U.S. Illnesses and Deaths Associated With Compounded or Repackaged Medications, 2001-19

Update note: This chart was updated in March 2020 and in February 2019 to include newly reported adverse events, remove previously listed events following additional investigation, and update information in citations.

Pew's drug safety project has identified 73 reported compounding errors or potential errors associated with more than 1,562 adverse events, including at least 116 deaths, from 2001 to 2019. 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 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.

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Year	Reported cases	Reported deaths	Adverse event(s)	Compounding error	Product	State where compounding occurred	State(s) where adverse event(s) occurred	Notes
2018- 2019 ³	8		Nausea, vomiting, lightheadedness, chills, fever, shaking, body aches, sneezing, low blood pressure, difficulty breathing, hospitalization	Product was labeled for use in dietary supplements, not injectable drugs; contained excessive levels of bacterial endotoxin	Injectable drug compounded with L-glutathione 200mg/ mL powder	Not reported	Not reported	The distributor of the ingredient L-glutathione was located in Alabama, but the location of the compounders was not reported.
2001- 20184	23	At least 2	Irregular heart rhythm, seizures, potentially lethal arrhythmias,	Products contained cesium chloride, which is not	Compounded products containing cesium chloride	Not reported	Not reported	Patients were administered cesium chloride to treat their cancer. It is not approved for this indication, and FDA subsequently issued a compounding
			fainting, cardiac arrest, and death Eye inflammation,	approved by FDA to treat disease.	28 adverse events were related to eye injections of			risk alert and banned its use in compounded products. Adverse events were identified upon
2016- 2018⁵	46		eye infections, high eye pressures, color variation, spots over vision	Not reported	repackaged sterile Avastin (bevacizumab); source of remaining 18 adverse events not reported.	FL	Not reported	inspection. Compounding facility failed to report these adverse events to FDA, and did not conduct an appropriate investigation.
2013- 2018 ⁶	At least 61		Endometrial cancer, prostate cancer, strokes, heart attacks, deep vein thrombosis,	Not reported	Compounded bioidentical implantable hormone pellets	FL and TX ⁷	Not reported	During a routine inspection, FDA identified a total of 4,202 adverse events that had been reported to the distributor of the products but never reported to FDA or the outsourcing facilities that compounded the
2010			cellulitis, and pellet extrusion					outdated data, only 61 adverse events could be officially attributed to the products themselves.
2017 ⁸	At least 43		Vision impairment, poor night vision, loss of color perception, photophobia, ocular discomfort, nausea, loss of balance, etc. ⁹	Product contained multiple substances, including poloxamer 407 and poloxamer 407 degradants	Injectable steroid antibiotic combination for administration in the eye	ТХ	ТХ	
2017 ¹⁰	2	1	loss of balance, etc. ⁹ One case of cardiac arrest; both experienced immediate	Product contained ungraded PEG 40	Injectable curcumin emulsion infusion	СА	Not reported	
2017 ¹¹	41		hypersensitivity reactions Septic arthritis	castor oil Bacterial contamination	Intra-articular injectable	ΓN	NJ	Investigation revealed inappropriate use and handling of pharmacy bulk
2017 ¹²	1		Hemorrhagic occlusive retinal vasculitis	Not reported	Intraocular injectable of triamcinolone, moxifloxacin, and vancomycin (TMV)	ιN	Not reported	packaged products.
2017 ¹³	2		Tissue erosion at injection site	High pH; no glutamine detected in samples	Compounded injectable of glutamine, arginine, and carnitine (GAC)	FL	Not reported	
201614	17	2	Fungal bloodstream	Contamination	Injectable saline, heparin, vancomycin, and	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
			infections		ceftazidime			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 ¹⁵	1		Overdose	Dose of manganese chloride 1,000 times stronger than usual dose	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
2016 ¹⁶	3		Overdose ¹⁷	Dose of morphine sulfate stronger than labeled concentration	Injectable morphine sulfate	IN	IL, IN ¹⁸	nerves and brain.
2016 ¹⁹	1		Abscesses and osteomyelitis	Contamination	Unknown injectable	Not reported	NM	Investigation revealed unsafe injection and compounding practices.
2016 ²⁰ 2015 ²¹	7		Thyrotoxicosis Hepatitis C	Super-potent compounded drug Contamination	Compounded oral liothyronine Unknown injectable	SD	Not reported CA	Investigation into the clinic revealed infection control breaches and
2013	,			Adulterated and	Unknown injectable			ongoing issues with infection control practices. Some samples of the product were found to contain a different amino
2015 ²²	Several		Unspecified	misbranded drug product (contained different API)	L-citrulline	NY	Not reported	acid (N-acetyl-leucine) than what the label claimed, and others did not contain any L-citrulline.
