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## Tuskegee Syphilis Study not Americas only Medical Scandal Chester M. Southam, MD, Henrietta Lacks, and the Sloan-Kettering Research Scandal

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### ABSTRACT

The words “human medical experimentation” conjure up visions of Nazi medicine, which has come to exemplify the worst evils in the history of humankind. Places like Auschwitz and Dachau, where human life was cheap and test subjects plentiful were used as laboratories.

In 2010 the US government apologized to Guatemala for allowing U.S. doctors to infect Guatemalan prisoners and mental patients with syphilis 65 years earlier, while acknowledging dozens of similar experiments were performed in the United States.

Among these included studies that often involved making healthy people sick or keeping sick patients ill, such as in the Tuskegee syphilis study.

These experiments were often life threatening and took place with the direct approval and/or supervision of some of the country’s most prestigious research institutions and some of the country’s leading medical researchers. Among these was the prestigious cancer research center in New York City, Sloan Kettering Hospital and its director of cancer research Chester Southam, MD.

### Can you give someone cancer?

In December 2011, following his diagnosis of cancer, Venezuelan president Hugo Chavez speculated that American agents had induced the disease in him and possibly other South American leaders by injecting them with cancer cells. Despite the State Department’s rejecting Chavez’s claims, there nonetheless was no shortage of CIA conspiracy theorists who accepted the charge. The media too grabbed onto the story, not only because of the outlandish nature of the accusation but also because of the underlying question it raised: Can you give someone cancer? (*Miami New Times*, March 7, 2013; *Slate*, December 30, 2011).

While direct communication of cancer from one host to another has been documented, and transplanting cancer cells to another person in an effort to cause cancer is possible, it is extremely rare. It has been shown in organ transplant recipients, mother-to-fetal transmission, and a few rare events such as one reported in 2015 in the *New England Journal of Medicine* where cancer cells from a tapeworm invaded a man’s body, spreading to his lymph nodes and his lungs. While ordinarily, the immune system would not allow this, in this case the man was severely immunosuppressed due to HIV/AIDS (Muehlenbachs et al. 2015). Other reported cases include transmission to a lab worker via a needle stick or a cut on the hand and one where a surgeon’s laceration developed into a sarcoma. In these cases, however, while the cancer cells grew locally at the point of entry, they failed to

progress beyond the site of entry (Welsh, 2011). It is well established that in normally functioning immune systems such cells (including cancer cells from another person) would be recognized as foreign and destroyed before they have a chance to wreak havoc (Janeway 1993). The reason we know this today is because decades ago researchers attempted to do just such a thing: injecting prison inmates and chronically ill hospitalized patients with live cancer cells. These experiments, carried out with little or no informed consent, took place in New York City, at one of the leading cancer research centers in the United States, despite the safeguards of the American healthcare and research ethics systems. While the scandal garnered headlines at the time (e.g., *New York Times*, January 26, 1964), it has since been largely forgotten, as have the people who unknowingly placed their bodies on the line to advance scientific knowledge, and it is a story that deserves retelling.

### A brief history of ethics in medical research

While the Nuremberg Code of 1947 is generally regarded as the first document to set out ethical regulations for human experimentation based on informed consent, rules to protect the welfare of people subjected to medical experimentation were in fact in place long before this including in Germany. The first detailed regulation of non-therapeutic research in Western

medicine came from the Prussian minister for religious, educational, and medical affairs in 1900, following the public outcry at the work of Albert Neisser, the discoverer of the gonococcus (Vollmann and Winau, 1996).

In 1898, Neisser, who was attempting to develop a syphilis vaccine, published a study that outlined his results as well as his methods and study participants. Public debate in the press as well as among academicians ensued: Neisser had injected serum from patients with syphilis into patients who were admitted to hospital for other medical conditions, none of whom had suffered from syphilis at the time of the experiment. The controversy rested on two issues: the first was that most (but not all) of these patients were prostitutes, while the second was that none of them had been informed about the experiment or asked for their consent. After four of the prostitutes subsequently developed syphilis, it raised the issue of whether or not it was the injected cells that had in fact caused their illness, or as Neisser insisted, they had contracted it separately by pursuing their occupation (Toellner, 1981).

