Target Audience: Pharmacists and Pharmacy Technicians

ACPE#: 0202-0000-18-022-L03-P/T

Activity Type: Knowledge-Based
Learning Objectives

At the completion of this knowledge-based activity, pharmacists and technicians will be able to:

1. Describe FDA activities during 2017 that affect pharmacy practice
2. Describe FDA’s direction & focus for 2018
3. State how changes in FDA regulations and policies affect the practice of pharmacy
Self-assessment questions

1) The FDA’s generic drug program saw the highest number of generic drug approvals and tentative approvals in 2017.
   a) True
   b) False

2) The FAERS Public Dashboard:
   a) Makes adverse event data accessible, interactive, and transparent
   b) Features only information that can establish causation
   c) Should help patients change their own medications
   d) Has no limitations.

3) The FDA Opioids Action Plan includes:
   a) Expanding use of advisory committees
   b) Strengthening post-marketing requirements
   c) Updating the REMS program for ER/LA opioids
   d) Developing warnings and safety information for IR opioid labeling
   e) All of the above
Mission

Promote and protect the public health

We protect the American people from unsafe or mislabeled food, drugs, and other medical products and to make sure consumers have access to accurate, science-based information about the products they need and rely on every day.

Center for Drug Evaluation and Research ensures that safe, effective and high quality drugs are available for U.S. consumers.
CDER’s Office of Compliance

Center for Drug Evaluation and Research

Office of Compliance

- Office of Drug Security, Integrity, & Response
- Office of Manufacturing Quality
- Office of Program & Regulatory Operations
- Office of Scientific Investigations
- Office of Unapproved Drugs and Labeling Compliance
CDER’s Office of Communications

Center for Drug Evaluation and Research

Office of Communications

Division of Online Communications
Division of Health Communications
Division of Drug Information
New Drug Approvals

Reflect Innovation

and

Enhanced Patient Care
### Notable Novel Drugs of 2017

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ALIQOPA</strong></td>
<td>Relapsed follicular lymphoma</td>
</tr>
<tr>
<td><strong>BAVENCIO</strong></td>
<td>Metastatic Merkel cell carcinoma</td>
</tr>
<tr>
<td><strong>BENZNIDAZOLE</strong></td>
<td>Chagas disease</td>
</tr>
<tr>
<td><strong>BESPONSA</strong></td>
<td>Relapsed or refractory B-cell precursor acute lymphoblastic leukemia</td>
</tr>
<tr>
<td><strong>CALQUENCE</strong></td>
<td>Mantle cell lymphoma</td>
</tr>
<tr>
<td><strong>EMFLAZA</strong></td>
<td><em>Duchenne Muscular Dystrophy</em></td>
</tr>
<tr>
<td><strong>GIAPREZA</strong></td>
<td>Hypotension in adults with distributive or vasodilatory shock</td>
</tr>
<tr>
<td><strong>IDHIFA</strong></td>
<td>Relapsed or refractory acute myeloid leukemia</td>
</tr>
<tr>
<td><strong>INGREZZA</strong></td>
<td>Tardive dyskinesia</td>
</tr>
<tr>
<td><strong>MEPSEVII</strong></td>
<td>Mucopolysaccharidosis type 7</td>
</tr>
<tr>
<td><strong>NERLYNX</strong></td>
<td>HER2-positive breast cancer</td>
</tr>
<tr>
<td><strong>PREVYMIS</strong></td>
<td>Cytomegalovirus</td>
</tr>
<tr>
<td><strong>RADICAVA</strong></td>
<td>Amyotrophic lateral sclerosis</td>
</tr>
<tr>
<td><strong>RYDAP</strong></td>
<td>Acute myeloid leukemia</td>
</tr>
<tr>
<td><strong>SILIQ</strong></td>
<td>Plaque psoriasis</td>
</tr>
<tr>
<td><strong>SYMPROIC</strong></td>
<td>Opioid-induced constipation</td>
</tr>
<tr>
<td><strong>TREMFIY</strong></td>
<td>Plaque psoriasis</td>
</tr>
<tr>
<td><strong>TRULANCE</strong></td>
<td>Chronic idiopathic constipation</td>
</tr>
<tr>
<td><strong>VERZENIO</strong></td>
<td>HR-positive; HER2-negative advanced or metastatic breast cancer</td>
</tr>
<tr>
<td><strong>VOSEVI</strong></td>
<td>Chronic hepatitis C virus</td>
</tr>
<tr>
<td><strong>XADAGO</strong></td>
<td><em>Parkinson’s disease</em></td>
</tr>
<tr>
<td><strong>XERMELO</strong></td>
<td>Carcinoid syndrome diarrhea</td>
</tr>
<tr>
<td><strong>XERMELO</strong></td>
<td>Carcinoid syndrome diarrhea</td>
</tr>
<tr>
<td><strong>XERMELO</strong></td>
<td>Carcinoid syndrome diarrhea</td>
</tr>
<tr>
<td><strong>ZEJULA</strong></td>
<td>Ovarian, fallopian tube, or primary peritoneal cancer</td>
</tr>
</tbody>
</table>
Impact on Public Health
Examples of notable novel First-in-Class approvals for 2017 include:

