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Testimony of Elizabeth Jungman, The Pew Charitable Trusts
before the Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives
January 30, 2018

Chairman Burgess, Ranking Member Green, and members of the Subcommittee:

Five years ago, the full extent of the fungal meningitis outbreak caused by contaminated compounded injections was still being revealed. As the case count and fatality count went up day by day, this Committee took action. The Energy and Commerce Committee oversight team investigated the root causes, and then Committee members worked with your counterparts in the Senate, and across party lines, to pass legislation that is already making a difference: the Drug Quality and Security Act (DQSA).

I am Elizabeth Jungman, director of public health programs at The Pew Charitable Trusts. Pew is an independent, nonpartisan research and public policy organization with a longstanding focus on drug quality issues, including pharmaceutical compounding.

Weakening the DQSA would threaten patient safety. I am here today to convey Pew's strong support for the continued, robust implementation and enforcement of the law. I will also share findings from a not-yet-published study showing that the DQSA has also helped spur state-level improvements in compounding oversight.

When this legislation was being developed, I worked for the Senate, and had the privilege of being a part of the negotiating team. As Members and other stakeholders who were here will recall, we knew that the changes in practice that experts told us were necessary to protect patients would not be universally popular. But each round of staff negotiations started with a new count of the illnesses and deaths discovered since we had last met, and that was a powerful motivator to persevere and create a bill that would protect patients. Years later, we cannot let ourselves forget the stories that created the imperative to act.

Patients get hurt when compounding goes wrong

While the meningitis outbreak is the most extensive known example of harm to patients from compounded drugs, there have been many other cases of serious illness, injury, and death associated with them. Appended to my testimony is information on more than 70 adverse events that have been publicly reported since 2001, although we think our list probably underestimates the scale of the problem.

For example, last year, 43 people in Texas were harmed after a compounded steroid antibiotic was injected into their eyes, including patients who suffered vision loss.[1] That is unacceptable; patients deserve access to compounded products that they can trust.

Patients should receive the highest-quality product that meets their clinical need

Poll data from the Pew Research Center indicates that the vast majority of Americans (87%) expect the government to play a "major role" in ensuring the safety of medicines and foods.[2] For most drugs, FDA fills that role by evaluating safety and effectiveness, and setting manufacturing quality standards. Compounded drugs are not subject to these protections.

An FDA-approved drug is the gold standard, and should be the first choice whenever possible. But some patients have medical needs that approved products cannot meet. For them, compounded drugs can be an important tool.

When a pharmacist tailors a drug for an individual patient who will use it immediately, the risks of any contaminants growing are limited, and the public health impact from any error is contained. States primarily oversee patient-specific compounding, which is called "traditional" compounding, and mandate quality standards appropriate to its risks.

But sometimes, clinical circumstances require that providers keep compounded drugs on-hand, known as "office stock." These products carry distinct risks for patients, because rather than being used immediately, they are often stored for a period of time before use, increasing the opportunity for any contaminants like bacteria and fungus to grow to dangerous levels. Also, they are frequently produced in bulk, multiplying the consequences of microbial contamination, adulteration, and under or over-potent products.

To mitigate these risks, Congress created a special category of compounder to supply office stock – outsourcing facilities, established under section 503B of the DQSA. FDA's quality standards for outsourcing facilities are similar to those for approved drugs, called current Good Manufacturing Practice standards (cGMP). In exchange for investing in meeting these standards, outsourcing facilities can compound drugs without prescriptions.

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[1] U.S. Food and Drug Administration, "Compounded Triamicinolone and Moxifloxacin Product for Intravitreal Injection by Guardian Pharmacy Services: Alert to Health Professionals - Serious Adverse Events Reported," accessed Nov. 14, 2017, https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm569123.htm.

[2] Pew Research Center, "Government Gets Lower Ratings for Handling Health Care, Environment, Disaster Response" (2017), file:///C:/Users/acohen2/Downloads/12-14-17-Government-release.pdf.

