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.

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.
2001-2018[4]	23	At least 2	Irregular heart rhythm, seizures, potentially lethal arrhythmias, fainting, cardiac arrest, and death	Products contained cesium chloride, which is not approved by FDA to treat disease.	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 risk alert and banned its use in compounded products.
2016-2018[5]	46		Eye inflammation, eye infections, high eye pressures, color variation, spots over vision	Not reported	28 adverse events were related to eye injections of repackaged sterile Avastin (bevacizumab); source of remaining 18 adverse events not reported.	FL	Not reported	Adverse events were identified upon 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, cellulitis, and pellet extrusion	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 products. Due to missing and 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	TX	TX	
2017[10]	2	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[11]	41		Septic arthritis	Bacterial contamination	Intra-articular injectable	NJ	NJ	Investigation revealed inappropriate use and handling of pharmacy bulk packaged products.
2017[12]	1		Hemorrhagic occlusive retinal vasculitis	Not reported	Intraocular injectable of triamcinolone, moxifloxacin, and vancomycin (TMV)	NJ	Not reported	
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	
2016[14]	17	2	Fungal bloodstream infections	Contamination	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[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 nerves and brain.
2016[16]	3		Overdose[17]	Dose of morphine sulfate stronger than labeled concentration	Injectable morphine sulfate	IN	IL, IN[18]	
2016[19]	1		Abscesses and osteomyelitis	Contamination	Unknown injectable	Not reported	NM	Investigation revealed unsafe injection and compounding practices.
2016[20]	7		Thyrotoxicosis	Super-potent compounded drug	Compounded oral liothyronine	SD	Not reported	
2015[21]	7		Hepatitis C	Contamination	Unknown injectable	CA	CA	Investigation into the clinic revealed infection control breaches and ongoing issues with infection control practices.
2015[22]	Several		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[23]	5		Redness, swelling, and pain at injection site	Contamination	Compounded betamethasone phosphate and betamethasone acetate	AL	Not reported	
2015[24]	Several[25]		Unspecified	High dose of vitamin D_3	Oral multivitamin capsule	FL	Nationwide[26]	High vitamin D_3 can cause significant short- and long-term effects.
2014-15[27]	Several[28]		Unspecified	Contamination	Sterile products	AL	Nationwide[29]	Administration of contaminated sterile products may result in serious and potentially life-threatening infections or death.
2014[30]	Unknown		Oversedation	Dose of midazolam labeled with incorrect concentration	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[31]	1	1	Toxicity	Not reported	Compounded topical anesthetic cream (ketamine)	TX	TX	
2014[32]	37		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[33]	1		Severe flushing, stinging, and dizziness	Dose of magnesium sulfate 200 times stronger than labeled concentration[34]	Compounded magnesium sulfate	TX	Not reported	
2013[35]	1		Bacterial bloodstream infection	Contamination	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[36]	15	2[37]	Bacterial bloodstream infection	Contamination	Injectable calcium gluconate	TX	TX	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 injection site	Unknown	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[39]	5		Serious bacterial eye infections	Contamination	Injectable bevacizumab for administration in the eye	GA	GA, IN	
2013[40]	8		Fungal eye infections	Contamination	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[41]	1		Kidney failure and acute injury of the liver and pancreas	Unknown	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[42]	12		Bacterial bloodstream infection	Contamination	Parenteral infusion	Not reported	IL	Facility inspection revealed deficiencies in the parenteral medication preparation and handling.
2012-13[43]	26		Bacterial and fungal infections in skin and soft tissue	Contamination	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[44]	793	76[45]	Fungal meningitis and other infections	Contamination	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[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 memory loss.
2011[55]	9		Bacterial eye infection, and one case of meningitis and encephalitis; four cases of loss of eyesight	Contamination	Injectable bevacizumab for administration in the eye	Not reported	TN	
