The Captive Lab Rat: Human Medical Experimentation in the Carceral State

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THE CAPTIVE LAB RAT: HUMAN MEDICAL EXPERIMENTATION IN THE CARCERAL STATE

LAURA I APPLEMAN

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THE CAPTIVE LAB RAT: HUMAN MEDICAL EXPERIMENTATION IN THE CARCERAL STATE

LAURA I APPLEMAN*

Abstract: Human medical experimentation upon captive, vulnerable subjects is not a relic of our American past. It is part of our present. The extensive history of medical experimentation on the disabled, the poor, the mentally ill, and the incarcerated has been little explored. Its continuance has been even less discussed, especially in the legal literature. The standard narrative of human medical experimentation ends abruptly in the 1970s, with the uncovering of the Tuskegee syphilis study. My research shows, however, that this narrative is incorrect and incomplete. The practice of experimenting on the captive and vulnerable persists. Our current approach to human medical experimentation disregards informed consent and privacy, allowing the pharmaceutical and medical industries to play an outsized role in shaping clinical research. The confusing amalgam of laws, rules, and codes loosely governing such research almost entirely fails to regulate or prevent patient mistreatment and abuse. Acquiring a true understanding of our system of mass incarceration requires us to unearth the hidden contours of our current experiments on the poor, the disabled, and the confined, and calls for a wholesale revision of the flawed legal and medical regime overseeing human medical experimentation.

INTRODUCTION

In 1949, the Quaker Oats Company collaborated with the Massachusetts Institute of Technology (MIT) and the Atomic Energy Commission (AEC) to lace oatmeal with radioactive tracers and feed it to seventy-four boys, aged ten to seventeen, who resided in an institution for the developmentally disabled.¹ The only consent obtained was from the institution’s director. The experiment-

ers lured the boys into participation by telling them that they would be joining a special “Science Club.”

Quaker was in the midst of a pitched battle with Cream of Wheat over hot breakfast cereal market share, and was concerned that their oats might prevent iron absorption (unlike farina). They slipped radioactive particles into the breakfasts of unknowing children as an experiment to trace how iron was internally absorbed. One of Quaker’s advertisements from the era boldly proclaimed “Eat Quaker Oats for Energy!”

This experimental research using captive human subjects—one of many since the beginning of the American carceral nation—is not an outlier story. In fact, this experiment reflects our broader approach towards those whom we incarcerate, institutionalize, or involuntarily confine. The extensive history of medical experimentation on the disabled, the poor, the chronically ill, and the imprisoned is deeply shocking, but has been little explored. The gross mistreatment of the unknowing, non-consenting, and physically captive—the “de-valued experiences of people of low social status”—presents a disturbing story that must be told if we are to understand and reckon with the future of those we confine.

Despite the confusing amalgam of rules and regulations that currently loosely oversees human medical experimentation, the typical history of human subject research does not discuss the modern era. The standard narrative concludes that by the mid-1970s, most medical research on captive populations

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2 Id.
3 Id.
4 Id.
5 Id.
6 “Captive” includes the incarcerated, institutionalized, or hospitalized, wards of the state, and long-term care residents, among others.
7 See generally Laura I Appleman, Deviancy, Dependency, and Disability: The Forgotten History of Eugenics and Mass Incarceration, 68 DUKE L.J. 417 (2018) (explaining how the incarceration of the disabled is a significant, yet often forgotten, part of the United States’ history of imprisonment).
ended.\(^{10}\) My research shows, however, that this history is incorrect and incomplete. As I detail, the practice of experimenting on the captive and vulnerable persists, whether inmates, the mentally ill, the institutionalized, or wards of the state. This is not a story that belongs to history. These practices endure today.

The full social ramifications of human medical experimentation on the captive and vulnerable have been little explored. This part of our past is well documented in medical journals, occasional media stories, and government reports, but is otherwise little mentioned in the legal literature, despite the continuing practice. Acquiring a true understanding of our system of mass incarceration requires us to unearth this history of experimenting on poor, disabled, and confined citizens, as well as sharply scrutinize today’s continuing human medical experiments in restrictive settings such as correctional facilities, foster care, psychiatric institutions, and hospitals.

