Corpse Exploitation: A Reevaluation of Consent

There is evidence to suggest that the United Kingdom's National Health Service was guilty of a bioethical violation in the period of 1974 to 1985. Testimony reveals that during this period, the NHS harvested "batches of pituitary glands from the corpses of British patients" and traded the glands in exchange for drugs from US company Pharmacia and Upjohn (Mackay). Numerous representatives from ethics boards and health councils have expressed their horror at this very serious violation of bioethics, clamoring for further investigation. The two primary areas of concern are whether the patients' consent was given prior to their deaths, and the implications of trading organs for drugs seeing that "at least 250 UK hospitals took part" (Mackay).

However one cannot be so quick to condemn the UK and rush to take punitive action. To begin with, the first document establishing international standards for bioethics was not even drafted until 1993, about two decades after the controversy began. Additionally, evidence clearly shows that Pharmacia and Upjohn, the US drug company, required the pituitary glands for research in synthesizing a human growth hormone. The research into the hormone was a direct response to a nation-wide fear of Creutzfeldt-Jakob Disease, which stunts growth in children. This "drugs-for-glands" relationship ended immediately after P&U invented the growth hormone in 1985 (Mackay). Furthermore the large quantity of drugs given to the NHS was distributed and used in hospitals across the country, potentially saving lives. These facts suggest a more complex ethical problem in the drugs-for-glands controversy, requiring additional research.

In this paper I hope to eliminate the idea that the NHS should be further investigated for their supposed violation of bioethics. In addition to the belief that the violation of consent was justified by the research it supported, I will explore the modern state of bioethical standards

using the Universal Declaration on Bioethics and Human Rights. This will be coupled with a conversation between Wesley Smith and Gary Belkin on the complex problems that current consent standards bring. Lastly, this conversation will establish a framework to observe modern examples of how consent legislation does not promote medical progress, instead oversimplifying and impeding research. These steps will lead the audience to the conclusion that the current standards for patient consent cannot be the first priority in research and that in the case of collecting samples from dead bodies especially, the benefits outweigh the ethical violations.

Established by the International Bioethics Committee in 2005, the Universal Declaration on Bioethics and Human Rights is currently the authority on human rights standards in medicine and research for United Nations member-states. It is of utmost importance to be cognizant of this document because in its definition of ethical standards, it also defines ethical violations. As earlier stated, neither this Declaration nor its predecessors were in place at the time of our controversy. Like the Universal Declaration of Human Rights, the UDBHR is lofty in its ideals, primarily emphasizing individual rights over those of the group. Article 6 in particular pertains to Consent, stating, "in no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent" (p. 7, UNESCO). This guideline seems to partially contradict that of Article 15 which states, "Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community" (p. 9, UNESCO). Had this accepted foundation of human rights in medicine been in existence at the time of the drugs-for-glands controversy, the UK would have certainly been in violation. So while the document shows how consent is one of the United Nations' key bioethical principles, the question we must consider is whether it *should* be such a key principle in judging cases like the UK controversy.

Before we look at two authors' who complicate and challenge the absolute authority of consent legislation, it is important to recognize those that stand by the legislation. The majority of the medical community stands by the UDBHR and the idea that no matter what the circumstances, no part of an individual's body should be used for medical research without complete and official consent. One Heather Goodare even published an article in the British Medical Journal called "Studies that do not have informed consent from participants should not be published". The title speaks for itself. Goodare introduces a key idea to keep in mind as we question bioethical norms and evaluate the drugs-for-glands case: do we treat consent in living patients vs. dead patients identically? Her polls show that tissue *donors* typically give clear consent to medical research. But when tissue is taken during treatment, where patients sometimes die, consent is less often given to use that tissue for future research (p. 1004, Goodare). The author goes on to cite a breast cancer patient. "In Victorian times they got upset about body snatching. Now they steal bits of your body when you're still alive" (p. 1004, Goodare). This comment brings Gary Belkin to mind, NYU's psychiatric professor who writes on the flaws of making medicine solely a moral issue. We will look at his views more in depth a little later. Because the patient's body-snatching comparison is simplified without any context of tissue usage in medical research, Belkin might call it a "dramatic reduction of concerns about medicine merely to issues of ethics" (p. 373, Belkin). Nevertheless it is important to keep the opinions of those like Goodare in mind, especially as we will later look at a case in India where a study without clear consent *was* published, the act of publishing itself being a factor in the study's impact.

