He was a young man when he committed suicide. He was a pharmacist, a husband, and a father of two. He was only 32 years old at the time of his death.

We cannot know for certain why he killed himself, but there are some facts we do know. Because of a compounding error committed at Doc's Pharmacy in Walnut Creek, Calif., the pharmacy where he worked, the batch of betamethasone injection prepared at the pharmacy was not properly sterilized; 13 people became ill and three people died. Unfortunately, this story is not unique.

People trust pharmacists. And the pharmacies that appear most worthy of trust are compounding pharmacies. In the course of their professional careers, many physicians, nurses, and other pharmacists will recommend a compounding pharmacy to people who trust their judgment.

**Special challenges**

When we select a compounding pharmacy or recommend it to others, how do we know that the one we recommend or select meets high and exacting standards?

Most of us are not in a position to make such a judgment. We base our choices upon reputation and the perception of high quality. But how can we know? To know, we need an assurance based upon professionally designed standards against which this healthcare organization has been tested.

For a hospital, the evidence is provided by Joint Commission accreditation. For a compounding pharmacy, it is provided by the seal of the Pharmacy Compounding Accreditation Board (PCAB).

Compounding pharmacy provides special challenges. It requires certain skills and knowledge. Warfarin errors account for a large number of claims filed against pharmacies each year, as attested to by the Pharmacists Mutual Insurance Co. Claims Study. When an error with warfarin is made, it usually involves one patient.

Many times, however, a pharmacy-compounded prescription is prepared in a batch of 5,
10, 25, or more prescriptions. One mistake may result in injury to several patients. There is nothing wrong with batch compounding. It improves quality as well as productivity. It means, however, that in compounding, quality standards must be higher.

Every compounding pharmacy must be tested against tough standards and must be willing to provide evidence that it has been tested and passed. Just as every hospital should be accredited by the Joint Commission, every compounding pharmacy should be accredited by the PCAB.

**An old story**

The story of Doc's Pharmacy is not unique, nor is it new. In 1937, the pharmaceutical manufacturer S.E. Massengill Co. made and marketed a product it called Elixir Sulfanilamide. One hundred seven people, mainly children, died after taking the drug. The manufacturer's chief chemist, a pharmacist, had used diethylene glycol as a solvent.

Diethylene glycol was a great solvent but a deadly poison. Today we know it as the primary ingredient in antifreeze. Elixir Sulfanilamide had never been tested for safety before it was marketed. At the time, such testing was not required under the food and drug laws. The next year, 1938, the Federal Food, Drug, and Cosmetic Act was passed, which required, among other provisions, that all manufactured drugs be proven safe before their introduction into U.S. commerce. Massengill's chief chemist and pharmacist, Harold Cole Watkins, later committed suicide.

**We have the standards**

As pharmacists and healthcare providers, we do not need legislation to set standards, nor do we need to test our quality procedures and techniques against those standards. Joint Commission and PCAB are voluntary accreditations. They provide evidence that tough standards have been used as benchmarks when physicians, nurses, patients, and pharmacists select and recommend compounding pharmacies on the basis of proven quality.

The 1999 IOM report *To Err Is Human* stands as a stark reminder that Joint Commission accreditation does not guarantee that errors will never occur. But PCAB, Joint Commission, and other accreditation bodies do improve the odds — a lot.

*These articles are not intended as legal advice and should not be used as such. When a legal question arises, the pharmacist should consult with an attorney familiar with pharmacy law in his or her state.*

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