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What's Inside…

Byetta Warning

The FDA announced that it is working with Amylin Pharmaceuticals, makers of Byetta, to add "stronger and more prominent warnings" to the product's label concerning the risk of acute hemorrhagic or necrotizing pancreatitis. This action is in response to reports of 6 patients taking Byetta who were hospitalized after developing a severe form of pancreatitis; two of the patients died. The FDA had previously issued an alert, in October, 2007, regarding 30 postmarketing reports of acute pancreatitis in patients taking Byetta. In those cases, the median time between start of therapy and onset of symptoms was 34 days, and 6 patients became ill shortly after their dose was increased from 5 to 10 mcg. The FDA recommends that Byetta be discontinued immediately if signs and symptoms of pancreatitis appear. Indicators include:

- **Persistent, severe abdominal pain that can radiate to the back and may be accompanied by nausea and vomiting**
- **Elevated serum amylase and/or lipase**
- **Characteristic radiological findings**

……RX NEWS……RX NEWS……RX NEWS……RX NEWS……

Simvastatin-Amiodarone Interaction: The FDA has reported that it continues to receive reports of rhabdomyolysis associated with the concurrent use of simvastatin and amiodarone, despite previous warnings and drug label changes instituted in 2002. Rhabdomyolysis, a severe form of myopathy which can lead to renal failure and death, is a dose-related adverse reaction to statins. The interaction, at least in part, is due to inhibition of the cytochrome P450 3A4 enzyme (CYP3A4) by amiodarone, which leads to increased plasma levels of simvastatin. In the 52 cases reported since 2002, the majority of affected patients were taking 40 to 80 mg of simvastatin daily in combination with amiodarone. The FDA announcement reminds prescribers and pharmacists that simvastatin doses greater than 20 mg should be avoided in patients taking amiodarone.

FDA Pediatric OTC Hearing: On October 2, the FDA held a public hearing on the safety and efficacy of OTC pediatric cough and cold medicines. One year after FDA advice prompted a voluntary recall of cold medicines aimed at children under 2 years of age, the agency is now considering those products labeled for children aged 2 to 6 years. Pending any decision on the matter, which may take a year or more, pharmacists counseling on the use of pediatric OTCs should stress the importance of using accurate, calibrated dosage spoons or cups, and urge parents to read all labels to prevent duplication of ingredients, such as acetaminophen, which may lead to unintentional overdosing.

Papain Products to be Withdrawn: The FDA has announced that all papain-containing topical products must be discontinued. Papain is an enzyme derived from papaya fruit and used for debridement of necrotic tissue in pressure, varicose, and diabetic ulcers. Papain was never approved by the FDA, and the agency reports that serious adverse effects, including anaphylaxis, have resulted from use of the product. Producers have been notified that they must stop manufacturing these products by November 24, 2008, and cease all shipments by January 21, 2009. A partial list of products to be discontinued follows:

Accuzyme	**Ethezyme**	**Panafil**
Allanfil	**Gladase**	**Pap Urea**
Allanzyme	**Kovia**	**Ziox**

Nasacort AQ Pediatric Approval: Sanofi-Aventis' **Nasacort AQ** has been approved for use in children aged 2 and older (previously it was indicated only for children 6 and older). The recommended starting (and maximum) dose for children aged 2 to 5 years is 1 spray in each nostril once daily.

ProAir Approved for Children: The FDA has approved Teva's **ProAir HFA** for use in children 4 years of age and older. The recommended dose for bronchospasm is 2 inhalations every 4 to 6 hours. An updated comparison chart of Albuterol HFA inhalers is available on our website at: ***www.prnnewsletter.com***.