Wesley Smith and Gary Belkin disagree with Goodare's belief that current bioethical rules on consent must be obeyed as absolutes. Smith's article "The Bioethics Threat to Universal

Human Rights" speaks on the mutation of bioethics' founding ideals, and can be used to deconstruct the supposed absolute truth of Article 6 in the UDBHR. He covers the origins of bioethics in 20th century hospice care, led by Christians valuing the sanctity of human life above all else (p. 64, Smith). He laments how bioethics now measures "the moral worth of individual human beings in order to determine how they should be treated in medicine" (p. 65-66, Smith). This observation can relate to the UK controversy in two ways, as it pertains to whether corpses should have the same rights as living patients in terms of tissue sampling. First, Smith might be suggesting that taking pituitary glands from corpses is just as bad as taking them from living humans as life must be treated equally in all. Conversely, his quote might suggest that by treating everyone equally through strict obedience to consent laws, we actually elevate the rights of corpses over the rights of patients with Creutzfeldt-Jakob Disease, promoting an inequality. Which of these two interpretations most closely follows the original idea of human sanctity? Smith follows the second interpretation more extensively in the latter part of his article. He speaks on euthanasia and how if the practice is *legally accepted*, "the termination of the patient's life may somehow help other human beings in need of organ transplantation" (70, Smith). And so it is the *law* that is the main obstacle to medical progress, not morality. Smith's stance that human life must be preserved at all costs further complicates the issue of how we view consent in dead versus living patients. Smith isn't the only one disturbed by bioethics' role in patient treatment however.

Earlier mentioned, Gary Belkin's essay "Moving Beyond Bioethics" uses history in tandem with sociology and anthropology to question why medical concerns must always be translated to moral or ethical terms. This question will reappear through the rest of the essay because the stakes are high: if we change the preconception that an individualistic idea of

consent overrides all other medically relevant information, we change the entire medical process along with its results. Belkin examines biomedical legislation like the aforementioned UDBHR, saying, “no wonder so much ink has been spilled for decades in the service of an obsession over the technique and integrity of the process of informed consent” (p. 375, Belkin). He argues that if we are to focus on the means and not the ends of medical research (which he believes should be reversed anyways), we must at least use “more rigorous social scientific, personal, and historical experience” instead of “moral analysis” (p. 381, Belkin). Both Smith and Belkin’s arguments challenge the currently established standards for consent, Smith pioneering the sanctity of human life and Belkin questioning the role of morality in medical progress. Both authors speak to the need to reconsider the prioritization of consent, and we can apply their ideas to modern facts regarding tissue usage and consent.

Unlike the UK in the 1970s, we now have legislation like Article 15 of the UDBHR, encouraging global support for medical research. However even with these vague guidelines, acquiring tissue samples is still a chaotic mess and potentially more problematic than the UK controversy was. Steve Silberman and Leslie Wolfe’s research further absolve the drugs-for-glands controversy from guilt as the problem of legitimately obtaining tissue for research appears to be nigh impossible. First, Silberman’s article “Libraries of Flesh: the Sorry State of Human Tissue Storage” reports how in 2005 the National Cancer Institute launched a revolutionary research program called the Cancer Genome Atlas. The technology and manpower were all there; they just required tumor samples that “biobanks” claimed they could easily provide. “One bank at a major university claimed to have more than 12,000 samples of glioblastoma in its collection. Only 18 of those were good enough to use” (2, Silberman). The article continues to disturb, revealing how biobanks around the world lack standard operating procedures.

