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This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice in collaboration with subcommittee members Vivian W. Sung, MD, MPH; Paul Tulikangas, MD; and Catherine S. Bradley, MD, MSCE; and liaison Beri Ridgeway, MD.

Assessing and Adopting New Medical Devices for Obstetric and Gynecologic Care

ABSTRACT: The purpose of this document is: 1) to help obstetrician–gynecologists better understand the U.S. Food and Drug Administration’s regulatory process for the marketing of medical devices; 2) to educate obstetrician–gynecologists on the importance of understanding available evidence on the safety, efficacy, and indications for devices in clinical practice; 3) to encourage obstetrician–gynecologists to report safety events associated with medical devices; and 4) to provide guidance on what to consider when adopting new medical devices. The decision to incorporate new technology in a patient’s care may be complex. Some medical devices are marketed for gynecologic conditions but may have unclear indications for use or unclear safety and efficacy profiles, or both. Patients often have questions about treatments and procedures involving devices, especially if a device has received media attention; therefore, a basic understanding of how devices are regulated and what type of data are or are not required before a device is brought to market is important for patient care. When adopting a new medical device, obstetrician–gynecologists should achieve proper training and should understand the evidence on safety and effectiveness and the indications for the device’s use. Obstetrician–gynecologists and other health care providers should be aware of the U.S. Food and Drug Administration’s Manufacturer and User Facility Device Experience database and, ideally, should become familiar with the adverse event report form and report serious adverse events that may be associated with a medical device, use errors, product quality issues, and therapeutic failures.

Recommendations and Conclusions

- When adopting a new medical device, obstetrician–gynecologists should achieve proper training and should understand the evidence on safety and effectiveness and the indications for the device’s use.
- When an obstetrician–gynecologist receives anything of substantial value, including royalties, from companies in the health care industry, such as a manufacturer of pharmaceutical agents and medical devices, this fact should be disclosed to patients and colleagues, when material.
- The American College of Obstetricians and Gynecologists encourages obstetrician–gynecologists to submit reports to the Manufacturer and User Facility Device Experience (known as “MAUDE”) database

when potential safety events associated with medical devices occur. Health care providers should report information as completely as possible.

- If available, training through professional societies with continuing medical education accreditation, rather than through industry sources with financial interests, is recommended.

Background

The United States is the largest medical device market in the world, with a market share of approximately \$140 billion (1). Medical devices are most commonly funded, developed, and sold by private (nongovernmental) industries for a profit. Industry and health care providers, including obstetrician–gynecologists, play important roles

in the adoption of new devices. When adopting a new medical device, obstetrician–gynecologists should achieve proper training and should understand the evidence on safety and effectiveness and the indications for the device’s use. They also should be vigilant about reporting device-related safety events. The purpose of this document is: 1) to help obstetrician–gynecologists better understand the U.S. Food and Drug Administration’s (FDA) regulatory process for the marketing of medical devices; 2) to educate obstetrician–gynecologists on the importance of understanding available evidence on the safety, efficacy, and indications for devices in clinical practice; 3) to encourage obstetrician–gynecologists to report safety events associated with medical devices; and 4) to provide guidance on what to consider when adopting new medical devices.

Medical devices are ubiquitous in gynecology. For example, when obstetrician–gynecologists perform endometrial ablations or endometrial biopsies, they are using medical devices. Even male and female condoms and pessaries are considered medical devices and are subject to FDA regulation. It is important for practicing obstetrician–gynecologists to understand the process for FDA approval and clearance and postmarket regulation of medical devices. Some medical devices are marketed for gynecologic conditions but may have unclear indications for use or unclear safety and efficacy profiles, or both. Patients often have questions about treatments and procedures involving devices, especially if a device has received media attention; therefore, a basic understanding of how devices are regulated and what type of data are or are not required before a device is brought to market is important for patient care. The FDA also regulates mobile medical applications when they are intended for use in the diagnosis of disease or other conditions or facilitate the cure, mitigation, treatment, or prevention of disease; however, this evolving area will not be covered in this document. For more information on the implementation of mobile health technology, including applications, see Committee Opinion No. 798, *Implementing Telehealth in Practice* (2).

Pathways to Market for Medical Devices

The FDA began regulating medical devices in 1976. Regulation of devices falls under the Center for Devices and Radiological Health within the FDA. The mission of the Center for Devices and Radiological Health is to protect and promote the public health by assuring that patients and health care providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products (3). The Center for Devices and Radiological Health also provides consumers, patients, caregivers, and health care providers with information about the products they oversee.