The majority of physicians aware of the case supported Neisser; the single exception was Albert Moll, a Berlin psychiatrist and highly regarded sexologist (Maehle 2012). While largely unrecognized in the medical literature, Moll is largely responsible for the formulation and elaboration of a theoretical conception of the contractual nature of the patient-doctor relationship and the development of informed consent, saying,

*"I have observed with increasing surprise that some medics, obsessed by a kind of research mania, have ignored the areas of law and morality in a most problematic manner. For them, the freedom of research goes so far that it destroys any consideration for others. The borderline between human beings and animals is blurred for them. The unfortunate sick person who has entrusted herself to their treatment is shamefully betrayed by them, her trust is betrayed, and the human being is degraded to a guinea pig..."* (Maehle 2009) Moll would go on to author one of the most comprehensive books on the subject of medical ethics, *Arztliche Ethik (Medical Ethics)* (Katz, 1997).

Following increasing pressure from Moll as well as the press, the Neisser case came under investigation by the public prosecutor and the Royal Disciplinary Court. The court found that although Neisser was a well-known medical authority and may have been convinced that the trials were harmless, he should have sought the patients' consent; he was fined, and was lucky not to receive a more stringent punishment, because two years later, upon further investigation into the case, government lawyers stated that conducting non-therapeutic research on a subject without consent fulfilled the criteria for causing physical injury (battery) in criminal law (Vollmann and Winau, 1996).

Additional action was taken by the Prussian Landtag (parliament), which commissioned a detailed report from the Scientific Medical Office of Health, which was composed of leading German physicians, including Rudolf Virchow. The commission stated that a physician who recognized that injected serum might cause infection had no right to inject such a serum, but that in any case both informing the subject and obtaining the subject's consent were preconditions to

experimentation. Informed consent became a mandatory precondition for any non-therapeutic research. Written documentation and clear responsibility of an institution's medical director for all human experimentation became legal doctrine, and all hospitals, clinics and medical directors were advised that any medical interventions other than for diagnosis, healing, and immunization were excluded under all circumstances if "the human subject was a minor or not

competent for other reasons" or if the subject had not given "unambiguous consent" after a "proper explanation of the possible negative consequences of the intervention (Goss, 2017). Others took the somewhat extreme position that purely scientific experimentation on human subjects was unethical even if they gave voluntary consent and that self-experimentation should always precede experiments on patients, noting that the scientific validity of the experiment did not serve to mitigate these conditions (Vollmann and Winau, 1996).

Ironically, the other main early attempt to protect a human research subject's autonomy would occur in Hitler's Germany. In the German Reich's Rundschreiben (Reich's Circular) of 1931 the Reich government issued detailed guidelines that clearly distinguished between therapeutic ("new therapy") and nontherapeutic ("human experimentation") research and set out strict precautions for each. The rules for new therapy were explicit: "New therapy may be applied only if consent or proxy consent has been given in a clear and undebatable manner following appropriate information. New therapy may be introduced without consent only if it is urgently required and cannot be postponed because of the need to save life or prevent severe damage to health..." When it came to non-therapeutic research there was no wiggle room; the law clearly stated that "under no circumstances [is it] permissible without consent" (Sass, 1983).

While it's thus clear that the basic concept of informed consent was developed long before the Second World War and these guidelines remained in place throughout the reign of Adolf Hitler, they failed to stop the unethical experiments taking place in Nazi concentration camps (Caplan, 1991). It would be these experiments and the subsequent postwar trials of the physicians involved in them that would lead to the creation of the Nuremberg Code, a document among whose 10 principles the longest is on informed consent (Kumar 2013).

## Informed consent

While it is widely believed that the Nuremberg Code has legal standing, in fact this document has no legal force behind it (Ghooi, 2011). In the US, legal informed consent owes its genesis to two landmark legal cases. *Schloendorff vs. The Society of New York Hospital* (1914) established the principle of patient consent and is considered one of the landmark legal cases in bioethics, while *Salgo v. Leland Stanford etc. Bd. Trustees* is responsible for adding 'informed' to the notion of 'consent.' A brief review of the Schloendorff case follows.