2011[56]	12		Bacterial eye infection; three patients had eye removals	Contamination	Injectable bevacizumab for administration in the eye	FL	FL	
2011[57]	5		Blindness	Unintended presence of another medication	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[58]	19	9	Bacterial bloodstream infection	Contamination	Parenteral nutrition solution	Not reported	AL	
2010[59]	1	1	Fatal overdose	Dose of sodium 60 times stronger than ordered	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[60]	1		Unspecified side effects	Dose of liothyronine 10 times stronger than ordered	Oral liothyronine (T3)	AZ	Not reported	Liothyronine overdose can result in shakiness, increased heart rate, and palpitations.
2009[61]	1	1	Fatality	Unknown	Injectable hydromorphone	TN	Not reported	
2009[62]	1	1	Fatal overdose	Dose of levothyroxine 18 times stronger than ordered	Oral levothyroxine pills	NC	Not reported	
2009[63]	9		Eye infection; at least one case of vision loss	Unknown	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[64]	1		Acute withdrawal	Dose of baclofen 7 percent of ordered dosage	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[65]	1	1	Fatal overdose	Dose of sodium chloride 10 times stronger than ordered	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[66]	1		Persistent inflammatory reaction	Unknown	Mesotherapy injections	Not reported	CO	Seven months after receiving mesotherapy injections, patient developed a persistent immune-mediated inflammatory reaction.
2007[67]	1	1	Fatal acute respiratory distress syndrome	Colistimethate sodium left in solution longer than recommended	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[68]	3	3	Fatal overdose	Dose of colchicine eight times stronger than labeled concentration	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[69]	8	1	Bacterial bloodstream infection	Contamination	Injectable fentanyl	Not reported	CA, MD	
2006[70]	1		Decreased consciousness, low blood pressure, and lack of oxygen	Mislabeled product leading to administration of different drug than ordered	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[71]	At least 70		Redness, swelling, bruising, rash, fever, and cellulitis	Betamethasone made with incorrect amount of preservative	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[72]	1	1	Fatal overdose	Dose of chemotherapy infusion diluted with toxic amount of sodium chloride	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[73]	1	1	Fatal overdose	Dose of zinc 1,000 times stronger than ordered	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[74]	3	1	Fatal overdose, cardiac arrest	Dose of lidocaine and tetracaine higher than usual	Topical combination anesthetic creams (lidocaine and tetracaine)	NC	NC	
2005[75]	19	1	Bacterial bloodstream infection	Contamination	Injectable magnesium sulfate	TX	CA, MA, NC, NJ, NY, SD	
2004-06[76]	80		Bacterial bloodstream infection	Contamination	Injectable heparinized saline	TX	MI, MO, NY, SD, TX, WY	
2004-05[77]	6		Bacterial eye infection; all cases had partial or complete loss of vision; two patients had eye removals	Contamination	Trypan blue eye drops	Not reported	Not reported	
2004-05[78]	11	3	Systemic inflammatory response syndrome	Contamination	Cardioplegia solution for administration during heart surgery	MD	VA	
2004[79]	2		Bacterial bloodstream infection	Contamination	Injectable heparin-vancomycin	FL	CT	
2003[80]	2		Overdose	Dose of liothyronine stronger than ordered	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[81]	1	1	Fatal overdose	Dose of lidocaine and tetracaine higher than usual	Topical combination anesthetic cream (lidocaine and tetracaine)	UT	AZ	
2002[82]	1		Toxicity	Dose of clonidine 10 times higher than ordered	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[83]	1		Toxicity	Dose of clonidine 87 times higher than ordered	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[84]	2		Meningitis	Contamination	Injectable methylprednisolone for administration in the spine	MI	MI	
2002[85]	7	2	Fungal meningitis and sacroiliitis	Contamination	Injectable methylprednisolone acetate for administration in the spine	SC	NC	
2001[86]	2		Bacterial bloodstream infection	Contamination	Injectable preservative-free heparinized saline	Not reported	Not reported	
2001[87]	1		Overdose	Dose of clonidine 1,000 times stronger than ordered	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[88]	13	3	Five cases of meningitis; five cases of epidural abscess; one patient had an infected hip joint; two unspecified	Contamination	Injectable betamethasone for administration in spine or joint	CA	CA	
2001[89]	4		Bacterial bloodstream infection	Contamination	Injectable ranitidine	Not reported	Not reported	

