? Or from OTC status to BTC status? If so what should these criteria or standards be for each scenario?

Certainly, public safety is paramount and standards can be established to transit medications to limit public access. History has demonstrated that the inhalation dosage form of metaproterenol, once approved for OTC status was returned to “prescription only” status because of safety concerns demonstrated through post-marketing surveillance.^{xi}

9. What effect would BTC availability have on patient access to medications in this category?

BTC availability will provide patients access to medications, particularly those for chronic conditions (such as hypercholesterolemia). It will not hinder product availability to the patient. What it will ensure is that there is a “caution” step prior to purchase that ensures the patient is a candidate for the product use and that the product is appropriate for the patient’s needs.

The effect on availability is evident when comparing scheduling status to the United Kingdom and Australia. The table below represents 119 selected medicines available in all three countries:

Table 1. Comparison of the scheduling of 119 medicines available in the USA, Australia, and the UK^{xii}

Country	Medicines available for general use	Medicines available from pharmacies without Rx	Total medicines available without Rx	Medicines for which a Rx is required
Australia	13	68	81	38
UK	6	66	72	47
USA	53	0	53	66

Gilbert A, et al. Int J Pharm Practice. 2006;14:1-10.

10. How could we evaluate where BTC improves patient access to medications?

Assessing "improvement" will be difficult without a concomitant analysis of patient health. Assessing increases could be done with studies on sales patterns before and after a switch.

11. Would BTC availability be cost-effective to patients? Please explain.

It is documented that nonprescription medicines do save patients money, an estimated 20 billion, when considering prescription drug costs, doctor visits, time out of work, insurance costs, and travel.⁷ BTC availability may be an extension of this model, increasing access to appropriate conditions.

However, the pharmacist would not establish the cost of BTC medications. That is established by the manufacturer of the product. Evidence of this is demonstrated with the pseudoephedrine products which are now sold from behind the pharmacist’s counter. Once these products were placed behind the counter, the price of the products did not increase. An important consideration regarding cost is recognizing that pharmacists need to be paid for their expertise and thus while the medication cost should not increase, a professional fee should be added.

12. What effect would BTC availability have on patient safety?

There are medications presently in the OTC status which may better serve the public in the BTC category to improve safe usage. The FDA releasing warnings regarding OTC analgesics² is an example of the need for better monitoring and counseling of these medications. The pharmacist can assess need, proper administration, side effects, and misuse.

A 2001 survey conducted by the National Center for Patient Information and Education^{xiii} involving 1011 adults (Median Age – 39.7 years) demonstrated that:

- 1) Only 51% read the label for first time use.
- 2) Only 41% read the label for use instructions for the first use.
- 3) Only 20% read the label for safety information when they took the medicine.
- 4) Only 20% read the label for safety information when they purchased the product.
- 5) Thirty-three percent admitted taking more than the recommended dosage
- 6) Sixty-six percent admitted taking more than the recommended number of tablets/capsules at a single time.
- 7) Sixty percent admitted that they took the next dose sooner than directed on the label.
- 8) Forty percent admitted taking more drug per day than recommended on the package on the false belief that the symptoms they were treating would be relieved sooner.
- 9) Only 34% who took a pain reliever could identify correctly the active ingredient in the product.

As the FDA investigates safe and effective use of pediatric cough and cold products^{xiv}, BTC status could also be extended to products for children ≥ 6 years old. The pharmacist can assure proper dosing and usage of medications, while also considering current guidelines regarding assessment, triage, or treatment of cough.^{xv}

Additionally, the pharmacist will have the ability to document adverse reactions with already implemented national surveillance such as MedWatch. This drug class will also be in-line with patient safety goals set forth by the Joint Commission such as reducing prescription drug errors, the “Do Not Use List”^{xvi}, and decrease nonprofessional personnel involvement.

