Update – Information on the FDA and the Fassier-Duval IM Telescopic System

The OI Foundation is closely monitoring recent actions by the US Food and Drug Administration (FDA) regarding the Fassier-Duval IM Telescopic System. The Fassier-Duval system, commonly known as the Fassier-Duval Rod or the FD Rod, is manufactured by a Canadian Company, Pega Medical, and sold internationally. The FD telescopic rod is used by many surgeons in the United States as surgical treatment for children with osteogenesis imperfecta.

On January 30, 2014 it was reported that the FD Telescopic IM System was part of an administrative detention imposed by the FDA which temporarily prevented Pega Medical from exporting the product to the United States. According to our sources, the reason for the detention is not related to the registration of the product but related to compliance with the quality system.

The OI Foundation has been assured that all parties involved are working as quickly as possible to correct the situation and a projected date to resume exporting the product to the US again is July 2014. This date is dependent on when the FDA schedules a review of the factory in Canada, however.

The OIF has learned that some surgeons have a supply of rods for scheduled surgeries since this is not a recall issue as there is no evidence that there are defects in the system. The OI Foundation recommends, however, talking with your surgeon if you have a surgery scheduled in the next three months that involves the FD system.

The OI Foundation will continue to monitor this situation closely and will post information on the OIF website and the official OIF Facebook page as it becomes available.

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