



SHORTAGES GALORE

HOW THEY ARE AFFECTING OUR SURGERY CENTERS AND WHAT WE CAN DO ABOUT IT.

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ABOUT US

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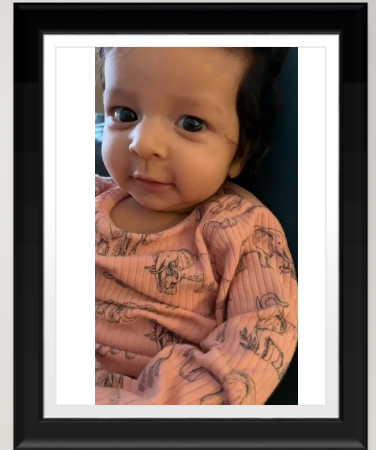
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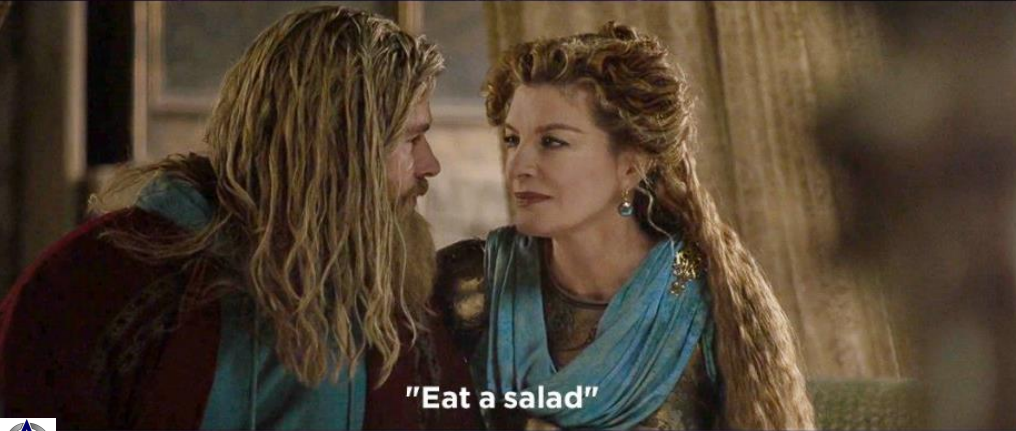
THANK YOU FOR LETTING ME SPEAK AGAIN!

The last time I spoke...

FIRST MESSAGE WAS FROM MY SISTER-IN-LAW AND NIECE



Even when the fate of the universe is at stake, moms will be moms.



"Eat a salad"



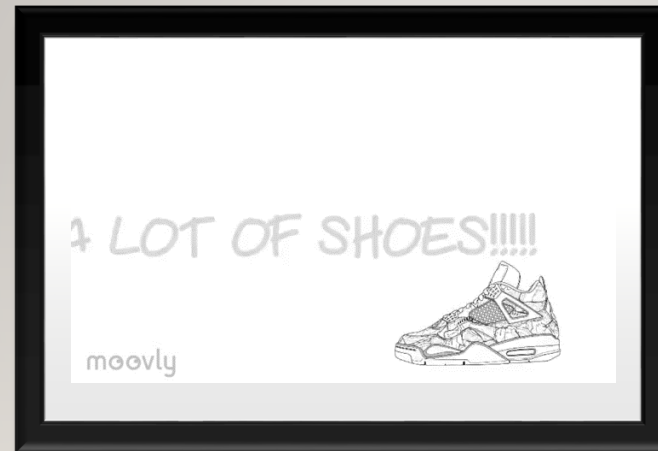
YOU LOOK LIKE MELTED ICE CREAM



FDA SHORTAGE

Food and Drug Administration Responsibility/Definition:

Drug Shortages can occur for many reasons. Manufacturers provide FDA most drug shortage information, and the agency works closely with them to prevent or reduce the impact of shortages.



WHAT IS SUPPLY CHAIN?



REASONS FOR BREAKS IN THE SUPPLY CHAIN

- Quality/manufacturing issues
- Delays in receiving raw materials and components from suppliers.
- Discontinuations
- Natural Disasters
- Limited Production lines
- Covid shutdowns
- Increase use of life saving measures

WHO WANTS TO MAKE JEFF BEZOS EVEN RICHER?

Whoever 1st texts the correct answer to

**908 – 334 -
5437**



WHICH MEDICATION IS **NOT** IN SHORTAGE? TEXT (908) 334 - 5437

- A. Fentanyl
- B. Versed
- C. Omnipaque
- D. Sterile water for Injection
- E. Tylenol

TEXT (908) 334 - 5437

FDA SHORTAGES WEBSITE AND ALERTS

- Searchable database with easy access to information about drugs in shortage, such as product availability, supply, and estimated duration of shortage.
- The database includes information about current drugs in shortage, resolved shortages, discontinuations of specific drug products, corresponding therapeutic categories, resource information, and relevant links.
- The FDA sends out alerts for medications which are in shortage which links to this website.
- However this can be delayed...

