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Berlin, August, 28th, 2023

Dear Members of the ECHA,

I am medical doctor and dedicated hernia surgeon since more than 20 years also one of the European specialists with degree of the UEMS as Abdominal Wall surgeon FEBS-AWS.

I fully support the efforts of the European Chemicals Agency (ECHA) to address the risks associated with PFAS. However, I call on the ECHA to consider a preliminary exemption for the irreplaceable hernia meshes made of fluoropolymers, especially PVDF, due to their unique properties:

Hernia meshes must provide permanent reinforcement of the abdominal wall or inguinal structures over the patient's lifetime. Extensive scientific research and clinical studies have demonstrated until now the safety and efficacy of PVDF hernia meshes, with positive long-term outcomes and low complication rates compared to available alternative materials.¹ The undesired high durability of PFASs becomes a decisive advantage when they are used in long-term implants.

A ban on fluoropolymer hernia mesh would also mean that specific treatment alternatives would no longer be available. A ban on these meshes limits the surgeon's treatment options to the disadvantage of the patient.

While the efforts to prevent the further spread of PFAS are understandable and sensible, a balanced consideration of the risks/benefits should nevertheless be made.

Therefore, and in the interest of patient safety I call on the European Chemicals Agency to grant an exemption for mesh implants made of fluoropolymers, in particular PVDF.

I will be happy to answer any questions you may have.

Sincerely yours,

Ralph Lorenz, Dr.med., FEBS-AWS

¹ Baker, Jason Joe, Stina Öberg, und Jacob Rosenberg. „Reoperation for Recurrence Is Affected by Type of Mesh in Laparoscopic Ventral Hernia Repair: A Nationwide Cohort Study“. Annals of Surgery Publish Ahead of Print (13. September 2021). <https://doi.org/10.1097/SLA.0000000000005206>.