FDA has indicated that forthcoming regulations will apply these quality standards flexibly, to allow compounders of varying sizes to register as outsourcing facilities.[3] But while tailoring standards to risk is sensible, and having more entrants to the outsourcing facility market could be a good thing, any flexibility in the standards that apply to outsourcing facilities must preserve the role that Congress created these facilities to fill: reliable sources for safe supplies of compounded office stock.

The prescription requirement helps ensure that compounded drugs are produced under appropriate standards

To ensure that all drugs are compounded under suitable quality standards and with appropriate oversight, it is essential that the two categories of business engaged in this practice – traditional compounders and outsourcing facilities – be clearly delineated and defined. To that end, Congress has twice determined – first 20 years ago, and then in 2013 – that traditional compounding should require a patient-specific prescription. If compounders want to sell stock supplies, they must invest in the equipment, training and specialized personnel necessary to comply with cGMP.

Furthermore, a clear dividing line helps ensure that both regulated facilities and regulators know who is responsible for overseeing any given compounder, and what rules apply. Congress considered a variety of ways to distinguish traditional compounders from outsourcing facilities, but the downside to other proposals, like designating categories based on production volume, was that the difficulty in enforcing them would have undermined accountability. The prescription requirement, in contrast, is very clear – you have a patient name on the pill bottle, or you don't. Congress decided – twice – that the benefits of that clarity outweighed the downsides of prohibiting office stock by traditional compounders.

States are important partners

The vast majority of compounded drugs are produced by traditional compounders – pharmacists or physicians who dispense patient-specific drugs, and are primarily regulated by states – and so appropriate state oversight of compounding is an important component of a safe marketplace.

In 2014, as many state officials sought to determine which reforms would help them oversee drug compounding most effectively, Pew convened an advisory committee of state pharmacy

[3] Nate Raymond, "Exclusive: FDA Plans New Compounding Pharmacy Policy, Agency Head Says," *Reuters*, Sept. 15, 2017, https://www.reuters.com/article/us-usa-fda-pharmacies-exclusive/exclusive-fda-plans-new-compounding-pharmacy-policy-agency-head-says-idUSKCN1BQ2RV; U.S. Food and Drug Administration, "2018 Compounding Policy Priorities Plan," accessed Jan. 22, 2018, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm592795.htm

regulators and other experts to identify best practices that were most achievable by states.[4] We then released an assessment of state policies, relative to those best practices, in 2016.[5] About two weeks from now, Pew, along with the National Association of Boards of Pharmacy, will release an update to that research,[6] but I can preview some findings today. They show that the majority of states now conform to best practices in two key areas.

First, among the best practices was a recommendation that states adopt widely-recognized quality standards established by the United States Pharmacopeial Convention (USP). The forthcoming report will show that the vast majority of state boards of pharmacy have adopted either those standards, or other strong quality standards, for the compounders they oversee.[7]