To reach the market, medical devices are either *approved* or *cleared* by the FDA. These two processes are very different. Approval from the FDA through the

premarket approval pathway requires stand-alone demonstration of reasonable assurance of safety and effectiveness. The premarket approval pathway, also known as the *PMA pathway*, is the most stringent pathway (4). The FDA clearance process uses the *510(k) premarket notification* pathway to demonstrate *substantial equivalence* to an already legally marketed device. That is, new 510(k) devices should be as safe and as effective as an already marketed device with the same intended use and similar technology. Although a device is on the market, there is no guarantee that clinical evidence was provided to the FDA to demonstrate safety and effectiveness for its marketed indication. The premarket approval pathway is the most stringent pathway to get a device to market.

The FDA has three regulatory classes for medical devices based on the degree of regulatory control necessary to provide reasonable assurance of the safety and effectiveness of the device (5) (Fig. 1). The regulatory class of a medical device generally determines whether the device will go through an approval or clearance review (6) (Table 1). For Class I devices, general controls are used to provide reasonable assurance of safety and effectiveness. General controls apply to all medical devices and include such provisions as device registration, labeling, registration and listing with the FDA, and good manufacturing practices. Class II devices require both general and special controls, which may include post-market surveillance, patient registries, special labeling requirements, premarket data requirements, performance standards, and guidelines.

Class II devices, such as pessaries and male and female condoms, are associated with moderate risk and are brought to market through the 510(k) pathway. The 510(k) pathway provides FDA clearance, not FDA approval. The 510(k) pathway allows manufacturers to cite a similar device already legally marketed, termed a *predicate device*. This clearance process requires demonstration that the new device is as safe and effective as an existing predicate device. A valid predicate device should be marketed legally and should have the same intended use and similar technology to the new device. If the FDA finds the new device substantially equivalent to the predicate device, then the new device may be cleared for market under the 510(k) pathway. In addition to meeting FDA labeling requirements, performance data in the form of bench or animal testing data, or both, often are needed to support substantial equivalence. In some cases, clinical data also are needed to support substantial equivalence. Clinical data are needed in cases in which bench or animal testing, or both, are not sufficient to address safety and effectiveness questions about differences between the new device and the predicate device.

A *Class III device*, defined as a medical device that supports or sustains human life, is of substantial importance in preventing impairment of human health, or presents a potential, unreasonable risk of illness or injury

