



USA Update

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Postmarket Safety Surveillance Lead
US Food and Drug Administration

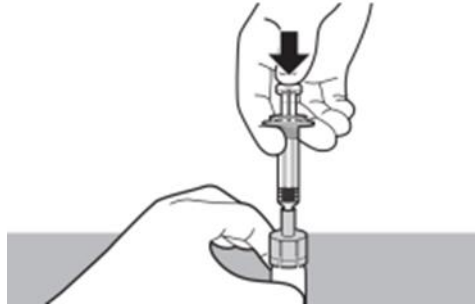
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President, Institute for Safe Medication Practices

FDA Key Updates for November 2022

- Finalized guidance for industry, *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Error*
- Funding study related to the use of tall man lettering, *Assessing the Effectiveness of Text Enhancements to Prevent Drug Name Confusion Errors*
- Research ongoing on the use of AI to standardize reviews of container labels, carton labeling, and Prescribing Information to ensure consistency across different products

Two Components Vaccines to Single Component



Rotavirus Vaccine



Meningococcal Vaccine

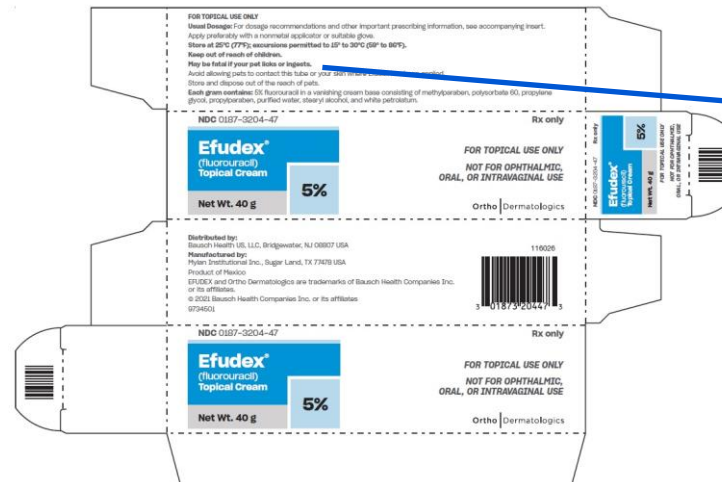


August 05, 2022

IMPORTANT PRESCRIBING AND DISPENSING INFORMATION

Subject: Minimizing wrong dose medication errors and revised Patients, Parents and Caregivers Fact Sheet for PAXLOVID (nirmatrelvir tablets; ritonavir tablets).

Dear Healthcare Provider,



May be fatal if your pet licks or ingests

Criminalization of Human Error and a Guilty Verdict: A Tragedy of Justice that Threatens Patient Safety

— Webinar:

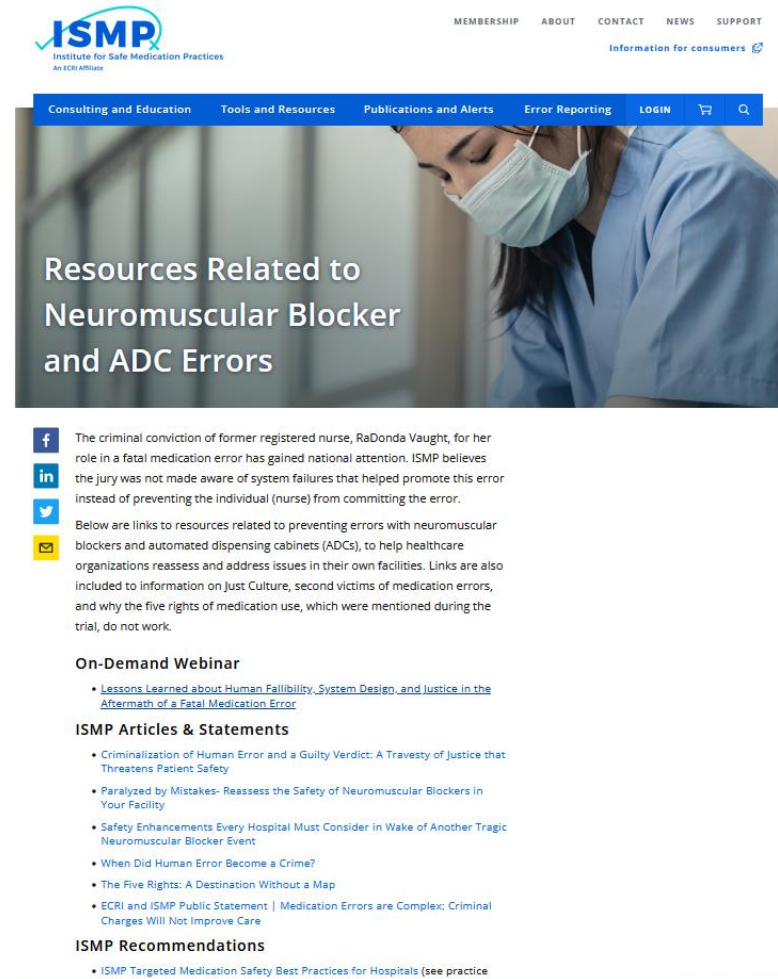
<https://www.ismp.org/events/lessons-learned-about-human-fallibility-system-design-and-justice-aftermath-fatal-medication>

