When compounded drugs are created in large volumes and shipped across the country, as was the case with injections linked to the national meningitis outbreak, producers should meet some of the same quality assurance requirements as drug manufacturers. The standard pharmacy compounding controls are not enough. A law passed in 2013 establishes a new category of compounding “outsourcing facilities” that will meet these higher standards, providing a safer source of compounded drugs made and purchased at larger scales.

References

Human skin can carry many kinds of bacteria and fungi, making the people who produce sterile drugs the greatest potential source of contamination. Contaminants in non-sterile ingredients can end up in a finished drug. Advance testing allows producers to reject highly contaminated materials.

Contamination in production environments can cause contamination in a drug. Frequent checks for contaminants in the air and on surfaces and personnel can help prevent this.

"Quality standards — what are the differences?"

Drug manufacturers are required to meet Good Manufacturing Practices—rigorous requirements enforced by FDA that describe a full set of quality systems for the manufacture, processing, and packing of pharmaceutical products. Under the Drug Quality and Security Act of 2013, large-scale compounders that voluntarily register with the FDA as “outsourcing facilities” must meet many of the same quality standards as drug manufacturers. Most sterile drug compounders follow the U.S. Pharmacopeial Convention, Chapter 797—a standardized compounding quality system that, while appropriate for traditional compounding, is not adequate to ensure the safety of large-scale sterile compounding practices.

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