P.R.N.

ISSN # 1941-9481

www.prnnewsletter.com

Volume 2, Number 9 | A Monthly Newsletter for Community Pharmacists | September, 2008

What's Inside…

Rx News……..1

Medicaid Update…….2

Law Review……2

Feature Article:
Attention Deficit/ Hyperactivity Disorder... 3

Practice Points..…… 4

Did You Know?..... 4

Pharmacy Fun……4

Breaking News

Pharmacist Vaccination Bill Becomes Law in N.Y.

On September 5, 2008, New York Governor David Paterson signed into law a measure that allows pharmacists in the state to administer flu and pneumococcal vaccines to adults. The act will take effect on December 4, 2008. Pharmacists wishing to administer vaccines must first obtain a certificate of administration from the Department of Education, which will require training in, among other things, techniques of administration, screening and obtaining informed consent, record keeping, and handling of emergencies, including anaphylaxis and needlesticks. The key points of the legislation include:

- **Pharmacists may administer only influenza and pneumococcal vaccines, under a non-patient specific regimen ordered by a physician or nurse practitioner**
- **Pharmacists may vaccinate adults only**
- **Pharmacists must first obtain a certificate of administration, the fee for which will be $100 every three years**
- **The program is voluntary. Pharmacists are not required to obtain certification**

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

More Bad News for Vytorin: The complete results of the Simvastatin and Ezetimibe in Aortic Stenosis (SEAS) study were published in the September 2 online edition of the New England Journal of Medicine, and once again **Vytorin** failed to meet the primary endpoint, in this case, reduction of aortic-valve and cardiovascular events.[1] This comes in the wake of the combination drug's disappointing performance in the ENHANCE trial. In that study, the endpoint was the degree of plaque formation in the carotid arteries, and the results showed that Vytorin worked no better than, and perhaps not as well as, simvastatin alone. The 18-month delay in reporting the results of that study also had some in Congress questioning whether Merck and Schering-Plough knew the results well before their January, 2008 release. Perhaps worst of all, an unexpected result of the SEAS trial showed an increase in cancer and cancer deaths in the Vytorin group compared to the placebo group (any cancer: 101 vs. 65 cases, cancer deaths: 37 vs. 20). When these data became known, researchers at Oxford University, who are conducting the SHARP trial (funded by Merck and Schering-Plough) analyzed the interim results of their trial and those of another ongoing study, IMPROVE-IT, to determine if the cancer risk would be duplicated.[2] Their analysis showed no increased risk of cancer in patients taking Vytorin vs. control groups (313 vs. 326 cases, p=0.61) There was, however, a non-significant increase in cancer deaths in patients taking Vytorin (97 vs. 72 deaths, p=0.07). When data from all three trials were combined, there remained an increased risk of cancer deaths (134 vs. 92 deaths, uncorrected p=0.007).

FDA Reaction: In a press release dated August 21, 2008, the FDA reported on its ongoing safety review of Vytorin and **Zetia** (ezetimibe) in relation to the results of the SEAS trial. FDA references the fact that the increased cancer diagnoses seen in SEAS were not duplicated in SHARP or IMPROVE-IT, and points out that most large prospective studies of statins alone show no difference in cancer incidence between active and placebo arms. For example, a study of 20,000 patients randomized to receive simvastatin 40 mg or placebo for up to 5 years revealed no significant difference in either cancer rates or deaths. The statement ends by recommending that, at this time, patients should not stop taking Vytorin and should speak to their doctors if they have questions about continuing their medication.

Expert Advice: In a New York Times article reporting on SEAS, a number of oncologists are quoted as agreeing with the Oxford researchers, who doubt that Vytorin caused the increased cancers in the study.[3] They believe the result was probably due to chance alone, based in part on the fact that many cancers take years to develop, and therefore it is unlikely that ezetimibe could cause cancer in the 3 year duration of the trial. However, the editors of the New England Journal of Medicine, in an editorial accompanying publication of the trial, cautioned that it is still uncertain whether the increased mortality rate seen in the combined study results can be ascribed to chance alone. They urged careful follow-up of patients in the ongoing SHARP and IMPROVE-IT trials in order to clarify the issue of cancer risk.

