



U.S. Department of Justice

***United States Attorney
Eastern District of Arkansas***

FOR IMMEDIATE RELEASE
June 23, 2009

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PUBLIC NOTICE:

UNAPPROVED DEVICES FOUND AT PINE BLUFF DOCTOR'S OFFICE

Little Rock – Jane W. Duke, United States Attorney for the Eastern District of Arkansas, announced today that on Wednesday, June 17, 2009, a search warrant was executed by agents from the Food & Drug Administration Office of Criminal Investigations at the office of Dr. Kelly Shrum, Arkansas Center for Women, LTD, in Pine Bluff, Arkansas. During the execution of the warrant, a version of the intrauterine device (IUD) Mirena that has not been approved by the United States Food and Drug Administration for distribution within the United States was found. The United States Attorney's Office has reason to believe that some of Dr. Shrum's patients received a version of that product that was manufactured in Europe for distribution outside the United States. It is unknown whether that version is safe and/or effective. In general, only those drugs that have been approved by the FDA may lawfully be brought into the United States. The FDA has not made any findings regarding the safety or efficacy of versions of Mirena that have not gone through the FDA approval process.

Patients who may have received a foreign version of Mirena are being contacted by mail. Patients who believe they have received one of these products and who do not receive a letter may call the FDA at 913-384-7429.

Patients having medical questions are advised to consult their Primary Care Physician (PCP) or the Jefferson County Health Unit at 870-535-2142. An FDA representative may be reached at 913-384-7429.

The United States Attorney's Office does not intend to release additional details at this time since the investigation is ongoing. Please **DO NOT** contact this office for further information.

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