DUPIXENT (dupilumab)
Treats adults with moderate-to-severe eczema

OCREVUS (ocrelizumab)
Treats adults with relapsing forms of multiple sclerosis and primary progressive multiple sclerosis

15 of the 46 novel drugs were identified as first-in-class

33% First-in-Class Drugs
Impact on Public Health

Examples of notable novel Drugs for Rare Diseases approvals or 2017 include:

**BRINEURA (cerliponase alfa)**
Treats pediatric patients with a specific form of **Batten** disease

**HEMLIBRA (emicizumab)**
Treats patients with **hemophilia A** who have developed antibodies called Factor VIII inhibitors

18 of the 46 novel drugs were approved to treat rare or “orphan” diseases

39%
Innovation
Methods for expediting innovative novel drugs to market

Fast Track – Breakthrough – Priority Review – Accelerated Approval

One or more expedited development and review methods

61%

Fast Track 39%

Breakthrough 37%

Priority Review 61%

Accelerated Approval 13%

Generic Drug Approvals

Ensuring Safe, Effective, and Affordable Medicines
Generic Drugs

FDA Reauthorization Act: Generic Drug User Fee Amendments

FDA-approved generic drugs account for 89% of prescriptions dispensed in the United States

Use of generic drugs saved the U.S. health system approximately $1.67 trillion in the past ten years

Reference: https://blogs.fda.gov/fdavoice/index.php/2018/02/2017-was-another-record-setting-year-for-generic-drugs/
1st Generics are a Public Health Priority

### Generic Drug Approvals

N=80

<table>
<thead>
<tr>
<th>Generic Drug Approvals</th>
<th>N=80</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Generics</td>
<td>1</td>
</tr>
</tbody>
</table>

### Table 2. Significant First Generic Drug Approvals in 2017

<table>
<thead>
<tr>
<th>Generic Drug Name</th>
<th>Brand Name</th>
<th>Indications (Abbreviated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atomoxetine Capsules</td>
<td>Strattera</td>
<td>Treatment of attention deficit hyperactivity disorder</td>
</tr>
<tr>
<td>Emtricitabine and Tenofovir Disoproxil Fumarate Tablets</td>
<td>Truvada</td>
<td>Treatment of HIV and for pre-exposure prophylaxis</td>
</tr>
<tr>
<td>Ezetimibe and Simvastatin Tablets</td>
<td>Vytorin</td>
<td>Management of high cholesterol</td>
</tr>
<tr>
<td>Mesalamine Delayed-release Tablets</td>
<td>Asacol HD</td>
<td>Treatment of moderately active ulcerative colitis</td>
</tr>
<tr>
<td>Prasugrel Tablets</td>
<td>Effient</td>
<td>Blood thinner</td>
</tr>
<tr>
<td>Sevelamer Carbonate Tablets</td>
<td>Renvela</td>
<td>Control of serum phosphorus levels in adults with chronic kidney disease</td>
</tr>
</tbody>
</table>

Reference: [https://blogs.fda.gov/fdavoice/index.php/2018/02/2017-was-another-record-setting-year-for-generic-drugs/](https://blogs.fda.gov/fdavoice/index.php/2018/02/2017-was-another-record-setting-year-for-generic-drugs/)
HURRICANE RELIEF EFFORT

Provide recommendations on how to handle food and medical products that may have been impacted by the storms.

Work with industry to assess damage and impact to facilities.

Help avoid food and crop loss.