2015 ²³ 2015 ²⁴	5 Several ²⁵		Redness, swelling, and pain at injection site Unspecified	Contamination High dose of vitamin	Compounded betamethasone phosphate and betamethasone acetate Oral multivitamin capsule	AL	Not reported	High vitamin D ₃ can cause significant
2014- 15 ²⁷	Several ²⁸		Unspecified	D ₃ Contamination	Sterile products	AL	Nationwide ²⁹	short- and long-term effects. Administration of contaminated sterile products may result in serious and potentially life-threatening
	1161		Our i	Dose of midazolam	Injected		No+	infections or death. Compounded midazolam, a sedating agent, did not match the concentration on the product label.
2014 ³⁰	Unknown		Oversedation	labeled with incorrect concentration	Injectable midazolam Compounded topical	IN	Not reported	concentration on the product label. Oversedation can result in a range of effects from increased sleepiness to severe difficulty breathing.
2014 ³¹	1	1	Toxicity	Not reported	anesthetic cream (ketamine) Intravitreal injections	ТХ	ТХ	Bevacizumab and ranibizumab were
2014 ³²	37		Not reported	Contamination	of bevacizumab or ranibizumab	FL	Not reported	repackaged in a manner that exposed sterile, preservative free vials to an uncontrolled environment.
2014 ³³	1		Severe flushing, stinging, and dizziness	Dose of magnesium sulfate 200 times stronger than labeled concentration ³⁴	Compounded magnesium sulfate	ТХ	Not reported	Voluntary recall of injectable mineral
2013 ³⁵	1		Bacterial bloodstream infection	Contamination	Injectable mineral product	ТХ	CA	product that contained bacteria with the potential for serious infection. A patient admitted to the hospital with an infection of the same bacteria.
2013 ³⁶	15	2 ³⁷	Bacterial bloodstream infection	Contamination	Injectable calcium gluconate	ТХ	ТХ	The Centers for Disease Control and Prevention (CDC) has not conclusively linked the deaths to the contaminated drug.
2013 ³⁸	6		Fever, flu-like symptoms, soreness at	Unknown	Injectable methylcobalamin	ТХ	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
			injection site					found that sterility and quality of the manufacturing process could not be assured.
2013 ³⁹ 2013 ⁴⁰	5		Serious bacterial eye infections Fungal eye infections	Contamination	Injectable bevacizumab for administration in the eye Injectable bevacizumab- triamcinolone for	GA Not reported	GA, IN NY	Fungal infection of the eye caused significant visual impairment that percisted for at least three months
2013	0		Kidney failure and	Contamination	administration in the eye	Notreported		persisted for at least three months from the incident. Product is marketed for dissolving fat. The patient developed difficulties
2013 ⁴¹	1		acute injury of the liver and pancreas	Unknown	product for administration under the skin	Not reported	Not reported	with digestion and metabolism as well as kidney failure, which required dialysis.
2012- 13 ⁴²	12		Bacterial bloodstream infection Bacterial and fungal	Contamination	Parenteral infusion	Not reported	IL	deficiencies in the parenteral medication preparation and handling. Skin and soft tissue infections resulted after intramuscular injection
2012- 13 ⁴³	26		infections in skin and soft tissue	Contamination	Injectable preservative-free methylprednisolone acetate	TN	AR, FL, IL, NC	of preservative-free product. Subsequent voluntary recall of sterile products was issued.
2012- 1344	793	76 ⁴⁵	Fungal meningitis and other infections	Contamination	Injectable preservative-free methylprednisolone acetate	МА	FL, GA, ID, IL, IN, MD, MI, MN, NC, NH, NJ, NY, OH, PA, RI, SC, TN, TX, VA, WV ⁴⁶	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. ⁴⁷
2012 ⁴⁸	47		Fungal eye infection; vision loss in majority of cases	Contamination	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 ⁴⁹	7		Bacterial bloodstream infection	Contamination	Injectable fentanyl	NC	NC	
2012 ⁵⁰	1		Overdose	Dose of flecainide four times stronger than ordered	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 ⁵¹	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 multidose vials. ⁵²
2011- 12 ⁵³	15		Bacterial bloodstream infection	Contamination	Sterile products	Not reported	WV	Adverse events resulted from the use of bulk saline bags for IV flushes in a physician office practice.
