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What's Inside…

FDA NEWS

FDA Orders Mandatory Recall of Kratom

In the latest episode in the agency's running battle against kratom, the FDA has issued its first-ever mandatory recall against kratom-containing products contaminated with salmonella. Kratom is a natural product extracted from the leaves of an evergreen tree *(Mitragyna speciosa)* native to Southeast Asia. Kratom has been marketed as a "natural substitute for opium" and as a "cure" for opioid addiction. While the FDA has taken several enforcement actions against the product in recent years (and the DEA once proposed making it a Schedule I substance), this is the first time the agency has used its authority to conduct a mandatory recall. The action was taken after several lots of kratom-containing products distributed by Triangle Pharmanaturals tested positive for salmonella, and the company failed to cooperate with an FDA request to conduct a voluntary recall.

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New York State 2018/2019 Budget Passes with Major Changes in Store for Pharmacy Practice

In the early morning hours of Saturday, March 31st, with less than 24 hours remaining to the April 1st deadline, the New York State legislature passed the budget for fiscal year 2018/2019. As anticipated, the legislation enacted contained several major initiatives affecting the practice of pharmacy in New York. Some of the key elements of particular interest to community pharmacists are discussed below.

- **Pharmacists now authorized to administer influenza vaccine to children aged 2 to 18 years of age:** Governor Cuomo's Executive Order 176, issued in January, temporarily allowed pharmacists in New York to vaccinate children against influenza; the budget legislation has amended the Education Law to make this change permanent. In addition, the "privacy area" provided by the pharmacy for vaccinations must now include "educational materials on influenza vaccinations for children," in addition to the already-mandated posting of the latest ACIP "Recommended Adult Immunization Schedule."
- **Pharmacy Benefit Manager (PBM) Reforms:** New rules eliminate both "gag clauses" and patient copay "clawbacks." Specifically, PBMs may not "prohibit or penalize a pharmacist or pharmacy from disclosing to an individual purchasing a prescription medication information regarding the cost of the medication, the availability of therapeutically equivalent alternative medications or alternative methods of purchasing the prescription medication, including but not limited to, paying a cash price." Regarding "clawbacks," PBMs may not "charge or collect from an individual a copayment that exceeds the total submitted charges by the pharmacy for which the pharmacy is paid. If an individual pays a copayment, the pharmacy shall retain the adjudicated costs and the pharmacy benefit manager shall not redact or recoup the adjudicated cost."
- **PBM Audit Fairness Measures:** Section 208-c has been added to the Public Health Law to address unfair practices by PBM pharmacy auditors. New rules include the following:
  - ♦ On-site audits may not occur during the first 3 calendar days of a month.
  - ♦ Pharmacies must be notified no later than 15 days before the date of an initial on-site audit. The PBM must include in such notice the list of specific prescription numbers to be included on the audit that may or may not include the final two digits of the prescription numbers.
  - ♦ The audit period shall be limited to a period of 24 months after the date a claim is submitted to, or adjudicated by, the PBM, and the auditor must accept, as validation of the pharmacy records, the written and verifiable records of the prescriber transmitted by any means of communication.
  - ♦ The number of prescriptions audited must be limited to no more than 100 randomly selected in a twelve-month period, except in cases of fraud.
  - ♦ The PBM must provide the pharmacy with a copy of the preliminary audit report within 45 days after the conclusion of the audit.
- **Measures to Combat the Opioid Epidemic:** The budget legislation also contains several new initiatives aimed at curbing the current opioid epidemic, which include the Opioid Stewardship Act and new limitations on opioid prescribing. For details on these efforts, see ***Pharmacy Law*** on page 2 of this issue.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Department of Health Endorses CDC Opioid Guidelines

In their most recent Medicaid communication, the New York State Department of Health published a review of the 2016 opioid prescribing guidelines issued by the Centers for Disease Control (CDC). The review stressed the following points:

- Non-pharmacologic and non-opioid pharmacologic treatments should be considered before initiating opioid therapy.
- Opioid treatment should be initiated at the lowest effective dose of an immediate release product.
- Pain should be evaluated initially, after 1 to 4 weeks, and then at least every 3 months.
- Consult the prescription monitoring program (PMP or I-STOP) to review patients' history of controlled substance usage.
- Set specific treatment goals and evaluate risk of overdose.
- Avoid increasing dose to ≥90 MME/day total (morphine milligram equivalents, equal to 90 mg hydrocodone or 60 mg oxycodone per day).