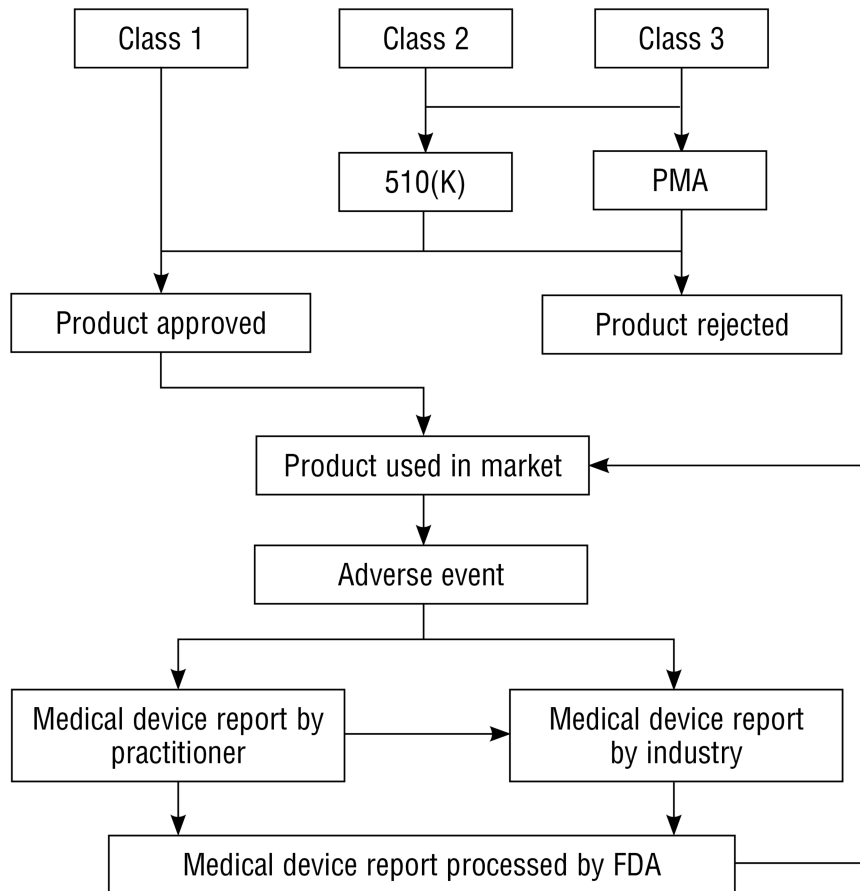


Figure 1. Flowchart of Medical Device Regulation and Reporting Pathway. Abbreviations: FDA, U.S. Food and Drug Administration; PMA, premarket approval. Modified from Teow N, Siegel SJ. FDA regulation of medical devices and medical device reporting. *Pharm Regul Aff* 2013;2:110.

Table 1. Examples of the U.S. Food and Drug Administration’s Device Classification and Regulatory Controls

Device Class	Regulatory Controls	Examples
Class I (30%)	<ul style="list-style-type: none"> • General controls only • Most exempt from approval or clearance 	<ul style="list-style-type: none"> • Surgical gloves • Metal speculum • Tongue depressor • Manual breast pump • Surface-mediated hemostatic devices
Class II (60%)	<ul style="list-style-type: none"> • General and special controls • Usually requires 510(k) clearance 	<ul style="list-style-type: none"> • Male and female condoms • Pessary • Biopsy needle • Midurethral slings • Vascular embolization device for fibroids • Uterine morcellator
Class III (10%)	<ul style="list-style-type: none"> • Highest control • Requires premarket approval 	<ul style="list-style-type: none"> • Endometrial ablation device • Adhesion barriers • Sacral nerve stimulator (implantable)

(eg, endometrial ablation devices or adhesion barriers). It requires submission of premarket data that provide standalone demonstration of safety and effectiveness. Class III devices are approved for market. Premarket approval is based on a determination by the FDA that the premarket approval application contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). Unlike devices cleared through the 510(k) pathway, devices approved through the premarket approval pathway nearly always rely on clinical data, as well as bench and animal data, to support marketing. The FDA has greater authority over the labeling, manufacturing, and postapproval changes for PMA pathway devices. In addition, the FDA often requires postmarket studies for PMA-approved devices.

Postmarket Surveillance

Requirements for postmarket surveillance vary depending on the device type and FDA requirements. Postmarket surveillance is important to determine long-term safety, evaluate how the device performs once in the community within different user settings, and identify unusual patterns of adverse events. These events may or may not require further action from the FDA.

There are different types of postmarket surveillance. First, there is medical device reporting, which is a general control (Box 1). The FDA has put this reporting program in place to identify, monitor, and capture adverse events and device malfunctions involving medical devices. These reports are called Medical Device Reports (known as MDRs). The FDA mandates that manufacturers, user facilities (eg, hospitals), and medical device importers report to the FDA a death or serious injury that was or may have been attributed to a medical device, or a medical device that was or may have been a factor in a death or serious injury, including events occurring as a result of failure, malfunction, improper or inadequate design, manufacture, labeling, or user error (7). In addition to these required reports, voluntary reports may be made by health care professionals, patients, and users of direct-to-consumer devices. These Medical Device Reports are housed in the MAUDE database, which is available to the public (Box 1).

Medical Device Reports to the FDA can be challenging to interpret because most events are reported without knowledge of the total population in which the devices were used (eg, denominator information often is missing). Other limitations include submissions that may be incomplete, inaccurate, untimely, and unverified. Because increased reporting to the MAUDE database by health care providers will improve the quality of the device's data, the American College of Obstetricians and Gynecologists encourages obstetrician-gynecologists to submit reports to the MAUDE database when potential safety events associated with medical devices occur. Health care providers should report information as completely as possible.

Box 1. Manufacturer and User Facility Device Experience (MAUDE) Database

The U.S. Food and Drug Administration's MAUDE database is one of the postmarket surveillance tools used to monitor medical device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.