Mary E. Schloendorff agreed to have her physician examine her under anesthesia and to have her fibroid tumor biopsied. Prior to the procedure, Schloendorff specified that she was not consenting to the removal of the tumor; nonetheless, while she was anesthetized, the surgeon, believing the mass was malignant, removed the

tumor. Schloendorff then sued the hospital. the course made its way to the New York Court of Appeals, which found that the operation to which the plaintiff did not consent constituted medical battery. Justice Benjamin Cardozo wrote that in the court's opinion:

*"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained."*

Schloendorff, however, received no monetary gain, since she had sued the hospital and not the surgeons; the court found that a non-profit hospital could not be held liable for the actions of its employees due to the legal principle of charitable immunity. Justice Cardozo's opinion is widely cited as the basis for the requirement to seek consent from patients before medical intervention is provided, upholding a patient's right to autonomous decision-making (Deverette, 1995).

The second case, the Salgo decision, marks the birth of the doctrine of informed consent as it is known today; the term "informed consent" was first used in this case. In 1957, Martin Salgo, age 55, consented to undergo a diagnostic procedure to locate the source of chronic pain in his leg; it was believed he was suffering from arteriosclerosis and that his aorta was also involved. He was advised to undergo diagnostic aortography. While under anesthesia, his aorta was injected with a contrast medium, and images were taken of the abdominal aorta. The next morning Salgo awoke to find that his lower limbs were paralyzed as a result of the contrast agent used in the procedure. Salgo subsequently sued his doctor, claiming that he was not informed about paralysis being a risk or possible complication of the contrast material. The court noted that a physician violates his duty to the patient if he withholds any facts necessary to form the basis of an intelligent consent by the patient to the proposed treatment. The court also noted that when discussing risk, the physician has discretion "consistent with the full disclosure of facts necessary to an informed consent." Salgo's doctor's defense argued that if patients were informed of all the possible complications, they would become frightened and would not consent to treatment. The court rejected this defense and ruled that simple consent was not sufficient for medical procedures; instead, sufficient disclosure of possible risks and complications, allowing "informed consent," was necessary for patients to make autonomous decisions, whether regarding a surgical procedure or a medical experiment (Osman, 2001).

While lacking legal standing, the Nuremberg Code did form an outline of what are now considered a physician's ethical duties, which were codified in a subsequent document created in 1964 in Helsinki, known as the Declaration of Helsinki, which addressed clinical research and humane treatment of study participants as well as issues such as informed consent. Like its predecessor, the Declaration of Helsinki has no legal standing or power (Shuster, 1997), but together they serve as models for regulators in most countries

and inform the current US federal research regulations, which require not only the informed consent of the research subject (with proxy consent sometimes acceptable, such as for young children) but also prior peer review of research protocols by a committee (the institutional review board) (NIH Office for Protection from Research Risks 1991). With such protections in place, one might assume that US citizens were protected against unethical or life-threatening medical experimentation; unfortunately, as we will see, this was not the case.

### Unclean hands

In jurisprudence, there is a doctrine known as "unclean hands" – if a defendant can prove that a plaintiff has "unclean hands," that is, has acted unethically, then the plaintiff's complaint will be dismissed (Upcounsel.com n.d.). During the doctors trial in Nuremberg, defense attorneys argued that this doctrine applied, stating that the German experiments were essentially equivalent to those that had been and were still being performed in US penitentiaries (Weindling, 2001). This statement had more than a kernel of truth to it. While there had been relatively little medical research into human disease in the US during the 1930s, this would change dramatically in the 1940s, when for the first time there would be US government funding for such research (Baader et al., 2005).

With the outbreak of WWII and the potential for American involvement in the conflict, there was a push for governmental involvement in and funding of academic research. In 1941, President Franklin D. Roosevelt authorized the establishment of the Office of Scientific Research and Development (OSRD). From 1941 through 1945, the OSRD's Committee on Medical Research would be responsible for developing and funding projects involving both human and animal subjects that studied, among other things, disease transmission and vaccine development. Susan Lederer, a professor of medical history and bioethics, notes that the human subjects involved in these studies were primarily "subjects of convenience" – individuals or populations conveniently and readily available to researchers, who included children in orphanages, patients in mental institutions, military personnel, and those incarcerated in penal institutions (Lederer 1995). This was an era in medicine when no one thought it necessary to ask permission to remove tissue samples from a patient or to ask permission to use such samples in medical experiments (Javitt, 2010). One such patient was an African-American woman who, following delivery of her fifth child by age 30, developed intense vaginal bleeding and sought care at the Johns Hopkins Hospital, which, although segregated, was the only hospital in her hometown of Baltimore that would treat African-American patients. Hopkins was a charity hospital, as its benefactor Johns Hopkins, founder of the university and hospital, stipulated in his will (Johns Hopkins Medicine n.d.). Although the woman would expire on October 4, 1951, from what would be diagnosed as cervical cancer, she would nevertheless become immortal.