OMNIPAQUE SHORTAGE

- Iodinated low osmolality contrast media used for CT and X-ray.
- Letter to customers sent out on 4/19!
- The full effects of the shortages did not start being felt until early May.
- Mid-May mitigation strategies started being released and picked up by the media.
- FDA reported the shortage on May 25th



MITIGATION STRATEGIES

- Supplies will be cut by 20% until normal production resumes (ETA ~ late June).
- The contents of intravenous contrast media should only be transferred to single-dose containers or syringes in the pharmacy under a laminar flow hood or other suitable ISO Class 5 environment according to USP <797>.
- Use alternatives iodixanol (Visipaque), iopamidol (Isovue), iopromide (Ultravist), and **ioversol (Optiray)**.



WHY CAN'T I USE THE OMNIPAQUE FOR MULTIPLE PATIENTS?

- Omnipaque is a single dose vial.
- Invasive MRSA associated with pain ASC and ortho ASC due to re-use of SDV. (7/12)
- Isovue was used as a MDV in a outpatient pain clinic resulting 3 hospitalizations and 1 possible death out of 26 patients.
- The inappropriate re-use of a SDV of Bupivacaine resulted in 7 joint infections in a 3 day span.

FDA EXTENSIONS

- The FDA has an extended use database
- The database is searchable by medication, lot, and expiration dates
- FDA is not requiring or recommending that the identified lot numbers in the table be relabeled with their new use dates. However, if a replacement product becomes available during the extension period, then the agency expects the lots in these tables will be replaced and properly disposed of as soon as possible.

THE PROVIDER
DO YOU MULTI-DOSE?

A SINGLE-DOSE VIAL (SDV) is approved for use on a **SINGLE** patient for a **SINGLE** procedure or injection.

SDVs typically lack an antimicrobial preservative. Do not save leftover medication from these vials. Harmful bacteria can grow and infect a patient.

DISCARD after every use!

SIZE DOES NOT MATTER!

SDVs and MDVs can come in any shape and size. **Do not assume** that a vial is an SDV or MDV based on size or volume of medication. **ALWAYS check the label!**

A MULTIPLE-DOSE VIAL (MDV) is recognized by its FDA-approved label. Although MDVs can be used for more than one patient when aseptic technique is followed, **ideally even MDVs are used for only one patient.**

MDVs typically contain an **antimicrobial preservative** to help limit the growth of bacteria. Preservatives have no effect on bloodborne viruses (i.e. hepatitis B, hepatitis C, HIV).

Discard MDVs when the beyond-use date has been reached, when doses are drawn in a patient treatment area, or any time the sterility of the vial is in question!

FDA's Reporting Safe Practices for Medical Injections:
www.usanonline.com/pain/pain-prag/
centerforhealthcareprofessional.org/

ONEANDONLYCANPAIN.ORG



BUT WHAT ABOUT THE INSPECTORS?



FDA EXTENSIONS RECOMMENDATIONS

When people ask questions, we tend to get nervous

- We recommend going above and beyond – in terms of documentation.
- Print page from the FDA website (leave with in your medication binder, code cart list)
- Label with the new expiration date
- Document suppliers, dates, and responses. Make sure the Medical Director, and administration are aware.

WHAT IF IT IS NOT ON THE DATABASE

- The FDA requires all outdated prescription drugs to be quarantined and physically separated from other prescription drugs until they are destroyed or returned to the supplier.
- “Surgery centers might keep expired medication in the anesthesia cart because they can’t get a new supply, but this is against regulations.”, AAAHC Surveyor.
- Document, Document, Document...
- Make sure administration and medical director are aware and it is optimally included in medical board meeting minutes.



FORM DEVELOPMENT

- Working on a developing a sample form to assist with documentation.
- Sample only but will hopefully make it easier to document.



HOW DO WE SOLVE THIS PROBLEM?

- Use other wholesalers and pharmacies
- Talk to other centers to get extra supplies
- Document, Document, Document
- Sign up for our free shortages/recalls newsletter outside

REFERENCES

- <https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages#table>
- <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6127a1.htm>
- <https://www.ashp.org/drug-shortages/shortage-resources/considerations-for-imaging-contrast-shortage-management?loginreturnUrl=SSOCheckOnly#>
- <https://www.ismp.org/resources/inappropriate-use-pharmacy-bulk-packages-iv-contrast-media-increases-risk-infections>
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- <https://www.reliasmedia.com/articles/142659-peek-behind-the-curtain-into-compliance-problem-areas>