13. In general, what are the benefits and costs to the healthcare system as a whole related to BTC availability?

Benefits include increased availability, decreased physician visit costs, increased likelihood many asymptomatic disorders will be treated if a physician visit is not required.

Logistics

1. Discuss logistical challenges for pharmacy storage and dispensing of the BTC drugs. How might these challenges be addressed?

There will of course be challenges in creating more storage space and means for appropriate documentation of encounters. However, pharmacy has demonstrated in the past few years that it is able to accommodate change. This has been proven by adapting to the following:

- a. Medication Therapy Management (MTM) through Medicare Part D^{xvii}
- b. Pharmacist-delivered immunization programs^{xviii}
- c. Health Insurance Portability and Accountability Act (HIPAA)^{xix}
- d. The Combat Methamphetamine Act¹
- e. OTC Emergency Contraception⁸

2. What dispensing procedures should be associated with BTC medications?

A nationally standardized documentation form would be ideal and facilitate with billing. Documentation within the patient profile for dispensing the medication should also be consistent with prescription records or already implemented programs for pharmacist-based immunizations, MTM, or preventative health clinics provided in pharmacies. There are procedures in place with prescription dispensing, as well as pseudoephedrine, that can be drawn upon. Certain states have a system that documents the sale of pseudoephedrine, however these programs do not document assessment and counseling.

3. What types of records should be kept in association with BTC dispensing? If such records were to include patient laboratory values, how would the pharmacist gain access to this information as well as other information in the patient's medical records?

It is important to document the pharmacist-patient interaction, similar to a visit to any other health provider. Standardized patient visit forms documenting subjective and objective data, assessment of problem, and therapeutic plan (BTC medication and nonpharmacologic measures) should all be included. There are computer programs available to maintain this information electronically.

Pharmacists also have the capability of managing a patient medication profile in the community setting. When a BTC medication is dispensed, it can be recorded within the profile similar to the Rx medications. Education of the patient to maintain all medications at one pharmacy location will be an important component to ensure a complete medication profile and detect drug interactions.

Access to laboratory data would pose a challenge in the community environment. Many pharmacists may order laboratory tests when working in a collaborative practice agreement with a primary care provider. Mechanisms to address this challenge must be explored, particularly the implementation of a portable electronic medical record.

4. How would patient privacy be protected in the retail setting? Please discuss any privacy concerns that would need to be addressed.

Pharmacists and pharmacies currently adhere to HIPAA¹⁹, assuring there are private areas in which they may be counseled on their medications. Some retail settings have taken it one step further to include private counseling rooms.

5. Should reimbursement be available to pharmacists for providing services associated with BTC dispensing? What type? What type of billing procedures could be utilized and how third party companies facilitate such reimbursements?

Yes, mechanisms of reimbursement should be explored. In the past, pharmacists have only been associated with the product and not recognized for cognitive services. The Modernization Medicare Act has brought pharmacist role in medication therapy management to the forefront, where they are being recognized and reimbursed for services.¹⁷ Pharmacists should be compensated for keeping patients healthier, not for dispensing more medications.

Examples of billing procedures include:

- a. Third party organizations reimburse pharmacists with dispensing fees. As pharmacists document and dispense BTC medications, they may submit for counseling fee reimbursement at the same time.
- b. This system for pricing does not necessarily need to only go through third party billing as patients may pay out of pocket for the medication and counseling fee for service.

6. Who would oversee a BTC program? What impact would it have on States and what might be the role for the State boards of pharmacy?

State Boards of Pharmacy are regulatory agencies which currently develop, implement, and enforce uniform standards for pharmacies with the goal of protecting patient health.^{xx} The addition of a BTC category would be within the role of this independent body. Once regulations are in place, the impact will be minimal as medications are continually moving from Rx to OTC status, as well as a constant influx of new medications to the market, with little effect to workload.

7. Would special training be needed for pharmacists to participate in dispensing BTC medications? If any, what type of training will this entail?