### Henrietta and her HeLa cells

On October 4, 1951, Johns Hopkins-trained physician and director of the Tissue Culture Laboratory in

the Hopkins Department of Surgery George Otto Gey appeared on national television to announce that a major breakthrough had occurred in cancer research (Skloot, 2000, Hanks and Bang, 1971). Gey had spent the majority of his career attempting to develop a method to grow cells outside the body. The problem was that cells cultured for laboratory studies survived for only a few days at most; but if he were able to keep cells alive “in culture,” this would allow researchers to experiment on the cells in ways not possible in the body, thus increasing their knowledge of cell biology, especially that of cancer cells, and thus potentially leading to a cure (Gold, 1986:16).

For Gey to accomplish his goal, he would require a constant supply of cancerous tissue samples. Luckily for him, he had a readily available supply at the major medical institution where he worked; however, these samples were obtained without the patient’s or their family’s knowledge or permission (Lucey et al., 2009). One such sample would come from the 31-year-old African American woman, Henrietta Lacks, who had died earlier on the day of Gey’s televised announcement.

Gey had earlier observed that Lacks’s cells were the first he had come across that could be divided multiple times without dying, and so on the day of her death, Gey had had Mary Kubicek, his lab assistant, take additional tissue samples while Lacks’s body lay in the Johns Hopkins morgue (Gold, 1986:19–22). Gey was able to start a cell line from Lacks’ sample by isolating one specific cell and repeatedly dividing it, meaning that the same cell could then be used to conduct many experiments. They became known as HeLa cells, because Gey’s standard method for labeling samples was to use the first two letters of the patient’s first and last names (Gold, 1986:18). These HeLa cells were in high demand by other researchers and were put into mass production. They were mailed to scientists around the globe, and the cell line would be used to make many important breakthroughs in biomedical research. For example, by 1954, Jonas Salk was using HeLa cells in his research to develop the polio vaccine; the cells used in the vaccine were mass-produced in the first- ever cell production factory at the Tuskegee Institute, in Tuskegee, Alabama, where African-American scientists not only helped to grow the HeLa cells but also evaluated Salk’s vaccine (Brown and Henderson 1983). In a twist of irony, “Black scientists and technicians, many of them women, used cells from a black woman to help save the lives of millions of Americans, most of them white. And they did so on the same campus—and at the very same time—that state officials were conducting the infamous Tuskegee syphilis study” (Skloot, 2010:97). What many people are unaware of, however, is that the HeLa cells were also participants in one of the largest ethical breaches in cancer research (*Prison Legal News*, March 15, 2008).

### Chester Southam, MD

Chester Southam earned his BS and MS degrees from the University of Idaho and received his MD degree from Columbia University in 1947. Following a one-year internship at New York City’s Presbyterian Hospital, he began training at Memorial Hospital for

Cancer (the forerunner to Sloan-Kettering Cancer Hospital), also in New York. Over the next 4 years he would rise to become a research fellow and eventually director of the hospital’s Division of Virology/Immunology. In 1951, he joined the faculty of Cornell’s medical college, where he was eventually awarded a full professorship (*New York Times*, April 10, 2002).

From 1954 through 1966, Southam would concentrate his research on two main questions: whether cancer could be transmitted from person to person and whether certain virus antibodies had anti-neoplastic properties. To answer these questions, he would utilize society’s most vulnerable citizens, including patients already diagnosed with cancer and undergoing gynecological surgery at Memorial Sloan-Kettering Cancer Hospital, incarcerated inmates, and frail, chronically ill nursing home patients (*The BMJ Opinion*, July 3, 2017). It was research that would raise ethical and moral issues that government regulators would later compare to those raised by Nazi experimentation (Arras 2008:75).

In 1953, Southam began what appear to have been his first human experiments to test his theory about virus antibodies with anti-neoplastic properties. To do this, he and various colleagues routinely inoculated cancer patients with dangerous viruses, including West Nile, Ilheus, and Bunyamwera viruses. A review of their published work makes the following statement:

“All patients were volunteers who had advanced neoplastic disease of an extent, type, and stage which precluded the possibility of therapeutic benefit from surgery, x-ray, or anti-neoplastic chemotherapeutic agents.”