- Health care providers are encouraged to report adverse events associated with medical devices to eMDR—Electronic Medical Device Reporting: <https://www.fda.gov/industry/fda-esubmitter/electronic-medical-device-reporting-emdr>.
- More information on reporting by health professionals: <https://www.fda.gov/Safety/MedWatch/HowToReport/ucm085568.htm>
- Questions and Answers About eMDR—Electronic Medical Device Reporting Guidance for Industry, User Facilities and FDA Staff: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm175805.htm>

U.S. Food and Drug Administration-mandated postmarket studies can collect safety and efficacy data for 510(k)-cleared or premarket-approved devices. For Class II premarket-approved devices, a postapproval study, which can be required as a condition of initial approval, is a clinical study that examines the long-term or real-world safety and effectiveness of the approved device. Another type of postmarket study is the Section 522 Postmarket Surveillance Study (8). This study type may be mandated by the FDA any time after the 510(k) clearance process or premarket application approval if certain criteria are met. Section 522 studies typically are designed to address specific questions. If an issue is identified during postmarket surveillance, there are regulatory actions the FDA may take.

After reaching the market, devices may be reclassified, recalled, adjusted, or simply no longer produced by the manufacturer for various reasons. Two examples relevant to obstetrician-gynecologists include: 1) in 2008-2011, the manufacturing company for Gen-Probe AccuProbe for group B streptococcus culture recalled all devices from certain lots because of high false-negative rates, possibly due to assay tubes not containing probe reagent; and 2) in 2010, the manufacturing company for Proceed surgical mesh voluntarily recalled certain lots because of the potential for delamination. In these examples, the FDA did not initiate the recalls.

Factors Influencing Adoption of New Technology

The decision to incorporate new technology in a patient's care may be complex. New devices may be cleared by the FDA without demonstration of rigorous clinical trial

data; therefore, it is helpful for obstetrician–gynecologists and other health care providers to understand how much clinical evidence exists for marketed devices, whether approved or cleared. Having a basic understanding of FDA regulatory pathways and device risk categories, indications for use, and existing evidence related to benefits and risks of a medical device before it is incorporated into practice is useful when counseling patients and during the informed consent process. If a new medical device fills a well-defined clinical need and few other treatments are available, the alternative of not providing treatment may be considered along with the known benefits and risks.

Obstetrician–gynecologists should be aware that the allure of new technology may affect patients' preferences, even if there is minimal evidence of benefit. A preference for cutting-edge care can incentivize hospitals or obstetrician–gynecologists and other health care providers to offer and advertise use of a new medical device to attract patients to their care. Direct-to-patient advertising can influence patients' impressions about treatment options. Thus, adoption of some new technologies may provide financial incentives to a hospital or to obstetrician–gynecologists and other health care providers by increasing patient numbers, regardless of patient outcomes.

Reimbursement for care that includes a new medical device may provide another financial incentive for hospitals, obstetrician–gynecologists, and other health care providers to use that device. Payment for performing a procedure that includes a new device may be higher than that for other procedures or treatments, incentivizing choice of that procedure and, thus, the use of that medical device.

Industry payments to obstetrician–gynecologists and other health care providers also may be a factor that influences treatment decisions, including medical device use (9). Physicians should understand that gifts tied to promotional information, even small gifts and meals, are designed to influence their behavior. The acceptance of any gift, even of nominal value, tied to promotional information is strongly discouraged. However, acceptance of cash donations, trips, and services directly from industry by individual physicians raises clear conflicts and is not ethical. When an obstetrician–gynecologist receives anything of substantial value, including royalties, from companies in the health care industry, such as a manufacturer of pharmaceutical agents and medical devices, this fact should be disclosed to patients and colleagues, when material (10, 11).

Considerations in Adoption of New Technology

When deciding to adopt new technology, obstetrician–gynecologists should consider the following issues: 1) the current state of the evidence and evaluation of the technology; 2) how to contribute to identifying issues related to the use of new technology to improve patient

safety; and 3) self-assessment of related training and skills that may be necessary to use the technology (ie, “Do I have the training and skills necessary to use this device for the FDA-approved or data-supported indications?”).

The Current State of the Evidence and Evaluation of the Technology

Obstetrician–gynecologists and other health care providers should consider whether there are clinical data that show a benefit compared with the currently used or recommended practice and what type of evaluation of short-term and long-term safety and efficacy exists relative to the intended indication or compared with existing, more established treatments. Published studies, systematic reviews, meta-analyses, and clinical guidelines are sources that may be useful to review before adopting a new medical device or treatment and can inform patient counseling and the informed consent process. Many devices may not have adequate data from comparative trials. If sufficient evidence is not available, this deficiency should be outlined in the informed consent process. Informed consent should incorporate shared decision making between the health care provider and the patient (12).