Part I of this Article discusses America’s history of experiments on the captive patient, whether enslaved, imprisoned, sequestered in asylums, institutionalized, or abandoned to the state.\(^{11}\) Part II reveals how our practice of experimenting on the incarcerated has continued through the late twentieth and early twenty-first century, despite the various federal and state laws ostensibly regulating such practices.\(^{12}\) Part III shows our troubling current state of captive medical experimentation, focusing on the evisceration of informed consent and privacy in such cases, and closely examining the role of the medical industry in furthering such research.\(^{13}\) In Part IV, I offer means of confronting and addressing the continuing practices of human medical experimentations on the vulnerable and captive.\(^{14}\) I argue for maintaining or tightening current restrictions and suggest that we should make use of future possible technological solutions, but warn that the root problems remain. I conclude by calling for a wholesale revision of the flawed oversight of human medical experimentation to best end the abuses that still endure.

I. A HISTORY OF CAPTIVITY AND EXPERIMENTATION

America’s long history of performing medical research and experiments on the captive and vulnerable is just beginning to enter public consciousness.\(^{15}\)

\(^{10}\) See HORNBLUM, supra note 8, at xv (asserting that most medical experimentation on institutionalized persons ended in the 1970s because regulation on such research was greatly increased).

\(^{11}\) See infra notes 15–193 and accompanying text.

\(^{12}\) See infra notes 194–423 and accompanying text.

\(^{13}\) See infra notes 424–520 and accompanying text.

\(^{14}\) See infra notes 521–599 and accompanying text.

In May 2018, New York City’s Central Park removed a statue of Dr. Marion Sims, the celebrated “father” of gynecology, after acknowledging his legacy of testing of gynecological surgical techniques on slaves without anesthesia.\(^\text{16}\) Instead of destroying the statue outright, the city moved it elsewhere, to better “remember darker moments in history, if not elevate them.”\(^\text{17}\)

Reckoning with the practice of eugenics in medical history has taken equally long within the law. An understanding of our past experience with eugenics and incarceration is just beginning to emerge. Likewise, the twined histories of medical research and experimentation on captive, vulnerable Americans have not truly permeated our standard understanding of the modern carceral state. This account seeks to fill in the missing narrative, with an eye toward moving to quick and necessary reform.

\textit{A. Asylums and Institutions}

Around the establishment of the American asylum, human medical experiments, which were routinely conducted on the involuntarily institutionalized, began to flourish. The proliferation of various institutions, including orphanages, reformatories, foundling homes, asylums, leper colonies, and hospitals, offered many subjects for medical experimentation in controlled test environments.\(^\text{18}\)

During the late nineteenth century, pediatric asylums in particular drew many doctors looking for tractable subjects.\(^\text{19}\) In 1883, for example, Dr. George L. Fitch, the resident physician to the Hawaiian leper colony,\(^\text{20}\) injected what he believed was the syphilis “virus” into six girls under the age of twelve.\(^\text{21}\) Fitch repeated his experiments on more leprosy patients and ultimately published his findings in a medical journal.\(^\text{22}\) Not long after, in 1895, Dr. Henry Heiman successfully exposed and cultivated gonorrhea in a disabled, epileptic four-year old boy and a developmentally disabled sixteen-year old

\[^{16}\]\text{See id.}\n\[^{17}\]\text{Id.}\n\[^{18}\]\text{Susan E. Lederer & Michael A. Grodin, \textit{Historical Overview: Pediatric Experimentation, in Children as Research Subjects: Science, Ethics, and Law} 3, 6 (Michael A. Grodin & Leonard H. Glantz eds., 1994).}\n\[^{19}\]\text{Id.}\n\[^{20}\]\text{Susan E. Lederer, \textit{Subjected to Science: Human Experimentation in America Before the Second World War} 61 (1995).}\n\[^{21}\]\text{Lederer & Grodin, \textit{supra} note 18, at 7.}\n\[^{22}\]\text{LEDERER, \textit{supra} note 20, at 61.}\n
boy in order to study the disease’s contagious nature.\footnote{23}{See Lederer & Grodin, \textit{supra} note 18, at 7.} He obtained no consent from the children or any of their parents or guardians.\footnote{24}{See id.}

