

Black Market IUD Cases, 2009–2013

THE BLACK MARKET IUD PROBLEM IN THE US

 **OVER 450**
BLACK MARKET IUDs
PROVIDED TO TEXAS
PATIENTS

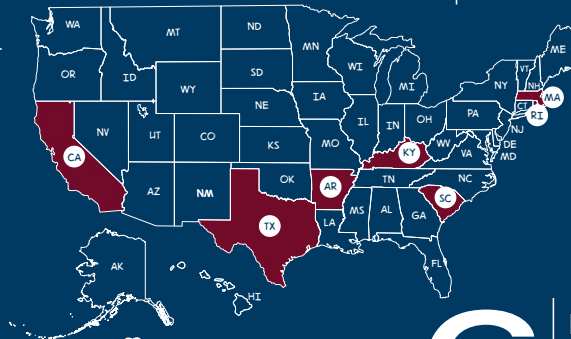
NUMBER OF STATES AFFECTED

7

ARKANSAS
CALIFORNIA
KENTUCKY
MASSACHUSETTS
RHODE ISLAND
SOUTH CAROLINA
TEXAS

NUMBER OF
DOCTORS INDICTED

35




OVER 
\$1,000,000.00
IN FRAUDULENT INSURANCE CLAIMS

6

LAWSUITS FOR
PATIENT INJURIES
BROUGHT IN
ARKANSAS

 THE PARTNERSHIP FOR
SAFEMEDICINES.org

 Since 2009, 39 individuals have been prosecuted for the purchase or sale of non-FDA approved intrauterine devices (IUDs). In 2010 the FDA issued a letter to healthcare providers warning that the effectiveness of black market IUDs could not be guaranteed, that they may have been manufactured or shipped in unsafe conditions and that billing for unapproved medical products could result in prosecution for insurance fraud. In 2012 researchers found that illicit online pharmacies were selling IUDs and teaching self-insertion with cartoons on YouTube.

Doctors purchasing discounted IUDs generate a profit for themselves by billing insurance, Medicare and patients at the same price they would for FDA approved devices. This pursuit of profit over safety puts both physicians and patients at tremendous risk.



SIGNIFICANT CASES INVOLVING BLACK MARKET IUDS

APRIL 2013



Kentucky: Dr. James S. Buck charged with causing the introduction of misbranded drugs after ordering IUDs from an online Canadian pharmacy. Pleaded guilty and was sentenced in August 2013 to 1 year probation, \$17,294 in restitution and a \$1,000 fine with a \$25 penalty fee.

MARCH 2013



Kentucky: Dr. Cahn Jeff Vo, owner of Bluegrass Women's Healthcare, indicted on 1 count each of introducing misbranded IUDs into interstate commerce, health care fraud and smuggling and 10 counts of mail fraud. Pleaded guilty to a misdemeanor charge of misbranding non-FDA approved birth control and to a felony charge of smuggling in September 2013. Sentenced to pay a \$25,000 fine and over \$50,000 in restitution.

AUGUST 2011



South Carolina: Jason Pampucha, an office manager at Advanced Women's Care of the Lowcountry, charged with and pleaded guilty to selling misbranded, non-FDA approved IUDs. Sentenced to 2 years probation.

OCTOBER 2010



Texas: The Texas Attorney General filed suit against 6 physicians in Grapevine for purchasing and selling non-FDA approved IUDs. According to an August 2011 issue of *Texas Medicine*, physicians settled the lawsuit by paying more than \$271,000 in civil penalties, attorneys fees and investigative costs.

(Continued on next page.)



BLACK MARKET IUDS (cont.)

JUNE 2010



Rhode Island & Massachusetts: The Rhode Island Department of Health (RIDH) announced an investigation of 28 providers in 10 Rhode Island OB-GYN medical offices and 1 Massachusetts office who had illegally imported non-FDA approved IUDs and inserted them into patients. RIDH required the practices to surrender the IUDs, provide them with the names and medical records of affected patients and notify the individuals. The investigation led FDA to issue a warning letter to physicians and an alert to consumers about unapproved IUDs. A class action suit was filed over this case in June 2010.

