RxCONNECTOR

A publication of the North Dakota Insurance Department

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Many Americans share prescription medications

If you've ever shared your allergy medicines, antibiotics or even painkillers with a family member or friend, you've got plenty of company: A new survey suggests many give away their prescription medicines or borrow them from others.

However, this can be an extremely bad idea, experts say. Prescription drugs, after all, are prescribed for a reason: Because a doctor or pharmacist needs to play a role in their use.

In the case of shared antibiotics, "we've managed to document that this is a real public health risk," said study author Richard Goldsworthy, CEO and director of research and development for The Academic Edge company in Bloomington, Ind.

"Don't share antibiotics," Goldsworthy advised. "You shouldn't have any leftover. You should have finished them all yourself."

In some cases, however, sharing drugs may not be very risky, Goldsworthy said, and is done for "pretty reasonable reasons."

The FDA has details about using medicine properly.
Source: HealthDay News

Adam W. Hamm
Insurance Commissioner

Welcome to the *RxConnector* newsletter!

Dear friends,

This newsletter is designed to keep you up-to-date about the Prescription Connection for North Dakota program and to keep you in the know about the various prescription assistance programs that are available. From time to time, we may also include other items of interest related to Medicare and the State Health Insurance Counseling (SHIC) program.

As always, thank you so much for all that you do for the Prescription Connection program. Without your help, our work would be that much harder. Your efforts are valued and appreciated.

If you have items of interest that you think should be included in this newsletter, we would love to hear about them. Please contact Sharon St. Aubin at sstaubin@nd.gov or call her at 1.888.575.6611.

Adam W. Hamm
Insurance Commissioner

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RxConnector is a publication of the Prescription Connection for North Dakota program.

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Paying for your vaccines

When your doctor recommends a vaccine for something other than flu, pneumonia or hepatitis B (all paid for by Medicare Part B), the vaccine should be paid for by your Medicare drug plan (Part D). All Part D plans must include all commercially available vaccines on their formularies, including the vaccine for shingles (herpes zoster). Your Part D plan will pay for the vaccination itself and for you to get the shot (administration).

However, the amount you pay for your vaccination could vary based on what type of facility from which you receive your vaccination. Before you get a vaccination, check coverage rules with your Part D plan and see where you should get your shot so that it will be covered for you at the lowest cost.

New latex glove cleared for use

On April 23, 2008, the Food and Drug Administration (FDA) cleared for marketing the Yulex Patient Examination Glove. This is the first medical device made from guayule latex, a new form of natural rubber latex.

How is it different from gloves made from traditional latex? The Yulex glove is made from latex that is derived from the guayule bush, a desert plant native to the southwestern United States. Gloves made from guayule latex may prove to be a safer alternative for some people with sensitivity to traditional latex.

Traditional latex gloves are made from the milky sap of a rubber tree. The sap contains a protein that may trigger allergic reactions in some people, especially after prolonged and repeated contact.

Available data on the guayule latex show that even people who are highly allergic to traditional latex do not react on first exposure to guayule latex proteins. Because there is no data on people's long-term experience with the Yulex glove, made by the Yulex Corporation of Maricopa, Ariz., the product will carry a warning for now about the potential for allergic reactions.

What are the signs of allergic reactions to latex? Mild reactions may include skin redness, rash, hives or itching. More severe reactions may include respiratory symptoms such as difficulty breathing, coughing spells and wheezing. Rarely, shock may occur.

What has FDA done to address glove allergy problems? The agency has taken many steps, including working with industry to develop a standard that identifies maximum protein and powder levels for medical gloves.

A 1998 rule requires that all medical devices containing latex carry a statement on the label warning about the risk of allergic reactions.

