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## Letter to the Editor

### Implant files: News and paradox



“The U.S. Food and Drug Administration today ordered the manufacturers of all remaining surgical mesh products indicated for the transvaginal repair of pelvic organ prolapse (POP) to stop selling and distributing their products in the U.S. immediately” [1]. On April 16, 2019, the Food and Drug Administration (FDA) banned the distribution of trans-vaginal meshes (TVM) indicated for pelvic organ prolapse (POP) surgeries. A radical decision, a therapeutic impact, a response of an experienced society, what are the reasons for this decision?

Based on its prior decision, which required TVM manufacturers to obtain a safety and effectiveness assurance for marketing these class III devices, an FDA-mandated-advisory-expert panel established the way of assessing risks and benefits of TVM. A favorable evaluation should be based on evidence of superior efficacy to compensate for the risks of mesh-specific complications. According to the FDA, manufacturers have not demonstrated that mesh repairs are superior to native tissue repairs. In the immediate aftermath of this announcement, the American company Boston Scientific has stopped producing and distributing the Uphold LITE<sup>®</sup> system world-wide, and Coloplast has decided to stop selling Restorelle DirectFix Anterior and Posterior mesh September 2019. Meanwhile, the distribution of TVM is currently suspended in the USA. Given the current confusion in the medical press, it should be noted that the FDA's announcement does not apply to the use of second generation mid-urethral slings for treating female urinary incontinence, nor to sacrocolpopexy/sacrohysteropexy meshes for treating POP. Even self-cut flat mesh can be used vaginally.

If the FDA announcement is clear, the brutality of its decision is surprising. Indeed, there is an FDA-supported and industry-funded non-randomized clinical trial comparing vaginal mesh with native tissue. The publication of the results to be made at two different follow-up times: the 522 post-market surveillance studies (522 order) at thirty-six months, and the premarket approval (PMA) at twelve months. The 12-months results show no added value for mesh procedures compared to native tissues procedures, in terms of efficacy, without any reference to the over-morbidity of one of the groups. The FDA remains attentive to the results at thirty-six months and committing, despite the suspension of the companies, to continue the search during this period. This information, in addition to the pressure of class-action associations supported by American health law firms, led to the withdrawal of TVMs. The decision of the FDA follows, in fact, the political line stopped in Scotland, Ireland, Australia, New Zealand and England.

Currently, patients who describe recurrence after native tissue surgeries should benefit from mesh repair procedures, vaginal or abdominal. According to training and surgical skills, the surgeons can also choose the appropriate approach; However, in the

countries mentioned above (Scotland, Ireland, Australia, New Zealand and England), they can no longer do that. The situation in France seems different: the public authorities Association française de normalisation (AFNOR), Agence nationale de sécurité du médicament (ANSM), and Direction générale de l'offre de soins (DGOS) have currently made no decision and rather initiated an observation process. The meshes manufacturers have been supervised by the ANSM services for data of sales and distribution since the PROLIFT case; Département d'Information Médicale (DIM) managers and pharmacists from our public and private hospital structures have been asked by the DGOS, delegated by the Ministry of Health, to detail the number of meshes used over the past year and the specialty of surgeons who perform these procedures (gynecologists, urologists or general surgeons). Currently, the French authorities do not seem to respond to a process of exclusion, suspension or limitation, but observation.

Being worried by the consequences of this decision and concerned about extending the restriction to meshes used in abdominal procedure as well, American and international professional societies (the American Association of Gynecologic Laparoscopists (AAGL), the American Urogynecologic Society (AUGS), the International Continence Society (ICS), the International Urogynecology Association (IUGA), The Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)) reacted unanimously and immediately: protesting against the decision to suspend or abandon vaginal meshes. Official letters, calls for evidence, and petitions have been sent to the FDA. In France, several meetings were held without any formal decision. Nevertheless, the advice given to the members of international societies can be safely applied in our country: support of clinical research, increasing registration, joint decision-making, reinforcing of consultations, longitudinal post-operative follow-up, abandonment of individual procedures and products without Conformité Européenne (CE) marking, follow evidence-based recommendations and techniques, referring patients to centers of expertise, and amplification of surgical training.

What can we do with these events?

In each country, on each continent, for the same pathology and concerning the same treatment, at a time of globalization, the different health authorities play their own part. This suspension induces a new distortion, which faces us with a scientific, political, and intellectual misunderstanding and opacity. As such, our British colleagues can, after a one-year period, reintroduce TVM, following the National Institute for Health and Care Excellence (NICE) recommendations, for the sub-group of complex patients (recurrence or high risk of recurrence). JP Roovers is a urogynecologist, Dutch, well experienced in mesh support and pelvic reconstruction surgeries, agreed to co-sign this editorial. We could have associated with many other European, Asian, American, African colleagues as well, who share the same opinion. Integrating our French colleagues in international societies is not a decoy but a

necessity; what is true for the economy, justice, and all these parameters constituting our society, is also true for our health systems. A harmonious European attitude should be a reality.

In our discipline, we have experienced a considerable evolution of the surgical practices and tendencies over the last twenty years. The procedures of the 80s are no longer necessary. In fact, the development of minimally invasive gynecological surgery has freed patients from many ailments and potential complications. For those of us who have witnessed this transition with enthusiasm, it is inconceivable to return to the techniques of yesteryear. Should it be crazy or visionary to push for minimally invasive surgery or mesh reinforcement? The answer seems obvious. It's up to us to find a balance between our ethics and the evolution of our practices.

The ball is in our court.

## References

- [1] FDA. <https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-womens-health-orders-manufacturers-surgical-mesh-intended-transvaginal>. (Accessed 4 June 2019).

Ohad Gluck

*Functional Pelvic Surgery & Oncology, Geoffroy Saint-Hilaire,  
Ramsay, Générale de Santé, Paris, France*

Jan Paul Roovers

*Department of Obstetrics and Gynecology, AMC Amsterdam, the  
Netherlands*

Bruno Deval\*

*Functional Pelvic Surgery & Oncology, Geoffroy Saint-Hilaire,  
Ramsay, Générale de Santé, Paris, France*

- \* Corresponding author at: 9 rue quatrefages, Geoffroy Saint-Hilaire, Ramsay, Générale de Santé, Paris, 75005, France.  
E-mail address: [bruno.deval@orange.fr](mailto:bruno.deval@orange.fr) (B. Deval).

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