Study: News Media Often Fails to Reveal Industry Funding of Research

In recent years, the mainstream media has become an important source of information regarding the latest pharmaceutical research. Patients, physicians, and pharmacists are all exposed to reports about "breakthrough" drugs and treatments via newspapers, television, radio, and the internet. Researchers at Harvard Medical School set out to determine if these popular media stories reported when medication research received funding from pharmaceutical companies. As the study's authors point out, "an increasing source of commercial bias in medical research is the funding of studies by companies with a financial interest in the results."[1] While peer-reviewed professional journals such as *JAMA* and the *New England Journal of Medicine* routinely disclose such funding, it was not known if general media outlets also revealed this important source of possible bias. The authors analyzed 306 news articles about medication research appearing in the nation's top 45 newspapers, as well as on the 7 primary news-based web sites (ABC News, CNN, Fox News, Time, MSNBC, CBS, and NPR). Their results, published in the October 1st issue of *JAMA,* showed that 42% of the time such news articles failed to state that the research being reported on had pharmaceutical company funding. The authors conclude by suggesting that news organizations consider establishing written policies mandating that all news articles about medical research indicate the source of funding for the studies discussed.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Early Fill Edit Instituted

Effective October 1, 2008, New York State's Medicaid Program will deny pharmacy drug claims if less than 75 percent of the previously dispensed supply has been used. This edit will apply to all prescriptions, new or refill, for the same drug and strength, regardless of prescriber or provider. Pharmacists can override this rejection under two specific circumstances, using the following codes in the Submission Clarification Code field:

03 Vacation Supply

04 Lost Prescription

"Lost Prescription" refers to any prescription that has been lost, damaged, destroyed, or stolen. Early fills and refills for controlled substances must comply with section 80.69 of the rules and regulations on controlled substances (NYCRR Title 10, Part 80).

Tamper-Resistant Prescriptions

The federal tamper-resistant prescription pad law (TRPP) goes into full effect on October 1, 2008. Under TRPP, written prescriptions issued for Medicaid recipients must contain all three tamper-resistant characteristics established by the Centers for Medicare and Medicaid Services (see the April, 2008 issue of ***PRN*** for more details on TRPP). The Official New York State Prescription form meets all federal requirements. If, however, a prescription is issued by an exempt facility on its own prescription form, which must contain a state-issued serial number label, the following added feature must now be present:

The quantity of the prescription MUST be preceded and followed by computer-generated asterisks:

Examples:

"Quantity ***50*"**

"Dispense*50***"**

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Major Changes to New York's EPIC Program

New York State has announced major revisions to its Elderly Prescription Insurance Coverage (EPIC), which covers state residents 65 and older with incomes of $35,000 or less (single) or $50,000 or less (married). Starting October 1, 2008, two important changes will affect generic drug use and coordination of Medicare Part D coverage.

Mandatory Generic Program

EPIC will now require prior authorization (PA) on prescriptions for brand-name drugs for which there is an "A"-rated generic equivalent available. This applies only to prescriptions where EPIC is the only payer; when EPIC is the secondary coverage, the rule does not apply. Prescribers may obtain prior authorization by calling the automated EPIC PA call line, available 24 hours a day, 7 days a week at:

1-800-256-8082

There are 2 situations where the pharmacist may initiate the prior authorization process:

1. **If the prescriber cannot be reached, the pharmacist may obtain authorization for a 72-hour emergency supply of the brand-name drug by calling the EPIC PA call line and selecting the Emergency Supply option. Once the 72-hour supply is dispensed, the prescription is no longer valid for the remaining quantity and refills.**
2. **If the generic is unavailable in the marketplace, the pharmacist may obtain a prior authorization for the original prescription and refills for six months by calling the EPIC PA call line and selecting the Generic Not Available option. Should the generic become available again, the prescription should be refilled using the generic.**

The following drugs are *exempt* from the Mandatory Generic Program and will not require prior authorization:

Clozaril	**Gengraf**	**Neoral**	**Tegretol**
Coumadin	**Lanoxin**	**Sandimmune**	**Unithroid**
Dilantin	**Levoxyl**	**Synthroid**	**Zarontin**

Maximizing Medicare Part D Coverage

If a claim is denied by an Epic enrollee's Medicare Part D or other primary coverage, the pharmacist must contact the prescriber **before billing EPIC**. This action will result in one of three possible outcomes:

1. **The prescriber changes the drug to one that is covered. Bill the primary plan, then bill the co-payment or deductible to EPIC with an Other Coverage Code (OCC) of 8.**
2. **The prescriber does not agree to change the drug. Bill the claim to EPIC with the Other Payer Reject Code, an OCC of 3, and a Submission Clarification Code (SCC) of 7. The prescriber need not be consulted again when refilling the prescription, but must be contacted whenever a new prescription is presented.**
3. **The prescriber could not be reached. Bill the claim to EPIC with the Other Payer Reject Code, an OCC of 3, and an SCC of 99, certifying an attempt to contact the prescriber was made. The pharmacist must attempt to contact the physician again prior to any refilling of the prescription.**

Feature Article..