AACP is confident that pharmacists graduating with the Doctor of Pharmacy degree are competent to participate in medication management approaches to improving patient care such as BTC approaches. Pharmacists that self-select as not comfortable providing BTC medication management can readily become competent through continuing education or certificate programs.

8. Would special training be needed for other pharmacy staff to aid in managing the work flow (storage, record keeping, distribution) and additional BTC responsibilities of the pharmacist(s) and the pharmacy? If so, what type of training or measures should be put in place?

The pharmacy can post signage to alert patients to speak to the pharmacist for particular medications and disease states. It will be critical that technicians are trained not to provide assistance with medication selection or purchase without a pharmacist consult.^{xxi} All levels of pharmacy personnel will be trained appropriately with the changes in pharmacy practice. In recent history, the profession has successfully achieved this with Medicare Part D, Medication Therapy Management, and The Combat Methamphetamine Act. Each pharmacy will implement operational procedures consistent with regulations set forth supporting BTC.

9. Could qualified healthcare professionals/providers other than pharmacists be responsible for dispensing BTC drugs? If so, what types of healthcare professionals/providers? And in what type of settings could this situation be accommodated?

Pharmacists are the medication experts and they are educated to counsel patients on the safe and effective use of medications. Most importantly, pharmacists are the only healthcare professional to receive a formal in-depth education in nonprescription medicines, either as integrated class work or as a stand alone course.¹⁰

10. What impact would BTC availability of drugs have on the practice of pharmacy?

Pharmacists have assumed an enhanced role in healthcare, and pharmacist-assisted self care will further complement this. Many community pharmacies currently offer disease management programs with physician referrals. In addition, pharmacists are already offering MTM services as well. The ability to make recommendations of this nature will also increase pharmacist job satisfaction.

Currently, 65,000 pharmacies in the United States handle all prescription drug distribution. If a few selected categories of medications were to be placed within the BTC category, this would not be a significant burden on our nation's pharmacies or pharmacists as they are already accustomed to providing counseling on prescription and nonprescription medications.

11. What impact would BTC availability of drugs have on the practice of medicine?

Pharmacists can serve to ensure safe and appropriate use of medication in a very accessible environment. In addition, greater access to medications will impact patients without health insurance who otherwise may go without care.