OCTOBER 2009

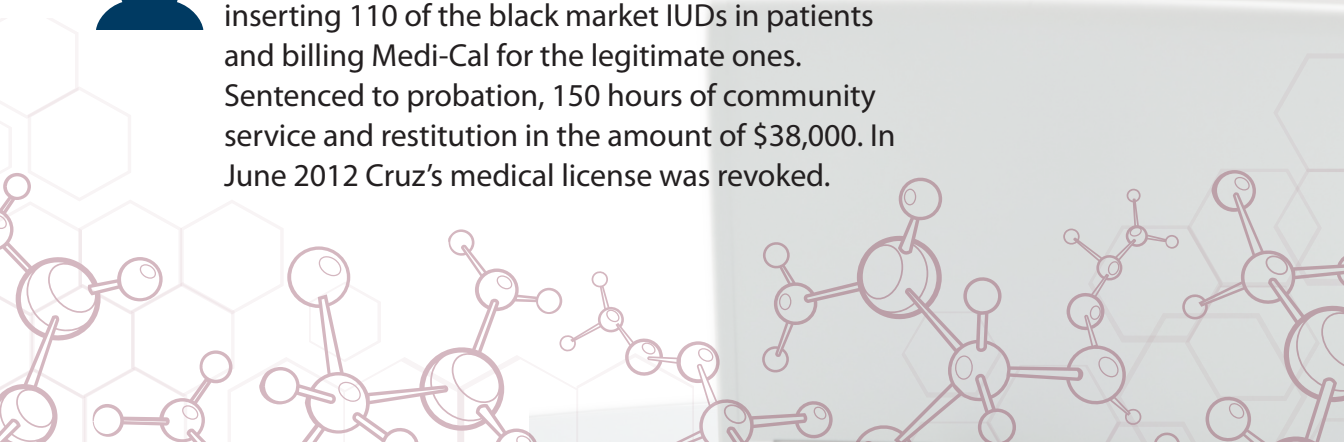
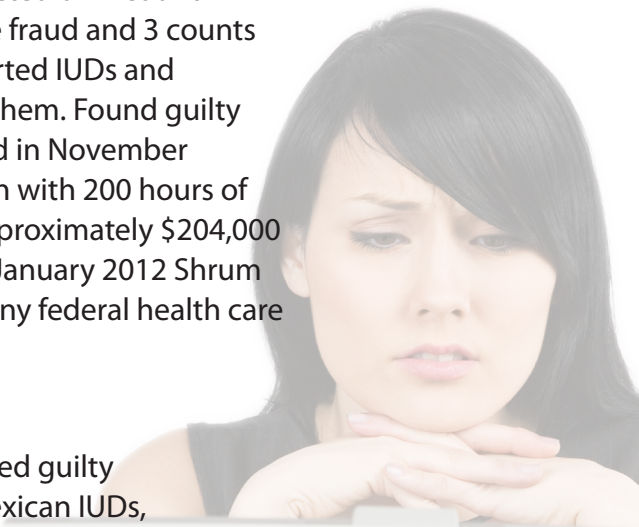


Arkansas: Dr. Kelly Dean Shrum indicted on 1 count each of misbranding and health care fraud and 3 counts of money laundering. He used imported IUDs and falsely billed Medicaid \$162,000 for them. Found guilty of misbranding and health care fraud in November 2010. Sentenced to 5 years probation with 200 hours of community service per year, paid approximately \$204,000 restitution and forfeited \$75,000. In January 2012 Shrum was excluded from participating in any federal health care program for a minimum of 10 years.

MAY 2009



California: Dr. Bayardo A. Cruz pleaded guilty to fraud for purchasing imported Mexican IUDs, inserting 110 of the black market IUDs in patients and billing Medi-Cal for the legitimate ones. Sentenced to probation, 150 hours of community service and restitution in the amount of \$38,000. In June 2012 Cruz's medical license was revoked.



How can patients and medical practices protect themselves?

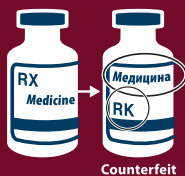


HEALTHCARE PROVIDERS: Importing drugs and medical devices or buying them from unlicensed distributors is illegal and dangerous to your patients. Prescription drugs and medical devices should only be purchased from wholesale drug distributors licensed in the United States.

The FDA keeps a list of verification sites by state:

<http://safedr.ug/fdalicense>.

In addition to sourcing medicines safely, healthcare professionals can spot therapeutic failure and educate patients about buying medications from safe sources. Learn more about protecting patients at http://safedr.ug/healthcare_pros.



PATIENTS receiving treatments in medical offices should ask their doctors to see the packaging of the medicine and any device involved in the treatment. **Examine the product packaging for accurate labeling and good condition and check the language on the label.** All prescriptions approved for sale in the US should have product descriptions in English.

Media Inquiries:

Please contact Demetrios Karoutsos
email: demetrios@safemedicines.org
phone: 202-617-3075

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SAFEMEDICINES
www.safemedicines.org

8100 Boone Blvd., Suite 220, Vienna, VA 22182

703.679.7233 || 703.679.SAFE