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Opening Remarks

Bleta Vuniqi, Acting Office Director
OHT 4: Office of Surgical and Infection Control Devices

U.S. Food & Drug Administration
Center for Devices and Radiological Health
General and Plastic Surgery Devices Panel Meeting
August 13, 2025

Clinical and Regulatory Overview of Dermal Fillers

Taili T. Mata, Ph.D.
Biomedical Engineer, Lead Reviewer

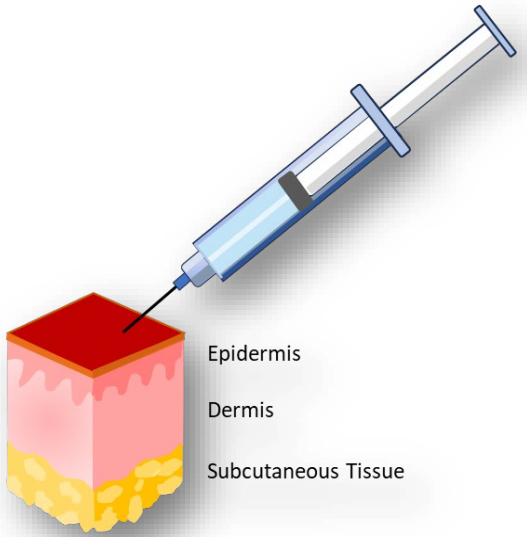
U.S. Food & Drug Administration
Center for Devices and Radiological Health
General and Plastic Surgery Devices Panel Meeting
August 13, 2025

Agenda

- Description
- Regulatory Process
- Indications for Use
- Benefits and Risks
- Removal
- Increasing Use

Device Description

- Dermal fillers, also known as injectable implants, are used to fill wrinkles and provide volume.
- Soft, moldable products composed of a variety of materials.
  - Natural vs synthetic
  - Absorbable (temporary) vs non-absorbable (permanent)
- Some fillers contain analgesics (approved drugs) to reduce pain.
  - Combination products regulated also by Center for Drug Evaluation and Research (CDER)



Dermal Fillers: Classification

- Class III devices.
  - Product codes **LMH, PKY**.
    - **LMH –** intended for use in the face
    - **PKY –** intended for use on the back of the hand

- Premarket Approval (PMA) process
  - Review focuses on **benefit/risk** with substantive review of preclinical and clinical studies and product labeling.

Dermal Fillers: Approvals

- Approved for various indications that include different anatomical areas **on the face and the hands** in adults over 21 years of age.

Anatomic sub-regions present location-specific risks

- Lips
- Cheeks/midface
- Perioral rhytids
- Nasolabial folds
- Chin
- Infraorbital hollows
- Jawline
- Temple

- Underlying anatomy
  - Nerves
  - Blood vessels
  - Muscles
  - Organs
- Anatomic region function

Filler Benefits and Risks

Benefits

- Correction of age-related deficits
- Augmentation of body structures for aesthetic purposes

Risks

- Shortly after injection (such as swelling and bruising)
- Late onset (such as nodules, granulomas)

Risks of Dermal Fillers

Common risks	Less common risks

• Swelling
• Pain/tenderness
• Firmness (induration)
• Bruising
• Redness
• Discoloration
• Itching
• Rash
• Difficulty in performing activities*
	• Granuloma
	• Lumps/nodules
	• Injection site infection
	• Open or draining wounds
	• Allergic reaction
	• Necrosis (tissue death)
	• Unintended intravascular injection leading to:
	  • Skin necrosis
	  • Damage to underlying structures
	  • Vision impairment/blindness and other eye or periocular complications
	  • Stroke
	• Reports of bone resorption after supraperiosteal injection

* Only observed when injected into the back of the hand.

Removal of Dermal Fillers

Possible Reasons for Removal:

- Intravascular injection, Visual disturbance and/or Impending necrosis
- Nodule formation
- Overcorrection
- Undesirable cosmetic result

*Options for removal **depend on the composition of the filler** injected*.*

***No products for removal have been approved by the FDA.**

With new indications and injection locations, unique risks may lead to additional reasons that device removal may be necessary.