Mental asylums also became a favored place to conduct medical experiments. In 1897, Dr. Henry Berkley, a Johns Hopkins neuropathy associate, tested various levels of thyroid extract on eight severely mentally ill patients.\footnote{25}{LEDERER, \textit{supra} note 20, at 50–51.} Berkley administered the extract in increasing doses, causing weight loss, circulation disturbances, digestive upset, irritability, and sometimes “frenzy” or great “mental excitement” in the inmates.\footnote{26}{See id.} One patient suffered severe mental and motor distress for seven weeks, with the symptoms continuing until her death.\footnote{27}{Id. at 61–62.} The minor payoff derived from this experiment? The discovery that even pure thyroid extract could harm a patient.\footnote{28}{Id. at 62.} The suffering of the patients merited little to no attention.\footnote{29}{See id. (noting that the experimenter’s conclusions did not discuss patient pain and suffering).}

Dr. Carl Janson famously quipped that he experimented on foundlings and orphans because they were “cheaper than animals.”\footnote{30}{Lederer & Grodin, \textit{supra} note 18, at 7.} The lack of reliable animal subjects at the turn of the twentieth century did lead to the use of institutionalized adults and children as “animals of necessity” for experimental testing of the bacterial causes of disease.\footnote{31}{Id.} Deliberate attempts to infect the institutionalized included exposure to “cancer, leprosy, syphilis, gonorrhea, tuberculosis, and yellow fever . . . .”\footnote{32}{Id.}

Doctors also used the institutionalized as experimental subjects for vaccines and diagnostic tests, only sometimes with incidental beneficial effect.\footnote{33}{Id.} In 1887, Dr. Joseph Stickler, in an attempt to find a scarlet fever vaccine, “inoculated” himself and several children with equine foot and mouth disease; this resulted in little contagion, but also zero vaccination effect.\footnote{34}{Id. at 61–62.} In 1912, Dr. Carl von Ruck tested his live tuberculosis vaccine on 262 North Carolina orphans, despite evidence suggesting that recipients of his tuberculosis “vaccine” succumbed to tuberculosis more frequently than the unvaccinated.\footnote{35}{Id.}

The first two decades of the twentieth century saw a grim expansion of vaccine testing on institutionalized children. Orphanages and children’s hospitals became staging grounds for attempts to develop measles, mumps, chicken
pox, and whooping cough vaccines. Consent was rarely obtained, even where parents were available to ask, and the vaccines usually failed, often with negative consequences for the children.

The U.S. Army also used asylum inhabitants to study common diseases. In order to better understand the spread of influenza in troops, Drs. Jonas Salk and Thomas Francis sprayed wild flu virus into the nasal passages of “large numbers” of mental institution inmates in 1941, almost all of whom developed the disease as a result.

In a second experiment, to test a newly created vaccine for American troops, Drs. Salk and Francis vaccinated half of the impoverished inhabitants of two state hospitals, purposely exposing all the patients to influenza. It is notable that even in a relatively recent report, an Army Medical History report recounted these experiments in admiration as “remarkable and daring,” with only an offhand admission that this would be found “highly unethical” today.

Researchers also found easy subjects in developmentally disabled children, because their institutions (and occasionally, their parents) readily gave permission for medical experimentation. At New York’s Willowbrook School, which housed children who were severely developmentally disabled, doctors tested a series of hepatitis vaccines from 1956 to 1970. The research involved purposefully infecting sixty healthy children with hepatitis to aid in vaccine development. Most developed hepatitis and suffered from symptoms including “fever, nausea, vomiting, intolerance to food, jaundice (a yellowing of the skin and eyes), and liver damage.”