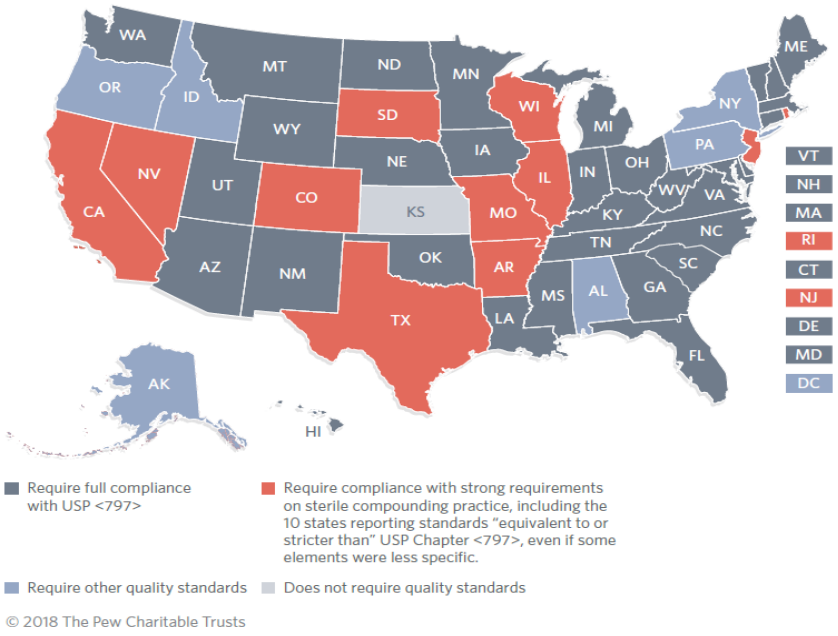

Fig. 1. State adoption of quality standards. Pew/NABP (forthcoming February 2018)

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[4] The Pew Charitable Trusts, "Best Practices for State Oversight of Drug Compounding" (2016), http://www.pewtrusts.org/~/media/assets/2016/02/best_practices_for-state_oversight_of_drug_compounding.pdf.

[5] The Pew Charitable Trusts, "National Assessment of State Oversight of Sterile Drug Compounding" (2016), http://www.pewtrusts.org/~/media/assets/2016/02/national_assessment_of_state_oversight_of_sterile_drug_compounding.pdf.

[6] The Pew Charitable Trusts and the National Association of Boards of Pharmacy, in press, "State Oversight of Drug Compounding" (2018). The report will be posted at the following URL on approximately Feb. 14, 2018: http://www.pewtrusts.org/statecompounding.

[7] Thirty-two state boards of pharmacy require traditional pharmacies that compound sterile drugs for humans to be in full compliance with the quality standards established by USP in its general Chapter <797> "Pharmaceutical Compounding—Sterile Preparations." An additional 11 states have strong requirements on sterile compounding practice – which 10 states characterized as "equivalent to or stricter than" USP Chapter <797>, even if some elements were less specific. An additional four states have pending policy changes that, if passed, would require full compliance with USP Chapter <797> or other strong state requirements.

Second, the best practices recommend that states align with federal law on the prescription requirement – and the forthcoming report will show that the vast majority of states now do. Thirty-nine states and the District of Columbia prohibit traditional pharmacies from compounding sterile office stock for humans – through their laws or regulations, state guidance, or by advising compounders to follow the federal law prohibiting the practice.

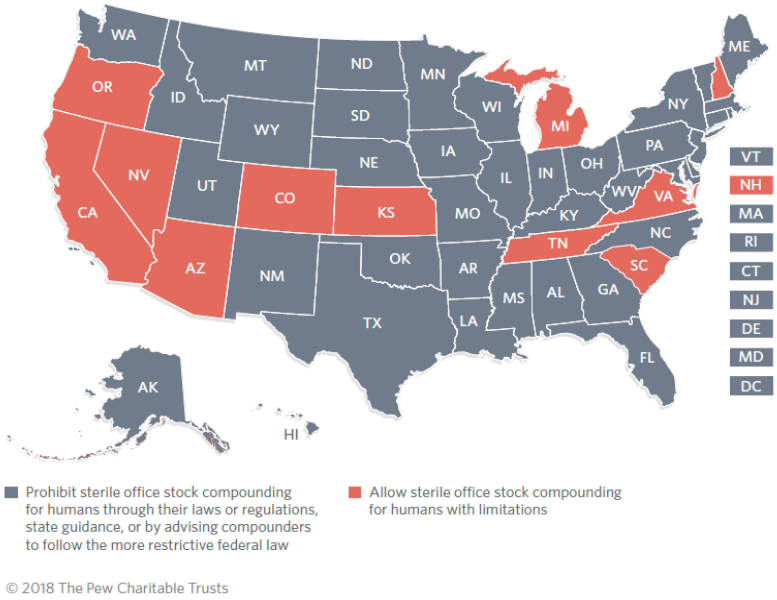

Fig. 2 State adoption of prescription requirement. Pew/NABP (forthcoming February 2018)

While many states fall short of the best practice standard of annual inspections, which would ensure compliance with these policies, states' adoption of key policies regarding quality standards and the prescription requirement are promising steps in ensuring that states are doing their part to ensure the safety of compounded drugs.

