Fall 2009

Maryland Board of Pharmacy news

In This Issue

The Mission of the Maryland Board of Pharmacy is to protect Maryland consumers and to promote quality healthcare in the field of pharmacy through licensing pharmacists and registering pharmacy technicians, issuing permits to pharmacies and distributors, setting pharmacy practice standards and through developing and enforcing regulations and legislation, resolving complaints, and educating the public.

Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, MD 21215
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Notice of Acceptance of Nominations for Board Commissioners

Home Infusion/Care Representative and Independent Representative

The Maryland Board of Pharmacy is comprised of ten (10) pharmacist members and two (2) consumer members. A member may serve a total of two consecutive four-year terms. Members' terms are staggered and Maryland law requires the Board of Pharmacy to notify all licensed pharmacists and other interested parties when four-year terms are scheduled to end. In addition, the Board must provide contact information for groups to which letters of interest may be submitted if an eligible individual is interested in being considered for nomination to the Board. The full text of the statute is found in Health Occupations §12-202.

Maryland law designates specific categories of representation for the 12 Board seats. The first term for the member serving in the **Home Infusion/Home Care** seat will expire April 30, 2010. The pharmacist currently filling that seat will not be eligible for reappointment because her employment is no longer related to Home Infusion/Care. The first four-year term for a member serving in a **Independent** seat will also expire April 30, 2010. The pharmacist currently filling that seat is eligible for reappointment.

Two (2) non-pharmacist consumer members are appointed by the Governor to the Board with the advice of the Secretary and the consent of the Senate. One of the two consumers currently serving in the **Consumer Member** seat is also eligible for reappointment in 2010. Pharmacist members are appointed by the Governor with the advice of the Secretary of the Department of Health and Mental Hygiene, from lists submitted by the appropriate association.

The requirements for appointment to the Board are as follows:

PHARMACIST APPOINTEES (10)
Maryland Resident
Licensed Maryland pharmacist
In good standing with the Board
Skilled and competent pharmacist
Possesses at least five years of professional experience

CONSUMER APPOINTEES (2)
Maryland Resident
May not have been a pharmacist
May not have a pharmacist in the household
May not have participated in pharmacy field
May not have had a substantial financial interest in a person regulated by the Board within two years prior to the appointment.

Independent Pharmacists:
The Maryland Pharmacists Association and the Maryland Pharmaceutical Society jointly submit three (3) pharmacists' names, who at the time of appointment, practice primarily in independent pharmacy for each open seat;

Home Infusion/Care Pharmacists:
The Maryland Society of Health-System Pharmacists submits three (3) pharmacists' names, who at the time of appointment, practice primarily in a pharmacy that specializes in the provision of home infusion/home care services for the open seat;

Lists of nominees are submitted by the contact associations to the Governor's Office for further consideration. Eligible licensed pharmacists who wish to be considered for

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From The Executive Director's Desk

LaVerne Naesea

GROWING PANGS!

Over the past few months, the Board has made many strides in implementing initiatives necessary to accommodate patient safety needs, trends in pharmacy, societal trends, and legislative mandates. Those strides have not been achieved absent discomfort to licensees related to the Board's processing of their requests, licenses, permits and complaints.

About two years ago, former Board President, John Balch provided an article in this newsletter entitled, *Change, Patience*. To paraphrase his introduction, he said that change comes very slowly at government agencies, often trying one's patience while the agencies strive to meet desired outcomes. As some of you may attest, former President Balch could not have better described the recent trying events experienced by some licensees when dealing with the Board of Pharmacy.

Admittedly, the relatively fast pace and host of changes happening at the Board of Pharmacy have painfully tested the patience of some licensees more so than when the agency operated at a slower pace. Board and staff members *themselves* have had very trying experiences while attempting to keep pace with changes at the Board. Thus, the Board is very empathetic with its customers' frustrations and would be remiss if it did not both offer an explanation for the circumstances that led to recent processing delays and apologize for related inconveniences.

Two years ago, the Board relocated its offices to a more expansive area on the first floor of the Patterson Avenue building in preparation for the addition of staff and anticipated increases in the storage space necessary for records related to implementation of the new pharmacy technician registration and administration of vaccines initiatives, the revised wholesale distributor application process, and new pharmacy and wholesale distributor inspection responsibilities. As it turned out, unavoidable problems related to implementing these initiatives created a *perfect storm*.