Scientists justified the deliberate infection by arguing that most Willowbrook residents caught hepatitis within their first year anyway, given the institution’s unsanitary conditions, overcrowding, close quarters, and rapid spread of infectious disease. As long as the results would ultimately benefit both the public and Willowbrook patients, the reasoning went, the intentional infection of disabled children and the suffering caused did not matter.

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36 Id.
37 Id.
39 Id. at 154.
40 Id. at 143.
41 Id. at 144.
44 OFFIT, supra note 43, at 37.
45 PAOLA ET AL., supra note 42, at 185–86.
46 See Goodwin, supra note 9, at 376 (noting that researchers were convinced that these experiments would ultimately benefit all parties involved).
In one particular case, the children’s parents consented to the experiment, but only because the doctor made their children’s enrollment into the asylum conditional upon consent to hepatitis infection.⁴⁷ Of course, these misrepresentations to the parents, along with the duress in the inducement, rendered such agreements invalid.⁴⁸ Similar federally funded experiments exposed Connecticut mental asylum patients to hepatitis, in hopes of separating out the different strains of the virus.⁴⁹

As mentioned previously, the developmentally disabled, “troubled,” and destitute boys who lived at the Fernald School in Waltham, Massachusetts also served as unknowing subjects of medical experiments. In the Fernald experiments, the children received doses of radioactive iron or calcium to determine whether phytates were blocking absorption of essential minerals.⁵⁰ With assistance from the federal AEC, MIT’s Radioactivity Center created the Fernald “Science Club” to induce the boys into participating in the experiments, where radioactive isotopes were mixed in to either milk or oatmeal to be consumed daily.⁵¹ This particular experiment involved seventy-four Fernald boys, stretching from 1946 to 1953.⁵²

Researchers and doctors favored the Fernald School as a place to implement a variety of experimental projects, given its “ideal population” of captive children a mere twenty or so miles away from the scientific research community in Boston.⁵³ Indeed, such was the diversity and sheer variety of ailments at Fernald that many researchers began to refer to the school as the “zoo.”⁵⁴

As a consequence, Fernald hosted numerous scientific studies on its wards for almost sixty years, including vaccine tests for childhood diseases such as whooping cough, measles, and diphtheria.⁵⁵ New nasal discharge drugs were tested on children with Down Syndrome.⁵⁶ Scientists tested hormones and performed biopsies on prepubescent children.⁵⁷ The radioactivity study,

⁴⁸ See Paola et al., supra note 42, at 185 (noting that such agreements have been questioned and characterized as “inadequate consent” due to duress at the time consent was given).
⁵⁰ Eileen Welsome, The Plutonium Files: America’s Secret Medical Experiments in the Cold War 231 (1999). Phytates are “chemicals found in cereals that can combine with iron and calcium to form insoluble compounds.” Id.
⁵¹ Id. at 231, 233–34.
⁵² Id. at 231.
⁵³ Id. at 232–33.
⁵⁴ Id. at 233.
⁵⁵ Id.
⁵⁶ Id.
⁵⁷ Id.
however, was the longest and most far-reaching of all the medical experiments.\(^5\)

The AEC’s radioisotope distribution system in Oak Ridge, Tennessee\(^6\) provided the radioactive calcium\(^6\) to assist the MIT scientists in their experiment. Although the AEC Subcommittee on Human Application generally discouraged testing of radioactive substances on “normal children,” it permitted larger doses of radioactive material for developmentally disabled children.\(^6\)

The AEC approved the trace radioactivity study with the Fernald boys, as well as a 1961 Harvard Medical School experiment that “administered small amounts of radioactive iodine to seventy children at the Wrentham State School,” in order to test a preventative countermeasure for potential nuclear fallout.\(^6\) The AEC also approved an experiment to inject a much larger amount of radioactive calcium into a child suffering from Hurler-Hunter syndrome.\(^6\)