Congressional support for the federal compounding law will help ensure its effectiveness

The DQSA was passed under the shadow of an unfolding tragedy. Congress – this committee – acted boldly, in the face of pushback and controversy, to draw clear lines that help ensure drug quality. This hearing is an important reminder of why Congress passed federal compounding law, and what could happen if Congress doesn't protect it, and encourage its robust implementation. I am honored to have had the opportunity to be a part of it, and welcome any questions.

A data table from THE PEW CHARITABLE TRUSTS | January 2018

U.S. Illnesses and Deaths Associated With Compounded or Repackaged Medications, 2001-17

Pew's drug safety project has identified 71 reported compounding errors or potential errors associated with 1,416 adverse events, including 114 deaths, from 2001 to 2017. However, a 2015 survey found that only 30 percent of states (13 of the 43 that responded) require sterile compounding pharmacies to report serious adverse events.[1] Of the states that require reporting, the type of information that is required to be reported may vary, further contributing to an incomplete picture of adverse events associated with compounded medications. Even in states with strong adverse event reporting requirements, illnesses and deaths caused by compounded drugs are not always linked to the compounding error.[2,3,4] Because many such events go unreported, this chart is an underestimation of the number of compounding errors since 2001. Contamination of sterile products was the most common error; others were the result of compounders' miscalculations and mistakes in filling prescriptions.

Drug compounding can be an interstate operation; compounders may prepare medicines in one state and ship them to another. States may encounter oversight challenges if an out-of-state compounder shipping into their jurisdiction is held to a different quality or regulatory standard than in-state compounders. As a result, for each row below, the state where the compounding error or potential error occurred and the state(s) where the adverse event(s) occurred are listed. Harmonized minimum quality standards for anyone who compounds drugs – in any setting – across states would help address challenges in regulating out-of-state compounders and ensure that all compounding meets strong baseline criteria for preparing safe drugs and protecting patients.

Year	Reported cases	Reported deaths	Adverse event(s)	Compounding error	Product	State where compounding error occurred	State(s) where adverse event(s) occurred	Notes
2017	43[5]		Vision impairment, poor night vision, loss of color perception, ocular discomfort, nausea, loss of balance, etc.	Not reported	Injectable steroid antibiotic combination for administration in the eye	TX	TX	
2017	2[6]	1	One case of cardiac arrest; both experienced immediate hypersensitivity reactions	Product contained ungraded PEG 40 castor oil	Injectable curcumin emulsion infusion	CA	Not reported	
2017	1[7]		Paralysis (partial: face)	Not reported	Compounded injectable	TX	TX	