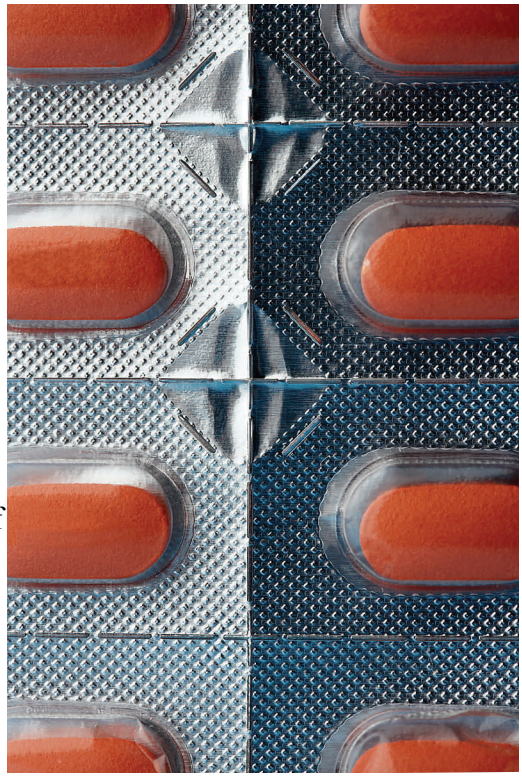
Source: FDA

A guide to drug safety terms

The Food and Drug Administration (FDA) approves a drug for marketing after determining that the drug's benefits of use outweigh the risks for the condition that the drug will treat. But even with a rigorous evaluation process, some safety problems surface only after a drug has been on the market and has been used in a broader population. This guide offers descriptions of some of the drug safety terms commonly used by FDA throughout the life cycle of a drug.

FDA review

Pre-clinical data: Before a drug can be tested in people in the United States, sponsors (drug manufacturers, research institutions and other organizations that develop drugs) must show FDA results of testing they have done in laboratory animals and what they propose to do for human testing.



New drug approval process: After the animal testing stage, FDA decides whether it is reasonably safe for the company to move forward with clinical trials—studies that evaluate the safety and effectiveness of a drug in healthy people and in patients. The drug company submits the results of such studies to FDA for review. The agency conducts a thorough review of the safety and effectiveness data, and considers how the benefits compare to the risks when making a decision of whether or not to approve a drug.

Adverse drug reaction: An adverse drug reaction, also called a side effect, is any undesirable experience associated with the use of a medicine in a patient. Adverse events can range from mild to severe. Serious adverse events are those that can cause disability, are life-threatening, result in hospitalization or death or are birth defects.

Taking medication

Medication guides: Medication guides are paper handouts/pamphlets that are required to be distributed to patients with certain medications by the pharmacist. Medication Guides convey risk information that is specific to particular drugs and drug classes, and they contain FDA-approved information that can help patients avoid serious adverse events. www.fda.gov/cder/Offices/ODS/medication_guides.htm

Consumer medication information (CMI): Compared to a medication guide, a consumer medication information sheet offers broader information on how to use a medicine. CMI sheets are not developed or regulated by FDA. These information sheets are prepared by pharmacies and given out with prescription drugs. CMI sheets are not available on the FDA website. The sheets help consumers understand key information about their prescription medicine, including how to take it, how to store it, and how to monitor their treatment. The sheets also include information on precautions and warnings, as well as symptoms of serious or frequent adverse events and what to do if you experience one.

Prescription drug labeling: Drug labeling, commonly called the package insert or the prescribing information, provides information to the physician about what a prescription medication is supposed to do, who should and should not take it, and how to use it. Labeling also includes information on a drug's side effects and warnings, and information from the clinical trials of the drug. Some prescription drug labeling also includes a part that describes the prescribing information in words that consumers will understand.

Nonprescription drug label ("drug facts"): For an over-the-counter (OTC), or nonprescription medicine, information printed on the medication bottle or package under the heading drug facts is important for taking care of yourself and your family. The drug facts tell you what a medicine is supposed to do, who should or should not take it, and how to use it. Safety information and instructions for use are

displayed in a uniform and easy-to-read format.

Boxed warning: This type of warning is also commonly referred to as a "black box warning." It appears on a prescription drug's label and is designed to call attention to serious or life-threatening risks.