Methadone Deaths Prompt FDA to Consider Physician Training Requirements

In response to increasing reports of deaths due to methadone use, the FDA is considering recommending specialized training for physicians who prescribe powerful narcotics. Prescriptions for methadone, once rarely seen in the community pharmacy setting, have increased sevenfold in the last decade, and deaths attributed to the drug have increased fivefold.[4] The growing use of methadone as an analgesic may be due, in part, to the recognition by physicians that chronic pain has been undertreated, and the need for a cheaper alternative to expensive, long-acting narcotics like Oxycontin. Methadone, however, requires more careful titration than some other opioids due to the fact that its elimination half-life (8 to 59 hours) greatly exceeds its duration of analgesic action (4 to 8 hours), leading to the possibility of dangerously high blood levels if patients exceed the recommended dose. Deaths have resulted from respiratory depression, as well as cardiac arrhythmias, and have been more prevalent in patients just starting therapy, patients being converted from other opioids, and patients using alcohol or benzodiazepines.[5] In 2006, the FDA issued a public health advisory and changed the prescribing information to recommend an initial dose of no more than 30 mg daily. *Editor's note:* When used in the treatment of opioid addiction, methadone may only be dispensed by a certified opioid addiction program (see federal regulations, 42 CFR Section 8).

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Preferred Drug Program Update

The New York State Department of Health has announced several changes to the Preferred Drug Program, effective August 20, 2008. The following drugs are now covered, and will no longer require prior authorization:

Preferred Agents

Cetirizine
Cetirizine-D
Exforge
Fluticasone Nasal Spray
Lovastatin
Lovaza
Opana ER
Simcor
Vyvanse

The following drugs are no longer covered, and will now require prior authorization:

Non-preferred Agents

Ambien CR
Coreg (brand only)
Nasacort AQ
Lofibra (brand only)
Metadate CD
Ritalin LA
Sular
Vytorin

Prescribers obtaining prior authorization should document the authorization number, ending in "W," on the prescription. Pharmacists filling such prescriptions must first validate the authorization by calling the pharmacy prior authorization line at **(877) 309-9493** (option "2" for pharmacists and then option "1" for non-preferred drugs). Prior authorizations are valid for the life of the prescription (up to 5 refills in 6 months). When submitting a claim for such prescriptions, the validated prior authorization number must be included in the prior authorization field ***without*** the "W." A complete list of preferred and non-preferred drugs can be accessed at:

https://newyork.fhsc.com

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Special Edition: Reader's Questions

From time to time, we will dedicate the Law Review column to answering questions of interest from our readers. Questions should pertain to issues of federal or state law affecting the practice of pharmacy in New York State. Address all such inquiries to *askprn@prnnewsletter.com*. We look forward to hearing from you!

Q: Since the implementation of the Official New York State Prescription Program, we have received a number of prescriptions for anabolic steroids, as well as benzodiazepines, upon which the prescriber has indicated a number of refills. Has there been any change to the regulations that would allow such refills?

A: No. Since all prescriptions are now issued on the Official New York State blank, which has a preprinted refill box, some physicians mistakenly believe that refills are now permissible on all Rxs. In fact, refills are still ***not permitted*** on prescriptions for C-II drugs, benzodiazepines, and anabolic steroids in New York State. The most common error involves anabolic steroids, which are schedule III drugs federally (which would allow refills), but schedule II in New York. Prescriptions for anabolic steroids should be kept in the C-II file. A list of commonly prescribed anabolic steroids follows:

Androderm (testosterone patch)	**Striant** (testosterone buccal)
Androgel (testosterone gel)	**Testim** (testosterone gel)
Android (methyltestosterone)	**Testosterone Injection**
Oxandrin (oxandrolone)	**Testred** (methyltestosterone)

As for benzodiazepines, while they are schedule IV drugs both federally and in New York, since 1989 New York State law has prohibited refills for drugs in this class. Prescriptions for benzodiazepines should be kept in the C-III-IV-V file.