2017	41[8]		Septic arthritis	Bacterial contamination	Intra-articular injectable	NJ	NJ	Investigation revealed inappropriate use and handling of pharmacy bulk packaged products.
2017	1[9]		Hemorrhagic occlusive retinal vasculitis	Not reported	Intraocular injectable of triamcinolone, moxifloxacin, and vancomycin (TMV)	NJ	Not reported	
2017	2[10]		Tissue erosion at injection site	High pH; no glutamine detected in samples	Compounded injectable of glutamine, arginine, and carnitine (GAC)	FL	Not reported	
2016	17	2[11]	Fungal bloodstream infections	Contamination[12]	Injectable saline, heparin, vancomycin, and ceftazidime	NY	NY	IV flush solutions were not compounded under quality standards set by the United States Pharmacopeial Convention and were used past appropriate beyond-use dating. The two deaths occurred within 12 weeks of the fungal infection, but it is unclear whether the deaths were a result of the infections.
2016[13]	1		Overdose	Dose of manganese chloride 1,000 times stronger than usual dose[14]	Injectable manganese chloride	Not reported	Not reported	High manganese dose of 800 mg, compared with usual dose of 0.15-0.8 mg/day. Patient showed no resulting symptoms, but manganese overdose can result in side effects on the nerves and brain.
2016	3		Unspecified serious adverse events	Dose of morphine sulfate stronger than labeled concentration[15]	Injectable morphine sulfate	IN	IL, IN[16]	
2016	6[17]		Septic arthritis	Contamination	Viscosupplementation knee injectable	Not reported	SC	
2016	1[18]		Abscesses and osteomyelitis	Contamination	Unknown injectable	Not reported	NM	Investigation revealed unsafe injection and compounding practices.
2016	7[19]		Thyrotoxicosis	Super-potent compounded drug	Compounded oral liothyronine	SD	Not reported	
2015	7[20]		Hepatitis C	Contamination	Unknown injectable	CA	CA	Investigation into the clinic revealed infection control breaches and ongoing issues with infection control practices.
2015	Several[21]		Unspecified	Adulterated and misbranded drug product (contained different API)	L-citrulline	NY	Not reported	Some samples of the product were found to contain a different amino acid (N-Acetyl-Leucine) than what the label claimed, and others did not contain any L-Citrulline.
2015	5[22]		Redness, swelling, and pain at injection site	Contamination	Compounded betamethasone phosphate and betamethasone acetate	AL	Not reported	
2015	"Several"[23]		Unspecified	High dose of vitamin D_3[24]	Oral multivitamin capsule	FL	Nationwide[25]	High vitamin D_3 can cause significant short- and long-term effects.
2014-15	"Several"[26]		Unspecified	Contamination[27]	Sterile products	AL	Nationwide[28]	Administration of contaminated sterile

								products may result in serious and potentially life-threatening infections or death.
2014	Unknown		Oversedation	Dose of midazolam labeled with incorrect concentration[29]	Injectable midazolam	IN	Not reported	Compounded midazolam, a sedating agent, did not match the concentration on the product label. Oversedation can result in a range of effects from increased sleepiness to severe difficulty breathing.
2014	1	1[30]	Toxicity	Not reported	Compounded topical anesthetic cream (ketamine)	TX	TX	
2014	37[31]		Not reported	Contamination	Intravitreal injections of bevacizumab or ranibizumab	FL	Not reported	Bevacizumab and ranibizumab were repackaged in a manner that exposed sterile, preservative free vials to an uncontrolled environment.
2014	1[32]		Severe flushing, stinging, and dizziness	Dose of magnesium sulfate 200 times stronger than labeled concentration[33]	Compounded magnesium sulfate	TX	Not reported	
2013	1		Bacterial bloodstream infection	Contamination[34]	Injectable mineral product	TX	CA	Voluntary recall of injectable mineral product that contained bacteria with the potential for serious infection. A patient admitted to the hospital with an infection of the same bacteria.
2013	15	2[35]	Bacterial bloodstream infection	Contamination[36, 37,38]	Injectable calcium gluconate	TX	TX	The Centers for Disease Control and Prevention (CDC) has not conclusively linked the deaths to the contaminated drug.
2013	6		Fever, flu-like symptoms, soreness at injection site	Unknown[39,40]	Injectable methylcobalamin	TX	Not reported	A compounded injection was recalled due to complaints of fever, flu-like symptoms, and soreness at the injection site. Subsequent Food and Drug Administration inspection found that sterility and quality of the manufacturing process could not be assured.
2013	5		Serious bacterial eye infections	Contamination[41, 42,43]	Injectable bevacizumab for administration in the eye	GA	GA, IN	
2013[44]	8		Fungal eye infections	Contamination[45]	Injectable bevacizumab-triamcinolone for administration in the eye	Not reported	NY	Fungal infection of the eye caused significant visual impairment that persisted for at least three months from the incident.
2013[46]	1		Kidney failure and acute injury of the liver and pancreas	Unknown[47]	Injectable combination product for administration under the skin	Not reported	Not reported	Product is marketed for dissolving fat. The patient developed difficulties with digestion and metabolism as well as kidney failure, which required dialysis.
2012-13[48]	12		Bacterial bloodstream	Contamination	Parenteral infusion	Not reported	IL	Facility inspection revealed deficiencies

