

Brief Summary of the General and Plastic Surgery Devices Panel Meeting March 23, 2021

Introduction:

A virtual meeting of the General and Plastic Surgery Devices Panel of the Medical Device Advisory Committee was convened to discuss and make recommendations regarding the risks and benefits of dermal fillers in two topic areas. The first topic addressed the general issues regarding risks associated with intravascular injections of dermal fillers. The second and final topic addressed general issues regarding patient preference and informed decision making. FDA convened this meeting to seek expert opinion on the clinical evaluation and regulation of dermal filler products.

Device Description:

Dermal Fillers are aesthetic devices for which the decision to proceed with the injection procedure is elective. Dermal fillers are Class III medical devices identified with product code LMH (implant, dermal, for aesthetic use) or PKY (implant, dermal, for aesthetic use in the hands). Dermal filler products have received premarket approval (PMA) for: correction of nasolabial folds and facial acne scars on the cheeks of patients over the age of 21; lip augmentation; correction of age-related volume deficits in the midface in adults over the age of 21; augmentation of the chin region in subjects over the age of 21; volume loss in the dorsum of the hands; and restoration and/or correction of the signs of facial fat loss (lipoatrophy) in patients with HIV.

Topic I: Risks Associated with Unintentional Intravascular Injection of Dermal Fillers.

The committee heard presentations from FDA regarding clinical and regulatory background on dermal fillers, a summary of medical device reports for dermal fillers, and strategies to assess and monitor for intravascular injection. Dr. Jean Carruthers, an invited external speaker, presented on the Prevention of Filler induced Vascular Occlusion, Blindness, and Stroke. In addition to these presentations, three manufacturers of approved dermal fillers presented on how each manufacturer mitigates the risks associated with vascular occlusion. Common mitigation strategies among manufacturers included clinical study evaluation and training programs. During the Open Public Hearing, the panel heard presentations from practicing physicians and representatives of professional societies, including the American Academy of Dermatology Association, the American Society for Dermatologic Surgery Association, the American Academy of Facial Plastic and Reconstructive Surgery, the American Academy of Ophthalmology, the American Society of Ophthalmic Plastic and Reconstructive Surgery, and the Aesthetic Society. Topics covered included strategies to decrease the risk of intravascular injection, methods to monitor for intravascular injection in clinical studies, clinical practice, how to treat intravascular injection if it occurs, and how to adequately train injectors to prevent intravascular injection.

The panel discussed and made recommendations on the inclusion of vision assessments to actively and deliberately monitor for intravascular injection in clinical trials and clinical practice. The panel recommended that for clinical trials, the collection of this data is appropriate and important to the continuing study of these adverse events. The panel did not think that there should be different approaches in clinical trials for different anatomic areas, as there is not sufficient data to determine what areas may be at higher risk for intravascular injection. In clinical practice, there

was consensus from the panel that brief vision assessments before and after treatment should be recommended regardless of indication for use. In addition, the panel recommended that injectors have a treatment plan in place, which includes establishing a relationship with a nearby ophthalmologist or retinal specialist. The panel discussed the utility of the collection of data on intravascular injection in the postmarket space, including post-approval studies and registries. The panel discussed that the collection of data in a post-approval study would be challenging, due to the low numbers of reports. A registry was suggested as a way to collect this information, but it was noted that the development and use of a registry also has limitations and challenges. There was a consensus that training is one of the key tools available to prevent intravascular injection events. Recommendations from the panel included establishing uniform training as well as annual refresher training to ensure that all injectors have up-to-date information.

Topic II: Patient Preference and Informed Decision Making

The committee heard presentations from FDA regarding how the Agency incorporates patient perspectives in medical device regulatory decisions as well as the Agency's Medical Device Development Tool (MDDT) program. The FDA also presented information on how effectiveness is assessed in dermal filler clinical trials, including challenges with this assessment as well as examples of strategies to improve the informed decision-making process and labeling.

The panel discussed and made recommendations on how publicly available validated effectiveness measures may be developed and implemented to permit a standardized evaluation of the effectiveness of dermal fillers. The panel recognized the challenges with the growing number of dermal filler products and indications for use and how to communicate this information to patients. With regards to the incorporation of diverse subject populations in clinical studies, the panel recommended that the Agency consider additional factors such as the age of subjects, the motivation for seeking treatment, socioeconomic status, and past history of procedures in the treatment area. The panel recommended that the Agency consider patient focus groups to determine the patient populations likely to seek treatment for new indications and products as well as ask manufacturers to provide information to support the proposed study population. The panel also discussed how to proactively incorporate patient preference information into the design of clinical studies, including the challenges that are associated with this proposal. The panel suggested that a clinical study may not be the appropriate method for the collection of this data as the risks and trade-offs are often unknown. The panel acknowledged the importance of this information and the difficulties in collecting it.

The panel next discussed and made recommendations on patient labeling and the informed decision-making process. It was agreed that consistent labeling would be an effective approach, and that the risks associated with intravascular injection should be presented separately and clearly to the patient. The panel cautioned that the statements regarding the most devastating adverse events should not be alarming and may be accompanied by information on the incidence of these events, if available. The panel also agreed that a patient decision checklist would help to ensure that patients are made aware of the risks associated with intravascular injection and acknowledge these risks prior to treatment. The last topic of the day was the proposal to include a patient information card which includes information on the device that was injected, area and volume of injection, adverse events information, and how to report adverse events. The consensus from the panel was that a version the example card presented would provide valuable information to the patient and any future healthcare providers as well.



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