The swell of applications and training programs received for the pharmacy technicians and wholesale distributor applications created the need for the Board to extend the acceptance and approval processes. The extensions should have allowed more time for Board and staff members to review and process information received. However, the simultaneous implementation of two different criminal background check requirements relating to applications for pharmacy technicians and wholesale distributor personnel led to further unanticipated staff burden and delay. Additionally, the Board's existing telephone system and limited administrative support could not accommodate the phone call overload; which began increasing exponentially due to the implementation of the new programs. Adding to the *overload*, the revised wholesale distributor statute required all facilities (in-state and out-of state) to be inspected by the Board or its designee, before a permit was issued and then news of the H1N1 influenza broke. Thus, new Board inspectors were required to inspect wholesale distributors in addition to performing annual inspections and the number of applications that needed to be processed for the administration of vaccines increased significantly — along with related phone calls from the applicants. Concurrent with the occurrence of the entire series of events described above, the Board's vendor contract to develop and implement an upgraded database to accommodate (and integrate) newly collected data with existing data, was unsuccessful, therefore, the issuance of a new contract bid and subsequent initiation of a new project was required. Thus, the *Perfect Storm…*

Board and staff members have patiently weathered the storm; wading through every bureaucratic obstacle while still accommodating the substantial changes. The results have yielded the completion of inspections of more than 650 distributors and a contract with the National Association of Boards of Pharmacy to perform inspections of the remaining out-of-state distributors. The timeframe for reviewing and approving pharmacy technician applications and training programs continues to decrease and Board inspectors are now averaging 125 pharmacy inspections per month. Board and staff members are working together to create a new telephone system, including acquiring additional personnel resources to cover increased calls, and acquiring temporary staff to process vaccine administration applications. Further, development of a new database system is in progress and is anticipated to be completed over the next six to eight months.

According to the Encarta Dictionary definition offered on my trusted PC, a *pang* is a "short sharp pain." The recent pangs experienced mutually by some licensees as well as Board and staff members may have been "sharp," but in the scheme of things, they have subsided significantly. Thanks to those who were affected — for your patience and understanding. The Board's ultimate goal is to continuously improve services for Maryland's pharmacy patients and practitioners. If that goal continues to be achieved, perhaps it's worth the occasional growing pangs.

Notice of Acceptance of Nominations for Board Commissioners

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nomination to either of the two upcoming pharmacist seats should provide a letter of interest along with a biographical form (available on the Board's web site http://www.mdbop.org/about/index.htm or through the association) to the appropriate association noted below:

Home Infusion/Care Representative
Maryland Society of Health System Pharmacists
8480-M Baltimore National Pike, #252
Ellicott City, MD 21042
410.465.9975
mshp@rxassociationmgt.com

Independent Representative
Maryland Pharmacists Association
Attn: Howard Schiff
1800 Washington Blvd. Suite 333
Baltimore, Maryland 21230
www.marylandpharmacist.org

Maryland Pharmaceutical Society
Attn: Jason Noel
PO Box 1182
Owings Mills, MD 21117
mdpharmsociety@yahoo.com

COMPLIANCE CORNER

Lenna Israbian-Jamgochian, Compliance Committee Chair and Board Commissioner

Information Relating to Incorrectly Filled Prescriptions

On April 14, 2009, Senate Bill 242 was enacted into law, requiring pharmacies to provide information to patients regarding the process for resolving incorrectly filled prescriptions. Effective October 1, 2009, pharmacy permit holders must provide such information in accordance with existing regulations by:

1) *Posting a sign that is conspicuously positioned and readable by consumers at the point where prescription drugs are dispensed to consumers; or*

2) *Including written information regarding the process with each prescription dispensed.*

The purpose of the original regulation COMAR 10.34.26.02 was for pharmacy permit holders to provide patients with information on how to report medication errors and the patient's role and responsibility in preventing medication errors. Therefore, since October 2003 pharmacies were required to provide information to patients regarding:

1) *A patient's rights when receiving a medication or a prescription;*

2) *The patient's role and responsibility in preventing a medication error;*

3) *The procedure to follow when reporting a suspected medication error to the pharmacy permit holder, pharmacist, health care facility, or other health care provider; and*

4) *How to report a suspected medication error to the Board.*

As a result, a pharmacy permit holder can now satisfy the informational requirement by posting a sign OR providing information with each prescription dispensed, provided that all four of the previous provisions from COMAR 10. 34.26.02 are included. This requirement does not, however, apply to a pharmacy owned and operated by a hospital, nursing facility, or clinic to which the public does not have access to purchase pharmaceuticals on a retail basis.

