



Drugs and Due Process

Catherine Brown, PharmD and Melanie MacDonald, JD



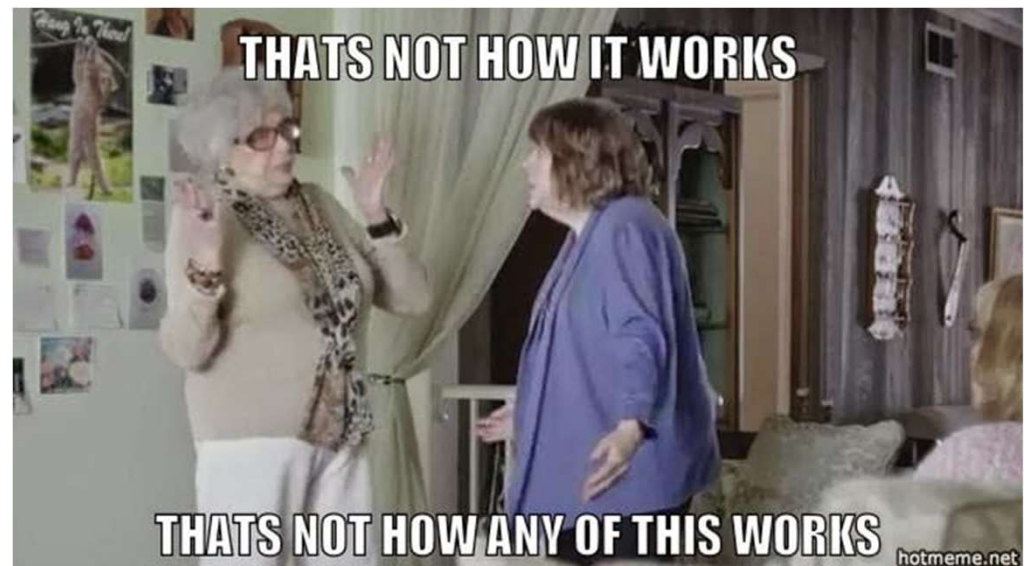
DRUGS

Disclaimers

- Catherine Brown is a licensed pharmacist, not a medical doctor, and she does not have a provider-patient relationship with anyone viewing this presentation.
- The information provided in this presentation about medications is for educational and entertainment purposes only and does not substitute for professional medical advice.
- Consult a medical professional if you're seeking medical advice, diagnoses, or treatment.
- Catherine Brown is not liable for risks or issues associated with using, acting upon, or writing about the information provided in this presentation.

Why it's important to get it right (Drugs AND Law!)

- You don't want to lose credibility with knowledgeable readers.
- You don't want to spread misinformation to uninformed readers.
- You don't want distracting factual errors that bump the reader out of your story.
- You don't want to break your plot because a reader knows "it wouldn't work that way in real life."
- You don't want excoriating reviews that turn off other readers.
- You don't want to lose repeat sales on future books.



ERRORS AND TROPES TO AVOID

THE SUBTLE, THE GLARING, AND THE
NOTORIOUS

Caveats

- The following advice applies mostly to real world stories.
 - Not fantasy with magic potions.
 - Not superhero universes where characters have superpowers and requiring reasonable suspension of disbelief.
 - Not science fiction with advanced tech and requiring reasonable suspension of disbelief.
- Some of the following scenarios that are advised against in general MAY WORK if the story is researched and set up well enough to support the choice.

DRUGS DON'T WORK THIS WAY

Superhero universes aside, drugs or vaccines (or radiation) can't change DNA to make a character morph into something else.

Cyanide pills won't eat your jaw away. I am looking at you, Skyfall.

Medications that make people smarter or turn them into geniuses don't exist.

Unless you're doing this on purpose for effect, booze is a poor painkiller for sewing up a wound. An actual anesthetic is a better choice.

Opiates / Narcotics constrict pupils – not dilate them. Withdrawal can make them dilate. So can other drugs.

Antibiotics will NOT cure a viral infection.

Made up drugs need to work in a way that makes sense. Side effects can't be bizarre. They should mimic something realistic.