The panel will be asked feedback on this topic.

Increasing and Evolving Use

- In **2024**, dermal filler procedures performed for both hyaluronic acid fillers and non-hyaluronic acid fillers experienced continued growth*.

~ 6.2 million dermal filler treatments from 2023 to 2024 in the US*

- **12 dermal filler PMAs** have been **approved** for new products or new indications **since 2021** General Issues Panel Meeting on Dermal Fillers.

*https://www.plasticsurgery.org/documents/News/Statistics/2024/plastic-surgery-statistics-full-report-2024.pdf

Evolving Use Evaluation

Increased interest in new injection locations for dermal fillers.

- Such as in the **décolletage / décolleté**, the thighs, and other areas of the body other than the face.
- Unique risks associated with dermal filler injection in the décolletage region due to **the proximity to breast tissue**.
- **Benefits and risks** of dermal filler injection in the décolletage.

The panel will be asked feedback on these topics.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Benefits and Risks of Dermal Fillers with New Indications for Use in the Décolletage Area

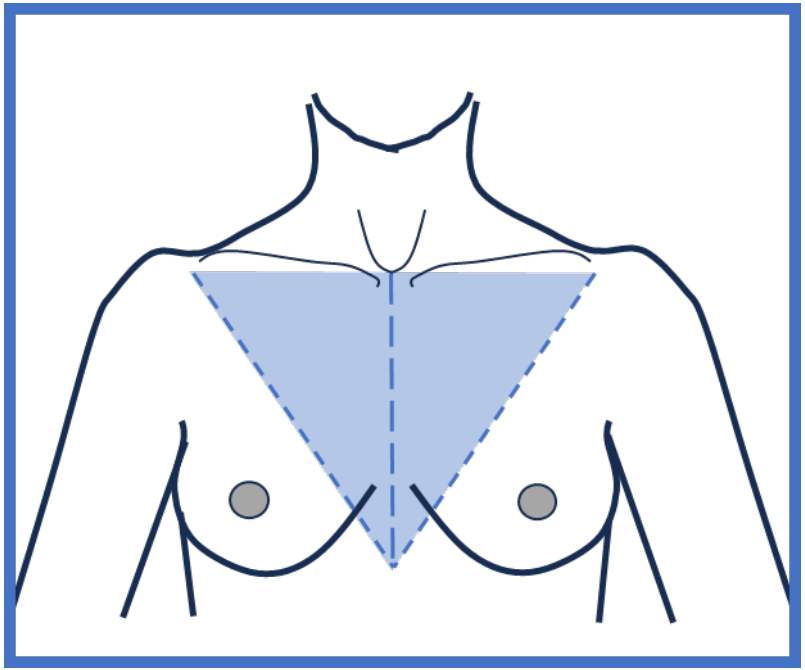
Sung Yoon, M.D., FACS
Medical Officer

U.S. Food & Drug Administration
Center for Devices and Radiological Health
General and Plastic Surgery Devices Panel Meeting
August 13, 2025