Q: In the July issue of *PRN*, you pointed out that pharmacy interns are not included in the 2 to 1 ratio of unlicensed person to pharmacists allowed in New York State. But isn't there also a limit of 1 full time or 2 part-time pharmacy interns per pharmacist?

A: The restriction of 1 full time or 2 part-time pharmacy interns per preceptor pharmacist applies only to interns participating in a required internship program. In addition, preceptor pharmacists in this setting must have practiced for at least one year prior to assuming a preceptorship. *PRN* has confirmed with the Board of Pharmacy that these restrictions *do not apply* to pharmacy interns who are employees of a pharmacy and who are working on their own time and not as part of an internship program. In such cases there are no restrictions on the number of interns working under the supervision of a licensed pharmacist.

Q: If a prescription is written for a 90-day supply of a controlled substance, but does not include a "condition code," may a pharmacist add the appropriate code to the prescription after consultation with the prescriber?

A: Yes. Assuming that the drug prescribed is one that is eligible for one of the 6 condition codes established by the Department of Health (see the January, 2008 issue of *PRN* for a discussion of the codes), a pharmacist may add the code to the prescription after confirmation from the prescriber. The pharmacist must document on the prescription the date the oral authorization was received and affix his or her signature. It should be noted that a pharmacist ***may not add*** any of the following pieces of information to a controlled substance prescription if they are missing:

Prescription date **Prescriber's signature** **Patient's name**
Drug name **Drug quantity**

Feature Article..

ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

September is Attention-Deficit/Hyperactivity Disorder (ADHD) awareness month. It is estimated that between 3 and 12% of school-aged children are affected by the disorder, though many experts believe the true prevalence to be between 5 and 8%. Boys are diagnosed at a rate 3 to 4 times greater than are girls. Three types of ADHD, based upon symptoms, have been established (see box below). Recently, there has been some controversy over the necessity of cardiac testing for ADHD patients (see discussion below). There follows a quick-review chart of the most commonly prescribed agents in the treatment of ADHD.

ADHD TYPES

1. Predominantly Inattentive Type: patients have difficulty paying attention to details, following instructions or conversations. Finishing tasks and focusing in the classroom may be difficult.

2. Predominantly Hyperactive-Impulsive Type: patients have trouble sitting still, may fidget, talk a lot, and act impulsively. Patients may have more accidents and injuries than others.

3. Combined Type: Above symptoms are equally present.

Current Issues: ECG Testing for ADHD?

In April, 2008, the American Heart Association (AHA) published guidelines in the journal *Circulation* suggesting that all children being considered for medication therapy for ADHD be given an electrocardiogram (ECG) before starting treatment. After some debate, the AHA released a joint statement with the American Academy of Pediatrics revising their opinion to state that an ECG is *not* mandatory, but may be used at the physician's discretion after obtaining a patient and family health history and doing a physical exam focused on cardiovascular risk factors.

