Substandard, non-approved drugs put patients at risk

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and the subsequent deaths of 15 individuals—has renewed scrutiny on the contemporary practice of pharmacy compounding. The risks to patients, and associated liability risk to prescribing physicians, largely outweigh the benefits when the practice goes beyond the traditional, extemporaneous role, according to Sarah Sellers from q-Vigilance LLC and Wulf Utian from Case Western Reserve University in the US. Sellers and Utian's opinion piece appears online in the journal *Drugs*, published by Adis.

There is a place for traditional pharmacy compounding to fulfill medical needs of individuals that cannot be met with commercially available products. For example, a child who is unable to swallow tablets may be offered the liquid form of a drug, or a patient with a known allergy to an ingredient might be given alternatives. But formulations that are produced outside national regulatory frameworks lack studies to support their quality, safety and efficacy.

The authors explain, "FDA-approved products produced under federal Good Manufacturing Practice represent an essential standard of pharmaceutical care relied on by US citizens. Deviations from this standard of care should be made only under rare circumstances of medical necessity. Physicians should be cautious in their judgments regarding what circumstances would justify setting aside a federal standard for a professional one."

Under the traditional model of pharmacy compounding, non-FDA

approved drugs are formulated to meet individual patient needs under the order of a physician. In contrast to this traditional role, compounding practices have emerged throughout the US and other countries, with direct marketing of formulations to both patients and prescribers. As a result, non-FDA approved, compounded drugs may be driven by largely unregulated pharmacy advertisements to physicians and patients, and they place prescribers in the backseat for decision making.

Sellers and Utian's paper outlines the essential differences between FDA-approved drugs and compounded drugs and reasserts the primary medical role of physicians when deciding what medical circumstances may necessitate treatment with non-FDA approved products. They also review the consequences of prescribing substandard drugs, including serious adverse events, and discuss the liability issues physicians need to consider when prescribing non-FDA approved drugs.

The authors conclude that it is in the interests of prescribers to remember that:

More information: Sellers S & Utian WH (2012). Pharmacy Compounding Primer for Physicians: Prescriber Beware. *Drugs*; DOI 10.2165/11640850-000000000-00000 , ow.ly/eqBPi

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