Updated Inspection Form to Reflect Expanded Pharmacist Administration Authority

As discussed in the Licensing Corner article, effective August 1, 2009, pharmacists are able to administer the *Herpes Zoster* and *Pneumococcal Pneumonia Vaccines* in Maryland after registering with the Board to administer vaccines. As a result, the community pharmacy inspection form of the Board of Pharmacy will be updated to reflect this expanded authority and Board of Pharmacy inspectors will be checking to ensure that medications are being stored at the appropriate temperatures.

Maintaining medications at proper temperatures, as indicated by the manufacturer, are crucial to maintaining drug stability. USP recommends a controlled room temperature as between 59°F and 86°F and a cold temperature in a refrigerator as between 36°F and 46°F. The new inspection form will also include a section for freezers, defined as thermostatically maintaining a temperature between -4°F and 14°F.

ANTIMICROBIAL RESISTANCE: The "Ignored" Health Care Threat

Jennifer Thomas, PharmD, Member, Maryland Pharmacy Coalition

The following is a summary of a full-length article regarding the issue of Antimicrobial Resistance. The full-length article and references can be found on the Maryland Board of Pharmacy website (www.mdbop.org) under "What's New."

Defining the Problem of Antimicrobial Resistance

Antimicrobial resistance is not a new phenomenon in our society. Since the inception of antibiotics, health care providers have been challenged by the issue of antimicrobial resistance. While changes in antimicrobial resistance have occurred over time and the estimated costs due to this public health crisis is estimated to be in the billions of dollars, the general medical community and the general public have not grasped the extent of the problem nor integrated the idea of stewardship with respect to antimicrobial therapy. It was not until the mid 1990's that professional organizations and governmental committees achieved enough influence in garnering political recognition of the problem.

Addressing the Problem of Antibiotic Resistance

Developments within the U.S. to address antimicrobial resistance began in earnest in 1999 with the creation of the U.S. Interagency Task Force on Antimicrobial Resistance. This Task Force, which included multiple federal agencies, was charged with developing a national plan to combat antimicrobial resistance. The Task Force developed a plan, "A Public Health Action Plan to Combat Antimicrobial Resistance" in 2001 which included thirteen items of top priority with a timeline to address each item. The thirteen items were identified under four broad categories: surveillance, prevention and control, research, and product development. In 2003, FDA partnered with CDC on its launch of its *Get Smart: Know When Antibiotics Work* campaign. The goal of the campaign is to educate consumers and healthcare professionals on the appropriate use of antibiotics. In the area of food safety, FDA published Guidance the for Industry #152 "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern." There are recommendations to drug sponsors on risk assessment approaches for evaluating the likelihood that an antimicrobial drug used to treat a food-producing animal may cause an antimicrobial resistance problem in humans.

Antibiotic Resistance Programs in Maryland

State level awareness of the issues of antimicrobial resistance is reflected in the passage of legislation, SB 286

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LICENSING CORNER

Michael Souranis, Licensing Committee Chair and Board Commissioner

Immunizations for Marylanders: Is an Ounce of Prevention Worth a Pound of Cure?

Involving pharmacists in immunizations greatly exemplifies the public health initiative to increase access to immunizations for the public. Pharmacists in a variety of practice settings are:

- Positioned uniquely to provide vaccinations in the community;
- Have routine access to patients in need of vaccinations;
- Can effectuate successful immunization rates in Maryland with their extensive knowledge and immunization training by providing valuable information to patients about the importance of immunizations, facilitating immunization delivery, and administering vaccines that avert disease and decrease the corresponding potential complications caused by the disease.

Nearly 50,000 adults in the United States die each year from vaccine-preventable disease or complications from such disease. Influenza kills an average of 36,000 people annually (with most of the deaths occurring in the elderly population) and is associated with more than $10 billion in costs with a moderately severe seasonal outbreak. Pneumococcal disease, which causes pneumonia and invasive infections, kills about 4,800 people annually. Together, influenza and pneumococcal disease are the eighth leading cause of death in the U.S., and are responsible for approximately 400,000 hospitalizations annually. Vaccination rates for influenza and pneumococcal disease among U.S. adults fall well below the U.S. Department of Health and Human Services' Healthy People 2010 goal of 90%.