Additionally, because well-preserved and documented samples are so rare, the tissue trade is booming as vendors circumvent laws against organ trafficking, "charging hefty processing and shipping fees" (6, Silberman). This current black market for tissue samples seems to be just as bad or worse than the UK drugs-for-glands controversy. In addition to bad samples resulting from the biobanks' lack of regulation, some specimens had been obtained from patients without adequate consent. "A single sample might require months of legal wrangling before it could be used" (2, Silberman). So even with legislation, obtaining consent continues to be a problem in restricting effective medical research. But how much of a problem? Should consent be the problem to focus on?

Leslie Wolfe's "Genetic Research with Stored Biological Materials: Ethics and Practice" looks at whether US laboratories correctly receive consent from their patients. The study organizes labs into study type, location, and how they word questions asking for consent. Wolfe's poll is critical of any imperfect procedures. However, the labs' relatively insignificant mistakes suggest that research is more important than perfectly following consent procedures. The study's results included how "none of the studies that included children mentioned plans to obtain their consent when they became legal adults or to inform them that their biological materials were being stored for use in future research" (p. 13, Wolfe). More importantly, Wolfe observed the problem that labs sometimes unnecessarily asked for consent, restricting future research (p. 15, Wolfe). So even this study so focused on keeping labs accountable in obtaining consent demonstrates how consent can restrict research. One might be slightly disturbed by the fact that the labs lacked perfect procedure seeing how they had to pass a federal standard to even participate in the poll (p. 16, Wolfe). But naturally, one is less disturbed by Wolfe's research than Silberman's research on the state of biobanks. This suggests that while checking all the

boxes for patient consent has some importance, the lacking state of human tissue storage easily takes priority. With Silberman and Wolfe in mind, we can evaluate modern *violations* of bioethics and how these cases also support the idea that consent should not be the top priority in dealing with these complex situations.

Bioethical violations in HPV vaccine research in India along with DNA tests in disabled children in London reveal how consent unnecessarily distorts already complex issues. Priya Shetty's "Vaccine Trial's Ethic Criticized" shows how four girls died after being subjects in HPV research. While it was later proved that the deaths were unrelated to the research, the scare brought the study to the limelight. Like in the UK controversy, doctors have cried that "consent was improperly obtained", even though both Indian and American ethics boards approved the research. "The problem was how different individuals or teams implemented it" (p. 427, Shetty). Leigh Turner, author of "An anthropological exploration of contemporary bioethics" would respond to the issue by saying that ethics are different in developing countries than developed countries and trying to strictly employ the same standards everywhere creates problems. Turner states research on how developing regions are "much more communal than the atomistic, individualistic urban centres of North America" then asking the question, "What happens when legal principles impose requirements concerning informed consent within regions where Western medicine is little understood, and personal autonomy is not altogether salient?" (p. 130, Turner). This it seems is the most important question when questioning whether we should globally prioritize consent. Turner's question spawns more, like whether devaluing consent and respecting different cultures might cause more problems than it solves.

Tracking back to Goodare's declaration that any research lacking consent should not be published, Shetty's article hints that *publicity* may be actually be a paramount factor in medical

research requiring human tissue samples. Does coverage of consent violation help or hurt medical progress, and does it support the idea that consent should be deprioritized? The "Drugs Controller General of India produced, for the first time, draft guidelines on the reporting of adverse events in clinical trials" (428, Shetty). This happened only after the media questioned the HPV research techniques, suggesting that publicity is beneficial to medical progress. Opposite to this point however is that the public became afraid of vaccinations after seeing headlines about death and lack of consent, which "could have a major impact on public health," (428, Shetty). These cases of publicity provide another lens through which to examine the UK drugs-for-gland controversy, because that entire operation was kept private. By not having to deal with public scrutiny of whether they had patients' consent or not, the UK successfully contributed to the development of a growth hormone while supplying hospitals with medicine in the process. Does the moral cost of taking tissues from dead bodies outweigh these benefits? These ideas suggest that public perception of bioethical adherence is just as significant as the adherence itself. We can return to Turner, who says "these are the kinds of topics that remains unexplored when the notion of 'informed consent' is seen as a straightforward, uncontroversial, unproblematic, obvious good" (p. 132, Turner).