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.

Endnotes

1 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.

2 A. Coukell, "Risks of Compounded Drugs," *JAMA Internal Medicine* 174, no. 4 (2014): 613–14, http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1819570; M.F. Farooqi et al., "Toxicity From a Clonidine Suspension," *The Journal of Medical Toxicology* 5, no. 3 (2009): 130–33, https://link.springer.com/article/10.1007%2FBF03161223; R.W. Moehring et al., "Outbreak of Bacteremia Due to *Burkholderia contaminans* Linked to Intravenous Fentanyl From an Institutional Compounding Pharmacy," *JAMA Internal Medicine* 174, no. 4 (2014): 606–12, http://dx.doi.org/10.1001/jamainternmed.2013.13768.

3 U.S. Food and Drug Administration, "FDA Highlights Concerns With Using Dietary Ingredient Glutathione to Compound Sterile Injectables," accessed June 20, 2019, https://www.fda.gov/drugs/human-drug-compounding/fda-highlights-concerns-using-dietary-ingredient-glutathione-compound-sterile-injectables.

4 U.S. Food and Drug Administration, "FDA Alerts Health Care Professionals of Significant Safety Risks Associated With Cesium Chloride," July 23, 2018, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-professionals-significant-safety-risks-associated-cesium-chloride.

5 U.S. Food and Drug Administration, "Pacifico National, Inc. dba AmEx Pharmacy 483 Report," June 20, 2019, https://www.fda.gov/media/128709/download.

6 U.S. Food and Drug Administration, "Statement on Improving Adverse Event Reporting of Compounded Drugs to Protect Patients," Sept. 9, 2019, https://www.fda.gov/news-events/press-announcements/statement-improving-adverse-event-reporting-compounded-drugs-protect-patients; J. Dohm, J. Kim, and J. Woodcock, "Improving Adverse Event Reporting for Compounded Drugs," *JAMA Internal Medicine* 179, no. 11 (2019): 1461-62, https://doi.org/10.1001/jamainternmed.2019.3830.

7 The business that was inspected by FDA, BioTE, obtained its products from two outsourcing facilities that were identified by the agency. One is located in Texas, the other in Florida.

8 U.S. Food and Drug Administration, "FDA's Investigation Into Guardian's Compounded Triamcinolone-Moxifloxacin Drug Product," accessed Dec. 4, 2018, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm610716.htm.

9 U.S. Food and Drug Administration, "FDA Alerts Health Care Professionals of Adverse Events Associated With Guardian's Compounded Triamcinolone and Moxifloxacin Product for Intravitreal Injection," accessed Dec. 4, 2018, https://www.fda.gov/Drugs/DrugSafety/ucm569114.htm.

10 U.S. Food and Drug Administration, "FDA Investigates Two Serious Adverse Events Associated With ImprimisRx's Compounded Curcumin Emulsion Product for Injection," accessed Dec. 4, 2018, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm570192.htm.

11 K. Ross et al., "Outbreak of Septic Arthritis Associated With Intra-Articular Injections at an Outpatient Practice — New Jersey, 2017," *Morbidity and Mortality Weekly Report* 66, no. 29 (2017): 777-779, http://dx.doi.org/10.15585/mmwr.mm6629a3.

12 U.S. Food and Drug Administration, "A Case of Hemorrhagic Occlusive Retinal Vasculitis (HORV) Following Intraocular Injections of a Compounded Triamcinolone, Moxifloxacin, and Vancomycin Formulation," accessed Nov. 14, 2017, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm578514.htm.

13 U.S. Food and Drug Administration, "FDA Investigates Two Adverse Events Associated With United Pharmacy's Compounded Glutamine, Arginine, and Carnitine Product for Injection," accessed Nov. 14, 2017, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm584125.htm.

14 A. Vasquez et al., "Notes From the Field: Fungal Bloodstream Infections Associated With a Compounded Intravenous Medication at an Outpatient Oncology Clinic—New York City, 2016," *Morbidity and Mortality Weekly Report* 65, no. 45 (2016): 1274–75, http://www.cdc.gov/mmwr/volumes/65/wr/mm6545a6.htm?s_cid=mm6545a6_w.

15 E. Hines et al., "Massive Intravenous Manganese Overdose Due to Compounding Error: Minimal Role for Hemodialysis," *Clinical Toxicology* 54, no. 6 (2016): 523–25, http://dx.doi.org/10.1080/15563650.2016.1178390. This source was published in 2016; information was not available about the timing of the adverse event.