2011 ⁵⁴	1		Toxicity	Dose of 4-aminopyridine 10 times stronger than labeled concentration	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
201155	9		Bacterial eye infection, and one case of meningitis and encephalitis; four cases	Contamination	Injectable bevacizumab for administration in the eye	Not reported	TN	memory loss.
2011 ⁵⁶	12		of loss of eyesight Bacterial eye infection; three patients had eye	Contamination	Injectable bevacizumab for administration in the eye	FL	FL	
			removals		Injectable bevacizumab for administration in the eye	СА	CA	Trace amounts of bortezamib, a cancer drug that is not intended for injection into the eye, were detected
2011 ⁵⁷	5		Blindness	Unintended presence of another medication	daministration in the eye			on a cample syringe
2011 ⁵⁷ 2011 ⁵⁸	5 19	9	Blindness Bacterial bloodstream infection	presence of another	Parenteral nutrition solution	Not reported	AL	on a sample syringe.
		9	Bacterial bloodstream	presence of another medication		Not reported	AL	on a sample syringe. Acute sodium overload can cause symptoms ranging from fluid retention to seizures and coma, affecting multiple organs including lungs and kidneys. The patient
201158	19		Bacterial bloodstream infection	presence of another medication Contamination Dose of sodium 60	Parenteral nutrition solution			Acute sodium overload can cause symptoms ranging from fluid retention to seizures and coma, affecting multiple organs including
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2011 ⁵⁸ 2010 ⁵⁹ 2009 ⁶¹ 2009 ⁶³ 2008 ⁶⁴ 2008 ⁶⁵ 2008 ⁶⁵ 2007 ⁶⁷ 2007 ⁶⁷	19 1 1 1 1 1 9 1 1 1 1 1 1 1 1 1 1 1 1		Bacterial bloodstream infection Fatal overdose Gunspecified side effects Fatal overdose Fatal overdose Gue case of vision loss Acute withdrawal Acute withdrawal fatal overdose fatal overdose fatal overdose fatal acute respiratory distress syndrome fatal overdose blood pressure, and lack of oxygen	presence of another medicationContaminationDose of sodium 60 times stronger than orderedDose of liothyronine 10 times stronger than orderedDose of levothyroxine 18 times stronger than orderedDose of baclofen 7 percent of orderedDose of sodium chloride 10 times stronger than orderedDose of sodium left in solution longer than la labeled concentrationColistimethate sodium left in solution longer than orderedDose of colchicine eight times stronger than labeled concentrationDose of colchicine eight times stronger than labeled concentrationBetamethasone made with incorrect arnout of ordered with incorrect arnout of orderedDose of colchicine chemotherapy	Injectable sodium chloride Oral liothyronine (T3) Injectable hydromorphone Oral levothyroxine pills Injectable preservative-for administration in the spine Injectable baclofen for administration in the spine Injectable sodium chloride Injectable colchicine Injectable colchicine Injectable colchicine Injectable betamethasone	ال ال AZ TN NC FL Not reported Not reported Not reported TX South reported AL	IL Not reported Not reported Not reported Not reported CO CO OR, WA OR, WA AZ Not reported	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. Liothyronine overdose can result in shakiness, increased heart rate, and palpitations. Patients developed orbital cellulitis, a type of infection that results in inflammation of the eye. The product included a fraction of the intended dose of baclofen. Patient experienced frequent and severe spasms. Acute sodium overload can cause symptoms ranging from fluid retention to seizures and coma, and affect multiple organs including lungs and kidneys. Seven months after receiving mesotherapy injections, patient developed a persistent immune- mediated inflammatory reaction. 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. 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. 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. The product was voluntarily recalled, and a subsequent reformulation furcher to preservative. An FDA investigation discovered at least 70 complaints associated with the drug.