Herpes Zoster (also known as "Shingles") will affect one in three Americans in their lifetime. This disease is characterized by a painful rash and is caused by the same virus that causes chicken pox. Significant complications such as severe pain syndrome and post-herpetic neuralgia can occur with this disease. These complications may last for months or years after the shingles rash heals.

As of August 1, 2009, pharmacists licensed by the Maryland Board of Pharmacy now have the ability to provide pneumococcal pneumonia and herpes zoster vaccines, in addition to the influenza vaccine. The 2008 Maryland legislature passed SB 717, Pharmacists – Administration of Vaccinations – Expanded Authority, which allows the pharmacist to also administer pneumococcal pneumonia and herpes zoster vaccines with additional requirements. The Maryland Board of Physicians, Maryland Board of Nursing and the Maryland Board of Pharmacy promulgated together, as mandated by the 2008 legislation, the proposed changes in the regulations to accommodate the two new vaccines. Below are the considerations that Maryland pharmacists who are already certified as a pharmacist immunizer, as well as those pharmacists considering becoming a pharmacist immunizer, should be cognizant of:

Current Certified Maryland Pharmacist Immunizers

Effective August 1, 2009, all pharmacists certified to administer vaccines may administer influenza, herpes zoster and pneumococcal pneumonia. Upon renewal, certified pharmacists must complete 4 CE's in vaccination (those pharmacists certified prior to October 1, 2008 must complete 4 CE's specifically related to herpes zoster and pneumococcal pneumonia). Please take a moment to review the new regulations because there are new requirements for herpes zoster and pneumococcal pneumonia. The new Regulation .09 sets forward the requirements for administration of the two new vaccines. A prescription is required and the pharmacist must notify the physician within 7 days of the identity of the patient, the identity of the vaccination, the route of administration, the site of the administration, the dose administered, and the date of administration.

The regulations, COMAR 10.34.32.01 - .09, are available on-line at the Division of State Documents website at: www.dsd.state.md.us. Click on COMAR on the left menu. Select the first option and then enter all eight numbers in the box provided: 10.34.32.01 and so forth. You may only access one regulation at a time and there are 9 regulations.

Maryland Pharmacists Considering Becoming a Certified Immunizer

During the initial registration to become a certified immunizer, pharmacists will have to provide evidence of the successful completion of a certification course approved by the Maryland Board of Pharmacy that includes current guidelines and recommendations of the Centers for Disease Control (CDC) for herpes zoster, influenza and pneumococcal pneumonia vaccines. Pharmacists will also have to possess an active certification in basic cardiopulmonary resuscitation obtained through in-person classroom instruction.

Please visit the Maryland Board of Pharmacy website (http://www.mdbop.org/forms/pharmacist.htm) for all of the requirements and applicable forms for pharmacist immunization certification and certification renewal. For the future, the 2009 Maryland legislature passed SB 700, Pharmacists - Administration of Vaccinations – Expanded Authority, which allows further expansion of pharmacist immunizers. This legislation allows the Board of Pharmacy, with the agreement of the Board of Physicians and the Board of Nursing, to determine which additional vaccines would be in the best health interests of the community for pharmacists to administer. No further statute changes will be required to add additional vaccines in the future.

Undoubtedly, pharmacists can facilitate increased vaccination rates for preventable diseases which in turn will foster a significant impact on immunization delivery for Marylanders. Thus, when it comes to vaccines, including but not limited to those mentioned above, an ounce of prevention is

LICENSING CORNER

definitely worth more than a pound of cure.

Should you have any questions, please contact the Maryland Board of Pharmacy at 410-764-4756.

Update on Student Exemption Status

The Maryland Board of Pharmacy recently updated the student exemption renewal process. Currently, student exemption cards have expiration dates that varied based on when the application was originally submitted. Many students were unsure about what to do in order to continue receiving student status exemptions when their cards expired. Soon, all students who are still currently eligible for student exemption status with the Board will receive new cards in the mail. These cards will not have an expiration date and are intended to be used throughout the student's entire time in pharmacy school. The new process will work as described below.

At the beginning of each new school year, students will be required to submit an affidavit from their pharmacy school by October 30 of each year in order to continue their exemption status. Upon receipt of the affidavit, the Board will update its website to indicate that the affidavit has been received and the student is still exempt. This year, students have been informed that the deadline for submission of pharmacy school affidavits has been extended to December 1, 2009.