16 U.S. Food and Drug Administration, "FDA Announces Pharmakon Pharmaceuticals' Nationwide Voluntary Recall of Purportedly Sterile Drug Products," accessed Dec. 4, 2018, https://www.fda.gov/Drugs/DrugSafety/ucm496346.htm.

17 U.S. Department of Justice, "Former CEO Convicted of Defrauding Food and Drug Administration and Distributing Adulterated Drugs," accessed May 6, 2019, https://www.justice.gov/opa/pr/former-ceo-convicted-defrauding-food-and-drug-administration-and-distributing-adulterated.

18 The drug product was distributed to Illinois and Indiana; information was not available about where adverse events occurred.

19 H.R. Simpson et al., "When Ignorance Is Not Bliss: Complications Associated With Homeopathic Injections From a Chiropractor," (paper presented at the annual conference for the Council for State and Territorial Epidemiologists, Boise, June 4-8, 2017), https://cste.confex.com/cste/2017/webprogram/Paper8601.html.

20 J. Woodcock and J. Dohm, "Toward Better-Quality Compounded Drugs — An Update From the FDA," *The New England Journal of Medicine* 377, no. 26 (2017): 2509-2512, http://dx.doi.org/10.1056/NEJMp1712905.

21 M.A. Foster et al., "Notes From the Field: Investigation of Hepatitis C Virus Transmission Associated With Injection Therapy for Chronic Pain — California, 2015," *Morbidity and Mortality Weekly Report* 65, no. 21 (2016): 547-549, http://dx.doi.org/10.15585/mmwr/mm6521a4.

22 U.S. Food and Drug Administration, "Medisca Inc 11/25/15," accessed Jan. 22, 2018, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm474892.htm.

23 Woodcock and Dohm, "Toward Better-Quality Compounded Drugs."

24 U.S. Food and Drug Administration, "FDA Announces Glades Drugs' Nationwide Voluntary Recall of Compounded Multivitamins Containing High Amounts of Vitamin D_3 (Cholecalciferol)," accessed Feb. 17, 2017, http://www.fda.gov/drugs/drugsafety/ucm474552.htm.

25 The source explicitly states that the adverse events were potentially associated with the compounded drug product in question.

26 The drug product was distributed nationally; information was not available about where adverse events occurred.

27 U.S. Food and Drug Administration, "FDA Announces Medistat RX's Nationwide Voluntary Recall of Sterile Drug Products," accessed Dec. 4, 2018, https://www.fda.gov/Drugs/DrugSafety/ucm461810.htm.

28 The source explicitly states that the adverse events were potentially associated with the compounded drug product in question.

29 The drug product was distributed nationally; information was not available about where adverse events occurred.

30 U.S. Food and Drug Administration, "Pharmakon Pharmaceuticals 5/21/15," accessed Dec. 12, 2016, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm448642.htm.

31 K. Krause, "Potent Pain Creams That Sold for Up to $28K Caused Deaths, Cost Government Millions," *Dallas News*, Nov. 12, 2017, https://www.dallasnews.com/news/crime/2017/11/12/potent-pain-creams-sold-25k-caused-deaths-cost-government-millions.

32 U.S. Food and Drug Administration, "Eastern Pharmacy, Inc. 10/29/14," accessed Jan. 22, 2018, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm423249.htm.

33 Woodcock and Dohm, "Toward Better-Quality Compounded Drugs."

34 U.S. Food and Drug Administration, "Walgreens Infusion Services 8/27/15," accessed Jan. 8, 2018, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm473497.htm.

35 U.S. Food and Drug Administration, "FDA Announces Voluntary Nationwide Recall of All Non-Expired Sterile Drugs From Abrams Royal Compounding Pharmacy," accessed Dec. 4, 2018, https://wayback.archive-it.org/7993/20170111160949/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm379634.htm.

36 U.S. Food and Drug Administration, "FDA Announces Nationwide Voluntary Recall of All Products for Sterile Use From Specialty Compounding," accessed Dec. 4, 2018, https://wayback.archive-it.org/7993/20170112025131/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm364644.htm.

37 The source explicitly states that it is unclear whether the reported deaths were related to the compounding error or potential error.

