LE RISPOSTE DI FDA – Ente regolatore USA per i dispositivi medici

1. **As the consent decree agreed by Philips RS "requires the Defendants to contract with an independent testing expert(…) to review and evaluate their testing, including biocompatibility data, on the new, silicone-based foam the company is using", *I kindly ask you to know if – as of today - FDA received:***

   interim or final data from Respironics and/or

   the independent expert's evaluation report;

FDA Response: The FDA has received a report from the independent testing expert regarding completed testing, but some of Philips' testing of the silicone-based foam remains ongoing.

2. **As we have gathered concerning data related to the new silicone-based foam, I kindly ask you what is FDA's evaluation of its safety as of today;**

FDA Response: At this time, the FDA's recommendations regarding the silicone-based foam have not changed. The results from the independent testing are needed to determine if the silicone-based foam used in the repaired devices does in fact present any risks to patients.

3. **As we have factual evidence that Respironics is exporting devices that are not allowed to be sold in the US, I kindly ask you to know if the conditions requested by the consent decree to lift the export ban have been met, and when the ban was lifted.**

FDA Response: The FDA generally does not discuss compliance-related matters except with the company involved. You may find it helpful to review paragraph 8.B. of the Consent Decree (see page 13).