Robust evidence may not be available for new medical devices; however, there are initiatives designed to improve the ability to collect longitudinal real-time data on the safety and efficacy of new devices. In 2016, the U.S. Congress passed the 21st Century Cures Act, which provides guidance on how best to use real-world data to evaluate technology (13). In addition, through the FDA Amendments of 2007 (14) and the FDA Safety and Innovation Act of 2012 (15), medical devices are assigned unique device identifiers to be reported in clinical coding and billing when a procedure is performed (14, 15). When fully implemented, this process will allow more careful tracking of outcomes when a device is used. Care must be taken when interpreting real-world evidence because the data are observational and, unlike evidence from randomized trials, can be biased by treatment decisions (16).

How to Contribute to Identifying Issues Related to the Use of New Technology to Improve Patient Safety

Safety concerns may result when technologies are adopted into practice (17). Reporting adverse events to the MAUDE database is voluntary for health care providers, but reporting can be extremely helpful in identifying potential device-related safety issues. In general, adverse events associated with medical devices likely are underreported by health care providers (18). Although the MAUDE database is just one of the sources used by the FDA to monitor postmarket device performance, it is important because it provides a mechanism for health care providers to report device-related

problems. Obstetrician–gynecologists and other health care providers should be aware of the FDA’s MAUDE database and, ideally, should become familiar with the adverse event report form and report serious adverse events that may be associated with a medical device, use errors, product quality issues, and therapeutic failures (Box 1). This information ultimately can help to improve patient safety.

Self-assessment of Related Training and Skills That May Be Necessary to Use the Technology

As a part of self-assessment, obstetrician–gynecologists should decide if they have the training and skills necessary to use a device for the FDA-approved or data-supported indications. They should assess their practice pattern and the needs of their community to determine if they are the best health care providers to adopt this technology.

In general, hospitals and institutions have governing bodies that help to ensure quality and safety of care. Typically, these organizations require health care providers to possess current qualifications and demonstrate competencies for the privileges granted. Credentialing verifies that obstetrician–gynecologists and other health care providers meet standards as determined by an organization by assessing their background and legitimacy. Privileging for specific procedures defines an obstetrician–gynecologist’s scope of practice and the clinical services he or she may provide. Often the manufacturer of a device helps to determine criteria by recommending or offering specific training. However, there is little guidance about what qualifies as adequate training on new procedures and technologies. Sometimes a certain number of proctored sessions are required; other times, only simulation sessions are required. Moreover, the number of proctored and simulation sessions can be highly variable between institutions. There also is significant variability in what is required for annual maintenance of privileges for specific procedures once they have been granted. Obstetrician–gynecologists should have the requisite surgical skills and experience with procedures offered to patients regardless of hospital privileging requirements. It is important for gynecologic surgeons to establish reasonable guidelines for surgical privileging. If available, training through professional societies with continuing medical education accreditation, rather than through industry sources with financial interests, is recommended.

Glossary

Approval: The process by which Class III medical devices go through the U.S. Food and Drug Administration’s premarket approval pathway and must establish reasonable assurance of safety and effectiveness before the device can be commercially distributed.

Clearance: The process in which the U.S. Food and Drug Administration finds a medical device to be substantially equivalent to a previously cleared device through the 510(k) premarket pathway and states that the device can be marketed in the United States. This order clears the device for commercial distribution.

Predicate Device: A Class I or II device that is legally marketed and has the same intended use and similar technology to a new device proposed for market.

510(k) Premarket Notification: A premarket submission made to the FDA to demonstrate that a medical device to be marketed is at least as safe and effective and is substantially equivalent to a legally marketed device that is not subject to premarket approval. Medical devices receive clearance through this process.*

Premarket Approval Application (or PMA): The most stringent type of device marketing application required by the FDA. A premarket approval application is an application submitted to the FDA to request approval for a medical device to enter the commercial market. Unlike premarket notification, Premarket Approval Application approval is based on a determination by the FDA that the application contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses. Medical devices are approved through this process.

Section 522 Postmarket Surveillance Study: Section 522 of the Federal Food, Drug and Cosmetic Act gives the FDA the authority to require a manufacturer to conduct postmarket surveillance of a class II or class III device that meets any of the following criteria: 1) its failure would be reasonably likely to have serious adverse health consequences; 2) it is expected to have significant use in pediatric populations; 3) it is intended to be implanted in the body for more than one year; or 4) it is intended to be a life-sustaining or life-supporting device used outside a device user facility.†

Substantial Equivalence: A new medical device is determined to be at least as safe and effective as the predicate. A claim of substantial equivalence does not mean the new and predicate medical devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.

