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News

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A Guide to Common Vaccinations

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Some of the most common vaccinations used in retail pharmacy inoculate against shingles; tetanus, diphtheria, and pertussis; influenza; hepatitis B; and pneumonia. These vaccines are recommended for a range of age groups and are life saving for many people. As pharmacists, it is crucial to know the rationale and incentive behind why we immunize. It is to protect our future as a population. Some diseases (like polio and diphtheria) have become very rare in the United States since the inception of vaccinations. Smallpox no longer impacts populations thanks to Edward Jenner's contributions in 1796. If we continue to vaccinate against other diseases, the same will be true someday for many other infectious diseases. Vaccinations are one of the best ways to put an end to the serious effects of certain diseases.

The shingles vaccines, Shingrix® and Zostavax®, are commonly used for persons 50 years and older. It is crucial to immunize against shingles because there are approximately 1 million cases in the US annually, and the lifetime risk of developing shingles is about 30%. According to the Centers for Disease Control and Prevention (CDC) website:

> Shingrix (recombinant zoster vaccine) [is] preferred over Zostavax (zoster vaccine live) for the prevention of herpes zoster (shingles) and related complications. CDC recommends two doses of Shingrix separated by 2 to 6 months for immunocompetent adults . . . Zostavax may still be used to prevent shingles in healthy adults 60 years and older. For example, you could use Zostavax if a person is allergic to Shingrix, prefers Zostavax, or requests immediate vaccination and Shingrix is unavailable.

Shingrix should not be administered to a person with a history of severe allergic reaction, such as anaphylaxis, to any component of a vaccine or after a previous dose of Shingrix or a Tdap, Td, DT, or DTaP vaccination.

Tdap (Adacel®, Boostrix®) is more commonly used in the retail setting and is given intramuscularly as a one-dose booster shot for adolescents at age 11 or 12, pregnant patients, and adults. Pregnant patients should be vaccinated during weeks 27 to 36 of gestation. According to the CDC website, in the first year after getting vaccinated, Tdap protects about seven out of 10 people who get it. There is a decrease in effectiveness in the following year. About three or four out of 10 people are fully protected four years after getting Tdap. There has been an increase in reported pertussis cases, so we must continue to vaccinate.

The hepatitis B virus (HPV) can be prevented with the hepatitis B vaccination (Engerix-B®, Recombivax HB®, or Heplisav-B®). Hepatitis B can cause a lifelong (chronic) infection that can lead to liver scarring (cirrhosis) and liver cancer. Most adults who get infected will recover fully. However, about 2% of adults will remain infectious and carry HPV for life. Per the CDC website, the following groups of people should get vaccinated against hepatitis B:

- Everyone zero through 18 years of age
- Anyone who wants to be protected from hepatitis B
- Sexually active people who are not in long-term, mutually monogamous relationships
- Men who have sex with men
- Anyone seeking evaluation or treatment for a sexually transmitted disease
- Health care or public safety workers who might be exposed to blood or body fluids
- Residents and staff of facilities for developmentally disabled people
- People with diabetes who are younger than 60 years old (people older than 60 should discuss the vaccine with their health care provider)

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National Pharmacy Compliance News

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The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

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- ♦ Dialysis and pre-dialysis patients
- ♦ People infected with human immunodeficiency virus
- ♦ People in close contact with someone who has a chronic hepatitis B infection
- ♦ Current or recent injection-drug users
- ♦ Travelers to areas of the world where hepatitis B is common (Asia, Africa, the Amazon basin in South America, the Pacific Islands, Eastern Europe, or the Middle East)
- ♦ People with chronic liver disease

There are two kinds of vaccines used for pneumonia that are commonly administered in the retail setting. These are the pneumococcal conjugate vaccine (PCV or PCV13) and pneumococcal polysaccharide vaccine (PPSV or PPSV23). CDC recommends PVC13, also known as Prevnar®, for all children younger than two years old, all adults 65 years or older, and people two through 64 years old with certain medical conditions. CDC recommends PPSV23, also known as Pneumovax®, for all adults 65 years or older, people two through 64 years old with certain medical conditions, and adults 19 through 64 years old who smoke cigarettes.

The influenza vaccine is recommended every year to persons age six months and older, including pregnant patients. Patients six months and older can receive an intramuscular 0.5 mL per dose of Afluria®, Fluarix Quad®, Flucelvax Quad®, FluLaval Quad®, Fluvirin®, or Fluzone Quad®. Only patients 65 years and older can receive the Fluzone® High-Dose intramuscular 0.5 mL vaccine. Every year in the US, millions of people are infected, hundreds of thousands are hospitalized, and up to 49,000 perish, according to CDC. Some people are at a higher risk of getting the flu. This includes people 65 years and older, people of any age with certain chronic medical conditions (such as diabetes, asthma, or heart disease), pregnant women, and young children. An annual flu vaccine is the first and best way to protect against the flu.

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