Monitoring after approval

Post-market surveillance: Post-market surveillance is the process by which a drug's safety is monitored on an ongoing basis after a drug is approved by FDA. Post-market surveillance seeks to identify problems that were not observed or recognized before approval and any problems that may arise because a drug may not be used as described in the drug labeling, or because a drug is being manufactured incorrectly.

Adverse event reporting system (AERS): AERS is a computerized database containing reports of adverse events. It supports FDA's post-market safety surveillance program for all approved drugs and therapeutic biologics.

MedWatch: MedWatch is FDA's safety information and adverse event reporting program. It provides important and timely medical product information to health care professionals, including information on prescription and over-the-counter drugs, biologics, medical devices, and special nutritional products. Health care professionals and consumers can also report serious problems they suspect are related to certain FDA-regulated products.

Removal from the market

Drug recall: A drug recall is an action taken by a firm to remove a product from the market that FDA considers to be in violation of the law. Recalls are classified as Class I, Class II or Class III. Class I recalls are the most serious and involve situations where there is a reasonable probability that the use of or exposure to a violative product, will cause serious adverse health consequences or death. A drug may be recalled due to factors such as problems with packaging, manufacturing, or contamination.

Drug withdrawal: In rare cases, FDA may need to reassess and change its approval decision on a drug. A conclusion that a drug should no longer be marketed is based on the nature and frequency of the adverse events and how the drug's benefit and risk balance compares with treatment alternatives. When FDA believes that a drug's benefits no longer outweigh its risks, the agency will ask the manufacturer to withdraw the drug.

Types of safety announcements

Early communication about an ongoing safety review: This type of communication is part of FDA's effort to communicate early with the public when the agency is still evaluating data and has not reached a conclusion. FDA shares information in the interest of informing doctors and patients about the issues that are under review and when FDA experts anticipate completing their review.

Public health advisories: These advisories provide important drug safety information and recommendations of actions that can be taken by patients or caregivers to avoid or minimize harm from a drug. They are issued when FDA has information that would help doctors and patients make better treatment choices.

Letters to health care professionals: These are letters—often referred to as "Dear Doctor" letters—that are developed by drug companies often with input from FDA. The letters educate health care professionals about new and important drug information.

Information for health care professionals: Also referred to as a Healthcare Professional Information sheet, this information from FDA is for doctors, pharmacists, nurses, and other health care professionals. It contains an "alert" (a summary of the new safety information), detailed information about the safety issue, factors to consider when making treatment decisions, information for health care professionals to discuss with patients about their roles in reducing the risks from the drug, and a summary of the facts or data that serve as the basis for the information in the sheet.

For more information
FDA's Center for Drug Evaluation and Research
www.fda.gov/cder/index.html

Source: FDA

Heart medicine Digitek recalled

Actavis Totowa LLC notified healthcare professionals of a Class I nationwide recall of all strengths of Digitek, a drug used to treat heart failure and abnormal heart rhythms. The products are distributed by Mylan Pharmaceuticals Inc., under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label.

The product is being recalled due to the possibility that tablets with double the appropriate thickness may contain twice the approved level of active ingredient. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Several reports of illnesses and injuries have been reported. Patients should contact their healthcare professional with questions.

Read the entire 2008 MedWatch Safety Summary, including a link to the manufacturer's press release regarding this issue at: http://www.fda.gov/medwatch/safety/2008/safety08.htm#Digitek

Feds try to cut costs of hospital errors

Federal health officials on Monday proposed adding dangerous blood clots in the leg and eight other conditions to the list of complications that Medicare won't pay to treat if they were acquired at the hospital.

Medicare set a new precedent last year by refusing to pay hospitals for treating certain "never events," conditions that occur as a result of hospital error. For example, if a patient was given the wrong blood type, Medicare would not pay the hospital more for treating that complication. Originally, eight conditions were covered under the new rules, which take effect Oct. 1.