Agenda

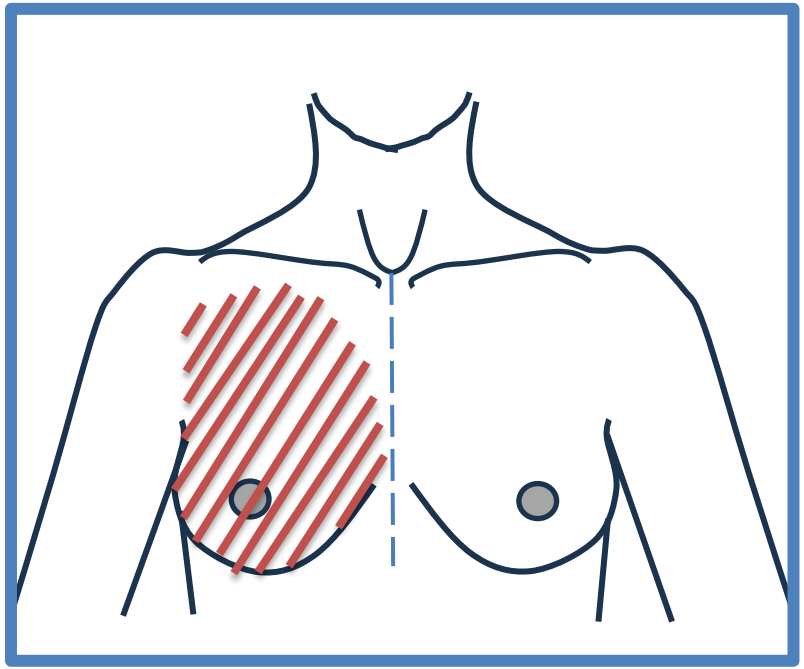
- Décolletage area as a new indication for use for dermal fillers
  - Anatomical location of décolletage and breast
  - Breast cancer
  - Potential benefits to the décolletage area
  - Risks specific to the décolletage area
  - Proposed strategies to address unique risks to the décolletage area
  - MDR analysis

Décolletage



No universally accepted anatomic landmarks

Décolletage



Breast

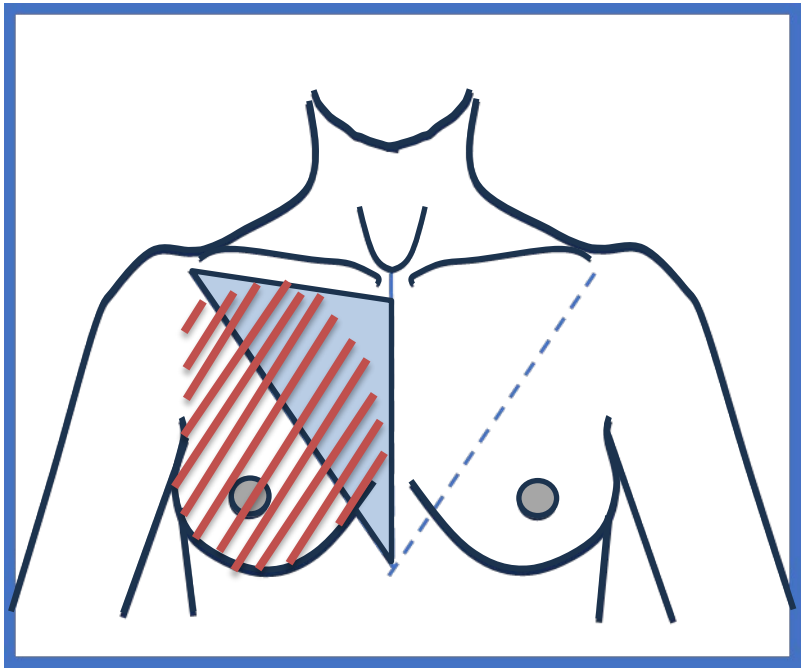
Horizontal:

- sternum → midaxillary line

Vertical:

- clavicle → rectus abdominis muscle inferiorly

Décolletage



Overlap of Décolletage and Breast Region

Breast Cancer

- Second leading cause of cancer death in women
- Lifetime risk of a woman in the US = ~13%
- Routine screening mammograms
- Patients receiving treatment for the décolletage are predominantly female

Indication for the Décolletage Area

- Injections to treat lines/wrinkles within this region

Risks Specific to the Décolletage Area

- Imaging interference
- Clinical exams
- Breast feeding and lymphatic system

Risk 1: Imaging Interference

Risk	Potential for dermal filler to cause interference or other findings on breast cancer screening studies
Evidence	• Literature documenting potential of dermal fillers to mask an underlying malignancy • Cervical lymph node enlargement following complications from filler injection into the face
Potential outcome	• Misdiagnosis via screening studies → additional unnecessary testing and/or procedures as well as delayed diagnosis of these patients.