For the innocent Fernald School boys participating in the MIT-created “Science Club,” the multiple X-rays, blood tests, and collection of their urine and stool samples seemed a tolerable price to pay for admittance.\(^6\) The boys thought that the tests were for either the 4-H club or for a vitamin study, and had no idea they were consuming radioactive isotopes with their breakfast.\(^6\)

The scientists also gave the boys’ parents misleading information. For example, the scientists sent letters explaining that the nutritional studies being done would benefit the boys, as the children received a “special diet ‘rich’ in various cereals, iron, and vitamins.”\(^6\) The letters never mentioned radioactivity.\(^6\) When the scientists did not receive a response, they assumed that the parents approved.\(^6\)

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58 See id. at 231 (noting that the radioactivity experiments were conducted on seventy-four children and went on for seven years).
59 The Isotopes Division of the Research Division at Oak Ridge was originally part of the Manhattan Project. Post-war, the Manhattan Project began distributing radioactive isotopes to various medical researchers and scientists for further experimentation. See Advisory Comm. on Human Radiation Experiments, U.S. Dep’t of Energy, Final Report 285 (1995).
60 See Welsome, supra note 50, at 233.
61 See id.
63 See Welsome, supra note 50, at 234 (noting that the AEC granted the Harvard Medical School permission to inject a child with fifty microcuries of radioactive calcium and that the associated scientific paper indicated that the researchers actually injected the individual with eighty microcuries). Hurler-Hunter syndrome is a “metabolic disorder that causes severe skeletal abnormalities, dwarfism,” and developmental disability. Id.
64 Id. at 235.
65 Id.
66 Advisory Comm. on Human Radiation Experiments, supra note 59, at 342.
67 See Welsome, supra note 50, at 235.
68 Advisory Comm. on Human Radiation Experiments, supra note 59, at 292.
This type of human medical experimentation using radioactive materials was not confined to children. For years, the AEC permitted experiments using radioactive substances on institutionalized, developmentally disabled adults. Between 1931 and 1933, for example, researchers injected mentally ill patients with 70 to 450 micrograms of radium-226 as part of an experimental therapy for mental disorders. The researchers hoped to construct a valid retention curve for radium in humans over several decades. The radium’s side effects were of little concern to the scientists.

Medical experimentation on institutionalized children included the physically disabled as well as the developmentally disabled. For five years, between 1955 and 1960, a Californian hospital and foundling home for physically and developmentally disabled children, Sonoma State Hospital, performed a variety of experiments on its patients. The experiments conducted on the children, without their or their parents’ consent, allegedly included radiation tests, pneumoencephalograms, a painful procedure by which air is injected into the brain and followed by a number of X-rays, and unauthorized dissection of the children’s brains after death.

Despite these myriad violations of children’s bodily autonomy, no current federal regulations specifically protect institutionalized children from discriminatory or unethical treatment in research involving human subjects. Although general regulations regarding the use of children in research apply, institutionalized children do not get any special or extra protection. This is just one example of how the law has failed to fully and comprehensively protect vulnerable, captive populations from human experiments.

B. Orphanages, Foundling Homes, and Children’s Hospitals

Institutions for children began to multiply in the 1830s. Both foundling homes and children’s hospitals were created to house neglected, deserted, ill,

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70 See id.
71 See id.
72 See id. (noting the injection of radium-226 with little tracking of the patients’ long-term health).
74 See id.
75 See ADVISORY COMM. ON HUMAN RADIATION EXPERIMENTS, supra note 59, at 323.
and destitute children as well as provide moral and medical care.\footnote{See id. at 96.} Because charity hospital patients in essence existed to provide training and clinical material for doctors, these children’s institutions provided experimentation opportunities for elite physicians.\footnote{See id. at 99–100.} Accordingly, the amount of pediatric medical experimentation that occurred is far greater than commonly appreciated.\footnote{See id. at 97.} In an era where healthy institutionalized children were sent out to work on farms in New York and the Midwest,\footnote{See id. at 99. In 1854, New York’s Children’s Aid Society began sending healthy orphans to farms across the country. Id. The asylums, orphanages, and pediatric hospitals were created to house the younger and less hardy candidates. Id.} their frailer brethren were made to earn their keep by being subjects in various medical research projects.