The general physical condition of these patients varied extremely, from apparently well to terminal. There was a wide range of diagnostic types, including epidermoid carcinomas, adenocarcinomas, lymphomas and leukemia and other sarcomas. Blood for antibody studies was obtained immediately prior to each virus inoculation and usually at weekly intervals thereafter during the period of hospitalization, and as frequently as was practicable after patients had been discharged to their homes. (Southam and Moore, 1954)

Nowhere in the statement is there any indication of informed consent having been obtained from the patients; what is clear is the overreaching attempt to make it known that these patients were terminal, with the implication that they were going to die anyway. These early studies, not unlike Southam’s later ones, would at times have serious consequences for the patients involved. An earlier paper authored by Southam noted some of the negative reactions suffered by some patients: “...caused mild encephalitis in 3 patients, and in the other patients caused no symptoms. Bunyamwera virus caused a very severe encephalitis with residual mental damage in one patient” (Southam and Moore, 1951).

### Sloan-Kettering and cancer immunology

Beginning in February 1954, Southam and his colleagues initiated their first human experiments in cancer immunology by injecting 14 previously diagnosed terminal cancer inpatients at the Memorial Hospital (which became Sloan-Kettering in 1948) with cancer cells. While hospital administrators stated that informed

consent was given by these patients, it was highly questionable whether this consent met the standards for informed consent, both from a legal and an ethical standpoint. In explaining their consent policy, the hospital administration said this: "...these patients knew that they were receiving cancer cells, understood the reasons for the experimentation, and consented to it orally" (Langer, 1964). In a paper (Southam et al., 1957) reporting the results of this experiment the description of informed consent is somewhat vague: "...All recipients were volunteers who were aware of the general purposes of the study and the nature of the implanted materials and who were agreeable to subsequent biopsies." This loose interpretation of informed consent would continue throughout Southam's professional career.

While the results of the study showed that the transplanted cancer cells did grow in the cancer patients, producing small nodules that if excised did not return and if left alone would continue growing for 4–6 weeks and then spontaneously disappear, this wasn't the whole story. Two of the patients died before the anticipated regression; while they had been diagnosed as terminal at the time of implanting the cells, the fact that they died before regression had occurred meant that one could only assume that these patients' nodules were not excised. Nonetheless, their deaths were attributed to their existing cancer. In four patients, cancer regrowth occurred at the implantation site following removal of the nodule, and in one patient, the implanted cells were found to have metastasized to the axillary nodes. This patient had been suffering from uterine adenocarcinoma, which according to Southam could "readily be distinguished from the implanted cells," and at autopsy her adenocarcinoma was found to be confined to the abdomen and perineum, confirming that the metastasis that had occurred was a result of the implanted cells (Katz et al., 1972:11).

With this information, Southam believed he could argue that cancer patients lacked immunity to the cancer cell implants and were in fact suffering from an immune deficiency to cancer cells; however, to prove this theory, it would be necessary to demonstrate that the effects observed with cancer patients did not also occur in healthy individuals. Of course, being able to recruit subjects willingly volunteering to be injected with cancer cells was unlikely, and as a result, in situations like this, many researchers have used themselves as their subject; when asked if he ever considered using himself, Southam replied that "I would not have hesitated, ...if it would have served a useful purpose. But, he continued, "to me it seemed like false heroism, like the old question whether the General should march behind or in front of his troops. I do not regard myself as indispensable – if I were not doing this work someone else would be – and I did not regard the experiment as dangerous. But, let's face it, there are relatively few skilled cancer researchers, and it seemed stupid to take even the little risk." While Southam would later say that this statement regarding self-injection was misquoted (Katz et al., 1972:49), it was a moot point, as he would find a ready supply of test subjects in the state of Ohio.

## The prison volunteers

"CANCER RESEARCH VOLUNTEERS NEEDED" was the headline of a notice posted in the May 19, 1956, issue of the *Ohio Penitentiary News*, a weekly newspaper written and published by prisoners that was distributed throughout the US for annual subscription fee of \$.50. The notice went on to explain that one of the ongoing issues in cancer research was why and how individuals without cancer (can) fight off cancer cells and prevent them from multiplying. But the explanation went further – it almost was made to sound diagnostic in nature, with the implication in the verbiage that any volunteer who had a previously undiagnosed or "hidden" cancer would be able to be diagnosed early and perhaps have a greater rate of survival. Below is such an example from the *British Medical Journal*.