I. Stimulants (C-II)

MDD = Maximum Daily Dose

Product (active)	Age Range	Duration	Starting Dose	MDD	Generic?
Adderall (amphetamine salts 5, 7.5, 10, 12.5, 15, 20, 30 mg)	≥3 years old	4 to 6 hours	3-5 years old: 2.5 mg qAM ≥6 years old: 5 mg qAM or BID	40 mg/day 40 mg/day	Yes
Adderall XR (amphetamine salts 5,10,15, 20, 25, 30 mg ER)	≥6 years old	8 to 12 hours	5 to 10 mg qAM	30 mg/day	No
Concerta (methylphenidate ER 18, 27, 36, 54 mg ER)	≥6 years old	10 to 12 hours	6-12 years old: 18 mg qAM ≥13 years old: 18 mg qAM	54 mg/day 72 mg/day	No
Daytrana (methylphenidate patch 10, 15, 20, 30 mg/9 hours)	≥6 years old	9 to 12 hours	10 mg/9 hours	30mg/9 hours	No
Dexedrine Spansule (dextroamphetamine 5, 10, 15 mg ER)	≥6 years old	6 to 8 hours	5 mg qAM	40 mg/day	Yes
Dextrostat (dextroamphetamine 5, 10 mg)	≥3 years old	4 to 5 hours	3-5 years old: 2.5 mg qAM ≥6 years old: 5 mg qAM	40 mg/day 40 mg/day	Yes
Focalin (dexmethylphenidate 2.5, 5, 10 mg)	≥6 years old	3 to 5 hours	2.5 mg BID (AM and Noon)	20 mg/day	Yes
Focalin XR (dexmethylphenidate 5, 10, 15, 20 mg ER)	≥6 years old	8 to 12 hours	5 mg qAM	20 mg/day	No
Metadate CD (methylphenidate 10, 20, 30, 40, 50, 60 mg ER)	≥6 years old	8 to 12 hours	20 mg qAM	60 mg/day	No
Ritalin (methylphenidate 5, 10, 20 mg)	≥6 years old	3 to 4 hours	5 mg BID (AM and Noon)	60 mg/day	Yes
Ritalin SR (methylphenidate 20 mg ER)	≥6 years old	4 to 8 hours	20 mg qAM	60 mg/day	Yes
Ritalin LA (methylphenidate 10, 20, 30, 40 mg ER)	≥6 years old	8 to 12 hours	20 mg qAM	60 mg/day	No
Vyvanse (lisdexamfetamine 20, 30, 40, 50, 50, 70 mg)	≥6 years old	10 to 12 hours	30 mg qAM	70 mg/day	No

II. Non-Stimulants (Selective Norepinephrine Reuptake Inhibitor)

Product (active)	Age Range	Duration	Starting Dose	MDD	Generic?
Strattera (atomoxetine 10, 18, 24, 40, 60, 80, 100 mg)	≥6 years old	24 hours	≤70 kg: 0.5 mg/kg qAM >70 kg: 40 mg qAM	100 mg/day	No

P.R.N.

P.R.N. (ISSN # 1941-9481)
is published monthly by:
PRN Publishing LLC
68-37 Yellowstone Boulevard
Suite C-22
Forest Hills, New York 11375
Phone & Fax (718) 263-4632

Founder and Editor:
James Murphy, RPh

Associate Editor:
Margaret McDonald, PharmD

Contributors:
Loriann Irving, PharmD
Lilian Papacharalambous, RPh

The information contained in P.R.N. is for educational purposes only. Always use professional judgment in clinical practice.

We welcome your input. Please forward any comments, suggestions, or questions to us at:
askprn@prnnewsletter.com

Visit us on the web at:
www.prnnewsletter.com

SUBSCRIPTION INFORMATION

Subscriptions are available:
One year (12 issues)…….$48.00
To pay by credit card via secure server go to the **SERVICES** page of our website: **www.prnnewsletter.com**
or
Send a check or money order payable to PRN Publishing to:

PRN Publishing
68-37 Yellowstone Boulevard
Suite C-22
Forest Hills, New York 11375

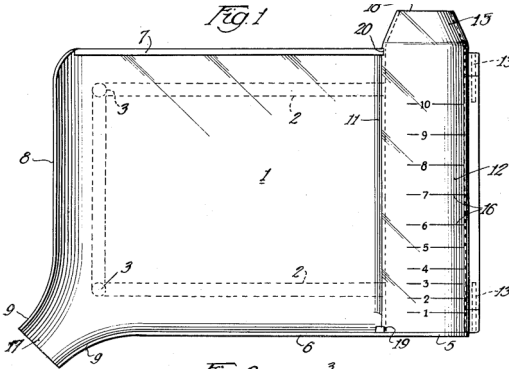
Practice Points: Use caution when substituting AEDs

