Imagine that a panacea for all ailments is discovered that can cure any disease, fix any problem and make anyone—no matter how sick—100 percent well again. Imagine further that it is provided at no charge to anyone who needs it with unrestricted access and unlimited availability. The only requirement is that the patient must take it exactly as instructed.

The physician clearly tells the patient, “Take two red pills twice a day, take one blue pill at bedtime, take one green pill only on Sunday, and one yellow pill once a day. Any questions?” The pharmacy fills the prescriptions and clearly lists these instructions on each bottle and the pharmacist reviews the instructions with the patient again. Is the patient able to decipher these “clearly” written instructions, take the medications and live a healthy life?

Based on research into patients’ ability to interpret prescription labels, the answer is an overwhelming NO. A 2006 study in the Annals of Internal Medicine showed that “Although 70.7 percent of patients with low literacy correctly stated the instructions, “Take two tablets by mouth twice daily,” only 34.7 percent could demonstrate the number of pills to be taken daily.”

Other studies have shown that using precise instructions on prescriptions enhance a patient’s ability to properly interpret them. For example, “Take one tablet by mouth in the morning and then one tablet by mouth in the evening” is better than simply “Take one tablet twice a day.” Also, using numerals instead of words for the number of tablets to be taken may increase comprehension. Therefore, “Take 1 tablet by mouth every morning” is preferred over “Take one tablet by mouth every morning.” This becomes even more important when English is not the patient’s primary language. In Spanish, “once” represents the number eleven, therefore, a label that says “Take one tablet once a day” could easily be misread as eleven times a day. Ensuring that the route of administration is included (i.e., “by mouth”) could help to minimize or prevent future avoidable complications such as oral antibiotics being placed in the ear.

In addition, other medical terminology such as “topically,” “inguinal,” “stat,” etc., must be translated into plain language (“skin,” “groin,” “now”) when printed on a prescription label. A quick test I have done to determine whether or not a patient can understand the label, is to ask my pharmacy technicians and/or other store personnel to explain the directions. If they cannot answer correctly, or provide discordant answers, the instructions probably are not sufficiently clear for most of your patients.

Now imagine that one of the magic pills requires prior authorization or requires lab work for monitoring. As health care professionals, these tasks are part of our daily lives, however, from a patient’s perspective, navigating the health care system can be confusing, overwhelming, and frustrating.

(continued on page 2)
FDA Safety Alerts: Prescription Acetaminophen Products to be Limited to 325 mg per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure

As health care professionals, all of us know the recommended maximum daily dose of acetaminophen is 4 grams, but many of our patients do not. Many prescriptions, as well as over-the-counter products, contain fairly high amounts of acetaminophen per dose, which can lead to an increased risk of overdose and possible acute liver failure. In 2007, the CDC estimated that out of 1600 cases of acute liver failure, acetaminophen-related was the number one etiology. The Toxic Exposure Surveillance System (TESS), now known as the National Poison Data System (NPDS) found in 2005 that acetaminophen-related overdose phone calls were 1,878 for OTC single-ingredient products, 6,653 for OTC combination products, and 1,470 for prescription-opioid combination products.

On January 13, the FDA asked drug manufacturers to limit the strength of acetaminophen to 325 mg per dosage unit. However, the maximum daily dose remains unchanged (4 grams). Additionally, all acetaminophen products will now have a black boxed warning about the risk of liver toxicity. The FDA states, "There are no data that indicate that taking more than 325 mg of acetaminophen per dosage unit provides more pain relief. This does not currently affect OTC products."

The elimination of higher dose products will take place over three years to avoid shortages of pain medication.

Sincerely,
Jeffrey Kretman, Pharm.D., Regional Clinical Pharmacist

References:
1. FDA. Prescription and Over-the-Counter Acetaminophen Products to be Limited to 325 mg per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure. Available at: http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm239871.htm.

Formulary Update Additions

<table>
<thead>
<tr>
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<td>Micardis® (telmisartan)</td>
<td>Treatment of hypertension</td>
<td>Maintenance dose of 20-80 mg once daily.</td>
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<td>Micardis® HCT (telmisartan/ hydrochlorothiazide)</td>
<td>Treatment of hypertension</td>
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<td>Tablet: 40/12.5 mg, 60/15 mg, 80/25 mg</td>
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<tr>
<td>Azer® (amiodipine/hydrochlorothiazide)</td>
<td>Treatment of hypertension</td>
<td>Initial therapy of 5/12.5 mg once daily. May increase to 10/25 mg once daily.</td>
<td>Tablet: 5/12.5 mg, 10/25 mg, 15/37.5 mg</td>
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2. Notes.
(continued from page 1)

Without clear instructions on how to request their provider to complete prior authorization requests, or where to go for lab work, many patients may get lost within the abyss of the health care system and go untreated, only to resurface in the emergency room.