When a character slips a drug in the drink to poison or sedate – do research for the right choice – some might not dissolve completely, and some would have a bitter or strange taste.

DRUGS DON'T WORK THAT FAST

Cyanide pills don't kill in seconds. Gas would. Pills would take several minutes.

Tranquilizer darts can take several minutes to work.

Collapsed diabetics won't recover in seconds from low OR high blood sugar. 15 minutes is more reasonable for low blood sugar.

Antidote for poisons don't work instantly. How long will vary, but a patient needs recovery time depending on the damage done.

Vaccines can't protect in seconds. It generally takes 2 weeks.

Anesthetics don't sedate instantly. Even the fastest ones can take 30-60 seconds.

Symptoms of poisoning also don't always appear immediately, depending on the agent.

THE CHARACTERS DID IT WRONG

Research your drug doses. Most are not measured in cc's or units! Units are uncommon (insulin, heparin, and IV penicillin come to mind) and cc's are outdated. Most meds are dosed in mg or mcg.

Using a tourniquet before giving an intramuscular shot is wrong. They are only needed to make veins prominent and that's an IV shot.

Don't have the bad guy inject a sedative into the neck. A 90-degree angle stab won't find a vein.

Surgical procedures with no anesthesia or analgesia is incorrect – and inhumane.

Giving a collapsed diabetic insulin instead of checking the blood sugar is unsafe. More collapses are from low blood sugar than high blood sugar.

Don't inject drugs directly into the heart through the chest wall. No one does it this way. I'm talking to you, Pulp Fiction. Use the veins or a muscle.

YOU'VE JUST KILLED THEM

Booze is a poor antiseptic for sewing up a wound. It damages tissue and many contain sugars that could promote infection.

Using epinephrine to treat an opiate / narcotic overdose doesn't work. USE naloxone (NARCAN)!

Taking too many Vicodin or mixing with alcohol will damage the liver, because it contains acetaminophen. I'm looking at you, Dr. House.

Giving a collapsed diabetic insulin to treat low blood sugar will make it worse and may kill them. Give a carbohydrate source.

You don't shock a patient out of asystole (a flat line). Use epinephrine and vasopressin. You shock them out of ventricular fibrillation. That's why they call it a defibrillator.

Random antibiotics won't work for random infections, so don't pick a name out of the air. Antibiotics are carefully chosen for the suspected or known infecting bacteria.

Mixing Valium or Ativan with alcohol is dangerous.

Using a paralytic without sedation/ anesthesia or ventilatory support will suffocate a patient.

NOW THAT'S ILLEGAL! OR AT LEAST UNETHICAL.

A character diverting a drug in a modern hospital by pulling it out of an unlocked drawer or cabinet when no one's looking won't happen with some very specific exceptions. Drugs aren't stored that way in real hospitals and clinics. They are locked up, so the diversion method would take that into account.

Doctors writing prescriptions for self or family is not typically illegal but is frowned upon. It says something about a character who does this. This was more common in the past.

Doctors giving a patient a placebo outside of a clinical trial is not illegal typically, but it can be unethical and is usually not done.

Health Care Providers with a convenient stash of prescription drugs in their home, car, briefcase, etc. in today's world are breaking the law.

Characters who aren't doctors, pharmacists, pharmacy techs, or nurses in a hospital won't have legal access to hospital drugs. The explanation would need to be believable.

THAT'S JUST RIDICULOUS.

Meth aside, unless the character is a chemist, like in *Breaking Bad*, most won't know how to make the average "legal" prescription pharmaceutical in the garage.

Truth serums don't exist in the real world.

Drugs that turn characters into zombies in a real-world setting aren't believable.

Big Pharma killing whistle blowers to hide the fact that their drug has terrible side effects isn't believable. Many drugs have serious side effects. Haven't you seen those ads on TV for side effect lawsuits? If you do it, set it up really well.

A character having the antidote for the poison is too convenient unless you set it up really well. I am talking to you, *Casino Royale*.

Big Pharma doesn't hide a cure they have because they make more money treating sick people. You'd have to set this up really well.