*Establishment registration and device listing for manufacturers and initial importers of devices 21 C.F.R. pt. 807 (2019).

†U.S. Food and Drug Administration. 522 postmarket surveillance studies—frequently asked questions (FAQs). Silver Spring (MD): FDA; 2018. Available at: <https://www.fda.gov/medical-devices/522-postmarket-surveillance-studies/522-postmarket-surveillance-studies-frequently-asked-questions-faqs>. Retrieved June 19, 2019.

References

1. International Trade Administration. 2016 top markets report medical devices: a market assessment tool for U.S. exporters. Washington, DC: ITA; 2016. Available at: https://www.trade.gov/topmarkets/pdf/Medical_Devices_Top_Markets_Report.pdf. Retrieved June 19, 2019.
2. Implementing telehealth in practice. ACOG Committee Opinion No. 798. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2020;135:e73–9.
3. U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH). Silver Spring (MD): FDA; 2012. Available at: <https://www.fda.gov/media/83238/download>. Retrieved June 19, 2019.
4. U.S. Food and Drug Administration. Premarket approval (PMA). Silver Spring (MD): FDA; 2019. Available at: <https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma>. Retrieved June 19, 2019.
5. Buch B. FDA medical device approval: things you didn't learn in medical school or residency. *Am J Orthop (Belle Mead NJ)* 2007;36:407–12.
6. Walter JR, Hayman E, Tsai S, Ghobadi CW, Xu S. Medical device approvals through the premarket approval pathway in obstetrics and gynecology from 2000 to 2015: process and problems. *Obstet Gynecol* 2016;127:1110–7.
7. How does FDA define the terms used in this part? 21 C.F.R. § 803.3. 2018. Available at: <https://www.govinfo.gov/content/pkg/CFR-2018-title21-vol8/xml/CFR-2018-title21-vol8-part803.xml#seqnum803.3>. Retrieved August 7, 2019.
8. Postmarket surveillance. 21 U.S.C. § 360l. 2018.
9. DeJong C, Aguilar T, Tseng CW, Lin GA, Boscardin WJ, Dudley RA. Pharmaceutical industry-sponsored meals and physician prescribing patterns for Medicare beneficiaries [published erratum appears in *JAMA Intern Med* 2016; 176:1411–2]. *JAMA Intern Med* 2016;176:1114–22.
10. Professional relationships with industry. Committee Opinion No. 541. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2012;120:1243–9.
11. American College of Obstetricians and Gynecologists. Code of professional ethics of the American College of Obstetricians and Gynecologists. Washington, DC: ACOG; 2018. Available at: <https://www.acog.org/-/media/Departments/National-Officer-Nominations-Process/ACOGcode.pdf?dmc=1&ts=20190213T1516113641>. Retrieved October 30, 2019.
12. Informed consent. ACOG Committee Opinion No. 439. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2009;114:401–8.
13. 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033-44. 2016. Available at: <https://www.govinfo.gov/content/pkg/PLAW-114publ255/html/PLAW-114publ255.htm>. Retrieved July 31, 2019.
14. Food and Drug Administration Amendments Act of 2007, 21 U.S.C. 301 Pub. L. No. 110-85, 121 Stat. 824-978. 2007. Available at: <https://www.govinfo.gov/content/pkg/PLAW-110publ85/html/PLAW-110publ85.htm>. Retrieved July 31, 2019.
15. Food and Drug Administration Safety and Innovation Act, 21 U.S.C. 301 Pub. L. No. 112-144, 126 Stat. 993-1132. 2012. Available at: <https://www.govinfo.gov/content/pkg/PLAW-112publ144/html/PLAW-112publ144.htm>. Retrieved July 31, 2019.
16. Resnic FS, Matheny ME. Medical devices in the real world. *N Engl J Med* 2018;378:595–7.
17. Innovative practice: ethical guidelines. ACOG Committee Opinion No. 352. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2006;108:1589–95.
18. Office of the Inspector General. Adverse event reporting for medical devices. Washington, DC: OIG; 2009. Available at: <http://oig.hhs.gov/oei/reports/oei-01-08-00110.pdf>. Retrieved June 19, 2019.

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