			infection					in the parenteral medication preparation and handling.
2012-13	26		Bacterial and fungal infections in skin and soft tissue	Contamination[49]	Injectable preservative-free methylprednisolone acetate	TN	AR, FL, IL, NC	Skin and soft tissue infections resulted after intramuscular injection of preservative-free product. Subsequent voluntary recall of sterile products was issued.
2012-13	778[50]	76	Fungal meningitis and other infections	Contamination[51,52]	Injectable preservative-free methylprednisolone acetate	MA	FL, GA, ID, IL, IN, MD, MI, MN, NC, NH, NJ, NY, OH, PA, RI, SC, TN, TX, VA, WV	Additional products (betamethasone, cardioplegia, and triamcinolone solutions) produced at the facility were also found to be contaminated, but adverse events linked to these products have not been reported.[53]
2012	47		Fungal eye infection; vision loss in majority of cases	Contamination[54]	Injectable brilliant blue-G (BBG) retinal dye and triamcinolone for administration in the eye	FL	CA, CO, IL, IN, LA, NC, NV, NY, TX	
2012	7		Bacterial bloodstream infection	Contamination[55]	Injectable fentanyl	NC	NC	
2012[56]	1		Overdose	Dose of flecainide four times stronger than ordered[57]	Oral flecainide liquid	Not reported	Not reported	Flecainide toxicity can cause abnormal heart rate and rhythms that can be severe and life-threatening, as well as increased liver enzymes, which can be an indicator of liver injury.
2012[58]	10	1	Bacterial bloodstream infection	Contamination	Contrast dye, anesthetic and steroid injections-single-dose vials	Not reported	AZ, DE	The outpatient pain clinic failed to follow Standard Precautions by using single-dose vials as multi-dose vials.[59]
2011-12[60]	15		Bacterial bloodstream infection	Contamination	Sterile products	Not reported	WV	Adverse events resulted from the use of bulk saline bag for IV flushes in a physician office practice.
2011[61]	1		Toxicity	Dose of 4-aminopyridine 10 times stronger than labeled concentration[62]	Oral 4-aminopyridine pills	Not reported	Not reported	Patient experienced stomach pain, anxiety, extreme sweating, and slow heart rate prior to developing life-threatening seizures. Following a complicated hospital stay, the patient sustained permanent short-term memory loss.
2011[63]	9		Bacterial eye infection, and one case of meningitis and encephalitis; four cases of loss of eyesight	Contamination[64]	Injectable bevacizumab for administration in the eye	Not reported	TN	
2011	12		Bacterial eye infection; three patients had eye removals	Contamination[65]	Injectable bevacizumab for administration in the eye	FL	FL	
2011	5		Blindness	Unintended presence of another medication[66]	Injectable bevacizumab for administration in the eye	CA	CA	Trace amounts of bortezamib, a cancer drug that is not intended for injection into the eye, were detected on a sample