Coordinate with federal and local partners to identify solutions to prevent shortages of life saving therapies.

www.fda.gov
Joint Information Center (JIC)

Managed communications and crisis inquiries on behalf of FDA

- Hospitals
- Government Agencies
- Specialty medical centers
- Pharmacy and nursing associations
- Retailers
- Patients and Caregivers

www.fda.gov
Hurricane Maria

- Products affected include dextrose, saline, sterile water for injection, and amino acids
- Temporary import from Baxter facilities in Ireland, Australia, Mexico, and Canada and B. Braun in Germany
- Expedited review of applications for new suppliers
Current Drug Shortages

• Emergency syringes
  – Expiration dating extended
  – Temporary import of sodium bicarbonate injection
  – Expediting review of additional manufacturers
  – Fresenius Kabi returned their sodium bicarbonate injection in vials to market
  – Sodium glycerophosphate is being temporarily imported by Fresenius Kabi
Drug Shortages: New vs. Prevented

Source: Internal, unpublished data
Compliance and Enforcement Actions

- Industry/firm regulatory meeting
- Injunction/shut down
- Consent decree
- Import alerts
- Seizures
- Warning letters
- Untitled letters
- Disqualifications
- Criminal indictments/convictions
- More...

- Adulterated
- Misbranded
- Unapproved
- Health Fraud
- Data Integrity
- CGMP violations
- GCP violations
- Compounding
- More......
Significant Warning Letters

- Targeted firms promoting selective androgen receptor modulators in body-building products
- Took action against 14 companies for selling illegal cancer treatments
- Warned companies marketing unproven products, derived from marijuana, that claim to treat or cure cancer
- 32 of 76 warning letters for CGMP non-compliance included data integrity violations
Compliance & Enforcement

Quality Safety Initiatives

Unapproved Drugs

Data Integrity Assurance

Supply Chain Integrity

Compounding

Priorities
New Proposed Risk-Based Enforcement Approach for Homeopathic Drug Products

Focus enforcement authorities on the following kinds of products:
• with reported safety concerns;
• that contain or claim to contain ingredients associated with potentially significant safety concerns;
• for routes of administration other than oral and topical;
• intended to be used for the prevention or treatment of serious and/or life-threatening diseases and conditions;
• for vulnerable populations; and
• that do not meet standards of quality, strength or purity as required under the law.
Drug Recalls

Source: Internal, unpublished data
Internet Enforcement: Operation Pangea X

• Global actions and results
  – launch of 1,058 investigations;
  – 3,584 websites were taken offline;
  – suspension of more than 3,000 online adverts for illicit pharmaceuticals; and
  – 25MIL illicit and counterfeit medicines and medical devices were seized worldwide (worth over 51MIL)

• U.S. actions and results
  – seized 100 website domain names
  – 13 warning letters to operators of 401 websites illegally selling products
FDA’s Adverse Event Reporting System (FAERS) Postmarketing Reports

How Drug Postmarketing Reports Get to FDA
FAERS Public Dashboard

• Released September 28, 2017
• Makes adverse event data accessible, interactive, and transparent
• However, many key points to consider when viewing FAERS data
  – Data quality may be poor – duplicate and incomplete reports
  – Causation is not established – only reflects reporter’s observations and opinions
  – Information is not verified
  – Cannot establish rate of occurrence of AE
• Patients should NOT stop or change their medications based on FAERS
• FAERS data by themselves are not an indicator that a drug is causing a reported adverse event
This page displays the number of adverse event reports received by FDA for drugs and therapeutic biologic products by the following Report Types:

- Direct Reports are voluntarily submitted directly to FDA through the MedWatch program by consumers and healthcare professionals.
- Mandatory Reports are submitted by manufacturers and are categorized as:
  1. Expedited reports that contain at least one adverse event that is not currently described in the product labeling and for which the patient outcome is serious, or
  2. Non-expedited reports that do not meet the criteria for expedited reports, including cases that are reported as Serious and expected, Non-serious and unexpected and Non-serious and expected.
CDER Alerts, Statements, and Medication Errors
FDA Drug Safety Communication: FDA warns that gadolinium-based contrast agents (GBCAs) are retained in the body; requires new class warnings

FDA Drug Safety Communication: FDA review finds no significant increase in risk of serious asthma outcomes with long-acting beta agonists (LABAs) used in combination with inhaled corticosteroids (ICS)

[12-19-2017] The U.S. Food and Drug Administration (FDA) is requiring several actions to inform patients and healthcare professionals about the potential long-term risks of gadolinium-based contrast agents (GBCAs). Gadolinium retention may occur, especially in patients with normal kidney function, and with any potential risks.

However, after additional review, the FDA is requiring several actions to inform patients and healthcare professionals about the potential long-term risks of gadolinium-based contrast agents (GBCAs). Gadolinium retention may occur, especially in patients with normal kidney function, and with any potential risks.