38 T. Sandle, "Sterile Products Produced by Downing Labs Recalled," *Digital Journal,* July 22, 2014, http://www.digitaljournal.com/life/health/sterile-products-produced-by-downing-labs-recalled/article/391739; U.S. Food and Drug Administration, "NuVision Pharmacy 483 Report," accessed Aug. 18, 2015, http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM348772.pdf..

39 U.S. Food and Drug Administration, Statement of Janet Woodcock, M.D., director, Center for Drug Evaluation and Research, before the Committee on Health, Education, Labor and Pensions, United States Senate, "Pharmaceutical Compounding: Proposed Legislative Solution," May 9, 2013, http://www.help.senate.gov/imo/media/doc/Woodcock2.pdf; U.S. Food and Drug Administration, "FDA Alerts Health Care Providers and Patients of the Nationwide Recall of All Lots of Sterile Products Distributed by Clinical Specialties Compounding Pharmacy," accessed Dec. 4, 2018, https://wayback.archive-it.org/7993/20170112024808/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm345019.htm; L.S. Edison et al., "Endophthalmitis Outbreak Associated With Repackaged Bevacizumab," *Emerging Infectious Diseases* 21, no. 1 (2015): 171–73, http://dx.doi.org/10.3201/eid2101.141040.

40 A. Sheyman et al., "An Outbreak of Fungal Endophthalmitis After Intravitreal Injection of Compounded Combined Bevacizumab and Triamcinolone," *JAMA Ophthalmology* 131, no. 7 (2013): 864–69, http://dx.doi.org/10.1001/jamaophthalmol.2013.88. This source was published in 2013; information was not available about the timing of adverse events.

41 B. Libby et al., "Multisystem Organ Failure Following LipoDissolve Injections," *Clinical Toxicology* 3, no. 4 (2013): 171, http://dx.doi.org/10.4172/2161-0495.1000171. This source was published in 2013; information was not available about the timing of the adverse event.

42 B.R. Yablon et al., "Outbreak of *Pantoea agglomerans* Bloodstream Infections at an Oncology Clinic – Illinois, 2012-2013," *Infection Control & Hospital Epidemiology* 38, no. 3 (2017): 314-319, http://dx.doi.org/10.1017/ice.2016.265.

43 Centers for Disease Control and Prevention, "Multistate Investigation of Suspected Infections Following Steroid Injections," accessed Aug. 15, 2013, http://www.cdc.gov/hai/outbreaks/TN-pharmacy/index.html.

44 U.S. Food and Drug Administration, "January 31, 2018: New England Compounding Center Pharmacist Sentenced for Role in Nationwide Fungal Meningitis Outbreak," accessed Dec. 5, 2018, https://www.fda.gov/ICECI/CriminalInvestigations/ucm594800.htm. Initially, the Centers for Disease Control and Prevention reported that 753 patients were harmed, and that 64 had died. FDA has since identified a total of 793 patients affected by this compounding error.

45 Ibid. Federal prosecutors identified a total of 76 deaths attributable to the outbreak in the subsequent criminal case against the pharmacy co-owner; J. Bidgood, "Pharmacist Gets 9-Year Prison Term in Deadly Meningitis Outbreak," *The New York Times*, June 26, 2017, https://www.nytimes.com/2017/06/26/us/pharmacy-meningitis-deaths-steroids-crisis.html.

46 Centers for Disease Control and Prevention, "Multistate Outbreak of Fungal Meningitis and Other Infections—Case Count," accessed Dec. 21, 2016, http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html. This webpage has not been updated since 2015, and thus does not reflect the current total adverse event count.

47 U.S. Food and Drug Administration, "Multistate Outbreak of Fungal Meningitis and Other Infections – Archive of Updates," accessed May 1, 2017, https://www.fda.gov/drugs/drugsafety/fungalmeningitis/ucm325037.htm.

48 C.A. Mikosz et al., "Fungal Endophthalmitis Associated With Compounded Products," *Emerging Infectious Diseases* 20, no. 2 (2014): 248–56, http://dx.doi.org/10.3201/eid2002.131257.