The new process is designed to reduce confusion among pharmacy students about the expiration of their student exempt status, as well as make the process easier for Board staff members. Should students have any questions about their Board status or the new process, please contact the Maryland Board of Pharmacy at 410-764-4756.

DISCIPLINARY ACTIONS

Pharmacists
Smeeta Patel, License #11805, Probation 11/2/09
David Lee, License #18121, Suspended 6/5/09
Devon Schlieper, License #17864, Probation 10/13/09
Norton Grossblatt, License #06165, Suspended 7/1/09
Ketankumar Patel, License #10301, Suspended 7/14/09
Paul Ejedoghaobi, License #17416, Suspended 8/17/09
Katherine Emery, License #11691, Probation 8/17/09

Pharmacy Technicians
Lauryn Miller, Registration #T03556, Suspended 6/5/09
Keri Calvert, Registration #T02041, Suspended 7/8/09
Deanna Higgs, Registration #T00892, Suspended 8/31/09
Tyrice Lightner, Registration #T02215, Suspended 9/22/09

Establishments
Medicine Shoppe Pharmacy #1183, Permit #01686, Suspended 7/14/09

ERRATUM - Summer 2009 Board of Pharmacy Newsletter

In the Summer 2009 newsletter, the pharmacist license number noted for Michael Ball under *Disciplinary Actions was incorrect*. The correct license number for Michael Ball is 09572.The Board apologizes for this error.

ANTIMICROBIAL RESISTANCE
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Antibiotic Resistant Infection Prevention Campaign, during the 2008 legislative session. This bill, subject to the availability and appropriation of funding, directed the development of a public awareness educational campaign on the critical healthcare issue of antibiotic resistant infections. The Maryland Pharmacy Coalition (MPC) supported the legislation and offered the professional support and expertise of pharmacists to collaborate with state and local public health officials in the development and dissemination of educational materials.

A current local and national initiative that is considered a negative campaign and will likely fuel development and selection of resistance is the "free antibiotics" program. As the world encourages the wiser use of antimicrobials, a contradictory message to the public is introduced by the free antibiotics advertisements and coverage by many pharmacy chains and insurance plans. Misconceptions arise due to the medication being "free" and this implies that it can be used whenever desired and requested by the patient. The campaign may increase pressure on prescribers to provide an antibiotic when it is not therapeutically necessary. In addition, there is also the concern of stockpiling antibiotics and inappropriate use for seasonal cold and flu and the current novel H1N1 influenza infection. The experts agree this sends the wrong message and is bad public health policy. In March 2009, the Infectious Diseases Society of America (IDSA) and the CDC sent joint letters to the supermarket/chain pharmacies to encourage them to join the CDC's campaign to encourage appropriate use of antimicrobials.

Appropriate Antibiotic Use and Stewardship

The concept of appropriate use of antimicrobial therapy as one of stewardship places the responsibility of resistance on many healthcare partners with different motivations: prescribers, patients, providers, industry and the public. In 2007, guidelines were published that addressed the development of programs to enhance antimicrobial stewardship in institutional settings and provide the outline and metrics to facilitate discussions and inclusion of key individuals, such as administrators, to obtain support (including budgetary) to ensure success of the program.

There are opportunities to expand these programs and the Maryland Society of Health System Pharmacists offers health systems the opportunity to engage in the professional organization's Antimicrobial Stewardship Committee. This committee initiative was founded in 2008 and has established relationships with the infection control practitioners of the state through the Maryland Association of Professionals in Infection Control (MD-APIC) and laboratory practitioners within their systems. Members are encouraged to invite and engage infectious diseases physicians in the meetings and discussions.

There are many opportunities for pharmacists to utilize their expertise for safe and appropriate antimicrobial use. As one of the most accessible healthcare professionals available to the public, the pharmacist has a responsibility at the point of dispensing, during counseling or obtaining a medication history, or through medication therapy management to share information on antimicrobials and the public health treat of resistance. In the current healthcare reform debate and legislative agenda, pharmacists have an opportunity to share their expertise and voice their opinion. **Now** is the time to contact your professional organizations and your congressional members to provide your position on addressing the issue of antimicrobial resistance.

ACETAMINOPHEN: Imperative Considerations For Health Care Providers

Lynette Bradley-Baker, Acetaminophen Coalition Chair and Board Commissioner

Background

It is imperative that all health care professionals be aware of the safety profile and potential benefits of the pain-reliever acetaminophen, one of the most widely used medicines in the United States. It is safe and effective when used in recommended dosages for patients according to their current health status. Over 24.6 billion doses of acetaminophen were sold in 2008.[1] Acetaminophen is sold under several brand names and is also available in over 600 cough and cold products, sleep aids, and prescription pain relievers.