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Potential outcome	• Misdiagnosis via screening studies → additional unnecessary testing and/or procedures as well as delayed diagnosis of these patients.
Proposed strategies for premarket clinical study and postmarket	• Collection of baseline imaging (mammogram, ultrasound, or MRI), preferably within 2 years prior to injection, and a post-injection imaging • Evaluation of imaging by committee with experience and expertise • Post-approval study if imaging evaluation not included in premarket study • Inclusion of radiographic images of the implanted device in the labeling

Risk 2: Clinical Exam Findings

Risk	Potential for positive findings during clinical examination
Evidence	• Granulomas, lumps/bumps, nodules, and migration may occur weeks to years after injection • Supported by literature and MDRs for dermal fillers in general
Potential outcome	• Mass in or near breast tissue due to prior dermal filler injection may be diagnosed as suspicious → additional testing, e.g. imaging or biopsy • Suspicious mass inaccurately diagnosed as dermal filler complication → delayed diagnosis and treatment

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Proposed strategies	• Recommend device cards be provided to patients and included in patient records • Post-Approval Study to assess late-onset adverse events and their effects on clinical diagnosis

Risk 3: Breast Feeding and Lymphatic System

Risk	Proximity to breast tissue may impact breast feeding and the lymphatic drainage system of the breast
Evidence	• Information related to this potential risk in the literature is limited
Potential outcome	• Negative impact on breast feeding • Obstruction or other adverse impact on the lymphatic drainage system