49 Moehring et al., "Outbreak of Bacteremia."

50 G. Wang et al., "Flecainide Toxicity in a Pediatric Patient Due to Differences in Pharmacy Compounding," *International Journal of Cardiology* 161, no. 3 (2012): 178–79, http://dx.doi.org/10.1016/j.ijcard.2012.06.028. This source was published in 2012; information was not available about the timing of the adverse event.

51 Centers for Disease Control and Prevention, "Invasive *Staphylococcus aureus* Infections Associated With Pain Injections and Reuse of Single-Dose Vials — Arizona and Delaware, 2012," *Morbidity and Mortality Weekly Report* 61, no. 27 (2012): 501-504, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6127a1.htm.

52 Centers for Disease Control and Prevention, "Protect Patients Against Preventable Harm From Improper Use of Single–Dose/Single–Use Vials," accessed Jan. 22, 2018, https://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html.

53 I. See et al., "Outbreak of *Tsukamurella* Species Bloodstream Infection Among Patients at an Oncology Clinic, West Virginia, 2011–2012," *Infection Control & Hospital Epidemiology* 35, no. 3 (2014): 300-306, http://dx.doi.org/10.1086/675282.

54 E. Schwam, "Severe Accidental Overdose of 4-Aminopyridine Due to a Compounding Pharmacy Error," *The Journal of Emergency Medicine* 41, no. 1 (2011): 51–54, http://dx.doi.org/10.1016/j.jemermed.2009.04.037. This source was published in 2011; information was not available about the timing of the adverse event.

55 B.A. Frost and M.A. Kainer, "Safe Preparation and Administration of Intravitreal Bevacizumab Injections," *The New England Journal of Medicine* 365, no. 23 (2011): 2238, http://dx.doi.org/10.1056/NEJMc1105759. This source was published in 2011; information was not available about the timing of adverse events.

56 R.A. Goldberg et al., "An Outbreak of *Streptococcus* Endophthalmitis After Intravitreal Injection of Bevacizumab," *American Journal of Ophthalmology* 153, no. 2 (2012): 204–8.e1, http://dx.doi.org/10.1016/j.ajo.2011.11.035.

57 Department of Veterans Affairs, Office of Inspector General, "Healthcare Inspection: Oversight Review of Ophthalmology Adverse Drug Events, VA Greater Los Angeles Healthcare System, Los Angeles, California," Report No. 12-01515-151 (2012), http://www.va.gov/oig/pubs/VAOIG-12-01515-151.pdf.

58 C.A. Thompson, "Bacteremia Outbreak Tied to Improper Filtration by Compounding Pharmacy," *American Journal of Health-System Pharmacy* 68, no. 22 (2011): 2110 and 2112, http://dx.doi.org/10.2146/news110075.

59 B. Vitello, "Lutheran General to Pay $8.25 Million in Baby's Death," *Daily Herald*, April 5, 2012, http://www.dailyherald.com/article/20120405/news/704059806.

60 Arizona State Board of Pharmacy v. Vicki Graves, "Consent Agreement for Civil Penalty and Continuing Education," Board Case No. 10-0061-PHR (May 14, 2010), https://pharmacy.az.gov/sites/default/files/documents/files/10-0061.pdf.

61 U.S. Food and Drug Administration, "PharMEDium Services, LLC 483 Report," accessed Dec. 21, 2016.

62 North Carolina Board of Pharmacy, "Consent Order: In the Matter of Deep River Drug," accessed Dec. 12, 2016, http://www.ncbop.org/Disciplinary%20Actions%20-%20PHARMACIES/DeepRiverDrug08944.pdf.

63 U.S. Food and Drug Administration, Responses for the record following hearing on "Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak," United States Senate Committee on Health Education, Labor and Pensions, May 16, 2013.

64 D. Kanter et al., "Acute Baclofen Withdrawal in a Patient Receiving Compounded Intrathecal Baclofen: A Case Report," *Archives of Physical Medicine and Rehabilitation* 89 (2008): E123, accessed Dec. 12, 2016, http://www.archives-pmr.org/article/S0003-9993(08)01152-0/pdf. This source was published in 2008; information was not available about the timing of the adverse event.

65 North Carolina Board of Pharmacy, "Consent Order of Discipline: In the Matter of Jewel Freeman," accessed Dec. 12, 2016, http://www.ncbop.org/Disciplinary%20Actions%20-%20PHARMACISTS/FreemanJewel10249.pdf.

