MEDICAL ALLEY ASSOCIATION

February 22, 2019

Congressman Jim Hagedorn
325 Cannon House Office Building
Washington, D.C. 20515

Congressman Tom Emmer
315 Cannon House Office Building
Washington, D.C. 20515

Congresswoman Angie Craig
1523 Longworth House Office Building
Washington, D.C. 20515

Congressman Collin Peterson
2204 Rayburn House Office Building
Washington, D.C. 20515

Congressman Dean Phillips
1305 Longworth House Office Building
Washington, D.C. 20515

Congressman Pete Stauber
126 Cannon House Office Building
Washington, D.C. 20515

Congresswoman Betty McCollum
2256 Rayburn House Office Building
Washington, D.C. 20515

Senator Amy Klobuchar
425 Dirksen Senate Office Building
Washington, D.C. 20510

Congresswoman Ilhan Omar
1517 Longworth House Office Building
Washington, D.C. 20515

Senator Tina Smith
720 Hart Senate Office Building
Washington, D.C. 20510

Members of the Minnesota Congressional Delegation:

I'm writing you today regarding an issue of great importance to small- and medium-sized medical technology manufacturers throughout Medical Alley.

Recently, a key source of sterilization for these manufacturers was abruptly shut down by state authorities due to environmental concerns. These concerns need to be taken seriously and should be handled in due course. The loss of this sterilization source, however, is posing severe challenges to manufacturers of life-saving medical devices.

The sterilization source in question is a preferred site for many small and emerging medical device manufacturers because of its large and significant medical device work and its known compliance to FDA and EU standards. For many of these low-volume manufacturers, this was their only qualified and validated sterilization source, as it is cost prohibitive for them to have secondary suppliers. Unlike other industries, where suppliers can be changed quickly, medical device companies are required to have their changes approved by the FDA. This is a complex process that can typically take anywhere from three to six months, but because this was a preferred source for many manufacturers, other sterilization sites will have increased demand and the process is likely to take even longer.

For these small- and medium-sized medical device manufacturers, even the short end of the typical window for approval is too long. Since the shutdown of this sterilization source was so abrupt, these manufacturers did not have notice or time to begin the process of changing suppliers. The result is that many have less than – at most – a two or three months' supply of their product processed. This means that hundreds of thousands of patients are at significant risk of having a significant disruption to the supply of sterilized devices for life-saving and life-supporting treatments.

To help avoid this potentially tragic scenario, we need your help in urging the FDA to provide alternative paths forward for these companies – such as “batch release” or expediting new source requests in this specific situation. These alternatives need to be available quickly to ensure patients are not impacted by a situation that they, or the manufacturers, had no part in causing.

Thank you for your consideration. Please let us know if we can provide any additional information.

Sincerely,

Shaye Mandle
President & CEO
Medical Alley Association

cc: Bobby Patrick, Director, Government Relations, Medical Alley Association