								syringe.
2011	19	9	Bacterial bloodstream infection	Contamination[67]	Parenteral nutrition solution	Not reported	AL	
2010	1	1	Fatal overdose	Dose of sodium 60 times stronger than ordered[68]	Injectable sodium chloride	IL	IL	Acute sodium overload can cause symptoms ranging from fluid retention to seizures and coma, affecting multiple organs including lungs and kidneys. The patient was exposed to a potent sodium-containing fluid that was entered incorrectly during the preparation of the medication, resulting in death.
2010	1		Unspecified side effects	Dose of liothyronine 10 times stronger than ordered[69]	Oral liothyronine (T3)	AZ	Not reported	Liothyronine overdose can result in shakiness, increased heart rate, and palpitations.
2009	1	1	Fatality	Unknown[70]	Injectable hydromorphone	TN	Not reported	
2009	1	1	Fatal overdose	Dose of levothyroxine 18 times stronger than ordered[71]	Oral levothyroxine pills	NC	Not reported	
2009	9		Eye infection; at least one case of vision loss	Unknown[72]	Injectable preservative-free hyaluronidase for administration in the eye	FL	Not reported	Patients developed orbital cellulitis, a type of infection that results in inflammation of the eye.
2008[73]	1		Acute withdrawal	Dose of baclofen 7 percent of ordered dosage[74]	Injectable baclofen for administration in the spine	Not reported	Not reported	The product included a fraction of the intended dose of baclofen. Patient experienced frequent and severe spasms.
2008	1	1	Fatal overdose	Dose of sodium chloride 10 times stronger than ordered[75]	Injectable sodium chloride	NC	Not reported	Acute sodium overload can cause symptoms ranging from fluid retention to seizures and coma, and affect multiple organs including lungs and kidneys.
2008[76]	1		Persistent inflammatory reaction	Unknown[77]	Mesotherapy injections	Not reported	CO	Seven months after receiving mesotherapy injections, patient developed a persistent immune-mediated inflammatory reaction.
2007[78]	1	1	Fatal acute respiratory distress syndrome	Colistimethate sodium left in solution longer than recommended[79]	Colistimethate sodium inhaled solution	Not reported	Not reported	The prodrug of colistin is better tolerated than the active drug to which it converts. More than half of the prodrug is converted within two days in solution at a certain temperature. This premixed product was in solution for five weeks before further dilution for administration.
2007	3	3	Fatal overdose	Dose of colchicine eight times stronger than labeled concentration[80]	Injectable colchicine	TX	OR, WA	IV doses that exceed the standard single-use therapeutic dose of 2-4 mg per episode of gout have resulted in life-threatening toxicity. In this case, the doses were eightfold these limits.
2007	8	1	Bacterial bloodstream	Contamination[81]	Injectable fentanyl	Not reported	CA, MD	

			infection					
2006	1		Decreased consciousness, low blood pressure, and lack of oxygen	Mislabeled product leading to administration of different drug than ordered[82]	Epidural morphine sulfate (fentanyl/bupivacaine was ordered)	MS	AZ	Both fentanyl and morphine are in the same class of sedative analgesics. The symptoms of decreased consciousness, hypoxia, and hypotension are consistent with higher than intended opioid exposure.
2006	At least 70		Redness, swelling, bruising, rash, fever, and cellulitis	Betamethasone made with incorrect amount of preservative[83,84]	Injectable betamethasone	AL	Not reported	The product was voluntarily recalled, and a subsequent reformulation continued to include an incorrect amount of preservative. An FDA investigation discovered at least 70 complaints associated with the drug.
2006	1	1	Fatal overdose	Dose of chemotherapy infusion diluted with toxic amount of sodium chloride[85]	Chemotherapy infusion	OH	OH	Acute sodium overload can cause symptoms ranging from fluid retention to seizures and coma, and affect multiple organs including lungs and kidneys.
2006	1	1	Fatal overdose	Dose of zinc 1,000 times stronger than ordered[86]	Neonatal parenteral nutrition solution	NV	NV	The dose was incorrectly entered for pharmacy preparation as milligrams instead of micrograms, resulting in a thousandfold overdose.
2005	3	1	Fatal overdose, cardiac arrest	Dose of lidocaine and tetracaine higher than usual[87,88]	Topical combination anesthetic creams (lidocaine and tetracaine)	NC	NC	
2005	19	1	Bacterial bloodstream infection	Contamination[89,90]	Injectable magnesium sulfate	TX	CA, MA, NC, NJ, NY, SD	
2004-06	80		Bacterial bloodstream infection	Contamination[91]	Injectable heparinized saline	TX	MI, MO, NY, SD, TX, WY	
2004-05	6		Bacterial eye infection; all cases had partial or complete loss of vision; two patients had eye removals	Contamination[92]	Trypan blue eye drops	Not reported	Not reported	
2004-05	11	3	Systemic inflammatory response syndrome	Contamination[93,94]	Cardioplegia solution for administration during heart surgery	MD	VA	
2004	2		Bacterial bloodstream infection	Contamination[95]	Injectable heparin-vancomycin	FL	CT	
2003	2		Overdose	Dose of liothyronine stronger than ordered[96]	Oral liothyronine (T3) pills	AZ	Not reported	Unused pills of both patients were analyzed, and the concentration of the active ingredient was found to be 800 and 900 times higher than intended. High T3 levels can result in shakiness, increased heart rate and palpitations.
2002-04	1	1	Fatal overdose	Dose of lidocaine and tetracaine higher than usual[97,98]	Topical combination anesthetic cream (lidocaine and tetracaine)	UT	AZ	