FDA requires post-market safety trials for Long-Acting Beta-Agonists (LABAs) issued on April 15, 2011.

[12-20-2017] The U.S. Food and Drug Administration (FDA) review of four large clinical safety trials shows that treating asthma with long-acting beta agonists (LABAs) in combination with inhaled corticosteroids (ICS) does not result in significantly more serious asthma-related side effects than treatment with ICS alone. In 2011, we required the drug companies that market LABAs to conduct these trials to evaluate the safety of LABAs when used in combination with ICS, and we reviewed the results of these recently completed trials.

Based on our review, the Boxed Warning, our most prominent warning, about asthma-related death has been removed from the drug labels of medicines that contain both an ICS and LABA. A description of the four trials is now also included in the Warnings and Precautions section of the drug labels. These trials showed that LABAs, when used with ICS, did not significantly increase the risk of asthma-related hospitalizations, the need to insert a breathing tube known as intubation, or asthma-related deaths, compared to ICS alone.
Real World Data and Evidence

Real World Data

• Data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials

21st Century Cures Act

• Additional focus on the use of these types of data to augment regulatory decision making

How it Helps

• Support new indications for existing drugs
• Demonstrate how a drug works in a population that was not studied
• Demonstrate how a drug works relative to another drug that was not included in the study
2017 Enhancements

- Improved search/filter capability
- REMS specific webpage updates
- REMS program reports

Program Page Contents

- Goals
- Summary
- REMS Materials
- Update History
Immediate Release
Opioid Analgesic REMS

Why REMS?

- 216 million prescriptions for opioids analgesics in the US in 2016
- 91% of opioid analgesics prescriptions in 2016 were IR
- IR opioid analgesics continue to be associated with abuse

Possible REMS Components:

- Medication Guides
- Training: Safe prescribing practices
- Training: Consideration of non-opioid alternatives

References:

https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm305245.htm
Clozapine REMS

Important considerations for pharmacists:
- Pharmacies must be certified through the Clozapine REMS program
- Certification must be renewed every 2 years
- Any questions from patients should be directed to providers
- FDA continues to work with the clozapine manufacturers for full implementation

Which resources to use first?

Pharmacist or provider questions: Clozapine REMS website (www.ClozapineREMS.com)

If your questions are not answered or need technical support: Contact the Clozapine REMS Call Center at 844-267-8678

Further questions: FDA Division of Drug Information
Email: druginfo@fda.hhs.gov
Phone: 855-543-3784

References:
https://www.clozapinerems.com/CpmgClozapineUI/home.u
https://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm497790.htm
Compounding Provisions of Federal Law

Section 503A Enacted 1997

Conditions under which drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, can qualify for exemptions from certain requirements of the FD&C Act:

(1) New drug approval requirements (section 505),
(2) Labeling with adequate directions for use (section 502(f)(1)), and
(3) Current good manufacturing practice (CGMP) requirements (section 501(a)(2)(B))

Section 503B Enacted 2013

Conditions under which drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility can qualify for exemptions from certain requirements of the FD&C Act:

(1) New drug approval requirements (section 505),
(2) Labeling with adequate directions for use (section 502(f)(1)), and
(3) Drug supply chain security requirements (section 582).

Outsourcing facilities remain subject to CGMP requirements.
Compounding Final Guidances and Regulations Issued

• Final Guidances
  – Compounded drugs that are essentially copies
  – Mixing, diluting, and repackaging biological products
  – Prescription requirement under section 503A
  – Repackaging drugs
  – Interim policies on compounding from bulk drug substances
  – 503B Product reporting
  – 503B Adverse event reporting
  – 503B Registration
  – Compounding under section 503A
  – Entities considering whether to register under section 503B
  – Fees for outsourcing facilities

• Final Rules
  – Modifications to the withdrawn or removed list under sections 503A and 503B
Compounding Policy Documents Under Development

• Draft or Revised Draft Guidances
  – CGMP Interim Guidance for Outsourcing Facilities
  – Compounding and repackaging radiopharmaceuticals
  – Facility definition under section 503B
  – Hospital and health system compounding
  – Insanitary conditions

• Proposed Rules
  – Bulk drug substances list under section 503A
  – Modifications to the withdrawn or removed list under sections 503A and 503B

• Draft memorandum of understanding
Compounding Risk Alerts

The information provided on this webpage is intended to alert health care professionals of adverse event reports related to compounded drugs. Providing this information to health care professionals should further FDA's goal of protecting patients from unsafe, ineffective, and poor quality compounded drugs.

