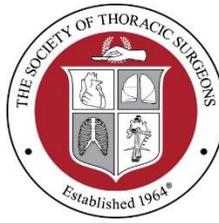


STS Headquarters

633 N Saint Clair St, Suite 2100
Chicago, IL 60611-3658
(312) 202-5800
sts@sts.org



Washington Office

20 F St NW, Suite 310 C
Washington, DC 20001-6702
(202) 787-1230
advocacy@sts.org

September 17, 2019

Sent via email

Norman Sharpless, MD
Acting Administrator
U.S. Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Heparin Shortage

Dear Acting Administrator Sharpless,

On behalf of the members of The Society of Thoracic Surgeons (STS), I write to request information on how the Food and Drug Administration (FDA) plans to address the impending patient care crisis related to the current heparin shortage.

Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,200 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical procedures within the chest.

Heparin, an anticoagulant, is used during surgery to reduce the risk of blood clots. Without heparin, many surgeries will become dangerous, if not impossible to perform. Yet many hospitals have only a few weeks' supply of heparin remaining and little information on how to acquire more.

We are aware that production problems may be a result of an outbreak of swine fever in China. We are also cognizant of problems with the quality of heparin products that were produced during the last such outbreak among the Chinese swine populations in 2007 and 2008. During that time, unbeknownst to U.S. manufacturers and the FDA, synthetic heparin products were passed off as authentic and some patients had severe, if not fatal, adverse events.

We respectfully request that FDA publish resources on how providers can access heparin during this shortage as well as information on how it intends to monitor the quality of the heparin supply.

Thank you for your attention to this important matter. Please contact Courtney Yohe, STS Director of Government Relations, at cyohe@sts.org or 202-787-1230 should you need additional information or clarification.

Sincerely,

A handwritten signature in black ink that reads "Robert S.D. Higgins". The signature is written in a cursive style with a large, prominent "R" and "H".

Robert S.D. Higgins, MD
President

CC

The Honorable Mitch McConnell
The Honorable Nancy Pelosi
The Honorable Frank Pallone
The Honorable Greg Walden
The Honorable Richard Neal
The Honorable Kevin Brady
The Honorable Chuck Grassley
The Honorable Ron Wyden
The Honorable Lamar Alexander
The Honorable Patty Murray