66 J.E. Strahan, J.L. Cohen, and J.A. Chorny, "Granuloma Annulare as a Complication of Mesotherapy: A Case Report," *Dermatologic Surgery* 34, no. 6 (2008): 836–38, http://dx.doi.org/10.1111/j.1524-4725.2008.34156.x. This source was published in 2008; information was not available about the timing of the adverse event.

67 K. McCoy, "Compounded Colistimethate as Possible Cause of Fatal Acute Respiratory Distress Syndrome," *The New England Journal of Medicine* 357 (2007): 2310–11, http://dx.doi.org/10.1056/nejmc071717. This source was published in 2007; information was not available about the timing of the adverse event.

68 Centers for Disease Control and Prevention, "Deaths From Intravenous Colchicine Resulting From a Compounding Pharmacy Error—Oregon and Washington, 2007," *Morbidity and Mortality Weekly Report* 56, no. 40 (2007): 1050–52, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5640a3.htm.

69 L.L. Maragakis et al., "*Sphingomonas paucimobilis* Bloodstream Infections Associated With Contaminated Intravenous Fentanyl," *Emerging Infectious Diseases* 15, no. 1 (2009): 12–18, http://dx.doi.org/10.3201/eid1501.081054.

70 U.S. Food and Drug Administration, "PharMEDium Services, LLC 13-Apr-07," accessed Dec. 5, 2018, https://www.fdalabelcompliance.com/letters/ucm076357.

71 U.S. Food and Drug Administration, "Med-South Pharmacy Inc. 28-Sep-07," accessed Dec. 5, 2018, https://www.fdalabelcompliance.com/letters/ucm076516; E. Greb, "FDA Censures Med-South Pharmacy for CGMP Violations," *PharmTech.com,* Oct. 18, 2007, http://www.pharmtech.com/fda-censures-med-south-pharmacy-cgmp-violations.

72 Institute for Safe Medication Practices, Medication Safety Alert, "Failed Check System for Chemotherapy Leads to Pharmacist's No Contest Plea for Involuntary Manslaughter," accessed Jan. 9, 2013, http://www.ismp.org/newsletters/acutecare/articles/20090423.asp.

73 M. Grissinger, "A Fatal Zinc Overdose in a Neonate: Confusion of Micrograms With Milligrams," *Pharmacy and Therapeutics* 36, no. 7 (2011): 393–94, 409, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3171817.

74 R. Paul, "Despite Court Ruling, FDA Still Warning Compounders," *Drug Topics,* Jan. 8, 2007, http://drugtopics.modernmedicine.com/drug-topics/content/despite-court-ruling-fda-still-warning-compounders; ABC News, "Death Prompts Calls for More Drug Scrutiny," April 21, 2005, http://abcnews.go.com/Primetime/Health/story?id=692826&page=1.

75 R. Sunenshine et al., "A Multistate Outbreak of *Serratia marcescens* Bloodstream Infection Associated With Contaminated Intravenous Magnesium Sulfate From a Compounding Pharmacy," *Clinical Infectious Diseases,* 45 (2007): 527–33, http://dx.doi.org/10.1086/520664; U.S. Food and Drug Administration, "PharMEDium Services, LLC 13-Apr-07 Warning Letter."

76 M.D. Gershman et al., "Multistate Outbreak of *Pseudomonas fluorescens* Bloodstream Infection After Exposure to Contaminated Heparinized Saline Flush Prepared by a Compounding Pharmacy," *Clinical Infectious Diseases* 47 (2008): 1372–79, http://dx.doi.org/10.1086/592968.

77 R. Sunenshine et al., "An Outbreak of Postoperative Gram-Negative Bacterial Endophthalmitis Associated With Contaminated Trypan Blue Ophthalmic Solution," *Clinical Infectious Diseases* 48 (2009): 1580–83, http://dx.doi.org/10.1086/598938.

78 A.S. Patel et al., "Outbreak of Systemic Inflammatory Response Syndrome Linked to a Compounding Pharmacy – Virginia, 2005" (poster presented at the 55th Annual Epidemic Intelligence Service Conference, 2006), http://www.cdc.gov/eis/downloads/2006.eis.conference.pdf; Maryland State Board of Pharmacy, "Order for Summary Suspension: In the Matter of Central Admixture Pharmacy Services, Inc.," accessed Jan. 9, 2013, http://www.dhmh.maryland.gov/pharmacy/docs/FormalOrders/C/C.A.P.S%2011-15-05.pdf.