Asylums and orphanages were popular sites to conduct medical experiments because consent issues rarely, if ever, surfaced.\footnote{See id. at 16.} Getting permission from any remaining parents or guardians was not considered an issue.\footnote{See Lederer & Grodin, supra note 18, at 13.} Dr. Alfred Hess’s research at the Hebrew Orphan Asylum in the 1920s on the dietary factors of rickets\footnote{Rickets is the deterioration of bones in children, often resulting from a severe vitamin D deficiency. Rickets can cause skeletal deformities such as bowed legs, knock knees, thickened ankles and wrists, and breastbone projections. See Rickets Overview, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/rickets/symptoms-causes/syc-20351943 [https://perma.cc/CGD7-QPKM].} and scurvy\footnote{Scurvy is a vitamin C deficiency that can lead to anemia, debility, exhaustion, spontaneous bleeding, pain in the limbs and especially the legs, swelling in some parts of the body, and sometimes ulceration of the gums and loss of teeth. See Peter Crosta, Everything You Need to Know About Scurvy, MED. NEWS TODAY (Dec. 5, 2017), https://www.medicalnewstoday.com/articles/155758.php [https://perma.cc/3EKV-ZPQ3].} is emblematic.\footnote{See Lederer, supra note 20, at 15–16.} Dr. Hess withheld orange juice from infants and young children until they developed the painful hemorrhages typical of scurvy, and he fed children a similarly restricted diet in an attempt to induce the bone-weakening symptoms of rickets.\footnote{Lederer \& Grodin, supra note 18, at 13.} Some of the children never fully recovered from the effects of these diseases.\footnote{Id.}

Vaccine testing also took place in orphanages because children often had not been exposed to infectious diseases.\footnote{See LEDERER, supra note 20, at 4 (providing examples of such testing).} In 1895, Drs. Walter Reed and George Sternberg tested the immunity granted by smallpox vaccines at orphanages in Brooklyn; the most common way to test immunity was to inject the children with active smallpox virus, which could kill or deform the patients.\footnote{Id.}
Researchers also repeatedly tested tuberculosis vaccines on orphans. In 1913, 262 children in a North Carolina orphanage were used to test a vaccine against the disease. The U.S. Senate eventually commissioned an investigation that called into question the vaccine’s safety and raised the possibility that the vaccine actually made the children more susceptible to tuberculosis.

Analogous research and tests were carried out on newborn infants to test gastric hunger. Similarly, children at St. Vincent’s Hospital were likewise infected with a contagious skin disease (molluscum contagiosum) and whooping cough. Typically viewed as expendable and unimportant, poor, abandoned, and vulnerable children have historically borne the brunt of medical research’s expanding scope.

C. Hospitals and Invalid Homes for the Poor

As hospitals expanded during the late nineteenth century, they served as yet another setting to perform human medical experiments, with or without consent. Unlike the modern hospital, the late nineteenth century and early-to-mid-twentieth century hospital was “less an institution for healing than a physician-centered venue for learning, training, and experimental approaches.”

Unregulated research on impoverished hospital patients continued, with little oversight, well into the twentieth century. Between 1943 and 1944, researchers at the Manhattan Engineer District’s Metallurgical Laboratory tested the changes in blood after total body irradiation (TBI) at the University of Chicago’s Billings Hospital. Eleven patients were subjected to X-ray radiation, eight with incurable neoplasms, and three with generalized, chronic illness. There is no record of any consent. As a result of the experiment, most of the patients’ white blood cells were severely diminished.

