



SHELHIGH POSITION STATEMENT

Revealing Facts Regarding the FDA Actions against Shelhigh

6 June 2007

Shelhigh is providing this outline in response to requests from customers and the public for information regarding the FDA's actions and statements against Shelhigh.

1. The FDA has quarantined Shelhigh products and repeatedly made statements to the public that Shelhigh products may cause a health hazard due to insterility although no reports of any such product health hazard have been received by Shelhigh from surgeons, patients, the FDA or any other health agency in the world.
2. The apparent purpose of the FDA quarantine is to financially strangle Shelhigh through the lack of sales while the FDA scrambles to prove its allegations. The FDA has shown no interest in moving quickly to trial as evidenced by the comments of Chief FDA Counsel, Eric Blumberg to the Federal Court that despite 10 weeks of full access to Shelhigh's facility, the FDA will want "lots of discovery" and that a trial regarding the resumption of Shelhigh operations could last "at least a year."
3. The FDA continued its attack against Shelhigh, Inc. by releasing a news program on its website, again promoting its misleading and specious allegations against the company. Meanwhile, the FDA continues to put up roadblocks to serious inquiries about its actions against Shelhigh by denying repeated requests from Shelhigh for proof of FDA allegations that Shelhigh products actually do present a health risk.
4. In an effort to get to the bottom of the FDA allegations Shelhigh repeatedly requested a copy of the FDA Health Hazard Evaluation (HHE). A Health Hazard Evaluation is mandated by Federal law and requires the FDA to prepare a report prior to requesting a product recall. The HHE must explain the basis for an FDA determination that a medical device can cause a patient health hazard and that the device should be recalled. The FDA refused to provide Shelhigh with an HHE, and admitted in its recent filing to the Court that it did not have evidence to support a health hazard to mandate a recall, and did not institute a mandatory recall.
5. The first detailed information required in an HHE is a "description of a defect, malfunction or error in use" of the device in question. Since there are no reported defects, malfunctions or errors with Shelhigh devices as the FDA alleges, the FDA does not have facts to support its request for a recall. In fact, the rate of adverse events for Shelhigh products—never conclusively linked to the product—is approximately 0.008%. There is no obvious reason, then, for the FDA to have taken such extreme action against a small

special needs medical company with unrivaled technology, and for the FDA's harmful public statements . Shelhigh has strict sterility procedures, which it has followed consistently since its founding nearly ten years ago.

6. Despite facts to the contrary, the FDA put false and misleading statements on its website that go far beyond even the allegations in its complaint, including unfounded statements that Shelhigh valves may “fail to function for the lifetime of the device” or other imagined problems far beyond the alleged issue of infection.
7. The FDA received Shelhigh's final responses to the FDA inspection 1-3 days before drafting its complaint for seizure. The FDA also refused all requests for meetings or verifications of any changes, and in fact never substantively discussed its observations with Shelhigh in the over four month period between the end of the inspection and the seizure. During that time, the FDA did not issue a warning letter, or request a recall or injunction, (for which the FDA has admitted it does not have the required supporting evidence).
8. Shelhigh wonders how members of the Center for Devices and Radiological Health (CDRH), the FDA New Jersey District, and FDA counsel could have read, reviewed, analyzed, met to discuss, and “all concluded” that Shelhigh's comprehensive responses to the FDA inspection were not satisfactory in a 1-3 day period, especially since the FDA refused to verify Shelhigh responses to the inspection.
9. FDA's complaint is replete with falsehoods and misleading statements. It is with these fabrications that the FDA tried to show “probable cause” an extremely low evidentiary standard (although the only standard needed to seize products).
10. FDA released trade secret information from the Shelhigh Master File, despite protests by Shelhigh over six months ago, before this release. The FDA has been repeatedly reminded of the seriousness of releasing extremely confidential information from the Master File (filed by law with the FDA in 1997), yet the FDA has refused to take any remedial action for its public disclosures.
11. FDA has been trying to gather evidence *after the fact* to support its allegations. After the seizure, FDA audited Shelhigh's reputable sterility contract laboratory for all documents related to Shelhigh for three weeks
12. Shelhigh notes that it is being forced to respond to a fog of confusion created by the FDA, and that the FDA is struggling to find any shred of evidence (*after the fact*) since its April 2007 quarantine in order to defend its actions. Shelhigh is doing its best to correct the unfair and false characterizations by the FDA through the courts.
13. Although the FDA constantly refers to earlier warning letters from 2000 and 2005, it has admitted to the Court that these letters have nothing to do with its current allegations (calling the letters “irrelevant”), and that it decided to quarantine Shelhigh products based on “probable cause” which it must now prove in a court of law. In an

egregious distortion of American ideals, the FDA wants the Court to presume Shelhigh's guilt and force the company to prove otherwise.

14. The FDA had intentionally mentioned the warning letters from 2000 and 2005 in an unsuccessful effort to show a continued violation.
15. The FDA has requested a voluntary recall of Shelhigh products from the market, and Shelhigh has declined this request due to a complete lack of evidence that would support the need for any product recall.
16. A Shelhigh distributor in the United States removed product from the market after being contacted directly by the FDA. The FDA *told* this distributor to issue a press release, and gave it the language to use in the press release. The FDA issued a statement two days before the formal recall by this distributor announcing a recall.
17. Shelhigh has been delivering life-saving products to surgeons around the world who have been using them successfully for nearly 10 years, and nothing that the FDA now claims can change that fact. What then is the real reason for the FDA actions?
18. The FDA may simply be trying to save face. FDA inspectors made mistakes during their inspection of the Shelhigh facility and apparently their supervisors "rubber-stamped" the inspectors' reports. The result of this approved misinformation caused the FDA to take unwarranted action against Shelhigh, and now the FDA would have to admit that all the time, effort and money they spent on Shelhigh revealed none of the problems that the inspectors reported.
19. Shelhigh believes that if the FDA had actually found a health hazard caused by Shelhigh products, it would have simply presented its findings instead of suggesting that Shelhigh devices may cause a health hazard.

The FDA has spent hundreds of thousands of dollars trying to shut down a small medical company. What is the FDA's goal? Why is it so focused on this small company that produces unrivaled life-saving technology? Is the FDA trying to cover for its own mistakes, which are now falling on the shoulders of the American taxpayer?

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