References

- ¹ The Combat Methamphetamine Epidemic Act 2005 (Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177). Available at: <http://www.deadiversion.usdoj.gov/meth/cma2005.htm>. Accessed on October 22, 2007.
- ¹ FDA proposes labeling changes to over-the-counter pain relievers. FDA News. Dec. 19, 2006. Available at: <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01533.html>. Accessed on October 19, 2007.
- ¹ . National Heart, Lung, and Blood Institute Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; National High Blood Pressure Education Program Coordinating Committee. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. JAMA. 2003 May 21; 289(19): 2560-72.
- ¹ Federal Register. October 23, 2007. Vol 72, No 204, Joint Meeting of the Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting. p. 60022. Available at: <http://frwebgate1.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=677386471445+0+0+0&WAISaction=retrieve>. Accessed October 29, 2007.
- ¹ Joint Meeting of the Nonprescription Drugs Advisory Committee and the Endocrinologic & Metabolic Drugs Advisory Committee January 13-14, 2005. Available at: <http://www.fda.gov/ohrms/dockets/ac/05/minutes/2005-4086M1.htm>. Accessed October 30, 2007.
- ¹ Spiro DM, Tay KY, Arnold DH, Dziura JD, Baker MD, and Shapiro ED. Wait-and-see prescription for the treatment of acute otitis media: A randomized controlled trial. JAMA 2006; 296: 1235-1241.
- ¹ Consumer Healthcare Products Association (CHPA). OTC facts and figures. Available at: <http://www.chpa-info.org/ChpaPortal/PressRoom/Statistics/OTCFactsandFigures.htm>. Accessed October 19, 2007.
- ¹ Pharmacy Access Partnership. Behind the counter: A review of Plan B. Available at: <http://www.pharmacyaccess.org/PlanBECNowAvailable.htm>. Accessed on: October 22, 2007.
- ¹ The J. Scott Group. Prescription compliance continues as a significant issue – no improvement seen – more than one-third of patients report not filling all Rx's – 65% of all Rx's show non-compliance with directions. Available at: http://findarticles.com/p/articles/mi_m0EIN/is_2006_July_10/ai_n16521366. Accessed on October 22, 2007.
- ¹ Covington T. Nonprescription drug therapy: Issues and opportunities. AJPE. 2006; 70 (6) Article 137.
- ¹ Dickinson BD, Altman RD, Deitchman SD, Champion HC. Safety of over-the-counter inhalers for asthma: Report of the Council on Scientific Affairs. Chest 2000;118: 522-526.
- ¹ Gilbert A, Rao D, Quintrell N. A review of pharmaceutical scheduling processes in six countries and the effect on consumer access. Int J Pharm Pract 2006; 14 : 1-10.
- ¹ Attitudes and beliefs about the use of over-the-counter medicines: A dose of reality: A national survey of consumers and health professionals. Harris Interactive, Inc; Bethesda, Md: National Council on Patient Information and Education; 2002. Available at: http://www.bemedwise.org/survey/summary_survey_findings.pdf. Accessed on November 5, 2007.
- ¹ FDA panel: No cold medications to children under 6. October 19, 2007. CNN.com/health. Available at: <http://www.cnn.com/2007/HEALTH/10/19/coldmed.fda/>. Accessed on October 30, 2007.
- ¹ Irwin, Richard S. Diagnosis and management of cough: ACCP evidence-based clinical practice guidelines. Chest 2006;129:24S.
- ¹ The Joint Commission. The official “do not use” list. Available at: http://www.jointcommission.org/NR/rdonlyres/2329F8F5-6EC5-4E21-B932-54B2B7D53F00/0/06_dnu_list.pdf. Accessed October 31, 2007.
- ¹ Pharmacist Services Technical Advisory Coalition. Medication Therapy Management Services CPT Billing Codes [press release]. Available at: <http://www.pstac.org/aboutus/profsvc.html>. Accessed October 22, 2007.
- ¹ Grabenstein JD. Pharmacy-based immunization delivery: a national certificate program for pharmacists. American Pharmacists Association, 2006.
- ¹ Federal Register. August 17, 2000, Part III, 45 CFR Parts 160 and 162: Health Insurance Reform: Standards for Electronic Transactions; Announcement of Designated Standard Maintenance Organizations; Final Rule and Notice, p. 50331.
- ¹ National Association of Boards of Pharmacy (NABP). Available at: <http://www.nabp.net/>. Accessed October 31, 2007.
- ¹ Pray WS. Chapter 2: Forces that shape the nonprescription product market. In: Nonprescription Product Therapeutics, 2nd ed. 2006. Page 28.