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91 Id. at 88.
92 Id.
93 Lederer & Grodin, supra note 18, at 7–11.
94 Id.
95 See Lederer, supra note 77, at 113.
96 See HARRIET A. WASHINGTON, MEDICAL APARTEID: THE DARK HISTORY OF MEDICAL EXPERIMENTATION ON BLACK AMERICANS FROM COLONIAL TIMES TO THE PRESENT 104–05 (2006). As Washington argues, a vast majority of these hospital patients were black, impoverished, or both. Id.
98 List of Experiments, supra note 69.
99 See id.
100 See id. (omitting any mention of the patients’ consent).
101 See id.
Many hospital-based radiation experiments in the early to mid-twentieth century enjoyed sponsorship from the U.S. government. During and after World War II, officers running the Manhattan Project decided to experimentally inject plutonium into unwitting hospital patients.\(^\text{102}\) The government wished to “clarify the relative toxicity of radium and plutonium and help establish tolerance levels for workers.”\(^\text{103}\) Four separate research institutions conducted experiments in 1946 and 1947, in which the researchers injected terminally ill patients with radioactive plutonium to determine how it would affect the body.\(^\text{104}\) None of the treatments were found to be therapeutic, and significant pain resulted for the patients.\(^\text{105}\)

The pace of experimentation on cancer patients with radioactive materials increased after World War II. In 1947, the Argonne Laboratory in Chicago intravenously injected twelve hospital patients with radioactive arsenic-76, to “study the uptake, retention, distribution, and excretion of arsenic.”\(^\text{106}\) The radioactive arsenic-76 failed to cure the cancers of the various subjects.\(^\text{107}\)

In the early 1950s, former Nazi physiologist Herbert Gerstner subjected 263 cancer patients to TBI at M.D. Anderson Hospital for Cancer Research in Houston, Texas.\(^\text{108}\) All of these patients had radioresistant carcinomas, for which “cure by conventional means was regarded as completely hopeless.”\(^\text{109}\) The TBI completely destroyed the patients’ bone marrow, leading to fatal anemia and rapid death.\(^\text{110}\) Although the patients signed a rudimentary release form, the release did not inform them of the risks and benefits.\(^\text{111}\) Many of the patients were indigent members of minority groups, although no precise records were kept.\(^\text{112}\)

In a similar vein, Dr. Chester Southam of Sloan Kettering spent 1963 to 1964 injecting live cancer cells into twenty-two highly debilitated patients (who did not have cancer)\(^\text{113}\) in long-term care at the Jewish Chronic Disease

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\(^{102}\) See id.

\(^{103}\) WELLSOME, supra note 50, at 80.

\(^{104}\) See David Pacchioli, Subjected to Science, PENN STATE NEWS (Mar. 1, 1996), https://news.psu.edu/story/141518/1996/03/01/research/subjected-science [https://perma.cc/3LNK-NZ4Q].

\(^{105}\) See List of Experiments, supra note 69 (explaining the therapeutic results of the various experiments).

\(^{106}\) See id.

\(^{107}\) See id.

\(^{108}\) WASHINGTON, supra note 96, at 229.

\(^{109}\) ADVISORY COMM. ON HUMAN RADIATION EXPERIMENTS, supra note 59, at 380–81.

\(^{110}\) WASHINGTON, supra note 96, at 229.

\(^{111}\) ADVISORY COMM. ON HUMAN RADIATION EXPERIMENTS, supra note 59, at 381.

\(^{112}\) See id.

\(^{113}\) See John D. Arras, The Jewish Chronic Disease Hospital Case, in THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 73, 73 (Ezekiel J. Emanuel et al. eds., 2008).
Hospital. All twenty-two were frail and elderly, many mentally incompetent, and several were survivors of the Holocaust who spoke primarily Yiddish. Despite the relatively recent establishment of the Nuremberg Code and the parallels to Nazi experimentation in concentration camps, the experiment was performed without any review board approval or interventions on behalf of the patients.