The wide spread utilization of acetaminophen by patients may increase the incidence and prevalence of misuse, which can lead to severe health care outcomes. Many cases of overdose are caused by patients inadvertently taking more than the current recommended dose (i.e., 4 grams a day) of a particular product, or by taking more than one product containing acetaminophen (e.g., an Over-the-Counter (OTC) product and a prescription drug containing acetaminophen).

In proper daily dosages, acetaminophen is eliminated by the body as it changes into metabolites that the body can easily eliminate in the stool or urine. Overdoses of acetaminophen often lead to acetaminophen induced hepatotoxicity. Acetaminophen induced hepatotoxicity is caused by a toxic metabolite of the parent compound and can lead to liver failure, which may result in liver transplant or death. The signs of liver disease include abnormally yellow skin and eyes (jaundice), dark urine, light-colored stools, nausea, vomiting and loss of appetite. The risk for liver damage may be increased in patients who drink three or more alcoholic beverages a day when taking acetaminophen-containing medicines. Serious cases of acetaminophen induced hepatotoxicity may lead to mental confusion, coma, and death.

Acetaminophen-induced hepatotoxicity continues to be a persistent important public health problem. As mentioned previously, this serious medical condition is usually related to exceeding the maximum daily dose of acetaminophen and is a leading cause of drug-induced liver injury in the United States. A study conducted by Larson indicated that 51% of acute liver failure cases between 1998 and 2003 were from acetaminophen-induced hepatotoxicity.[2]

What can I do as a Health Care Provider?

There is limited data available describing patient/consumer behavior with acetaminophen products or consumer understanding of acetaminophen toxicity. However, based on the prevalence of liver injury, it appears that there are distinct factors associated with acetaminophen and acetaminophen products that contribute to this public health problem. These factors include:

- Taking any amount of acetaminophen over the recommended total daily dose may lead to liver injury (the patient's health status and daily activities determine their recommended total daily dose);
- There is a wide array of OTC and prescription acetaminophen products used in a range of doses for various indications;
- It can be difficult to identify acetaminophen as an ingredient in OTC and prescription products due to labeling abbreviations (i.e., APAP indicating Acetaminophen);
- Multiple products exist for children containing different strengths (infant formulations are more concentrated than children formulations) and can cause confusion amongst adults for appropriate dosing;
- The association between acetaminophen and liver injury is not common knowledge amongst patients.

As health care providers, we can provide useful information regarding the safe use of acetaminophen, as well as other pain relievers, for our patients. Suggestions include education and reminders to consumers about being aware of acetaminophen often being used in combination products (both over-the-counter as well as prescription) and assisting patients in learning to read labels is paramount to increasing the awareness of acetaminophen in drug products. There are several websites available that are useful for patient information regarding safe acetaminophen usage. Some of them are listed below for reference and potential patient referral.

Over-the-Counter Pain Relievers/Fever Reducers: Using Acetaminophen and NSAID Medicine Safely

US Food and Drug Administration

See: www.fda/gov/cder/drug/analgesics/default.htm

How to read the OTC Drug Facts Label

National Council on Patient
Information and Education (NCPIE)

See: www.bemedwise.org/label/label.htm

The (Potential) Future for Acetaminophen

The Food and Drug (FDA) Center for Drug Evaluation and Research (CDER) Joint Meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee, and the Anesthetic and Life Support Drugs Advisory Committee held hearings on June 29-30, 2009 to address the public health problem of liver injury related to the use of acetaminophen in both over-the-counter (OTC) and prescription products. Members of the Maryland Acetaminophen Coalition attended the hearings and one of the members, Rebecca Drake, addressed the expert FDA panel during the public session (see insert regarding Rebecca's personal story about the potential dangers of acetaminophen). At the conclusion of the hearings, the panel recommended the following to the FDA:

- Prescription medications that combine acetaminophen with other painkilling ingredients should be removed from the market
- Acetaminophen-containing products will contain a black-boxed warning regarding the potential for liver damage with overuse
- Reduction of the current recommended daily dose of acetaminophen (which is 4 grams per day)
- Maximum of 650 mg of acetaminophen in a single dose form
- The 1,000 mg single dose form of acetaminophen should be available via prescription only
- Over-the-counter combination prescription products containing acetaminophen should remain on the market

We will have to wait to determinate whether the FDA will accept and implement the recommendations of the Advisory Committee. Nonetheless, the importance of the issue of proper utilization of acetaminophen continues to be discussed in health-care practitioner arenas and provides a substantial opportunity for effective counseling interactions with patients regarding this commonly-used pain reliever and antipyretic. Let's seize the moment and continue to educate ourselves and our patients regarding acetaminophen!

