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As a co-petitioner, I strongly support Public Citizen's petition to the Food and Drug Administration (FDA) to ban the marketing of all currently available non-absorbable surgical mesh products designed and labeled for transvaginal repair of pelvic organ prolapse (POP) and to order all manufacturers to recall such products.

The overriding ethical obligation of physicians should be to put the interests of their patients ahead of all other considerations. As the agency charged with approving drugs and medical devices, the FDA has a similar ethical obligation: to place the best interests of patients — those who will take drugs or use medical devices — ahead of all other considerations. Device manufacturers operate by different rules. They see their primary obligation to be "maximizing shareholder value" by increasing company profits. There is thus a fundamental conflict of interest between physicians and the FDA on one side and device manufacturers on the other.

Once a device has been approved for release into the marketplace by the FDA, device manufacturers will do everything they can to sell as many devices as possible, irrespective of whether or not the use of such devices is truly in the best interests of patients. For them, FDA approval to market the device is tantamount to declaring such devices to be "in the best interests of patients." Under these circumstances, the interests of patients are subordinated to the profit motive and the interests of company shareholders.

The Institute of Medicine has recently declared that the current 510(k) premarket notification process for medical devices (such as the non-absorbable surgical mesh kits now widely marketed for the treatment of POP) is fatally flawed. As presently structured, the 510(k) process cannot meet its stated goal and cannot ensure that non-absorbable mesh implants for transvaginal repair of POP are both safe and effective. Indeed, there is substantial evidence that such mesh is neither safer nor more effective than traditional native tissue repair operations for these conditions, without the use of synthetic mesh, and that the use of such mesh is associated with serious and sometimes irreversible harm to the patients in whom it is used. I commonly see patients who have been harmed by these mesh products in my own clinical practice. The FDA cannot meet its ethical obligations to put the best interests of patients first under these conditions.

The medical profession has shown itself to be both unwilling and unable to provide critical scrutiny and scientific evaluation of devices released into the marketplace under the current system. The result is a clinical free-for-all actively promoted by device manufacturers in the pursuit of corporate profits, with patients as the innocent injured bystanders of this process. Because of the inadequate pre-market evaluation of devices such as the transvaginal non-absorbable mesh kits currently marketed for the treatment of POP, physicians are unable to give patients the meaningful information on risks and benefits needed for informed consent for surgery. As a result of the current system, physicians are also defaulting on their primary ethical obligations related to patient care.

The non-absorbable synthetic transvaginal meshes currently marketed for the treatment of POP should be removed from the market until their use has been proven to be safe and effective through well-designed, mandatory clinical trials.