The rules proposed Monday add nine conditions, including:

- Deep vein thrombosis, or a blood clot within the vascular system, which occurred in 140,010 cases for the fiscal year ending Sept. 30.
- Ventilator-associated pneumonia, which occurred in 30,867 cases.
- Bloodstream infections with the staph aureus bacteria, 27,737 cases.
- Legionnaire's disease, which occurred in 351 cases.

The proposed rule would apply to more than 3,500 acute care hospitals. Medicare gives hospitals a single payment based on the average cost of treating a patient with a particular diagnosis. Officials said hospitals cannot try to charge the patient for the costs associated with treating a "never event."

Congress in 2006 gave the Centers for Medicare and Medicaid Services the power to prevent Medicare from giving hospitals higher payments for the extra costs of treating a patient when infections and other preventable conditions occur during a hospital stay.

Under the government's reimbursement policy, hospitals are also required to report on 30 measures designed to assess quality of care. Medicare is proposing to add 43 new measures to the list. If hospitals don't report the measures, then they don't qualify for a full update in their reimbursement rates.

Source: United Press International

Effect of Wal-Mart generic drug discount program on pharmaceutical industry

The Newark *Star-Ledger* on Tuesday examined how analysts say the "overall impact" of Wal-Mart stores' generic prescription drug program on the pharmaceutical industry "has been relatively small" (Cohen/Fitzgerald, Newark *Star-Ledger*, 4/22).

The program, which began in September 2006, offers discounts for 361 prescriptions that represent different formulations of 157 generic medications. Most of the generic medications cost $4 per 30-day prescription, although several family planning treatments cost $9 (*Kaiser Daily Health Policy Report*, 3/18).

Wal-Mart has said that the program saved customers more than $1 billion in 2007 and that 30 percent of customers who purchased generic medications through the program were uninsured.

According to the *Star-Ledger*, it is "clear Wal-Mart's generic discount program has benefited consumers with low incomes or without insurance; forced some competitors to respond with similar discount plans; and has been a factor in the overall trend toward increased usage of cheaper generic drugs."

Source: Kaiser Daily Health Policy Report

Medicare creates a competitive bidding program

The new Competitive Bidding Program will change the way Medicare pays for durable medical equipment, prosthesis, orthotics and supplies. Products included in the program include oxygen supplies and equipment, power wheelchairs, scooters, mail-order diabetic supplies, enteral nutrients, hospital beds, negative pressure wound therapy devices, other items including walkers. To check for specific included products, call 1-800-Medicare or visit www.medicare.gov

The people affected by the new Competitive Bidding Program are those who have Original Medicare and the permanent residence is in a ZIP code that is part of a Competitive Bidding Area (CBA) or if you get certain items while visiting a CBA.

Starting July 1, 2008, we will begin to see the effect of this new program in certain areas of the country called "competitive bidding areas." North Dakota is not one of those areas, however, if a North Dakota resident is visiting in a CBA and purchases an item such as a walker, the North Dakota resident should buy or rent from a contract supplier. If a non-contract supplier in a competitive bidding area furnishes a competitively bid item, the Medicare beneficiary will be given an Advance Beneficiary Notice (ABN). By signing this notice, the beneficiary is agreeing to pay for the item if Medicare does not pay for it. If the beneficiary does not sign an ABN, (s)he is not responsible for payment for the item or service.

New York Times examines debate over 'dental therapists'

The *New York Times* on Monday examined the debate over a program in Alaska that uses "dental therapists" to provide care to Alaska Natives who lack access to dentists.

Under the program, after dental therapists receive two years of "intensive training" at the University of Alaska-Anchorage, they can perform routine tooth extractions and fill cavities. Patients who need root canals and complex extractions must be referred to dentists. Dental therapists must be supervised by a dentist, either onsite or offsite through documents and X-rays. The therapists, who are allowed to practice only in Alaska and only on Alaska Natives, are paid about $60,000 annually—one-half to one-third dentists' typical incomes—through a federally-funded program that provides dental care to 136,000 Alaska Natives throughout the state. The program, which aims to have 100 fully trained dentists on staff, so far has only 75 participants, and "the number of vacancies is growing," according to the *Times*. According to Ron Nagel, a dentist and a consultant for the Alaska Native Tribal Health Consortium, dental therapists are a less-expensive option to provide dental care for people who otherwise might not have access to it.