Since the world has yet to discover a true panacea, ensuring that patients understand how to take their medications properly as well as effectively navigating through the health care system becomes even more paramount. After all, even a magic potion only works when taken properly.

Please feel free to contact me with your comments and suggestions at 1-877-693-8271 x85366 or via e-mail at jeffrey.kreitman@amerihealthmercyhp.com.

Sincerely,

Jeffrey Kreitman, Pharm.D., Regional Clinical Pharmacist

References:

FDA Safety Alerts

FDA Safety Alert: Prescription Acetaminophen Products to be Limited to 325 mg per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure

As health care professionals, we all know the recommended maximum daily dose of acetaminophen is 4 grams, but many of our patients do not. Many prescriptions, as well as over-the-counter products, contain fairly high amounts of acetaminophen per dose, which can lead to an increased risk of overdose and possible acute liver failure. In 2007, the CDC estimated that out of 1600 cases of acute liver failure, acetaminophen-related was the number one etiology. The Toxic Exposure Surveillance System (TESS), now known as the National Poison Data System (NPDS) found in 2005 that acetaminophen-related overdose phone calls were 1,879 for OTC single-ingredient products, 6,651 for OTC combination products, and 1,470 for prescription-opioid combination products.

On January 13, the FDA asked drug manufacturers to limit the strength of acetaminophen to 325 mg per dosage unit. However, the maximum daily dose remains unchanged (4 grams). Additionally, all acetaminophen products will now have a black boxed warning about the risk of liver toxicity with overdose. This should not change current prescribing regimens. Patients can still be directed to take 1-2 tablets of pre-packaged products.

FDA assertions are made with regards to acetaminophen products to be reduced to 325 mg per dosage unit [Internet]. [updated 2011 Jan 13, cited 2011 Jan 13]. Available from: http://www.fda.gov/Drugs/SafetyAlerts/ucm239894.htm.

Product Updates

<table>
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<tr>
<th>Drug</th>
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<tr>
<td>Antinune™ (chlorpromazine/ hydrochlorothiazide)</td>
<td>Treatment of hypertension</td>
<td>The effects result from a combination of inhibition of the RAAS, inhibition of calcium channel-mediated mesangiocirculation, and increase of sodium chloride excretion that lowers blood pressure to a greater degree than the individual components.</td>
<td>One tablet once daily during use</td>
<td>Tablet: 150/25 mg, 300/50 mg, 450/75 mg, 600/100 mg</td>
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<tr>
<td>Actemra® (tocilizumab)</td>
<td>Treatment of moderate to severe active rheumatoid arthritis in adults who have had inadequate response to one or more DMARD anti-rheumatic therapies</td>
<td>Inhibits IL-6-mediated signaling by binding to both soluble and membrane-bound IL-6 receptors (sIL-6R and mIL-6R), and, if cells, lymphocytes, monocytes and fibroblasts.</td>
<td>Initial dose of 4 mg/kg given once every four weeks as a 20-minute IV infusion.</td>
<td>Vial (suspension): 80 mg/ml in 20 mg, 40 mg/ml in 40 mg/ml</td>
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<tr>
<td>Halaven™ (vinorelbine)</td>
<td>Treatment of metastatic breast cancer who have previously received at least two chemotherapeutic regimens, including an anthracycline and taxane.</td>
<td>Inhibits the growth phase of microtubules leading to disorganization of mitotic spindles and cell death.</td>
<td>1.4 mg/m² given IV over two to five minutes on days one and eight of a 21-day cycle</td>
<td>Vial (suspension): 1 mg/ml</td>
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<td>Oral once daily</td>
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Even a Magic Potion Only Works When Taken Properly

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- FDA Safety Alerts
- Product Updates
- Formulary Updates

**Formulary Website Access**

Access the Keystone Mercy Website 24 hours/7 days a week at www.keystonemercy.com/pharmacy/formulary/online/index.aspx. The formulary is updated on a quarterly basis. We recommend adding this link as a favorite in your computer’s web browser for easy access.