CELEBRATING AMERICAN PHARMACIST MONTH

October is American Pharmacist Month. The annual celebration of the profession, originally known as National Pharmacy Week, originated in 1925, and was expanded and renamed American Pharmacist Month in 2004. The American Pharmacists Association sponsors the event and offers many suggestions for promoting pharmacy, including a planning guide, press releases, fact sheets, and more, on its website at: ***www.pharmacist.com***.

A Message from the American Pharmacists Association

Pharmacists: Your Leading Medication Advocate

You have just taken your mother to an assisted living facility and in the process have identified the 14 prescription vials stored in various places around her former home. Or perhaps your employer has switched insurance carriers and you are learning that your prescription benefits have changed as well. Possibly you, who are never sick, have suddenly contracted the worst cold with a persistent cough that is preventing the sleep you so desperately need. What do you do? To whom do you turn?

The answer is simple and the solution is — wherever you look. The nation's pharmacists stand ready to address these and many other issues the modern consumer has navigating the changing world of medicines, health care, and self care.

The pharmacist's most visible role is certainly in the community. Quite a bit of attention has recently been directed to the fact that growing volumes of prescriptions and the increasing hassles of insurance coverage have caused pressures to mount in the community pharmacy. Nonetheless, consumers can turn to these pharmacists for more than they might realize.

After six years of college education largely focused on medications and how they work, pharmacists are truly medication experts. In what may seem like a simple act of filling a prescription, pharmacists do a lot — they check patients' records to make sure that one prescription doesn't duplicate another or interact badly. They may sometimes ask questions to monitor whether side effects are occurring and to avoid giving medications to which patients may be allergic.

Pharmacists can also be allies in getting the most value out of medication. When appropriate, pharmacists can recommend lower-cost generic alternatives or even over-the-counter medications. And they have information about programs that can help consumers access lower-cost medicines. Most important, pharmacists help consumers make the medicine work — so patients get the effect they are expecting. While consumers also need to inquire of their employer and/or insurer about how their prescription coverage is designed, pharmacists can help identify those medications that are and are not covered. They can discuss these issues and alternatives that will cost patients less money. Mostly, they can advocate for the very best medicine for your health.

Pharmacists aren't only in traditional pharmacies. They are everywhere you look and even in places you might least suspect. Recent research studies have highlighted the life-saving role pharmacists can play in our nation's hospitals. Supermarkets, health centers, and doctor's offices are increasingly hiring pharmacists. In all settings, pharmacists are consulting directly with doctors and patients about selecting and using the right medications and monitoring patients' progress on medication therapies. Pharmacists are consulting with assisted living facilities, nursing homes, and other residential care settings where some of the most vulnerable older people reside.

So remember that when you have a question, problem, or even just a curiosity about medications, look around! You are not ever very far from one of the nation's practicing pharmacists.

America's Most Trusted Professions

Each year, starting in 1976, the Gallup Poll has asked Americans to rate the honesty and ethical standards of the members of various professions. Pharmacists were first included in the questionnaire in 1981, and by 1988 the profession had risen to the top spot — most trusted profession. Pharmacists maintained that position for an unprecedented 10 straight years before being eclipsed in 1999 by the newly added profession of nursing. Still, pharmacists continue to finish in second or third place every year and received their highest positive rating ever, 72%, in last year's poll. By the way, for many years the title of *least* trusted profession belonged to car salesmen, but they were beaten out for the bottom spot last year when Gallup added a new profession to the list: *lobbyists!*

A Brief History of American Pharmacy

1761: Dr. Hugh Mercer opens his apothecary shop in Fredericksburg, VA. Considered by some to be the first pharmacy in America, its patrons included Mary Washington, mother of future President George Washington.

1821: The Philadelphia College of Pharmacy is established as the first pharmacy school in the United States. The College of Pharmacy of New York follows in 1829.