Maria Cheng's article "Incest Inadvertently Discovered" reveals how dilemmas can unexpectedly arise even when consent is ethically obtained. Again we see that the binary of followed versus broken rules is too simple a system to fairly evaluate the situation. Cheng reports how in London, "scientists conducting DNA tests on disabled children may inadvertently make startling discoveries of incest" (p. 1, Cheng). There is a current lack of legislation on what scientists are meant to do in this situation; the tests were not intended to show similarity of the parents' DNA. But should the doctors report the results to the police seeing how "the pregnancy

[that resulted in the disabled child] might have been the product of abuse"? (p. 1, Cheng) What do doctors do when they discover crimes unrelated to their original research? The case clearly exemplifies how simplified standards of consent will be insufficient as medical research advances and should not be researchers' top priority. Reiterating Article 6 of the UDBHR, "in no case should a collective community agreement…substitute for an individual's informed consent" (p. 7, UNESCO). But in Cheng's report, isn't the collective community agreement that incest should be punished superseding the individual's consent to have their DNA analyzed solely for their sickness and nothing else?

Both Shetty and Cheng's articles differ from the original UK controversy in that they deal with tissue samples from *living* patients. But like the rest of the evidence, they suggest that as research moves forward, a binary interpretation of consent or lack thereof is an outdated and inefficient standard. In a case where the individual does not understand what he/she is consenting to, do bioethical standards still apply? These two modern cases of questionable and complex bioethical violations serve as both markers and warnings for the future, cementing the idea that we cannot accept current absolutist laws and that determining the correct course of action must consult multiple points of view. I am skeptical that bioethical violations will ever disappear completely. But as the previous evidence suggests we may be able to at least consider redefining the prioritization of consent in medical research, whether it be through an increased or decreased federal presence. Cheng quotes Ross Upshur, director of the Centre for Bioethics at the University of Toronto: "You can't put Pandora back in the box, but you also can't stop scientists from exploring legitimate avenues of genetic discovery" (p. 2, Cheng).

Works Cited

Belkin, Gary S. "MOVING BEYOND BIOETHICS: History and the search for medical humanism." Johns Hopkins University: Perspectives in Biology and Medicine 47 (2004): 372-85. Proquest. 17 Nov. 2013.

Cheng, Maria. "Incest Inadvertently Discovered Through DNA Tests May Raise Ethical Dilemma." The Ledger 10 Feb. 2011. Associated Press. 30 Oct. 2013.

Goodare, Heather. "Studies that do not have informed consent from participants should not be published." British Medical Journal 316 (1998): 1004-005. Proquest. 17 Nov. 2013.

Gray, John. "A Modest Proposal." New Statesman 17 Feb. 2003. Progressive Media International. 30 Oct. 2013.

Mackay, Neil. "NHS traded human tissue for drugs." Sunday Herald [Glasgow] 12 Mar. 2000: 1-3. Proquest. 30 Oct. 2013.

Shetty, Priya. "Vaccine trial's ethics criticized." Nature: News in Focus 474 (2011): 427-28. 30 Oct. 2013.

Silberman, Steve. "Libraries of Flesh: The Sorry State of Human Tissue Storage." Wired 24 May 2010. Condé Nast. 30 Oct. 2013.

Smith, Wesley J. "The Bioethics Threat to Universal Human Rights." Human Life Review 37 (2011): 63-72. Proquest.

Turner, Leigh. "An anthropological exploration of contemporary bioethics: The varieties of common sense." Journal of Medical Ethics 24 (1998): 127-33. Proquest. 17 Nov. 2013.

United Nations. Educational, Scientific and Cultural Organization. Division of Ethics of Science and Technology. Universal Declaration on Bioethics and Human Rights. Paris, 2005.

Wolf, Leslie E., Timothy A. Bouley, and Charles E. McCulloch. "Genetic Research with Stored Biological Materials: Ethics and Practice." Mar.-Apr. 2010. ProQuest. National Institute of Health Public Access. 30 Oct. 2013.