GENERAL MYTHBUSTING

Incidental occupational exposure (police, EMT) to tiny amounts of fentanyl killing someone is a misconception.

There's NOT an antidote for every poison.

Using caffeine won't sober up a drunk. Only time does that.

Addiction is not synonymous with tolerance or dependence, but they can lead to addiction. Tolerance = needing more drug to get the same effect (common with alcohol). Dependence = you have symptoms when the drug is removed (common with caffeine and nicotine).

Charcoal will NOT take care of every poison ingestion. Ipecac use is outdated.

Dietary supplements are natural, but that doesn't mean they are always safe.

Sucking poison out of a snake bite wound is no longer recommended.

RESEARCHING DRUGS

WHAT TO RESEARCH AND HOW

Drugs/Medications: What to Research

- What the drug is used for – aka the Indications
- How the drug works – aka the Pharmacology
- How long the drug lasts – aka the Pharmacokinetics
- How the drug is taken (or given) – aka Route/Administration (+with/without food)
- How much of the drug is given – aka the Dosing
- The side effects of the drug – aka the Adverse Events and the Warnings or Precautions
- When a drug should never be used – aka the Contraindications
- What drugs the drug should never be mixed with – aka the Drug Interactions
- How the drug is available - aka Dosage Forms
- Controlled/Non-controlled status

In short....
... but not so short...

The Prescribing Information

https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019115s030s031lbl.pdf

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use FENTANYL CITRATE INJECTION safely and effectively. See full prescribing information for FENTANYL CITRATE INJECTION. FENTANYL CITRATE Injection, for Intravenous or Intramuscular use, CII

Initial U.S. Approval: 1968

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; CYTOCHROME P450 3A4 INTERACTION; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS
See full prescribing information for complete boxed warning.

- Fentanyl Citrate Injection exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions. (5.1)
- Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. (5.2)
- Concomitant use with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of fentanyl. (5.3, 7, 12.3)
- Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation. (5.4, 7)

RECENT MAJOR CHANGES

Boxed Warning	12/2016
Indications and Usage (1)	12/2016
Dosage and Administration (2)	12/2016
Contraindications (4)	12/2016
Warnings and Precautions (5)	12/2016

INDICATIONS AND USAGE

Fentanyl Citrate Injection is an opioid agonist indicated for:

- analgesic action of short duration during the anesthetic periods, premedication, induction and maintenance, and in the immediate postoperative period (recovery room) as the need arises.
- use as an opioid analgesic supplement in general or regional anesthesia.

MINIMUM EQUIPMENT AND INTUBATION PREREQUISITES FOR SIGNS AND SYMPTOMS OF RESPIRATORY DEPRESSION AND SEDATION. (5.4, 7)

RECENT MAJOR CHANGES

Boxed Warning	12/2016
Indications and Usage (1)	12/2016
Dosage and Administration (2)	12/2016
Contraindications (4)	12/2016
Warnings and Precautions (5)	12/2016

INDICATIONS AND USAGE

Fentanyl Citrate Injection is an opioid agonist indicated for:

- analgesic action of short duration during the anesthetic periods, premedication, induction and maintenance, and in the immediate postoperative period (recovery room) as the need arises.
- use as an opioid analgesic supplement in general or regional anesthesia.
- administration with a neuroleptic as an anesthetic premedication, for the induction of anesthesia and as an adjunct in the maintenance of general and regional anesthesia.
- use as an anesthetic agent with oxygen in selected high risk patients, such as those undergoing open heart surgery or certain complicated neurological or orthopedic procedures.

DOSAGE AND ADMINISTRATION

- Fentanyl Citrate Injection should be administered only by persons specifically trained in the use of intravenous anesthetics and management of the respiratory effects of potent opioids.
- Ensure that an opioid antagonist, resuscitative and intubation equipment, and oxygen are readily available. (2.1).