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- ⁱ The Combat Methamphetamine Epidemic Act 2005 (Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177). Available at: <http://www.deadiversion.usdoj.gov/meth/cma2005.htm>. Accessed on October 22, 2007.
- ⁱⁱ FDA proposes labeling changes to over-the-counter pain relievers. FDA News. Dec. 19, 2006. Available at: <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01533.html>. Accessed on October 19, 2007.
- ⁱⁱⁱ . National Heart, Lung, and Blood Institute Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; National High Blood Pressure Education Program Coordinating Committee. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. JAMA. 2003 May 21; 289(19): 2560-72.
- ^{iv} Federal Register. October 23, 2007. Vol 72, No 204, Joint Meeting of the Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting. p. 60022. Available at: <http://frwebgate1.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=677386471445+0+0+0&WAISaction=retrieve>. Accessed October 29, 2007.
- ^v Joint Meeting of the Nonprescription Drugs Advisory Committee and the Endocrinologic & Metabolic Drugs Advisory Committee January 13-14, 2005. Available at: <http://www.fda.gov/ohrms/dockets/ac/05/minutes/2005-4086M1.htm>. Accessed October 30, 2007.
- ^{vi} Spiro DM, Tay KY, Arnold DH, Dziura JD, Baker MD, and Shapiro ED. Wait-and-see prescription for the treatment of acute otitis media: A randomized controlled trial. JAMA 2006; 296: 1235-1241.
- ^{vii} Consumer Healthcare Products Association (CHPA). OTC facts and figures. Available at: <http://www.chpa-info.org/ChpaPortal/PressRoom/Statistics/OTCFactsandFigures.htm>. Accessed October 19, 2007.
- ^{viii} Pharmacy Access Partnership. Behind the counter: A review of Plan B. Available at: <http://www.pharmacyaccess.org/PlanBECNowAvailable.htm>. Accessed on: October 22, 2007.
- ^{ix} The J. Scott Group. Prescription compliance continues as a significant issue – no improvement seen – more than one-third of patients report not filling all Rx’s – 65% of all Rx’s show non-compliance with directions. Available at: http://findarticles.com/p/articles/mi_m0EIN/is_2006_July_10/ai_n16521366. Accessed on October 22, 2007.
- ^x Covington T. Nonprescription drug therapy: Issues and opportunities. AJPE. 2006; 70 (6) Article 137.
- ^{xi} Dickinson BD, Altman RD, Deitchman SD, Champion HC. Safety of over-the-counter inhalers for asthma: Report of the Council on Scientific Affairs. Chest 2000;118: 522-526.
- ^{xii} Gilbert A, Rao D, Quintrell N. A review of pharmaceutical scheduling processes in six countries and the effect on consumer access. Int J Pharm Pract 2006; 14 : 1-10.
- ^{xiii} Attitudes and beliefs about the use of over-the-counter medicines: A dose of reality: A national survey of consumers and health professionals. Harris Interactive, Inc; Bethesda, Md: National Council on Patient Information and Education; 2002. Available at: http://www.bemedwise.org/survey/summary_survey_findings.pdf. Accessed on November 5, 2007.
- ^{xiv} FDA panel: No cold medications to children under 6. October 19, 2007. CNN.com/health. Available at: <http://www.cnn.com/2007/HEALTH/10/19/coldmed.fda/>. Accessed on October 30, 2007.
- ^{xv} Irwin, Richard S. Diagnosis and management of cough: ACCP evidence-based clinical practice guidelines. Chest 2006;129:24S.
- ^{xvi} The Joint Commission. The official “do not use” list. Available at: http://www.jointcommission.org/NR/rdonlyres/2329F8F5-6EC5-4E21-B932-54B2B7D53F00/0/06_dnu_list.pdf. Accessed October 31, 2007.
- ^{xvii} Pharmacist Services Technical Advisory Coalition. Medication Therapy Management Services CPT Billing Codes [press release]. Available at: <http://www.pstac.org/aboutus/profsvc.html>. Accessed October 22, 2007.
- ^{xviii} Grabenstein JD. Pharmacy-based immunization delivery: a national certificate program for pharmacists. American Pharmacists Association, 2006.
- ^{xix} Federal Register. August 17, 2000, Part III, 45 CFR Parts 160 and 162: Health Insurance Reform: Standards for Electronic Transactions; Announcement of Designated Standard Maintenance Organizations; Final Rule and Notice, p. 50331.
- ^{xx} National Association of Boards of Pharmacy (NABP). Available at: <http://www.nabp.net/>. Accessed October 31, 2007.
- ^{xxi} Pray WS. Chapter 2: Forces that shape the nonprescription product market. In: Nonprescription Product Therapeutics, 2nd ed. 2006. Page 28.