Automatic Refill Policy

The Department of Health has sent out a reminder notice to pharmacies to reiterate that automatic refill programs ***are not permitted*** for prescriptions filled under New York State Medicaid. Only the following refill requests are allowed:

- Request for a refill by a Medicaid member or designated caretaker who initiates the request to the pharmacy.
- Provider directly contacts a Medicaid member by phone or electronic means (text, etc.). Documentation of the contact must be maintained and available for audit purposes.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

New York State Addresses the Opioid Crisis in Latest Budget

The recent passage of the 2018/2019 New York State budget saw several attempts by legislators to deal with the rampant abuse of prescription opioid medications. Two of the key measures in this effort are detailed below:

- **The Opioid Stewardship Act:** An amendment to Article 33 of the Public Health Law (title 2-A) will establish an "Opioid Stewardship Fund." The act will require all manufacturers and distributors who sell or distribute opioids in New York State to make an annual "stewardship" payment to the fund. The total fund will be set at $100 million annually, and each manufacturer's or distributor's payment toward the fund will be based on their percent share of the total opioids sold in the state. The fund will be used to support services offered by the State Office of Alcoholism and Substance Abuse Services (OASAS). OASAS provides programs for opioid treatment and recovery, abuse prevention, and education. The fund will also be used to support the state's Prescription Monitoring Program, also known as I-STOP.
- **Opioid Treatment Plans:** A new regulation will prohibit prescribing opioids for a period greater 3 months, unless the patient's medical record contains a written treatment plan that follows national guidelines (exceptions are made for cancer and palliative care patients). The exact wording of the amendment is as follows:

  "*No opioid shall be prescribed to a patient initiating or being maintained on opioid treatment for pain which has lasted more than 3 months or past the time of normal tissue healing, unless the medical record contains a written treatment plan that follows generally accepted national professional or governmental guidelines.*"

The Opioid Epidemic and Pharmacist's Corresponding Liability

Section 1306.4 of Title 21 of the Code of Federal Regulations states that pharmacists have a "corresponding liability" for the proper dispensing of controlled substances, ensuring that such prescriptions have been issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice. This creates a legal burden on the pharmacist dispensing controlled substances to attempt to determine the legitimacy of a prescription, often with sparse or incomplete information available. This responsibility has taken on a new urgency in the face of the opioid epidemic. Several organizations, including the Drug Enforcement administration (DEA), have issued lists of "red flags," or warning signs, to assist pharmacists in making this critical decision.

DEA's "Red Flags"

The DEA publishes a Pharmacists Manual, one section of which is dedicated to assisting pharmacists in detecting fraudulent prescriptions for narcotics. They list the following criteria, which may indicate that a prescription was not issued for a legitimate medical purpose:

- **The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in the area**
- **The prescriber writes for antagonistic drugs such as depressants and stimulants, at the same time. Drug abusers often request prescriptions for "upper and downers" at the same time.**
- **The patient presents with prescriptions written in the names of other people.**
- **A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same prescriber.**
- **People who are not regular patrons or residents of the community, show up with prescriptions from the same prescriber.**

SubSys, The OxyContin Model, and the Opioid Crisis

On the morning of October 26, 2017, the billionaire owner of Insys Therapeutics, John Kapoor, was arrested by federal agents in Arizona, and charged with engaging in conspiracies to commit racketeering, mail fraud and wire fraud. The indictment centered on a scheme to bribe practitioners in several states in order to get them to prescribe the company's sublingual fentanyl spray, **SubSys**.