- Individualize dosing based on the factors such as age, body weight, physical status, underlying pathological condition, use of other drugs, type of anesthesia to be used, and the surgical procedure involved. (2.1)
- Initiate treatment in adults with 50 to 100 mcg (0.05 to 0.1 mg) (1 to 2 mL). (2.2)
- Initiate treatment in children 2 to 12 years of age with a reduced dose as low as 2 to 3 mcg/kg. (2.2)

DOSAGE FORMS AND STRENGTHS

- Injection: 50 mcg (0.05 mg)/mL in single-dose Fliptop vial. (3)
- Injection: 50 mcg (0.05 mg)/mL in single-dose ampule. (3)

CONTRAINDICATIONS

- Hypersensitivity to fentanyl. (4)

WARNINGS AND PRECAUTIONS

- Risks of Skeletal Muscle Rigidity and Skeletal Muscle Movement:** Manage with neuromuscular blocking agent. See full prescribing information for more detail on managing these risks. (5.5)
- Severe Cardiovascular Depression:** Monitor during dosage initiation and titration. (5.6)
- Serotonin Syndrome:** Potentially life-threatening condition could result from concomitant serotonergic drug administration. Discontinue Fentanyl Citrate Injection if serotonin syndrome is suspected. (5.7)
- Adrenal Insufficiency:** If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid. (5.8)
- Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness:** Monitor for sedation and respiratory depression. (5.9)

ADVERSE REACTIONS

Most common serious adverse reactions were respiratory depression, apnea, rigidity, and bradycardia. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Hospira, Inc. at 1-800-441-4100, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Concomitant Use of CNS Depressants:** May decrease pulmonary arterial pressure and may cause hypotension. See FPI for management instructions. For post-operative pain, start with the lowest effective dosage and monitor for potentiation of CNS depressant effects. (5.4, 7).
- Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics:** Avoid use with Fentanyl Citrate Injection because they may reduce analgesic effect of Fentanyl Citrate Injection or precipitate withdrawal symptoms. (7)

ADVERSE REACTIONS

Most common serious adverse reactions were respiratory depression, apnea, rigidity, and bradycardia. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Hospira, Inc. at 1-800-441-4100, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Concomitant Use of CNS Depressants:** May decrease pulmonary arterial pressure and may cause hypotension. See FPI for management instructions. For post-operative pain, start with the lowest effective dosage and monitor for potentiation of CNS depressant effects. (5.4, 7).
- Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics:** Avoid use with Fentanyl Citrate Injection because they may reduce analgesic effect of Fentanyl Citrate Injection or precipitate withdrawal symptoms. (7)

USE IN SPECIFIC POPULATIONS

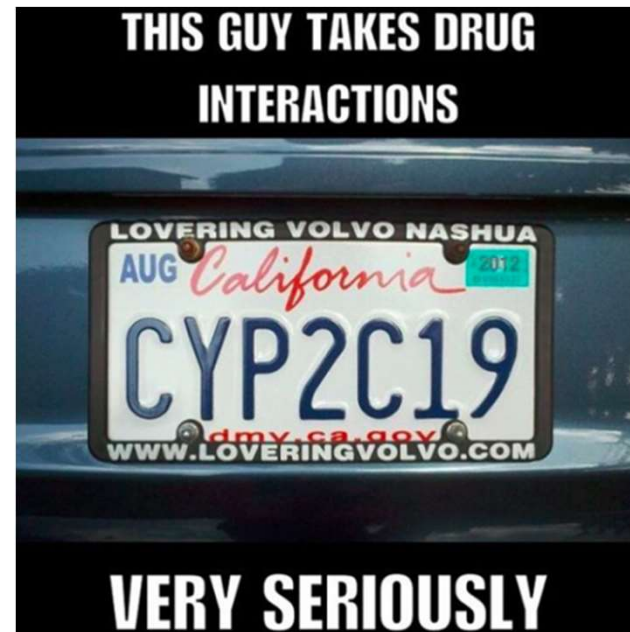
- Pregnancy:** May cause fetal harm. (8.1)
- Lactation:** Infants exposed to Fentanyl Citrate Injection through breast milk should be monitored for excess sedation and respiratory depression. (8.2)
- Geriatric Patients:** Titrate slowly and monitor for CNS and respiratory depression. (8.5)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 12/2016