[1] IMS Health, IMS National Sales Perspectives, Year 2004-2008.

[2] Larson AM, Polson J, Fontana RJ, et al.. Acetaminophen-Induced Acute Liver Failure: Results of a United States Multicenter, Prospective Study. Heptatology 2005;42:1364-1372.

My Personal Experience With The Danger Of Acetaminophen Overuse

Rebecca Drake, PharmD Member
Maryland Acetaminophen Coalition

As a pharmacist, I spend my working days doing my very best to protect my patients. Oftentimes, pharmacists are the last line of defense from overdoses, rare side effects and drug-drug interactions. Not unlike most pharmacists, I try to share my knowledge with my family about the correct usage of medications. However, sometimes I do not have an opportunity to share what may appear to be basic, but very important, information with them. For example, acetaminophen is a safe and effective drug, but patients need to be careful to follow the directions because it may cause liver damage. Now, my family is all too familiar with the dangers of acetaminophen, but sadly, they did not learn them from me.

My 24-year old sister died from a toxic accumulation of acetaminophen which was taken over a period of only two weeks. A zany, outgoing and fun-loving young woman, she was preparing for her first trip abroad: our brother's wedding in Thailand. A few weeks before she left, she began experiencing significant acid reflux. Her doctor scheduled an endoscopy to be performed in a little over two weeks, and in the interim, she was started on a Proton Pump Inhibitor (PPI) and an H2 blocker. Finally, she was told to take acetaminophen for the pain.

No one is sure how much acetaminophen she was taking each day or if she was even told how much was too much. Before her endoscopy was performed, she awoke with acute abdominal pain. She was taken to a local emergency room, where it was discovered that her liver enzymes were elevated to dangerous levels. She was evacuated via helicopter to the nearest liver transplant center. She did receive a liver transplant. Unfortunately, her new liver proved to be too little, too late. The donor liver was unable to sufficiently reduce the toxicity in her blood, and she died of acute liver toxicity in November 2008. She missed our brother's wedding, and we miss her dearly.

The Last Mile in Health Care Delivery: A Consumer's View of the Importance of the Pharmacist

Al Leandre, Board Commissioner

The concept of the "last mile" refers to the final mile driven in the global logistics chain that most of our daily consumable products travel just before arriving at the store. While we don't give a second thought to the travel path of the goods that stock the shelves of the department stores, most experts in global supply chain consider the last mile to be the most critical. Likewise we don't consider the total lifecycle of our healthcare delivery, but we all know that getting our prescription filled is often a critical step to achieve better health outcomes. The fact is that while we talk about going to the doctor when we don't feel well, we very seldom talk about getting our prescriptions filled after the doctor's visit and yet we don't begin to feel better until after starting our medication. This is why this last step or the last mile in health care delivery is so critical.

I would like to illustrate the concept of the last mile in personal terms. In 2007, I ordered a Ford truck directly from the manufacturer. My F-250 Super Duty truck was built at a plant in Kentucky, was transported by rail and arrived at the dealership by truck. In this instance, the last driven mile that delivered my truck to the dealership lot was on wheels and not rail. This last mile was also the most critical mile to me because that was the step that delivered the vehicle to the dealership and in turn allows the dealer to deliver it to me, the consumer. A similar process exists in health care. The patient receives care from a physician, but the last step in that care chain is often the pharmacist. Let's talk about my wife who underwent oral surgery three weeks ago. Her oral surgeon, the physician, performed beautifully. He extracted four wisdom teeth and a cyst that was infected and causing my wife a great deal of pain and stress. The surgeries went very well, but now try to imagine the pain that my wife was suffering an hour later. The surgeon prescribed two drugs in order to combat the post surgical pain and to fight infection. Both drugs can only be dispensed by a licensed pharmacist with a valid prescription from a physician. The first drug was Percocet a very potent Schedule-II narcotic also known by its generic name Oxycodone and Acetaminophen. The second drug was an antibiotic, Amoxicillin. The doctor prescribed both drugs prior to the surgery so that the pharmacist could dispense them to my wife and that she would be able to get a starter dose minutes after surgery. This physician – pharmacist accord worked well and ended up making a lot of sense; it made a tremendous difference to both my wife and me as the husband (nurse) in charge. The pain and infection management became the most significant part of the post-surgery period and the medicine prescribed was the only means of combating both pain and infection. The pharmacist came in during the last mile of my wife's health care delivery and it was indeed the most critical mile.