For many years there has existed, one of many puzzling phenomena in the growth of cancer cells that still needs an answer; is still unsolved. Live cancer cells can be transferred from one individual to another. In the person who has cancer, the cancer cells will live and grow. In the person who has no cancer in his body, all of the transferred cells will die, eventually, after a short period of growth. It is this part of the problem that requires some further observation and study. Just how the normal individual who does not have cancer can kill off the transplanted 'Foreign' cancer cells, is the present important problem. So far, in past experiments, all attempts at growing one person's cancer cells in another individual, who does not have cancer, have ultimately failed. This is so, definitely, as far as we know now, that if transplanted cells do not grow, when injected into another person, it follows, that the injected person does not have cancer. If the cells do grow, it would indicate that the person injected probably does have a hidden or lurking cancerous growth somewhere in his body. (*BMJ*, 1956)

Researchers may have worried that they would have difficulty recruiting volunteers, or they may have honestly believed that the project was so benign that selection criteria were not needed – in any case, those criteria were almost non-existent. Inmates with history of TB, syphilis, osteomyelitis, cardiac disease, or hypertension would all be eligible to participate in the study. The researchers need not have worried: while the study called for 25 volunteers, the warden received applications from 130 of the 3,800 convicts in the penitentiary. While using prisoners for medical experimentation was common practice in the US at the time, most studies offered some form of financial incentive or a reduction in sentence, whereas in this case no incentives were offered. Most participants indicated that their reason for volunteering was that someone in their family had died of cancer, while others felt that this would be a way of redeeming themselves in the eyes of society: they had been "blanks all their lives" and were glad to have the opportunity to do something useful.

Each inmate was given a release to sign that indicated that the experiment was being carried out by the Division of Medical Research, College of Medicine, The Ohio State University, and the Sloan-Kettering Institute for Cancer Research, New York City. The release text ran as follows: "This study, as it has been explained to me, is intended to determine whether or not

presumably live cancer cells can be successfully transplanted, indirectly, from one individual to another. I have been told that the cancer cells will be transplanted to my body by means of direct needle injection under my skin....” The principal investigators were listed as “Doctors Charles A. Doan, Alice E. Moore, and Chester M. Southam, or their associates.”

While Southam’s prison inmate experiments raised ethical concerns, and some of his peers in the medical community believed that the research had violated the bioethical principles of informed consent, non-maleficence, and beneficence, the research would nonetheless continue for 12 years, eventually involving over 200 inmates. Sloan-Kettering received between \$300,000 and \$500,000 (between \$3 million and \$5 million in today’s dollars) in federal funds from the National Cancer Institute and funding from the American Cancer Society (*AP News*, August 16, 1985). With his reputation as a cancer expert, and emboldened by the backing of prestigious institutions such as Sloan-Kettering, the American Cancer Society, and the federal government, Southam would now find a new research study for his HeLa cells, which he had injected into the Ohio State Penitentiary inmates (Skloot, 2010:168). This next project would not go as well for Southam, however.

### The Jewish Hospital for Chronic Diseases

In 1963, with funding from the United States Department of Public Health and the American Cancer Society, Southam and colleague Emanuel Mandel began a study to test Southam’s hypothesis that chronically ill patients who were not suffering from cancer would be able to reject implanted cancer cells as rapidly as patients who were not suffering from any disease and faster than those who were already afflicted with cancer. Southam hoped to be able to demonstrate that the apparent absence of immunity in the cancer patients was in fact attributable to cancer, and not simply to the general debility that accompanies any severe, chronic illness.

While his theory was proven correct and was recognized as one of the leading research experiments in the cancer field, there was a problem: how he had reached that conclusion. When it was revealed, the press had a field day, with magazines such as *Good Housekeeping* blaring vivid and critical headlines like “How doctors use patients as guinea pigs” (October, 1965:79). *Science Magazine* put it thus: “A number of circumstances made the case particularly newsworthy. The patients in question were 22 seriously ailing and debilitated inhabitants of a relatively obscure Brooklyn institution, The Jewish Chronic Disease Hospital(JCDH).

