Artificial heart research: an historical perspective

Business, Work

Artificial Heart Research: An Historical Perspective (Rayan R. Joshi Third-year paperFoodand Drug Law Advisor: Peter Barton Hutt) Good reasons for artificial hearts: * There are not enough heart donors (“ Each year, about 30, 000patients are deemed eligible candidates for heart transplantation. However, only a small fraction of this group, numbering about 2000, actually winds up receiving donor hearts. Given the current figures, it is unlikely that the supply of donor hearts will increase enough to render all transplantation a viable means of combating end-stage heart disease on a macro level.) Public opinions * Dr. Cooley believed that focusing the public's attention on thetechnology's future potential would have a positive effect on the field of research as a whole.

* However, Cooley had grossly miscalculated in the realm of public opinion * Confronted with the gruesome images of a suffering human patient, society at large began to regard the entire held of artificial heart technology as “ more monstrous than miraculous," and research efforts in this area were quelled to a substantial degree. Nevertheless, given the state of the economy in the 80’s, and the aversion towards this area of research held by many members of society, the Jarvik team (a team working on designing a artificial heart) was strapped for much needed funding. * The extremely large amount of media coverage provided to the Clark operation proved to be a double-edged sword for researchers in this area.

While the press' love affair with Clark's story initially focused public attention on the amazing potential benefits of heart research, the vivid and disturbing images of Clark's suffering after his operation shifted public opinion squarely in the opposite direction. Commentators who had once championed the

efforts of ambitious heart surgeons now openly questioned whether it was appropriate for human physicians to be “ playing God" in this area. If society were to somehow lose interest in the potential benefits of MCSS technology, then researchers in this area would lose access to the public and private funding that they desperately need in order to ensure continued advancement. * The scientific import of the heart, combined with its cultural significance, renders heart research a particularly sensitive area in which to pursue the betterment of society. Nevertheless, pioneers with the courage to plow forward in this field over the last half century have saved countless lives as a result of their unwavering efforts.

One thing, however, remains clear. If society is ever to reap the full rewards offered by MCSS technology, it will have to recalibrate its attitudes regarding the field in a more open-minded direction, one that hinges less on short term success, and more on long-term progress. Heroic patients like Barney Clark have accepted this challenge. Time will tell if society at large is capable of doing the same. There are two main branches of heart technology. Partial Artificial hearts: Partial devices supplement patients' natural heart function, assisting those patients whose organs, while somewhat viable, are incapable of functioning adequately on their own Total artificial hearts: (we should focus on this !!) * Total artificial hearts (TAH), on the other hand, are devices that actually replace patients' natural hearts. Such devices are designed for situations in which natural organs are so damaged that even supplementation via a partial device isn't enough to produce sufficient circulatory function.

Collectively, partial and total artificial heart devices are classified as mechanical circulatory support systems (MCSS). 3 ways these technologies help 1 First, devices can serve as“ bridges" to transplant, allowing patients' conditions to stabilize while they await the delivery of donorhearts. 2 Second, partial devices can be used, either temporarily or permanently, to allow a patient's natural heart to rest and recover following periods of distress. 3 Finally, TAH devices can potentially serve as permanent replacements for those patients whose natural hearts are too damaged to permit recovery through alternative means.

Replacement TAH devices represent the cutting edge of technology in this field. Rules and regulations * Artificial heart technology is subject to FDA regulation under the Federal Food, Drug, and Cosmetic Act of 1938 (Act"). * The Medical Device Amendments of 1976 (Amendments") to the Act establish three regula- * tory classes for medical devices, ased on the degree of control necessary to assure that the various types of * devices are safe and e ective. " * Artificial heart devices are considered part of Class III, and are thus subject to the heaviest possible regulation. A Class III device is defied in the Amendments as one that supports or sustains human life or is of substantial importance in preventing impairment of humanhealthor presents a potential, unreasonable risk of illness or injury. * Class III medical devices may not be marketed by firms until the FDA has approved a pre-market approval (PMA) application under Section 515 of the Act. Dr. Michael E. DeBakey- a prominent surgeon at the Baylor College of Medicine in Houston * His research interests led him to form a team whose purpose was

to explore the feasibility of building an artificial device that could replace the natural human heart.