The Alaska program currently has fewer than 12 dental therapists practicing. However, some dentists who specialize in public health said the program should be offered nationwide to provide dental care to the about 100 million U.S. residents who cannot afford treatment, according to the *Times*.

The American Dental Association and Alaska Dental Society oppose the program, saying dentists—who receive four years of post-collegiate training—should be the only providers allowed to perform fillings and extractions. The two groups filed a lawsuit to block the program but dropped the suit last summer after a state court judge issued a ruling critical of the dentists. According to the *Times*, ADA officials say that they do not want patients to receive substandard care and note that dental therapists might not be able to handle emergencies such as uncontrolled bleeding that sometimes occur in routine procedures.

The *Times* reports that some dentists in public health programs say the groups are actually concerned about dental therapists becoming low-cost competition. According to a 2006 study by the Baylor College of Dentistry that compared the quality of about 600 procedures in more than 400 patients, the quality of procedures performed by dental therapists was no different from that provided by dentists (Berenson, *New York Times*, 4/28).

Health care industry spent $445M on Federal lobbying in 2007

Health care interests spent $445 million on federal lobbying in 2007—more than any other sector of the economy—to finish as the top spender for the second consecutive year, according to the Center for Responsive Politics (CRP), *CQ HealthBeat* reports.

A more specific breakdown of 20 industries that spent the most on lobbying in 2007, pharmaceutical and medical products companies rank first with $227 million in spending, while health insurance companies spent the second-most at $138 million. Hospitals and nursing homes spent $91 million, ranking fifth; while health professionals spent $70 million, ranking 15th; and HMOs/health services spent $52 million, ranking 19th.

Among specific organizations or companies, the Pharmaceutical Research and Manufacturers of America spent the third-most at $22.1 million, the American Medical Association spent the fourth-most at $22.1 million and the American Hospital Association was fifth, spending $19.7 million. The U.S. Chamber of Commerce spent the most of any organization ($53 million), followed by General Electric ($23.6 million).

According to the CRP, the pharmaceutical industry has spent $1.3 billion on federal lobbying in the last decade, more than any other industry. In addition, the drug industry's reported lobbying increased by 25 percent from 2006 to 2007. Lobbying firm Patton Boggs, whose clients include Bristol-Myers Squibb and Hoffman-La Roche, reported $41.9 million in 2007 revenue—an increase of 20 percent over 2006—and the most among Washington, D.C.-area firms (Reichard, *CQ HealthBeat*, 4/14).

Overall, corporations, labor unions and others spent $2.79 billion on lobbying in 2007, up 7.7 percent from 6, the CRP data show.

Source: Kaiser Daily Health Policy Report

NeedyMeds starts forums

NeedyMeds.com has started an online forum for patient advocates. The forum is called "NeedyMeds Forums." Once the advocate registers and is confirmed by one of their administrators, the advocate will be able to participate in online conversations with colleagues around the country about patient advocacy topics that are important to the advocate and how the advocate can help the underserved.

If a topic of interest to the advocate is not listed, the advocate can start one. The Forums will be an online place where—regardless of location in the country, or the advocate's position in their organization—ideas can be shared, participants will be updated on programs, and there will be support for each other in the very important work that is done by advocates.

NeedyMeds Forums is open only to patient advocates (those who work or volunteer for an organization or company). This forum is not for patients or other individuals who seek healthcare assistance or support, so please do not tell them to register as their requests will be denied. If you are as excited about this new feature of NeedyMeds and would like to join, click here to get started: http://forums.needymeds.com/

PAP updates

Dermik Laboratories PAP has a new application effective February 2008.