1823: Louis J. Dufilho, Jr., the first licensed pharmacist in the United States, opens his apothecary shop in New Orleans, LA.

1852: The American Pharmaceutical Association is formed. In 2004, it is renamed the American Pharmacists Association.

1906: In response to adulterated food products and toxic patent medicines, the Pure Food and Drug Act becomes law and the FDA is formed (then called the Bureau of Chemistry).

1938: The Elixir Sulfanilamide disaster prompts the creation of the Food, Drug, and Cosmetic Act, which requires that drugs been proven safe and be adequately labeled (see "Did You Know" on page 4 for the story of the 1937 Elixir Sulfanilamide disaster).

1951: The Durham-Humphrey Amendment creates the "federal legend," categorizing prescription vs. non-prescription drugs.

1970: The Controlled Substance Act establishes drug schedules I through V, and consolidates enforcement agencies.

1984: Provisions of the Hatch-Waxman Act simplify the process for marketing generic drugs, greatly increasing their market share over time.

1990: The Omnibus Budget Reconciliation Act (OBRA '90) mandates prospective DUR and patient counseling by pharmacists.

2004: The Bachelor's Degree in Pharmacy is phased out. The entry-level degree for the profession becomes the Pharm.D.

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OFF-LABEL USE: LETROZOLE

Letrozole (Femara®) is an aromatase inhibitor indicated for the treatment of breast cancer in postmenopausal woman. Off-label uses include:

Ovulation Induction: In the treatment of infertility, letrozole has been shown to have an equal or greater effect than that of clomiphene citrate.[2] While there has been some concern regarding fetal toxicity, a recent study found no evidence of teratogenicity in short-term use for ovulation induction.[3] Doses have ranged from 2.5 to 7.5 mg daily for 5 days (days 3 to 7 of cycle).

Endometriosis: Several studies demonstrated letrozole to be effective in treating endometriosis in woman poorly responsive to other treatments. The usual dose is 2.5 mg daily in combination with a synthetic progestin, such as norethindrone or desogestrel.

DID YOU KNOW?

DID YOU KNOW that the single most important drug regulation in U.S. law resulted from a tragedy that led to the deaths of 107 people, many of them children? The Food, Drug, and Cosmetic Act of 1938 was enacted after what became known as the Elixir Sulfanilamide disaster. In October, 1937, the FDA began receiving reports of deaths due to ingestion of a new, liquid form of the sulfonamide antibiotic sulfanilamide, manufactured by S.E. Massengill of Bristol, Tennessee. Investigators determined that the sweet-tasting vehicle the drug was dissolved in was diethylene glycol, otherwise known as antifreeze. The company's chief chemist was apparently unaware of the toxic nature of the solvent; he committed suicide shortly after the cause of the deaths was revealed. Unfortunately, the tragedy was repeated nearly 70 years later when, in 2006, at least 115 people died in Panama after using a popular cold remedy. The product was made with syrup, imported from China, marked 99.5% pure glycerin. It was later determined that the syrup actually contained diethylene glycol.

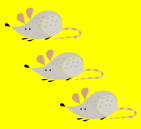
PHARMACY FUN

The rebus, or picture puzzle, was popularized by the television game show "Concentration." This month we present three drug names in rebus form, and the first reader to submit the correct answers to us at *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

Hint: the 3 drugs are related in some way, and generic names are used!

1.  +  +  + **N**

2.  + **O** +  +  + **N**

3.  + **A** +  + **N**

Answers to last month's ***PHARMACY FUN***:
1. ***b*** 2. ***e*** 3. ***f*** 4. ***i*** 5. ***c***

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1. Hochman M, et al. News media coverage of medication research. *JAMA*. 2008 Oct 1;300(13):1544-50.
2. Begum MR, eta al. Comparison of efficacy of aromatase inhibitor and clomiphene citrate in induction of ovulation in polycystic ovarian syndrome *Fertil Steril* 2008 Jan 3.
3. Tulandi T, et al. Congenital malformations among 911 newborns conceived after infertility treatment with letrozole or clomiphene citrate. *Fertil Steril* 2006 June;85(6):1761-5.