SubSys is indicated for use only in cancer patients, but the government is charging that Mr. Kapoor and his company persuaded physicians, through kickbacks and bribes, to write large numbers of prescriptions for the highly addictive pain killer for patients who were not diagnosed with cancer. Acting U.S. Attorney William D. Weinreb stated that "in the midst of a nationwide opioid epidemic that has reached crisis proportions, Mr. Kapoor and his company stand accused of bribing doctors to overprescribe a potent opioid and committing fraud on insurance companies solely for profit."

While Mr. Kapoor awaits trial, currently free on a $1 million bond, the case continues. On March 16, federal prosecutors arrested five New York doctors charged with accepting kickbacks, in the form of fraudulent "speaker's fees," in exchange for prescribing SubSys. As disturbing as these allegations are, what may be worse is the fact that this is not the first time we have witnessed such behavior, and the last time it happened, many believe, it actually led to the opioid crisis we are facing today.

The OxyContin Model

In May of 2007, Purdue Pharma pleaded guilty to criminal charges of "misbranding, with intent to defraud or mislead," its opioid painkiller OxyContin. The company paid a then-record fine of $600 million, and three of the company's top executives were ordered to pay a total of $34.5 million. But "misbranding" doesn't tell the whole story of how OxyContin became so phenomenally successful, generating an estimated $35 billion in revenue for Purdue. The misbranding centered around the company's claims that OxyContin was less addicting than other opioids, for which there was no evidence whatsoever. But Purdue went further; they recruited more than 5,000 physicians to attend all-expenses-paid "seminars" in sunny vacations spots around the country, including Boca Raton and Pebble Beach. In addition, they established a well-paid "speakers' bureau" of doctors who influenced their fellow practitioners, many of them primary care physicians, to make more liberal use of opioids for non-cancer pain. The company even admitted to exploiting a misconception that many physicians then held, namely that oxycodone was *less* potent than morphine (it is actually 1.5 to 2 times *more* potent). Purdue was also able develop a sophisticated database of U.S. prescribers, which allowed them to identify and target physicians who were prescribing the most opioids. The combined force of these tactics led to the incredible success of OxyContin. It turns out, however, that these ideas were not new, or even unique to the marketing of OxyContin. In fact, they were a family affair.

The Sackler Connection

Purdue Pharma, the maker of OxyContin, was originally a small pharmaceutical manufacturer known as Purdue Frederick, located in lower Manhattan. In 1952 it was purchased by the Sackler brothers, Arthur, Mortimer, and Raymond, all physicians specializing in psychiatry. While the company was run by the two younger brothers, the eldest, Arthur, had other things on his plate. Years earlier, he had started working at an advertising agency which specialized in medical products (he eventually bought the company). In a recent *New Yorker* article[1], Patrick Radden Keefe described Sackler as having a "Don Draper-style intuition for the alchemy of marketing." Given the task of selling the then-new drug Valium, Arthur produced ads so effective and persuasive to physicians that within a few short years it became the best selling drug in the Western World, and held that position for more than a decade. At one point, it was estimated that no less than 15% of the U.S. population was taking the drug, for everything from "psychic tension" to hypochondria. By the mid-1970s, the overuse and abuse of Valium and other benzodiazepines led to a 60 Minutes expose and Senate hearings chaired by Edward Kennedy. By 1989, New York State had instituted regulations that, for all intents and purposes, reclassified benzodiazepines as Class II narcotics (they remain C-IV, but prescribers and pharmacists must prescribe and dispense them as if they were C-II). And while Arthur had passed away before the marketing of OxyContin, his brothers had apparently learned a lot from their elder sibling about optimizing the sales of prescription drugs.

An advertisement for Valium from 1971

The Opioid Crisis

The latest CDC statistics indicate that deaths from prescription opioids, like OxyContin, have more than quadrupled since 1999. In the period from the year 2000 to 2016, more than 600,000 people died from drug overdoses, and currently, on average, 115 Americans die every day from opioid-involved overdoses. Looking back at the history of this epidemic, it seems that the board rooms of corporate America may be more to blame than are the back rooms and shooting galleries of our drug-riddled communities.

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ASK PRN...