Please contact compounding@fda.hhs.gov if you have any questions regarding the information provided in a compounding risk alert below:

- FDA investigates two adverse events associated with United Pharmacy's compounded glutamine, arginine, and carnitine product for injection
- A case of hemorrhagic occlusive retinal vasculitis (HORV) following intraocular injections of a compounded triamcinolone, moxifloxacin, and vancomycin formulation
- FDA alerts health care professionals of adverse events associated with Guardian’s compounded triamcinolone and moxifloxacin product for intravitreal injection

Reference:
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm570188.htm
Compounding: Inspections, Oversight Actions, and Recalls

Source: Internal, unpublished data
The DSCSA Path

- **Product Tracing & Verification**
  - 2014-2015

- **Product Identification (Serialization)**
  - 2017-2018

- **Product Verification (down to package level)**
  - 2019+

- **Electronic, Interoperable System**
  - (product tracing down to package level)
  - 2023

- **Licensure standards for 3PLs and wholesale distributors**

www.fda.gov
“Dispenser” Requirements

### Product Tracing
- Exchange lot level transaction documentation

### Product Verification
- Quarantine and investigate
- Respond if receive notification of illegitimate product
- Notify FDA if illegitimate product found
- Recordkeeping

### Authorized Trading Partner
- Buy only from manufacturers/repackagers or wholesale distributors with valid registration or licensure

[www.fda.gov](http://www.fda.gov)
Definitions

**Suspect Product** – reason to believe that a product is potentially:

- counterfeit, diverted, stolen;
- subject of fraudulent transaction; or
- intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans

**Illegitimate Product** – *credible evidence that the product is actually* any of the above
PROTECT YOUR PATIENTS
Know your responsibilities under the Drug Supply Chain Security Act

The Drug Supply Chain Security Act (DSCSA) includes requirements that pharmacies must follow to protect patients from receiving harmful drugs, such as counterfeit or other illegitimate drugs.

The DSCSA was enacted in 2013 to further secure our nation’s drug supply. It creates a tighter, closed prescription drug distribution system to prevent harmful drugs from entering the supply chain, detect harmful drugs if they do enter the supply chain, and enable rapid response when such drugs are found.

By law, pharmacies are required to:

1. Confirm the entities you do business with are licensed or registered
   To help determine whether trading partners who you do business with (manufacturing, repackers, wholesale distributors, third-party logistics providers, and pharmacies) are licensed or registered:

2. Receive, store, and provide product tracing documentation
   The law requires drugs to be traced as they move through the supply chain, and pharmacies must:

3. Investigate and properly handle suspect and illegitimate drugs
   Pharmacies must have a process to investigate and handle suspect and illegitimate prescription drugs, which includes drugs that may be or have evidence that it is counterfeit, diverted, stolen, intentionally adulterated, or unfit for distribution, including steps to:
Notify FDA of Illegitimate Products

- Required to:
  - Notify FDA of illegitimate product within 24 hours of determination (must also notify other trading partners).
  - Consult with FDA that a notification is no longer necessary to request termination of notification.

- Who must notify?:
  - Dispensers (primarily pharmacies)
  - Manufacturers
  - Repackagers
  - Wholesale distributors

Boston -- The former supervisory pharmacist of New England Compounding Center (NECC) was sentenced today in connection with the 2012 nationwide fungal meningitis outbreak that killed 64 and caused infections in 793 patients.

Glenn Chin, 49, of Canton, Mass., was sentenced by U.S. District Court Judge Richard G. Stearns to eight years in prison, two years of supervised release, and forfeiture and restitution in an amount to be determined later. In October 2017, Chin was convicted by a federal jury in Boston of 77 counts, including racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead.

“Mr. Chin was a pharmacist, but again and again he acted with complete disregard for the health and safety of patients,” said United States Attorney Andrew E. Lelling. “Mr. Chin will now be held responsible for producing contaminated drugs that killed dozens and grievously harmed over 750 people across the country. No patient should suffer because the hand of a medical profession has failed its patients, and we will continue to work with our law enforcement partners to ensure that those who break the law are held accountable.”
Innovation in Drug Development

- FDA approved the first drug in the U.S. with a digital ingestion tracking system
- FDA approved the first once-monthly injectable buprenorphine product
FDA pioneered PFDD meetings to address the need for direct patient input collection.