Points of Caution with Prescribing Information

- Technical jargon abounds
- Easy to misunderstand or misinterpret details
- Not always regularly updated unless information is critical to safety or helps a drug company sell more drug
- Not comprehensive



How to find the prescribing information

- Google search: “Drug Name (brand OR generic)” and “prescribing information”
- A link on the drug company web site for the drug entitled “prescribing information”
- Physician’s Desk Reference (maybe) – look for a current edition
- Food and Drug Administration (FDA) -
<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>
- PI Hack: Look for the Medication Guide
 - Found at the end of the prescribing information for SOME drugs – not all
 - Written in friendly language
 - These will not typically appear for drugs given in a hospital setting
 - <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=medguide.page>
- What if it’s a non-prescription or “Over the Counter Drug?” – No prescribing information – read the drug facts on drug company site

Other good sources for drug information

- <https://www.mayoclinic.org/drugs-supplements> (friendly language)
- <https://reference.medscape.com/drugs> (more jargon)
- <https://dailymed.nlm.nih.gov/dailymed/> (more jargon)
- <https://medlineplus.gov/druginformation.html> (friendly language)
- Patient Directed Manufacturer's Website (friendly language)
- Medical Literature = clinical trials, review articles – “papers” (all jargon)
- Recently published Drug Handbooks at the library (varying levels of jargon)
- Health care professional (doctor, PA, ARNP, pharmacist, nurse)
- Drug Information Specialist - Me: chbrownauthor@gmail.com

Tips on Realistic Drug Side Effects

Most Common

- Nausea and vomiting
- Skin irritation or rash
- Diarrhea
- Constipation
- Allergic reaction
- Dry mouth
- Drowsiness
- Dizziness
- Irritability
- Appetite changes
- Fatigue
- Flu-like symptoms

Most Serious

- Bleeding
- Risk of Infection
- Seizure
- Kidney damage
- Liver damage
- Breakdown of muscle tissue
- Life threatening skin reactions
- Low blood cell counts
- Anaphylactic reaction
- Cancer
- Suicidality
- Birth Defects
- Death

Tips for Making Up a Fictitious Drug

- IF YOUR CHARACTERS ARE HUMAN AND YOUR DRUG IS NOT JUST A MAGIC POTION IN DISGUISE – try to model it on a real drug.
 - Most fiction/film where a fictitious drug is done well use this method.
 - If you decide on differences from a real existing drug – research to be sure they are realistic.
- If it is meant to treat a fictitious disease – model your disease on a real disease.
 - You lose credibility if your disease is something like a pandemic of third-degree bursitis
- Make sure the characteristics of the drug – time of onset, duration, side effects all make sense.
 - Mimic side effects of existing drugs for HUMAN CHARACTERS
 - Keep them internally consistent for NON-HUMAN CHARACTERS – match the imagined alien or mythical physiology
- If it is a drug that's equivalent to a controlled drug, be sure its handling is consistent with real laws in a real-world setting, or that you develop your fantasy or science fiction world with a social construct that makes sense.
- The same follows for a drug that is equivalent to an illegal drug in the real world.
- Do plenty of research on your drug and your disease.

Tips for Proper Depictions of Medications in the Modern Hospital



- There is tight control by Pharmacy Services for all medications used in the hospital – WHY?
 - Prevents medication errors
 - Prevents drug diversion
 - Regulatory requirements by State Department of Health and Joint Commission for Hospital Accreditation
- All medications are locked up at all times.
- Extra oversight for “controlled” medications (Opioids/Narcotics, benzodiazepines, stimulants, anabolic steroids, others) [also called CII – CV]
 - Tracing paperwork
 - Double signatures
 - Witnesses for wastage of unused portions



Automated Dispensing Cabinets

Stay in Touch

- <https://www.chbrownauthor.com/>
- Facebook: <https://www.facebook.com/chbrownauthor>
- Twitter: <https://twitter.com/chbrownauthor>
- Email: chbrownauthor@gmail.com
- PNWA