Flawed data behind regulation of high-risk women's health devices

May 20 2016

Some high-risk medical devices used in obstetrics and gynecology were approved by the FDA based on flawed data, according to a recent study from Northwestern Medicine.

The investigators assessed the regulation of women's health devices approved by the FDA in the last 15 years. The authors suggest that their results, published in the journal *Obstetrics and Gynecology*, indicate that the agency's approvals should be based on clinical studies more rigorous than currently required, both before and after the devices go to market.

"Devices are a huge part of the medical care that we provide women on a daily basis," said study first author Dr. Jessica Walter, a resident in

obstetrics and gynecology at Northwestern University Feinberg School of Medicine. "We found that there's an opportunity to increase the burden of proof required for a device to be approved for public use."

The team identified 18 high-risk devices approved by the FDA from 2000 to 2015, most of them for endometrial ablation (reducing menstrual flow), contraception and fetal monitoring. Four of the devices—22 percent—were approved even though they failed to demonstrate efficacy in clinical trials. Six of the devices—33 percent—were not required to undergo post-market studies to survey ongoing safety.

Three devices were eventually withdrawn from the market after approval. Of those three, two were not reviewed by physician experts on the FDA's obstetrics and gynecology advisory committee. The other was reviewed but not recommended for approval by the committee.

"We looked at the class of devices with the highest potential risk to patients—the devices that had to go through the most rigorous pre-market approval process," said senior author Dr. Steve Xu a resident in dermatology. "Despite this being the most stringent pathway, and despite the fact that we've had multiple safety issues connected to OB-GYN devices affecting millions of women worldwide, the evidence leading to approval has a lot of weaknesses."

The authors point to controversial medical devices like a permanent contraceptive device approved by the FDA in 2002 that is now being evaluated after numerous reports of adverse events including pain, organ damage and unintended pregnancy. The device, meant to last a lifetime, was approved based on short-term evidence and insufficient post-market follow-up, explain the study authors.

"There are no explicit requirements about conducting randomized-

controlled trials or post-market surveillance for medical devices. Requirements are decided on a case-by-case basis," Xu said. "There are much higher standards for the approval of new drugs, whether oral, injectable or even topical. The important question to ask is: should we really be holding high-risk medical devices to a lower standard of evidence than drugs?"

The authors note in the paper that the 21st Century Cures Act—healthcare legislation passed in the House of Representatives in May 2015—currently contains provisions that would reduce medical device regulation. The bill is being considered by the Senate.

"There are provisions that would broaden the definition of the 'valid scientific evidence' manufacturers need in order to prove medical benefit. Our concern is that this would lead to more devices getting approved with even less clinical evidence that they are both safe and effective," said Walter.

She and Xu said they believe that clinicians - in all specialties that use medical devices, not just obstetrics and gynecology - have a responsibility to understand how FDA regulation works and to take a more active role collecting and reporting data about the complications and unintended outcomes that result from devices. They also recommend that the FDA seek more input from expert advisory committees and rely on higher quality studies.

"I think some stakeholders believe that increasing regulation means stifling innovation, and that if we make it harder for these devices to be approved potentially life-changing devices will have a higher barrier to actually getting to market," Walter said. "But that hasn't necessarily been shown in the literature."