79 M.R. Held et al., "Life-Threatening Sepsis Caused by *Burkholderia cepacia* From Contaminated Intravenous Flush Solutions Prepared by a Compounding Pharmacy in Another State," *Pediatrics* 118, no. 1 (2006): e212–e215, http://pediatrics.aappublications.org/content/118/1/e212.long.

80 Arizona State Board of Pharmacy, "Amended Complaint and Notice of Hearing: In the Matter of Apothecary Shop of Phoenix, Inc.," accessed Dec. 22, 2016, https://pharmacy.az.gov/sites/default/files/documents/files/03-0015%20B.pdf.

81 Paul, "Despite Court Ruling"; ABC News, "Death Prompts Calls."

82 J. Suchard and K. Graeme, "Pediatric Clonidine Poisoning as a Result of Pharmacy Compounding Error," *Pediatric Emergency Care* 18, no. 4 (2002): 295–96, http://journals.lww.com/pec-online/Citation/2002/08000/Pediatric_clonidine_poisoning_as_a_result_of.14.aspx. This source was published in 2002; information was not available about the timing of the adverse event.

83 Ibid. Information was not available about the timing of the adverse event.

84 N. Shehab et al., "U.S. Compounding Pharmacy-Related Outbreaks, 2001-2013—Public Health and Patient Safety Lessons Learned," *Journal of Patient Safety* (2015), http://dx.doi.org/10.1097/PTS.0000000000000188.

85 Centers for Disease Control and Prevention, "*Exophiala* Infection From Contaminated Injectable Steroids Prepared by a Compounding Pharmacy—United States, July-November 2002," *Morbidity and Mortality Weekly Report,* 51, no. 49 (2002): 1109–12, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5149a1.htm; North Carolina Department of Health and Human Services, Division of Public Health, "*Exophiala (Wangiella) dermatitidis* Fungal Infection Outbreak," *Epi Notes* 2002-4 (December 2002–February 2003): 4–6, http://epi.publichealth.nc.gov/pdf/en2002-4.pdf; D. Brown, "Previous Fungal Meningitis Outbreak a Decade Ago Resulted in No Oversight Changes," *The Washington Post,* Nov. 5, 2012, https://www.washingtonpost.com/national/health-science/previous-fungal-meningitis-outbreak-a-decade-ago-resulted-in-no-oversight-changes/2012/11/05/8417d84e-1fa8-11e2-9cd5-b55c38388962_story.html?utm_term=.2ec5b1bfe374.

86 J.F. Perz et al., "*Pseudomonas putida* Septicemia in a Special Care Nursery Due to Contaminated Flush Solutions Prepared in a Hospital Pharmacy," *Journal of Clinical Microbiology* 43, no. 10 (2005): 5316–18, http://dx.doi.org/10.1128/JCM.43.10.5316-5318.2005.

87 M. Romano and A. Dinh, "A 1000-Fold Overdose of Clonidine Caused by a Compounding Error in a 5-Year-Old Child With Attention-Deficit/Hyperactivity Disorder," *Pediatrics* 108, no. 2 (2001): 471–72, https://www.ncbi.nlm.nih.gov/pubmed/11483818. This source was published in 2001; information was not available about the timing of the adverse event.

88 R. Civen et al., "Outbreak of *Serratia marcescens* Infections Following Injection of Betamethasone Compounded at a Community Pharmacy," *Clinical Infectious Diseases* 43 (2006): 831–37, http://cid.oxfordjournals.org/content/43/7/831.full.pdf+html; California Board of Pharmacy, "Decision: In the Matter of the Statement of Issues Against Robert Eugene Horwitz," Oct. 15, 2008.

89 D. Selenic et al., "*Enterobacter cloacae* Bloodstream Infections in Pediatric Patients Traced to a Hospital Pharmacy," *American Journal of Health-System Pharmacy* 60, no. 14 (2003): 1440–46, https://www.ncbi.nlm.nih.gov/pubmed/12892028.

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