— Resource Page:

<https://www.ismp.org/resources-related-neuromuscular-blocker-and-adc-errors>

— Newsletter Article:

<https://www.ismp.org/resources/criminalization-human-error-and-guilty-verdict-tragedy-justice-threatens-patient-safety>



The screenshot shows the ISMP website interface. At the top, there is a navigation bar with links for MEMBERSHIP, ABOUT, CONTACT, NEWS, and SUPPORT. Below this is a secondary navigation bar with links for Consulting and Education, Tools and Resources, Publications and Alerts, Error Reporting, and LOGIN. The main content area features a large image of a healthcare professional wearing a mask, with the text "Resources Related to Neuromuscular Blocker and ADC Errors" overlaid. Below the image, there are social media icons for Facebook, LinkedIn, and Twitter, followed by a paragraph of text. The text discusses the criminal conviction of a former registered nurse and provides links to resources related to preventing errors with neuromuscular blockers and automated dispensing cabinets (ADCs). There is also a section for "On-Demand Webinar" and "ISMP Articles & Statements" with a list of links. At the bottom, there is a section for "ISMP Recommendations" with a link to "ISMP Targeted Medication Safety Best Practices for Hospitals".

ConsumerMedSafety.org – ISMP Consumer Website

<https://new.consumermedsafety.org/>

The screenshot shows the homepage of ConsumerMedSafety.org. At the top left is the logo for ConsumerMedSafety.org. To its right is a navigation menu with links for Medication Safety Tips, Featured Resources, About Us, and Reporting Medication Errors. Further right is the ISMP logo with the text "Brought to you by ISMP Institute for Safe Medication Practices". Below the navigation is a search bar with the text "Find the information you need to protect yourself and your loved ones from medication errors." and a "SEARCH" button. Below the search bar is a button that says "Or browse all safety articles". To the right of the search bar is a call to action: "If you or a loved one have experienced a mistake with a medication or have a safety concern to share with others, we would like to hear from you." with a "Report a Medication Error" button. Below this is a large banner for an "FDA Alert" with the headline "Beware of vaping products with unproven health claims" and a "Learn More" button. The banner features an image of various colored e-cigarettes. Below the banner is a section titled "About Us" with the text "We help every day folks take medication safely" and "ConsumerMedSafety.org is provided to you by the Institute for Safe Medication Practices (ISMP). This unique website is designed to help you, the consumer, avoid mistakes when taking medicines." To the right of this text is an illustration of a diverse group of people, including a doctor, a patient, and a caregiver.