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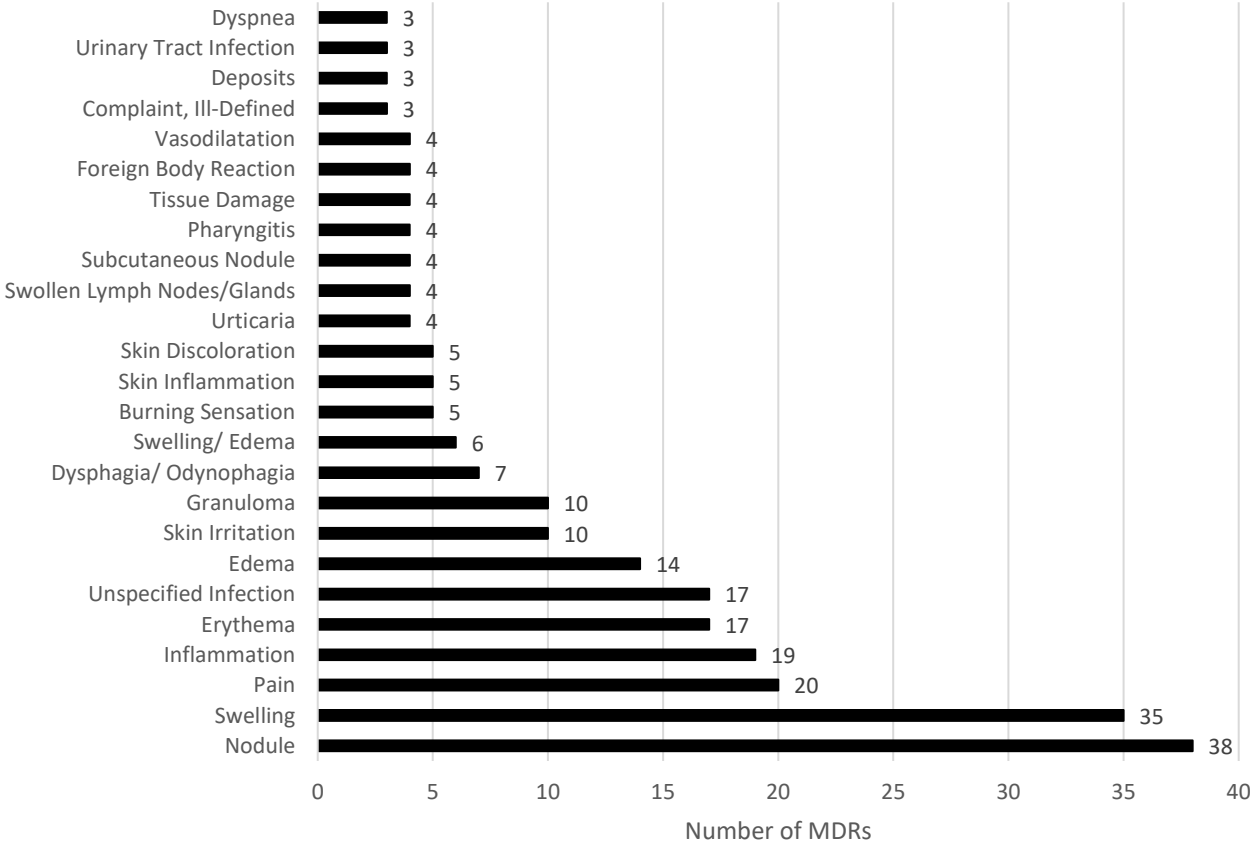
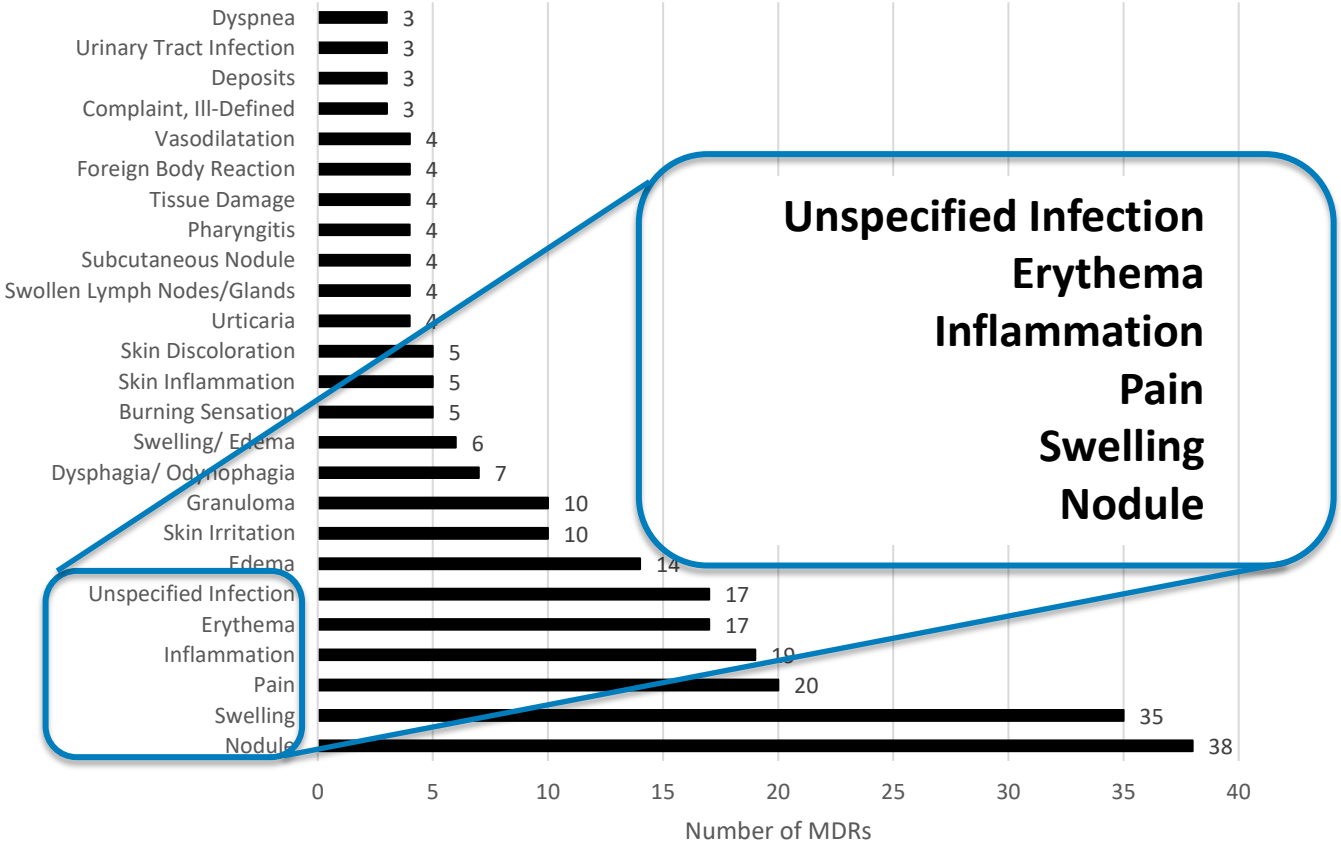
MDR Analysis