Consumers placed in the position that my wife and I were are very aware and appreciative of the pharmacist and their role in our health care. It is my hope that all consumers reach this level of acknowledgement and gratitude for pharmacists and the "last" mile that they serve each and every day.

Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, MD 21215-2299

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Maryland Board of Pharmacy

STAFF ROSTER CONTACT INFORMATION	
EXECUTIVE • 410-764-4794	
LaVerne Naesea, Executive Director; LaToya Simmons, Executive Secretary	Responds to inquiries regarding Board Operations, Board Members and Board Minutes
ADMINISTRATION • 410-764-5929	
Patricia Gaither, Administration & Public Support Manager; Vacant, Public Information Officer; Anasha Page, Office Secretary; Vacant, Secretary/Receptionist	Responds to inquiries regarding Fiscal, Budget, Procurement, Travel, Personnel and Public Information
LEGISLATION AND REGULATIONS • 410-764-4794	
Anna Jeffers, Legislation and Regulations Manager	Responds to inquiries regarding Legislation and Regulations and Pharmacy Practice Committee
COMPLIANCE • 410-764-5988	
Vacant, Pharmacist Compliance Officer; Emory Lin, Pharmacist Inspector; Joseph Taylor, Lead Inspector; Nancy Richard, Inspector; Jeannelle McKnight, Inspector; Shanelle Young, Inspector; Steven Kreindler, Compliance Coordinator; Colin Eversley, Compliance Investigator; Vanessa Thomas Gray, Compliance Secretary	Responds to inquiries regarding Complaints, Pharmacy Practice, Disciplinary, Inspections, Investigations and Pharmacists Rehabilitation
LICENSING • 410-764-4756	
Summer Goodman, Licensing Manager; Doris James, Licensing Specialist; Fannie Yorkman, Licensing Specialist; Laurie Cohen, Licensing Secretary; Keisha Wise, Licensing Clerk	Responds to inquiries regarding Licensing, Permits, and Registration, Reciprocity, and Scores
MANAGEMENT INFORMATION SERVICES • 410-764-5929	
Tamarra Banks, MIS Manager; Michelle Xu, Database Officer	Responds to inquiries regarding Computer, Database and Website and On-line Renewals

BOARD COMMISSIONERS

President: Donald Taylor
Secretary: Rodney Taylor
Treasurer: Michael Souranis
Cynthia Anderson
Lynette Bradley-Baker
David Chason
Harry Finke, Jr.
Mayer Handelman
Lenna Israbian-Jamgochian
Alland Leandre
Richard Matens
Reid Zimmer

BOARD COUNSEL

Linda Bethman
Francesca Gibbs

BOARD MEETINGS

The Pharmacy Board meetings are held the third Wednesday of each month and are open to the public from 9:00 a.m. – 12 noon at 4201 Patterson Avenue, Baltimore Maryland 21215.

The Board encourages all interested parties to attend the monthly Board Meetings.

2009 PUBLIC BOARD MEETINGS DATES

Third Wednesday of each month
9:00 am – 5:00 pm

October 21, 2009
November 18, 2009

December 16, 2009

COMMITTEE MEETING DATES	
Executive Committee Meetings First Wednesday of each month 10:00 am-12:00 pm	**Licensing Committee Meetings** Fourth Wednesday of each month 9:30 am-12:00 pm
Disciplinary Committee Meetings First Wednesday of each month 1:00 pm-4:30 pm	**Practice Committee Meetings** Fourth Wednesday of each month 1:00 pm-4:30 pm
Emergency Preparedness Committee Meetings* Second Wednesday of each month 9:00 am-12:00 pm	**Long Term Care Workgroup Meetings*** Monthly Meetings (except during the Legislative Session) Meeting Dates and Times TBD
Public Relations Committee Second Wednesday of each month 3:00 pm-5:00 pm	**Acetaminophen Coalition Task Force Meeting*** Second Wednesday every other month 1:00 pm to 2:45 pm
***open to the public**	