Bridge information from meetings into tools able to collect key information about patient’s experience.

Explicitly consider patient disease experience in early stages of drug development.

Translate patient experiences into a validated measurement set to be used in clinical studies.
FDA launched a new external stakeholder meeting request system that will help non-industry groups meet with CDER staff to discuss drug development and safety issues more easily.
Biosimilars

- Developing interchangeable biological products
  - As of December 2017, 9 approved biosimilars
  - BsUFA reauthorized through September 2022

- Nonproprietary Naming of Biological Products
  - Proper name of biological product will include core name and 4-letter lowercase suffix to distinguish
  - Suffix should be composed of four lowercase letters with at least three distinct letters and should be unique, devoid of meaning, nonproprietary, free of legal barriers

- Training:
  - CDERLearn course launched in February 2016 (with 1.5 hours CE)
  - Patient and Prescriber Outreach Materials available

The Opioid Crisis: An FDA Priority

Take immediate steps to reduce the scope of the epidemic of opioid addiction

• **May 2017**: Established an FDA Opioid Policy Steering Committee (OPSC)

• **September 2017**: Solicit public input on how FDA authorities can or should be used to address the crisis docket recently closed and plans are to review over 900 comments received.

• **January 2018**: FDA hosted a public hearing to bring stakeholders together to discuss new approaches. Docket comment period open until March 16, 2018.
The Opioid Crisis: FDA’s Priorities & Strategies

1. Decreasing Exposure & Prevent New Addiction
   - Appropriate Dose/Duration Labeling
   - Appropriate Packaging, Storage, and Disposal
   - Health Care Provider Education

2. Supporting the Treatment of Those With Opioid Use Disorder
   - Naloxone
   - Medication Assisted Treatment (MAT)

3. Fostering the Development of Novel Pain Treatment Therapies
   - Partnerships & Meetings
   - Abuse Deterrent Formulations (ADFs)
   - Pain Treatment Alternatives

4. Improving Enforcement & Assessing Benefit-Risk
   - Improving Enforcement
   - Assessing Benefit-Risk
Implementing FDA’s New Comprehensive Plan for Tobacco and Nicotine Regulation

✓ Announced July 2017 as a multi-year roadmap to reduce tobacco-related disease and death

✓ New approach places nicotine and the issue of addiction at the center of regulatory efforts

✓ Agency to pursue lowering nicotine in cigarettes to non-addictive levels and create more predictability in tobacco regulation

Reference: https://www.fda.gov/TobaccoProducts/NewsEvents/ucm568425.htm
CTP: Every Try Counts

✓ December 2017: FDA launched new adult smoking cessation campaign using messages of support
✓ Ads are displayed in 35 counties across the US in gas stations, convenience stores, and retailer locations

Reference: https://www.fda.gov/TobaccoProducts/PublicHealthEducation/PublicEducationCampaigns/EveryTryCountsCampaign/ucm588395.htm
Center for Devices and Radiologic Health Update

- Companion Diagnostics
- Genetic Test Advances
- Glucose Monitoring Devices
What’s Next
CDER 2018 Priorities

- Implement the opioid crisis action plan
- Further progress in regulating compounding
- New drug regulatory program modernization
- OTC monograph reform
- Implement CURES legislation
- Carry out reauthorized fee-based approval programs
Resources for Pharmacists

Learn More: Stop By Our Exhibit!

Exhibit 117
Resources for Pharmacists

• Listservs
  • Drug Safety Communications (DSC)
  • Drug Information

• Apps
  • Drug Shortages, Orange Book, NDC Apps
Resources for Pharmacists

**Drug Info Rounds Videos - on the FDA website and YouTube**

https://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm

**Drug Safety Podcasts – FDA website and iTunes**


Reference: https://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm
Pharmacists at FDA/CDER

USAJOBS

Pharmacist - Direct Hire
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

https://www.usajobs.gov/
Self-assessment questions

1) The FDA’s generic drug program saw the highest number of generic drug approvals and tentative approvals in 2017.
   a) True
   b) False

2) The FAERS Public Dashboard:
   a) Makes adverse event data accessible, interactive, and transparent
   b) Features only information that can establish causation
   c) Should help patients change their own medications
   d) Has no limitations

3) The FDA Opioids Action Plan includes:
   a) Expanded use of advisory committees
   b) Strengthened post-marketing requirements
   c) Updating the REMS program for ER/LA opioids
   d) Develop warnings and safety information for IR opioid labeling
   e) All of the above