When one seeks medical treatment, the expectation is that all reasonable precautions have been taken to ensure that medical procedures are as safe as can be possible. This expectation is based on the right to universal healthcare, now mandated under the Affordable Care Act of 2010. That right is positive, since in order to have it the government and society must provide something for their citizens. We also know that doctors ideally operate under the banner of “do no harm,” an ethical mandate to reduce suffering when possible. However, this does not always happen. New technologies in the field of medical devices are key to making surgeries faster, safer, and with more positive outcomes. The FDA regulates these devices to make sure that they are safe additions to a surgeon’s set of tools.

In this case, “the Olympus Corp. failed to alert regulators to a cluster of 16 infections in patients who underwent procedures with its scope in 2012, according to a warning letter posted online Monday by the Food and Drug Administration” (Al Jazeera). It was known to the Olympus Corp. that completely sterilizing their scope was extremely difficult due to the design of its multifunctional head, but instead of reporting this flaw to the FDA and potentially losing sales, the Olympus Corp decided not to report the infections. Instead of adhering to deontological ethics, where each step of a process must be conducted ethically for the process to be ethical, the company committed the deontologically unethical step of lying about the safety of their instrument. On the other hand, creating a scope that can assist surgeons in curing or alleviating
the pain of patients is clearly an ethical goal. From a *utilitarian* point of view the fact that Olympus Corp. achieved this ethical goal, even in part, is enough to excuse the unethical way that it was reached. It appears that the FBA is approaching the situation with a utilitarian view as “despite these problems the FDA has repeatedly said the devices should stay on the market because they fill an important need in a half-million procedures performed each year.”

In my opinion the FBA has been remiss, not in allowing the devices to stay on the market, but in not investigating the issue sooner. The only reason this particular issue was even discovered was because Olympus Corp is being investigated for other reasons. They also found that the company does not even have a procedure for reporting issues for its devices, something that is required for all companies that make medical devices (Associated Press). Many medical procedures carry infection risk but that risk must be well understood by a consenting patient in order for the procedures to be performed. Because the FDA did not do its job in properly scrutinizing medical device companies not only were the patients who had the surgery exposed to risk, but additionally all the other patients, staff, and visitors to hospitals were needlessly exposed.

I agree that utilitarian solutions are often the best we can hope for with current technologies when dealing with the ever-evolving medical field, however, the best way to be sure the most ethical path is being taken is to be transparent with risks.

**Work Cited**