#### Nazi doctors?

In August 1963, a group of three physicians at JCDH, Avir Kagan, David Leichter, and Perry Fersko, expressed their concern about the methods used in Southam’s research, and the issue was brought to the Hospital’s Medical Grievance Committee for investigation however, instead of condemning these practices, the committee found no irregularities and instead commended the research. The three physicians

resigned in protest and took their concerns to William Hyman, a hospital board member and an attorney. When Hyman asked the hospital for the relevant patient records, he was refused; then, believing that the hospital board of directors would side with him, he asked for their support, but the board instead endorsed the findings of the grievance committee. This forced Hyman to go through the courts and the press, with the latter quoting Hyman’s description of Southam’s experiments as “acts which belong more properly in Dachau” (Katz, 1972) and labeling the case “the hottest public debate on medical ethics since the Nuremberg trials of Nazi physicians” (Langer, 1964).

On July 7, 1964 in another twist of irony, the Appellate Division of the State Supreme Court ruled that a member of a hospital’s board of directors did not have the right to inspect the medical records of patients, citing patient physician privacy protection (*New York Times*, July 7, 1964). This ruling would eventually be overturned by the New York State Court of Appeals on the grounds that “[t]he privacy of the patient could be protected, as the trial court had pointed out, by a simple order requiring that the patient’s name be concealed” (Ratnoff 1966).

Following this ruling, Hyman pressed his case with New York Attorney General Louis L. Lefkowitz, who rejected Southam’s assertion that oral consent had been given, saying that the patients “had not sufficient mental or physical ability to comprehend what was being told to them or what was being done to them,” and that those patients with such capacity had been misled.

Lefkowitz’ who was outraged, saying “every human being has an inalienable right to determine what shall be done with his own body,” and sought to revoke Southam’s license to practice medicine (Katz 1972).

Following a lengthy hearing, the New York State Board of Regents said that the “[z]eal for research must not be carried to the point where it violates the basic rights and immunities of a human person,” and found both Southam and Mandel guilty of “fraud or deceit” and unprofessional conduct, voting to suspend their licenses. However, this was later changed to a period of probation, Mand the disciplinary action had little if any effect on Southam’s professional career, as he eventually published the results of his study from the JCDH in the *Annals of the New York Academy of Sciences*, where no mention was made of the lack of informed consent.

In 1968, Southam was elected president of the American Association for Cancer Research. He died in 2002.

While the 1966 expose on the shortcomings of patient consent procedures penned by Harvard professor Henry Beecher (1966) in the *New England Journal of Medicine* cited the Southam case, it would take more than a decade until the post-Tuskegee outcry propelled the formation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the publication of the commission’s Belmont Report, and, ultimately, the proliferation of institutional review boards to monitor experimentation.

### Conclusion

One might wish to believe that unethical medical experimentation on human subjects is a thing of the past

and that today's modern medicine still hides its collective head in shame for its ethical stumbles in the mid-20<sup>th</sup> century, unfortunately this is not the case. While stricter enforcement of rules and the introduction of IRBs have had a dramatic effect on unethical practice in the United States, this cannot be said of other some countries, where US-based companies and research organizations continue to exploit the absence of adequate laws to protect human subjects. While these issues are beyond the scope of this paper, it is important to understand that they do continue.

A 2008 report published by the Center for Research on Multinational Corporations revealed details of many such unethical trials, carried out in India, Nigeria, Russia, Argentina, and Nepal, among others. It revealed, for instance, the unrecorded deaths of 14 women in Uganda during a trial of the anti-HIV transmission drug Nevirapine, in a study sponsored by Boehringer Ingelheim and the US National Institutes of Health (NIH). It also revealed that eight patients in Hyderabad, in India, had died during a trial of the anti-clotting drug streptokinase—and that none of them were aware that they were part of an experiment (Somo.nl, n.d.) Even at Sloan-Kettering, almost 60 years after Southam's research, the institute would again make headlines when, in December 2018, a report in the *New York Times* disclosed that the hospital's chief medical officer, José Baselga, failed to disclose corporate ties in dozens of scientific articles he authored.

In fact, Baselga received millions of dollars in payments from companies involved in medical research, potentially compromising the work (*New York Times*, September 8, 2018)

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