2011 ⁵⁸ 2010 ⁵⁹ 2009 ⁶¹ 2009 ⁶² 2009 ⁶³ 2008 ⁶⁶ 2008 ⁶⁶ 2007 ⁶⁷ 2007 ⁶⁷	19 1 1 1 1 1 9 1 1 1 1 1 1 1 1 1 1 1 1		Bacterial bloodstream Bacterial bloodstream Fatal overdose Inspecified side Fatal overdose Fatal overdose Fatal overdose Fatal overdose Fatal overdose Acute withdrawal Fatal overdose Secterial bloodstream Inflammatory reaction Bacterial bloodstream Inflexion sessed Secterial bloodstream Secterial bloodstream Inflexion sessed Subsciencesses syndrome	presence of another medicationContaminationDose of sodium 60 times stronger than orderedDose of liothyronine 10 times stronger than orderedDose of levothyroxine 18 times stronger than orderedDose of baclofen 7 percent of ordered dosageDose of sodium chloride 10 times stronger than orderedDose of sodium than orderedDose of sodium stronger than orderedDose of sodium eight times stronger than labeled concentrationColistimethate sodium left in solution longer than labeled qiffienent drug than orderedDose of colchicine eight times stronger than labeled concentrationBetamethasone made with incorrect amount of sodium chlorideDose of chemotherapy tinfusion diluted with toxic amount of sodium chloride	Parenteral nutrition solution Parenteral nutrition solution Injectable sodium chloride Oral liothyronine (T3) Injectable preservative- free hyaluronidase for administration in the spine Injectable baclofen for administration in the spine Injectable sodium chloride Injectable sodium chloride Colistimethate sodium inhaled solution Injectable colchicine Injectable fentanyl Injectable fentanyl	IL AZ TN RC RL Not reported Not reported Not reported TX MS	IL Not reported Not reported Not reported Not reported Not reported CO Not reported CO Not reported CA, MD AZ	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. Liothyronine overdose can result in shakiness, increased heart rate, and palpitations. Patients developed orbital cellulitis, a type of infection that results in inflammation of the eye. The product included a fraction of the intended dose of baclofen. Patient experienced frequent and severe spasms. Acute sodium overload can cause symptoms ranging from fluid retention to seizures and coma, and affect multiple organs including lungs and kidneys. Seven months after receiving mesotherapy injections, patient developed a persistent immune- mediated inflammatory reaction. 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 ize weeks before further dilution for administration. IV doses that exceed the standard single-use therapeutic dose of 2-4 mg per episode of gout have resulted in ithe same class of sedative analgesics. The symptoms of decreased consciousness, hypoxia, and hypotension are consistent within higher than intended opioid exposure. The product was voluntarily recalled, and a subsequent reformulation continued to include an incorrect amount of preservative. An FDA investigation discovere at least 70 complaints associated with the drug. Acute sodium overload can cause symptoms ranging from fluid affect multiple organs including lungs and kidneys.
2011 ⁵⁸ 2010 ⁵⁹ 2009 ⁶¹ 2009 ⁶³ 2008 ⁶⁴ 2008 ⁶⁵ 2008 ⁶⁵ 2007 ⁶⁷ 2007 ⁶⁷	19 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		 Bacterial bloodstream infection Fatal overdose Unspecified side effects Fatal overdose Fatal overdose Acute withdrawal Fatal overdose fatal overdose inflammatory reaction Fatal overdose Fatal overdose Sectorial bloodstream Fatal overdose Bacterial bloodstream consciousness, low blood pressy, and claulitis Fatal overdose 	presence of another medicationContaminationDose of sodium 60 times stronger than orderedDose of liothyronine 10 times stronger than orderedDose of levothyroxine 18 times stronger than orderedDose of baclofen 7 percent of ordered dosageDose of sodium chloride 10 times stronger than orderedDose of sodium left in solution longer than labeled concentrationColistimethate sodium left in solution longer than cherondurt leading to administration of different drug than orderedBetamethasone made with incorrect amount of sodium chlorideDose of zinc 1,000 times stronger than orderedDose of zinc 1,000 times stronger than ordered	Parenteral nutrition solution Injectable sodium chloride Oral liothyronine (T3) Injectable hydromorphone Oral levothyroxine pills Injectable preservative- free hyaluronidase for administration in the eye Injectable sodium chloride Mesotherapy injections Mesotherapy injections Injectable colchicine Injectable colchicine Injectable fentanyl Injectable fentanyl Injectable betamethasone	ال ال AZ TN NC FL Not reported Not reported Not reported TX South reported AL	IL Not reported Not reported Not reported Not reported CO CO OR, WA OR, WA AZ Not reported	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. Liothyronine overdose can result in shakiness, increased heart rate, and palpitations. Patients developed orbital cellulitis, a type of infection that results in inflammation of the eye. The product included a fraction of the intended dose of baclofen. Patient experienced frequent and severe spasms. Acute sodium overload can cause symptoms ranging from fluid retention to seizures and coma, and affect multiple organs including lungs and kidneys. Seven months after receiving mesotherapy injections, patient developed a persistent immune- mediated inflammatory reaction. 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 iw weeks before further dilution for administration. IV doses that exceed the standard single-use therapeutic dose of 2-4 mg per episode of gout have resulted in plife-threatening toxicity. In this case, the doses were eightfold these limits. 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. The product was voluntarily recalled, and a subsequent reformulation complaints associated with the drug. Acute sodium overload can cause symptoms raiging from fluid affect multiple organs including lungs
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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.

Endnotes

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