The history of total artificial hearts 60’s * The development of total artificial heart technology can be traced to the early 1960's. * Indeed, by 1965, * a federal artificial heart program had been created, and its enabling legislation asserted that the program's * The visions of Cooley and Liotta came to fruition on April 4, 1969. That day, Cooley implanted an artificial heart into the chest cavity of 47 year old Haskell Karp of Skokie, Illinois, a printing estimator with a long history of heart related problems. Karp died from an infection and related complications shortly after having the operation

* In response to the relativefailureof the Karp experiment, stunted for more than a decade. 70’s * by 1971, Dr. DeBakey himself became convinced that existing total artificial heart technology could not overcome the hurdles intrinsic within the human body. DeBakey was primarily concerned with two major problems. * First, scientists had to develop a power source that could be totally implantable, in order to reduce the risk of infection that was created by tethering artificial devices to external sources through skin penetrating pumps. Second, researchers had to discover and refine a non-clotting surface for the parts of the pump that actually came into contact with blood. Otherwise, the associated risk of stroke in patients would remain too high to warrant use of the technology. DeBakey ultimately determined that his time was better spent pursuing alternative avenues of heart research, asserting “ I decided to stop putting my energies and efforts into a total artificial heart. " 80’s *

In the early 1980's a new figure named Dr. Robert Jarvik embarked on the quest for a well-functioning total artificial heart. The Jarvik-7 (his design of a artificial heart) was a total heart that completely replaced the natural organ within the body's chest cavity * On December 2, 1982, a patient, Barney Clark received a Jarvik-7 implant in Salt Lake City. * Barney Clark was able to survive 112 days with the device however it came with a lot of complications. His blood kept clotting as it went through the heart which caused several strokes. * The artificial heart also had technological malfunctioning * The Jarvik-7 was implanted in a second patient, 53 year-old William Schroeder, at the Humana Heart Institute in Louisville, Kentucky. Schroeder actually survived on the device for 18 months.

* Like Clark, however, Schroeder was plagued by multiple strokes, infections, and hemorrhages throughout the course of his treatment. * When asked directly for his opinion about the Jarvik-7, Schroeder made a horrible gesture, like he'd like to kill it or strangle it. * After Schroeder's death, public sentiment against artificial heart research reached alarming levels. * In response, FDA effectively revoked the IDE granted to the Jarvik-7 program. * Most researchers now became convinced, as DeBakey had a decade earlier, that the quest for an effective total rtificial heart was simply a fruitless endeavor. * . As a result of these forces, researchers and surgeons now began to bolster their efforts at finding alternative ways to combat heart disease 90’s * As doctors becamemore adept at using anticoagulant drugs to reduce the risk of stroke associated with these transplants, the success rate of the device continued to improve. * Indeed, since 1993, 147 patients have

been supported by Jarvik's original artificial heart, and 88 of these patients ultimately survived till their scheduled organ transplants

The non-pulsatile LVAD * Dr. Richard Wampler, began to develop a non-pulsatile LVAD. Wampler was convinced that the body might not necessarily need a pulse to function effectively. This belief in “ continuous flow" pumps was rooted in his observations of how blood actually functions within the human body. * After 1988. Indeed, over 100 patients who could not utilize standard LVAD systems were saved by this technology. Notes mechanical circulatory support systems (MCSS) Total artificial hearts (TAH) the American Heart Association

LVAD = left ventricular assist device “ bridge to recovery. "= using partial artificial hearts you can help the patient stay alive while waiting for a donor. And in some cases an LVAD device can even “ cure” the heart so that it can beat on its own, and does not need a donor. AbioCor Implantable Replacement Heart: This device is a fully implantable prosthetic system, intended as a destination therapy for patients whose natural hearts are severely damaged due to conditions involving coronary heart disease or some form of congestive end-stage heart failure