The computer program used in our pharmacy now automatically prints both the Federal and state controlled substance required statements on the prescription labels of all scheduled drugs dispensed. Are we still required to attach an orange auxiliary label containing the statements?

Your computer system would, indeed, satisfy the Federal requirement, but not the New York State regulation. Reviewing the pertinent statutes will explain why:
The **Federal regulation** (CFR 21 Sec. 290.5) reads as follows:

- *The label of any drug listed as a "controlled substance" in schedule II, III, or IV of the Federal Controlled Substance Act shall, when dispensed to or for a patient, contain the following warning: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.*

The New York State law is more specific and has some additional requirements:
The **New York State regulation** (section 3333 of the Public Health law) states:

- Controlled substance prescription labels must contain the legend, prominently marked or printed in boldface or upper case lettering: "CONTROLLED SUBSTANCE, DANGEROUS UNLESS USED AS DIRECTED."
- Such container shall be identified as a controlled substance by either (i) an orange label; (ii) a label of another color over which is superimposed an orange transparent adhesive tape; or (iii) an auxiliary orange label affixed to the front of such container and bearing the legend, prominently marked or printed "Controlled Substance, Dangerous Unless Used As Directed."

GOT QUESTIONS? WE HAVE ANSWERS!
Send your questions to us at:
askprn@prnnewsletter.com

PRN welcomes your questions on any topics relating to the practice of pharmacy. All answers are researched by our staff and, when necessary, discussed with the appropriate regulatory agencies. The information provided is not intended as legal advice, nor is it a substitute for professional judgment in clinical practice.

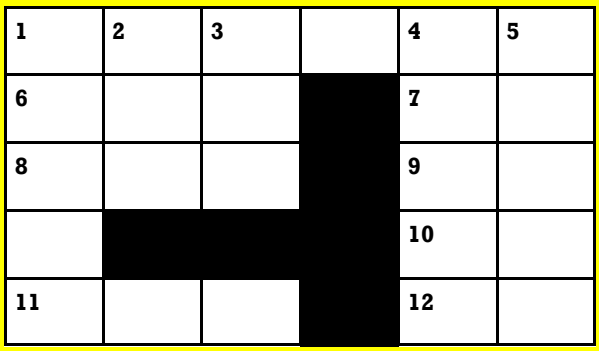
DID YOU KNOW?

DID YOU KNOW that one of the most important drug classes in the antihypertensive arsenal was discovered because banana plantation workers in Brazil were found to suddenly collapse from hypotension after being bitten by snakes? The Brazilian pit viper (Bothrops jararaca) secrets a venom that causes, among other things, a precipitous drop in blood pressure. Researchers, first in Brazil and later in England and the U.S., studied the compound to learn how it created this effect, and eventually, they discovered the angiotensin converting enzyme (ACE) inhibitor. The first commercially available ACE inhibitor, captopril, was approved by the FDA in 1981.

PHARMACY FUN

It's crossword puzzle time here at Pharmacy Fun! Hint: most, but not all, of the answers are related to one theme. The first reader to submit the correct answers to *puzzle@prnnewsletter.com* wins a set of *PRN* stylus pens.

Across:
1. Insulin glargine
6. Kreskin's specialty
7. What diabetics should say to 5 down
8. Neutral Protamine Hagedorn
9. What you need to get in
10. Often proctors exams
11. One way to increase blood sugar
12. Latin abbreviation for one-half
Down
1. Old Lilly long-acting insulin
2. Cleopatra's end
3. Humulin N or Novolin N
4. What insulin is measured in
5. What diabetics should avoid drinking



Answers to last month's ***PHARMACY FUN***:
1. Tripoli — Lipitor 2. subpar — Buspar 3. insane — Nesina 4. saltine — Astelin
5. carbine — Benicar 6. coast — Actos 7. sultan — Lantus 8. insolent — Lotensin
9. octaves — Vasotec 10. anecdotal — Aldactone

References:
1. Keefe, Patrick Radden. "Empire of Pain." *The New Yorker.* October 30, 2017. Print.