2002[99]	1		Toxicity	Dose of clonidine 10 times higher than ordered[100]	Oral clonidine capsules	Not reported	Not reported	Patient showed early signs of central nervous system depression (somnolence and drowsiness) and miosis (constricted or small pupils).
2002[101]	1		Toxicity	Dose of clonidine 87 times higher than ordered[102]	Oral clonidine liquid	Not reported	Not reported	Patient showed signs of central nervous system depression, consistent with severe clonidine toxicity. Miosis (constricted or small pupils) was also noted.
2002	2		Meningitis	Contamination[103]	Injectable methylprednisolone for administration in the spine	MI	MI	
2002	7	2	Fungal meningitis and sacroiliitis	Contamination[104,105,106]	Injectable methylprednisolone acetate for administration in the spine	SC	NC	
2001	2		Bacterial bloodstream infection	Contamination[107]	Injectable preservative-free heparinized saline	Not reported	Not reported	
2001[108]	1		Overdose	Dose of clonidine 1,000 times stronger than ordered[109]	Oral clonidine liquid	Not reported	Not reported	During preparation of liquid clonidine from solid pills, milligrams were substituted for micrograms, resulting in a thousandfold overdose. Patient's initial presentation included hyperventilation, an unusual feature of clonidine toxicity. Severe clonidine toxicity can result in low blood pressure, central nervous system depression (lethargy, mental status changes), and cardiopulmonary instability (heart and breathing problems).
2001	13	3	Five cases of meningitis; five cases of epidural abscess; one patient had an infected hip joint; two unspecified	Contamination[110,111]	Injectable betamethasone for administration in spine or joint	CA	CA	
2001	4		Bacterial bloodstream infection	Contamination[112]	Injectable ranitidine	Not reported	Not reported	
Total	**1,416**	**114**						

This chart includes U.S. illnesses and deaths associated with compounded or repackaged medications from 2001 to the present. Adverse events were drawn from FDA and CDC resources as well as journal and news articles.

In the total, "several" reported cases were counted as two adverse events, and an "unknown" number of reported cases were counted as zero adverse events.

[1] The Pew Charitable Trusts, "National Assessment of State Oversight of Sterile Drug Compounding" (February 2016), http://www.pewtrusts.org/~/media/assets/2016/02/national_assessment_of_state_oversight_of_sterile_drug_compounding.pdf.
[2] Allan Coukell, "Risks of Compounded Drugs," JAMA Internal Medicine 174, no. 4 (2014): 613–14, http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1819570.
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