Targeted Medication Safety Best Practices - Updated for 2022-23

<https://www.ismp.org/guidelines/best-practices-hospitals>

- Initially introduced in 2014 with six Best Practices, the Targeted Medication Safety Best Practices for Hospitals are updated every 2 years.
- The 2022-2023 list now comprises 19 best practices
 - 3 new best practices
 - 4 archived
 - 1 combined



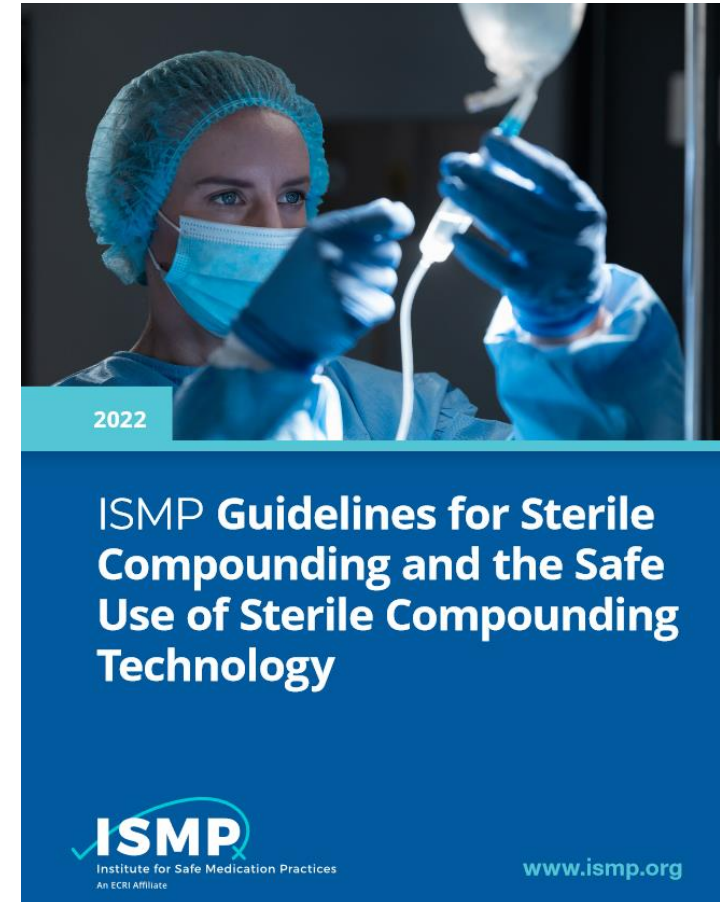
2022-2023 New ISMP Best Practices

- Safeguard against errors with oxytocin use
- Barcode verification to care areas beyond inpatient care units
- Layer error-prevention strategies throughout the medication use process to improve safety with high-alert medications

Sterile Compounding Guidelines

<https://www.ismp.org/resources/guidelines-sterile-compounding-and-safe-use-sterile-compounding-technology>

- Released May 4, 2022
- Address safe practices related to use of
 - Automated compounding devices
 - IV workflow management systems (IVWFS)
 - Robotic compounding automation
- For each type of technology, address
 - Essential attributes
 - Safe pharmacy processes
 - Safety gaps & associated best practices
- Recommend best practices when technology is not available



Guidelines for Safe Medication Use in Perioperative and Procedural Settings

<https://www.ismp.org/resources/guidelines-safe-medication-use-perioperative-and-procedural-settings>

- Released August 10, 2022
- Developed to support hospitals, ambulatory surgery centers, and other procedural locations in addressing identified national gaps in perioperative and procedural medication safety
- New guidelines:
 - Address best practice associated with labeling of medications across all phases of perioperative and procedural care
 - Challenge common practices that limit the protections offered by proven safety technologies, including smart infusion pumps
 - Support use of barcode-scanning for real-time drug identification and electronic record documentation throughout perioperative and procedural care



**ISMP Guidelines for
Safe Medication Use
in Perioperative and
Procedural Settings**

ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

www.ismp.org

Specialty Pharmacy Medication Safety Membership

— Basic

- Specialty Pharmacy Resource page
 - Toolkits on website

— Plus

- Include all offerings in Basic Membership
- Additional resources
 - ISMP Community/Specialty Pharmacy Newsletter
 - Bi-monthly Specialty Pharmacy user group meeting
- Proactive Risk Assessment Tool

— Premium

- Include all offerings in Advanced Membership
- Risk assessment of new specialty medications as they become available on market



Questions?