MDR Analysis

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Patient Preference Information

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Division of Patient Centered Development
August 13, 2025

Patient Preference Information (PPI)

FDA Guidance Document: *Patient Preference Information – Voluntary Submission, Review in PMAs, HDE Applications, and De Novo Requests and Inclusion in Decision Summaries and Device Labeling. August 2016*

PPI Definition: Qualitative or quantitative assessments of the relative desirability or acceptability to patients of specified alternatives or choices among outcomes or other attributes that differ among alternative health interventions

- Not a patient-reported outcome (PRO) or other clinical trial endpoint or outcome

PPI and Benefit-Risk Determination

- CDRH assesses benefits and risks to establish a reasonable assurance of safety and effectiveness
- CDRH recognizes that patient preference information can supplement the assessment of benefits and risks
- PPI studies consider how patients weigh the benefits and risks of treatment options*

**FDA Guidance: Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications Guidance for Industry and Food and Drug Administration Staff (Issued August 30, 2019)*

PPI and Benefit-Risk Determination

- PPI can be useful during FDA's benefit-risk assessment in several major ways:
  - Help identify the most important benefits and risks of a device for a particular indication for use from a patient's perspective
  - Clarify what benefit-risk (B/R) trade-offs of a given device are acceptable from the patient perspective
    - E.g., risk tolerance for a given benefit

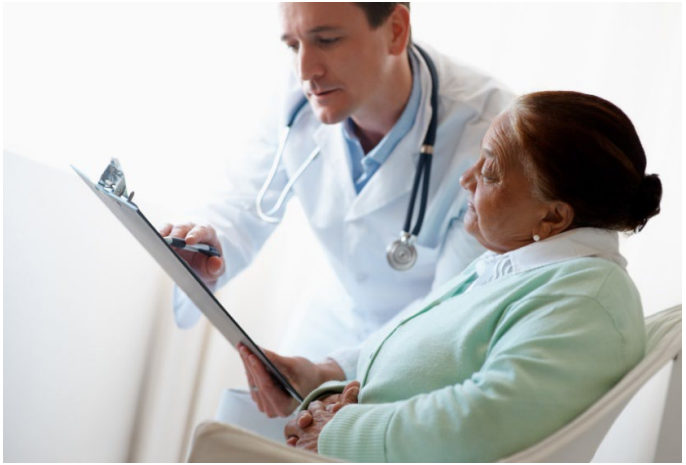
Recommended Qualities of PPI Studies*

Well-designed processes. and conducted PPI studies can provide valid scientific evidence regarding patients' risk tolerance and perspective on benefit. This may inform FDA's evaluation of a device's benefit-risk profile during the PMA, HDE application, and De Novo request review

A. All about Patients
   - Patient Centeredness
   - Sample Representativeness
   - Capturing Heterogeneous Patient Preferences
   - Comprehension by Study Participants

