

FDA Cautions Against Using Unapproved IUDs

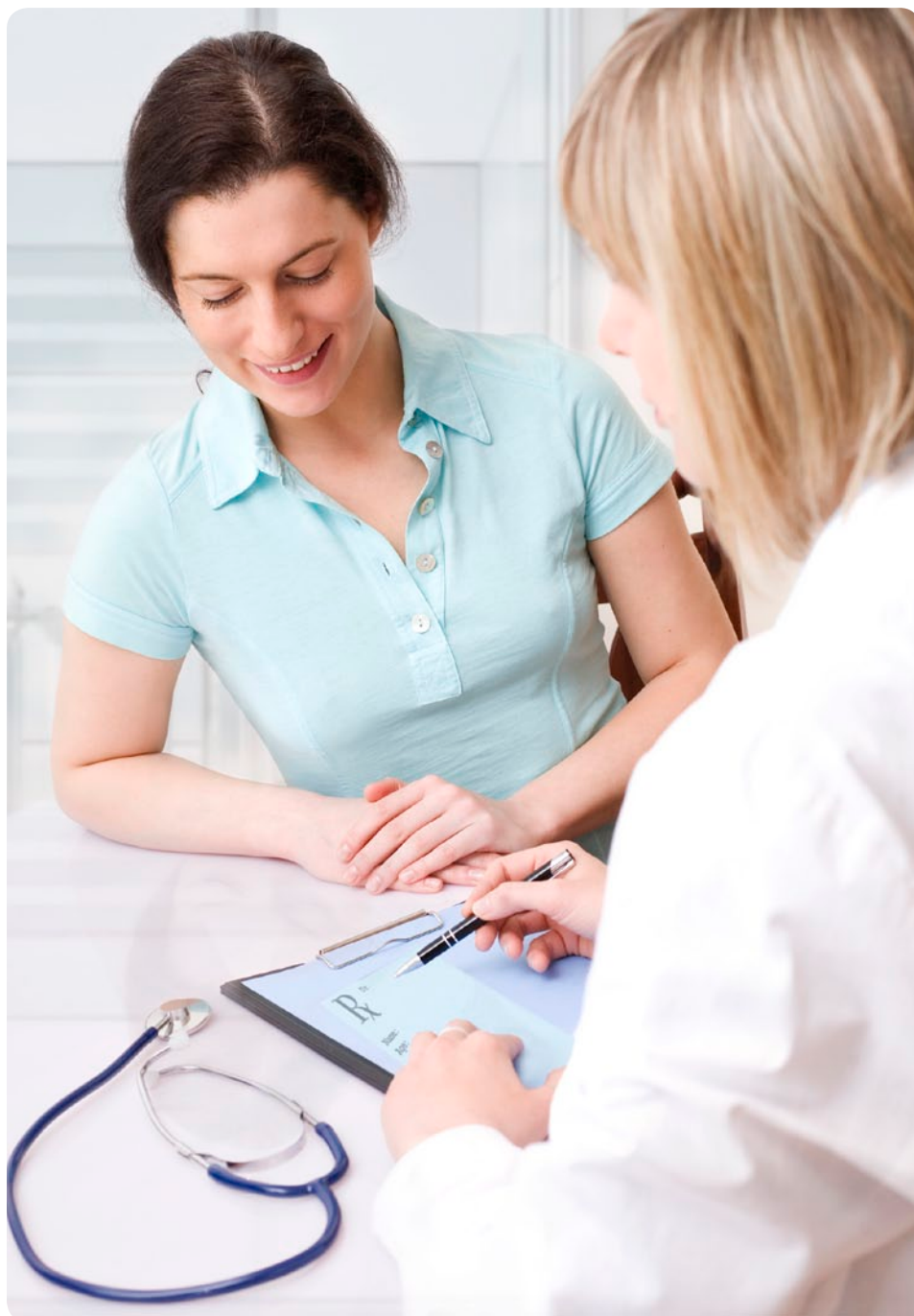
Federal health officials are warning medical practitioners around the country not to use unapproved intrauterine devices (IUDs).

In a July 22 letter, the Food and Drug Administration (FDA) reminds health professionals that using unapproved IUDs raises concerns about effectiveness and safety—as well as the potential for fraud and counterfeiting.

“Federal law requires that IUD/IUSs (intrauterine systems) be FDA-approved prior to marketing. This law is designed to protect patients from products that are unsafe and ineffective,” Theresa Toigo, FDA’s liaison with health professionals, says in the letter. “The recent issue with patients in Rhode Island unknowingly receiving imported, unapproved IUD/IUSs highlights the unacceptable risk patients may be exposed to when a product’s identity, purity, source, handling, and storage cannot be verified.”

Still, patients can use their FDA-approved IUDs with confidence, Toigo says.

FDA experts say women who received unapproved IUDs



Federal law requires that IUDs be FDA-approved prior to marketing. This law is designed to protect patients from products that are unsafe and ineffective.

from practitioners in Rhode Island, Massachusetts, and Kentucky could be at an increased risk for unwanted pregnancy.

The small, T-shaped devices—often made of flexible plastic or copper wire—are inserted into a woman's uterus to prevent pregnancy. Some IUDs also deliver small amounts of hormone as added protection from pregnancy.

FDA says women should not try to remove IUDs by themselves. The agency is advising women who think they may have an unapproved IUD to use another form of birth control—such as condoms, birth control pills, or the patch—and contact their health care professional. Women may want to ask:

- What advantages are there for keeping my IUD in?
- Should I think about having my IUD removed?
- If I keep my IUD in, how long should I use another form of birth control?
- If I want my IUD removed, can I get a new, FDA-approved one?
- I don't want to use condoms. Will other birth control products, such as the pill, patch, or ring, be equally effective?
- Will this affect my ability to get pregnant in the future?
- What should I do if I think I'm pregnant?

Nationwide Problem

What started out as a Rhode Island investigation has spread beyond the state's borders. The FDA is aware of

the use of these unapproved products in several states and is continuing to investigate.

FDA says doctors, nurses, midwives—and possibly patients themselves—might buy unapproved products from what appear to be Canadian or other foreign websites in a bid to save money. Purchasing medical products from websites that are outside of the U.S. may be illegal and may increase the risk of receiving a potentially harmful product, since many websites sell products that are not FDA-approved and could be manufactured in other countries.

"Unapproved products bring a lot of unknowns into the equation," says FDA compliance officer Kathleen Anderson. "An Internet ad may claim to sell IUDs made in Canada, but there's no way to be sure. They might have been made anywhere in the world and in unsanitary or undesirable conditions."

Advice for Consumers

FDA investigators routinely monitor the Internet for the sale of unapproved drugs and devices in an effort to protect the public, but the rapidly growing number of websites trafficking in fraudulent medical products means consumers must remain alert.

Experts advise consumers to learn how to buy health-related products safely over the Internet. Legitimate Internet pharmacies

are licensed by the appropriate state board of pharmacy and follow laws and regulations of the state where they operate.

Legitimate Internet pharmacies will also display a seal from the National Association of Boards of Pharmacy—known as VIPPS seal or Verified Internet Pharmacy Practice Sites. VIPPS pharmacies are listed at vipps.nabp.net/verify.asp.

FDA is also asking the public to report information about the distribution of unapproved IUDs. To contact the agency's criminal investigators visit www.fda.gov/oci.

Find this and other Consumer Updates at www.fda.gov/ForConsumers/ConsumerUpdates

Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumerenews.html