Design of a Microfluidics Device for Facile Processing of Encapsulated Stem Cells
(Technical Report)

Evaluating the Morality of the FDA in its Regulation of Infuse™
(STS Research Paper)

An Undergraduate Thesis Portfolio

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Developing a healthcare medical device, diagnostic, or therapy requires careful attention to detail to avoid safety complications. In the technical project, a 3D-printed microfluidic device was designed specifically for efficient stem cell encapsulation within microvortices. Stem cell therapies, if not fabricated appropriately, can be ineffective if they are not encapsulated in immune-cell-resistant polymers or dangerous if they increase the risk of cancer or an adverse fibrotic response. Thus, it is important to consider designing a device for stem cell fabrication that achieves purity and consistency. While loosely connected, by bringing to light the problems associated with Medtronic's Infuse™, I expand upon the ethical role of regulatory agencies towards ensuring product safety. These projects have a similar focus to maximize safety with a greater understanding of FDA shortcomings and by developing a more robust technology.

In my technical project, a microfluidic device was created that could be used for preparing stem cells for repairing neurodegeneration after a stroke. Microfluidics is a powerful tool that focuses particles under high pressure within small fluid volumes. It has been used traditionally for diagnostics and disease modelling. In the 1600s, Leonardo Da Vinci noticed that when fluid moves from a channel with a small width to a channel with a large width, it forms spiraling vortices. Pervious labs have since utilized this phenomenon with microfluidics to label cells with fluorescent beads. For our project, we explored if immune-resistant polymer tags can attach to stem cells when both are localized within microvortices. Using computational modelling, we calculated the fluid flow necessary for vorticial formation. Additionally, we 3D-printed several microfluidic devices and quantified vorticial presence. By demonstrating a proof of concept, our device paves the way for novel, robust cell encapsulation.

After being approved by the FDA in 2002, Medtronic's spinal product Infuse™ has caused issues to thousands of people including life-threating swallowing and breathing issues.

While the parties deemed responsible include Medtronic for developing an unsafe product and doctors for using the product in off-label inappropriate situations, I argue the FDA should also be held morally accountable for this healthcare tragedy. Using William David Ross' adaptation of Kantian duty ethics, I first suggest the FDA acted unethical, breaking Ross' ethical norm of "reparations," by sending out the warning notice about off-label uses way too late and avoiding to expose corruption of fraudulent data and conflicts of interest in a timely manner. Secondly, with inadequate testing of the device, the FDA fails to protect U.S. citizens from the adverse effects of the rhBMP-2 protein within Infuse™ and thus breaks Ross' "non-maleficence" norm. Lastly, by maintaining an aged rule that prevents products from containing information about off-label adverse risks, the FDA inherently acted unjustly towards the 85% of patients from 2002-2007 who received Infuse™ in off-label fashion. In true Kantian ethic fashion, I also argue that these norms were self-evident (no other norms supersede them), and point out that in breaking these norms, the FDA also broke rules in their own Code of Ethics.

By working on these projects simultaneously, I gained an appreciation for the importance of ethics in healthcare. Evaluating the morality of the FDA in its regulation of Infuse™ has been informative towards our device design should our technology be used clinically. As was the case with Infuse™, the FDA may fail to fulfill its duty to ensure safety, unethically avoiding to act to address safety concerns and fix outdated laws. Thus, it is important when attempting to commercialize a device, such as our microfluidic device, to satisfy not only FDA safety requirements but also scientifically-backed safety as determined by responsible engineers. If these two projects were done separately, minimal consideration would be given to the design of the microfluidic device to ensure purity and consistency for developing safe stem cell therapies.

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