B. Good Study Design
   - Established Good Research Practices
   - Effective Benefit-Risk Communication
   - Minimal Cognitive Bias
   - Relevance

C. Good Study Conduct and Analysis
   - Study Conduct
   - Logical Soundness
   - Robustness of Analysis of Results



*FDA Guidance: Patient Preference Information - Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling (Aug 2016)

An Important Step in PPI Study Design

- Identification of key attributes that characterize the B/R profile for a given device and indication for use.
  - Attributes typically include device-related features or outcomes, such as, benefits, risks, duration of effect, and frequency of use
  - **Established good research practices** in the development of PPI studies recommend not more than 9 attributes
  - Chosen attributes should be of clinical and regulatory **relevance** and salient to patients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Questions for the Panel

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Acting Assistant Director
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U.S. Food & Drug Administration
Center for Devices and Radiological Health
General and Plastic Surgery Devices Panel Meeting
August 13, 2025

Décolletage refers to the area of the chest or cleavage between the breasts up to the collarbone. Beyond the anticipated adverse events of filler injections, dermal filler injection into the décolletage area includes the following unique risks which are specific for this anatomic area:

a) Potential for dermal filler to cause interference or other findings on breast cancer screening studies

b) Potential for positive findings during clinical examination

c) Proximity to breast tissue which may impact breast feeding and the lymphatic drainage system of the breast.

Panel Question 1:

The benefit risk profile of dermal filler devices for the décolletage indication may vary based on patient specific factors such as their risk for breast cancer, risk for scarring, or their age and potential to receive larger cumulative volumes over their lifetime.

a. Does the panel recommend additional risks to be considered for injection into the décolletage area?

b. Does the panel have recommendations about specific subpopulations to be studied or to be excluded because the benefits may never outweigh the risks?

Panel Question 2:

Given the risks unique to this anatomic location, FDA proposes the following additional criteria to be incorporated in the premarket and/or post-market mitigation strategies for the patient subpopulation that may be candidate for injection into the décolletage area:

Risk	Proposed Strategies for Mitigation
Interference or other findings on breast cancer screening studies	• Collection of baseline imaging (e.g., mammogram, ultrasound, or MRI), preferably within 2 years prior to injection and post-injection imaging • Evaluation of imaging by committee with experience and expertise • Post-approval study if imaging evaluation not included in premarket study • Inclusion of radiographic images of the implanted device in the labeling
Potential for positive findings during clinical examination	• Recommend device cards be provided to patients and included in patient records • Post-Approval Study to assess late-onset adverse events and their effects on clinical diagnosis
Proximity to breast tissue may impact breast feeding and the lymphatic drainage system of the breast	• Premarket follow-up until quiescence of inflammatory response • Post-Approval Study to evaluate effects on lactation and lymphatic system

Panel Question 2:

Does the panel agree with the proposed strategies for risk mitigation?

Based on the risks discussed, does the panel recommend additional assessments or mitigations that should be considered and included?

Does the panel recommend this data be provided in the premarket study before approval to inform the patient in the labeling?

Does the panel have recommendations on assessment of long-term adverse events or the duration of follow-up of the patients?

Panel Question 3:

Currently, there are several approaches reported for treatment of adverse events after dermal filler injections such as aspiration/drainage, extrusion, excision, or enzymatic degradation. FDA has not approved any product for enzymatic degradation or removal of dermal fillers. Does the panel have recommendations for how the benefit-risk profile for dermal fillers injected into the décolletage should be evaluated considering the current removal options? How should the available removal options for a specific device be communicated to patients in the labeling and other patient materials?

Panel Question 4:

A patient preference study may help inform FDA's benefit risk assessment as part of the premarket review of devices for this new indication. Considering the risks identified in the prior questions, which key risks would the panel recommend for incorporating into a patient preference study to estimate the maximum risk that patients would be willing to accept? In other words, are there specific risks that the panel is most concerned about given the potential benefit for this new indication?


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