Mead Johnson Nutritionals (a division of Bristol-Meyer Squibb) renamed its PAP to "Helping Hands for Special Kids."

Validus Pharmaceuticals has a new PAP, "**Equetro Patient Assistance Program,**" that provides free Equetro for 3 months to eligible applicants.

Genzyme and American Kidney Fund have a new PAP, "**Renagel Medicare Part D Assistance Program**." Call 800-847-0069 for information.

Romark Laboratories' PAP for Alinia has a new application and fax number. Call 813-282-8544 for information.

Vistakon Pharmaceuticals has added IQUIX ophthalmic solution 1.5 percent (levofloxacin) to its PAP and has a new application.

Forest Pharmaceuticals added Bystolic Tablets (nebivolol) to its PAP.

AstraZeneca Cancer Support Network (AZ CSN) has updated its program. Call 866-992-9276 for recent changes.

Case flash: different start dates for Medicare coverage

Mrs. H became eligible for Medicare when she turned 65 this year. Because her birthday is in February, Mrs. H's Initial Enrollment Period runs from November to May (the three months before her birth month, her birth month, and the three months following her birth month). Since Mrs. H is not yet receiving Social Security benefits, she was not automatically enrolled into Medicare. She went to her local Social Security office in March to enroll in Original Medicare Parts A and B. However, the representative there informed Mrs. H that her Medicare coverage would not be effective until July 1. Mrs. H was confused, because she thought that Medicare coverage should begin the month after her birth month.

Mrs. H called the Medicare Rights Center. She spoke to a hotline counselor who confirmed that July 1 was too long to wait, but that Mrs. H. was also incorrect about when her coverage should start. The counselor explained that when your Medicare coverage begins depends on when you enroll during your Initial Enrollment Period. If you enroll the month after your birth month, as Mrs. H was trying to do, your coverage should begin the third month after your birth month. Therefore, Mrs. H's coverage should begin in May.

The counselor suggested that perhaps the Social Security representative confused Mrs. H's situation with the timeline of coverage for the General Enrollment Period. He explained that when people do not enroll in Medicare when they are first eligible, they must usually enroll during the General Enrollment Period, which runs from Jan. 1 to March 31 every year. Their coverage would begin on July 1.

The counselor helped Mrs. H find a Medicare publication that explains Medicare enrollment guidelines and start dates for coverage. He encouraged Mrs. H to take the publication with her when she went back to the Social Security office. At the Social Security office, Mrs. H explained that since she was still in her Initial Enrollment Period, she should not have to wait until July 1 for her Medicare coverage to begin. The representative was able to correct Mrs. H's enrollment record so that her Medicare coverage would become effective May 1.

Source: Medicare Watch

FDA cannot properly inspect foreign companies that manufacture medications, medication ingredients

FDA does not have adequate resources to inspect foreign companies that manufacture medications or medication ingredients, and current funding levels for the agency will not address the issue, according to a Government Accountability Office report presented on Tuesday at a hearing of the House Energy and Commerce Oversight and Investigations Subcommittee, the Newark *Star-Ledger* reports. The subcommittee convened the hearing in response to reports that contaminated batches of the blood thinner heparin contained an active ingredient supplied by a Chinese manufacturing facility that FDA had not inspected (Cohen, Newark *Star-Ledger*, 4/23).

According to the report, FDA inspects only eight percent of the more than 3,000 foreign companies that manufacture medications or medication ingredients shipped to the U.S. (Rockoff, Baltimore *Sun*, 4/23).

FDA also lacks accurate data on which foreign companies manufacture medications or medication ingredients shipped to the U.S., the report found (Newark *Star-Ledger*, 4/23). In addition, the report estimated that FDA would require $67 million annually to inspect such companies every two years. FDA has budgeted only $11 million for such inspections in 2008 and $13 million in 2009, according to the report (Greising, *Chicago Tribune*, 4/22).

Source: Kaiser Daily Health Policy Report