As the safety and efficacy of IUDs are being appreciated by more clinicians and by more women, the demand for these devices has grown. Unfortunately, the prices of these devices have also increased over the last few years. The cost of the IUD, when amortized over the average time of utilization, is very low, but that does little to buffer women from the initial sticker shock. In times of economic hardship, effective contraception is especially important. Clearly, the women who have already invested in their devices are in a very enviable position. However, for today’s patient who needs effective contraception, the upfront cost of IUDs can be overwhelming. Even insured women may find insurance coverage for IUDs to be inadequate.

Each of the IUD manufacturers has special pricing for the public sector. The LNG-IUS manufacturer also donates units to the ARCH Foundation to distribute to indigent women desiring an LNG-IUS. However, clinicians may be tempted by lower priced units advertised on web sites for their private patients who do not qualify for these programs. If you type into your search engine “IUD,” an impressive array of such web sites pops up, each offering low prices. The lack of transparency of these web sites is disturbing, but their prices are alluring. We are trapped between competing ethical values of beneficence (making IUDs accessible) and patient safety. This debate is not confined to IUDs and other contraceptive devices, but in the context of these devices, there are additional elements to consider.

While no one wants to be cast as an apologist for the pharmaceutical industry, the fact is that there is considerable confusion about what the term “FDA approved” really means. Many people believe that “FDA approval” involves only the original testing of the drug or the device for efficacy and safety. In this understanding, any IUD that has the same design as the product that was originally approved by the FDA should be considered FDA approved, regardless of where it was manufactured or how it was transported. Some have argued that as long as the product is the same or “comparable to” the US FDA-approved product, it should be considered FDA approved. The FDA actually is responsible for maintaining quality control long after it initially approves a product. The FDA periodically inspects manufacturing plants all over the world that manufacture products for US consumers. The Today Sponge® plant was closed by FDA inspectors for potential contamination along its production line, even though none of the products that had been produced was contaminated.

More recently, a production line for a series of vaginal antifungal and antibacterial products was closed by the FDA until identified problems could be corrected. Obviously, if manufacturers are not making products approved by the FDA for US consumers, the FDA would not inspect their manufacturing plants to provide ongoing assurance that quality standards are being maintained. For products that are temperature sensitive, such as the LNG-IUS and the vaginal contraceptive ring, conditions during transport may substantially impact product efficacy. If one orders an item online from the UK or Canada, the product may be shipped in the hull of an airplane [where the temperature drops to below 59°F (15°C)] or may be allowed to rest on a warehouse platform in the heat [temperatures above 86°F (30°C)]. In these extremes of heat, the product destabilizes and may not deliver the drug as desired.

These web sites offer many IUDs that are clearly not FDA approved but could confuse buyers. For example, http://www.northdrugmart.com/drug-tt-380-slimline-copper-iud.html offers the TT 380 Slimline Copper IUD, the UT 380 Copper IUD and the Multiload Copper IUD, none of which is FDA approved. The second IUD is described as “a plain copper T IUD,” but the loading is accomplished by pulling on the strings to draw the arms back into the introducer. The website http://www.drugworldcanada.com offers a Copper T Model TCu 380A IUD which it says “compares to the IUD sold as ParaGard in the USA.” Although it is offered in a web site that looks as if it is coming from Canada, the fine print says that the IUD comes from Europe (manufactured by Eurim-Pharm Vertriebs GmbH) and is not even dispensed by its own affiliated Canadian pharmacy.

Another concerning feature about these websites is that they directly address patients. This conjures up a disturbing image of patients bringing to clinical offices devices from unknown sources and asking them to be placed without knowing the product source and purity. In addition, much of the information is incorrect and inconsistent with US labeling. For example, http://www.globaldrugsdirect.com tells women to tell their doctors immediately if “serious side effects” occur with Mirena and lists lack of menstrual period...
as the first such “serious side effect.” http://www.PharmacyEscrow.com says that, in some cases, the effect of Mirena lasts for 5 years — and it advises women not to use the device if they are HIV infected or using St. John’s Wort. The site also tells women to “keep it (the IUD) away from moisture, heat and direct sunlight”... and to “keep Mirena away from the reach of pets and children in order to avoid unwanted accidents. Avoid keeping it in the bathroom or nest (sic) to the kitchen sink.”

http://all-drugs-online.com tells women to “check the label on the medicine for exact dosing instructions” and advises them, “If you miss a dose of Mirena IUD, contact your doctor right away.” It informs diabetic women that Mirena may affect their blood sugar. The site also provides a long list of potential drug interactions, none of which is relevant to the LNG-IUS.

Not only is the information out of date and often seriously wrong, but the lack of correct English raises even more suspicions that these products may not be distributed from sources which we believe them to be. For example, http://MosaicMedicalSupplies.com states, “moreover, it is advised keep on visiting your doctor once or twice in every 3 months to make sure that whether IUD system is still placed in apt position or not.”

The problems we experienced in California with foreign IUDs were not only medical, but also legal. A few providers placed foreign units in patients and billed the state under its Medicaid programs for reimbursement. However, because they had not used FDA-approved products, this practice was considered to be Medicaid fraud. One physician has already settled and has agreed to bring in all restitution and to pay costs of the investigation when he is sentenced. One physician is at risk for jail time. However, he still faces action by the California Medical Board. As a result of the misguided altruism (or greed) of a few clinicians, all IUD providers in the state programs must now retain a patient-specific invoice for at least 3 years for each IUD they place.

Subscribers to Contraception who do not work in the US may be puzzled by this discussion. Their puzzlement underscores the dysfunctionality of the US health care system, which does not provide ready access to the most effective forms of contraception, but fully reimburses pregnancy-related costs. It is clear that prevention would be much more cost-effective. We need to find a better way to solve this problem, but initially not by crossing a legal line or by potentially risking patient health with use of medical devices not approved by the US FDA.

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