Editor's Note: This month we introduce a new column, part of a rotation of several features appearing in this section, including Natural Products *and* Off-Label Use. Practice Points *will discuss current issues of interest related to the day-to-day practice of pharmacy in the community setting.*

For several years now, there has been some controversy over the appropriateness of generic substitution of antiepileptic drugs (AEDs). While the FDA maintains that there is no significant difference between brand and generic formulations, even in narrow therapeutic index drugs such as AEDs, some neurologists and their patients claim that substitutions have led to breakthrough seizures. In 2006, the American Academy of Neurology issued a position statement opposing the generic substitution of AEDs without prior consent of both the physician and patient.[6] This position is echoed in a bill currently before the New York State legislature (A09303/S5016) that would prohibit any change in formulation (brand to generic, generic to brand, or generic to generic) of an AED without the written consent of patient and prescriber. While it seems the jury may still be out on the subject of the efficacy of some generic AEDs, it would be prudent at this time for pharmacists to protect their patients, and themselves, by always obtaining consent before substitution AEDs, even one generic for another. This vigilance is especially important now that some pharmacy software programs are known to automatically substitute generics on refills of prescriptions originally filled with the brand-name drug.

DID YOU KNOW?

DID YOU KNOW that the sanitary counting tray, used by most pharmacists even today, was invented by Mack R. Fields and patented by Abbott in 1950? U.S. patent # 2,530,009 (see original patent drawing at right) reveals the secret of the strange numerical scale on the cover— it is to be used to create a chart matching the level of pills in the chamber (1 to 10) to the most appropriate vial size stocked by the pharmacy. Do you know anyone who has ever made such a chart?!



PHARMACY FUN

September, of course, is back to school month, and in honor of that fact we present our first annual Back To School Quiz. Cast your mind back to those distant (or not so distant) halcyon days when you roamed the campus of your alma mater, your head filled with facts, figures, and formulas. How many of them do YOU remember? Send the correct answers to the following matching column to us at *puzzle@prnnewsletter.com* for a chance to win a custom-printed *PRN* binder.

1. Moles of solute per liter of solution	**a. $CH_3CH_2CH_2OH$**	**f. CH_3CH_2OH**
2. Isopropyl Alcohol	**b. Molarity**	**g. Osmolarity**
3. Ethyl Alcohol	**c. Normality**	**h. CH_3COCH_3**
4. Moles of solute per kg of solvent	**d. Tonicity**	**i. Molality**
5. Equivalents per liter of solution	**e. $CH_3CHOHCH_3$**	**j. CH_3CH_2COOH**

Answers to last month's **PHARMACY FUN**:
1. Octreotide 2. Codeine 3. Terbutaline 4. Aspirin 5. Vancomycin 6. Indomethacin 7. Ursodiol 8. Streptomycin
The Emperor's real name: OCTAVIUS

References:
1. Rossebø A B, et al. Intensive lipid lowering with simvastatin and ezetimibe in aortic Stenosis. *N Eng J Med* online 9/2/08 at *www.nejm.org*.
2. Peto r, et al. Analyses of data from three ezetimibe trials. *N Eng J Med* online 9/2/08 at *www.nejm.org*.
3. Alex Berenson, "For Widely Used Drug, Question Of Usefulness Is Still Lingering," *New York Times*, September 2, 2008.
4. Erik Eckhilm, "Methadone Rises as a Painkiller With Big Risks," *New York Times*, August 17, 2008.
5. FDA Public Health Advisory: Methadone Use for Pain Control May Result in Death and Life-Threatening Changes in Breathing and Heart Beat. July, 2008 at *www.fda.gov/cder/drug/advisory/methadone.htm* (accessed 8/17/2008).
6. American Academy of Neurology: Position Statement on the Coverage of Anticonvulsant Drugs for the Treatment of Epilepsy. November, 2006 at *www.aan.com/globals/axon/assets/2323.pdf* (accessed 9/3/08).