Although the patients had theoretically consented to the experiment, they were not aware of the cancer cell injection. Instead, Dr. Southam told the patients they were being injected with human cells grown in test tubes, cells that would create a temporary nodule. While technically correct, this was not the entire truth. Although the experiment stopped in 1964 due to a public outcry, Dr. Southam ultimately became the president of the American Association of Cancer Research in 1968.

This tolerance for experimentation on unknowing cancer patients continued through the early 1970s. In Cincinnati, radiologist Dr. Eugene Saenger used experimental, high-dose TBI on approximately ninety cancer patients with localized, radio-resistant cancers. The TBI used by Dr. Saenger consisted of magnavolt X-rays, cobalt-60, or cesium-137, in amounts equal to approximately 15,000 chest X-rays to the entire body. Although by the 1940s, scientists knew that TBI was only effective against certain radiosensitive cancers, such as leukemia and lymphoma, Saenger still obtained funding from the Pentagon.

115 See Arras, supra note 113, at 77.
116 The Nuremberg Code holds, among other things, that the “voluntary consent of the human subject is absolutely essential,” stating:

[B]efore the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.

NUREMBERG CODE ¶ 1 (1947).
117 See Goodwin, supra note 9, at 376.
118 See Arras, supra note 113, at 73.
119 See Hornblum, supra note 114.
120 See id.
122 WASHINGTON, supra note 96, at 233.
123 Id. at 234.
None of this information was shared with the Cincinnati cancer patients, who were told only that TBI was the appropriate treatment. The majority of the cancer patients were poor or working-class, and about sixty percent were African-American. Saenger’s research partner, Clarence Lushbaugh, explained that they chose “slum patients” because “these persons don’t have any money and they’re black and they’re poorly washed.”

The TBI resulted in death for one out of four patients, who perished within the month, “suffering anemia, vomiting, and crashing white blood cell counts.” The results were so drastic that even other doctors criticized Saenger’s experiments, calling them “too dangerous” and “terrible human studies.” Whether there was written signed consent is disputed, but highly unlikely. The experiment ended in 1972 after the Department of Defense cut the funding for the nearly million-dollar research.

Despite the controversy over the TBI experiments, Saenger taught at the University of Cincinnati Medical School until his death. The Radiological Society of North America gave him its highest honor, a Gold Medal, for his work in radiology, including his TBI experiments. Saenger never suffered any serious repercussions from the experiments.

Only a tiny, out-of-the-way plaque at the University of Cincinnati memorializes the seventy patients who died from the experiments, required as part of the settlement made by the university with the patient survivors and their families. This small, neglected plaque exemplifies the way that we remember the history of these experiments on poor, often minority individuals institutionalized in hospitals for necessary treatments. Little attention was paid then to their rights or their suffering, and little more attention is paid now.

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124 See id.
125 See Dicke, supra note 121.
126 WASHINGTON, supra note 96, at 235.
127 Id. at 234.
128 Id.
129 See id. at 235 (noting that the hospital did produce signed consent forms but that the patients’ survivors questioned their validity).
130 See id.
131 See Dicke, supra note 121.
132 See id.
133 See id.; see also WASHINGTON, supra note 96, at 236 (explaining that the American College of Radiology “exonerate[ed] Saenger of wrongdoing on the basis of his denials and by ignoring the rules that governed experimentation during his tenure as a [Department of Defense] researcher”).
D. Prisoners

The number, size, and frequency of medical experiments that have been carried out on incarcerated citizens are too vast to fully recount. Instead, this Section explores the most infamous and troubling of these studies, leading to inescapable conclusions when looking at them in toto.

Prisoners have often been viewed as the perfect experimental test subjects, given their captivity, their limited freedoms, and the sheer number of potential bodies in one place. As such, inmates were subjected to many inhumane medical experiments throughout the twentieth century. In the 1920s, for example, inmates at San Quentin penitentiary were subjected to experiments in testicular transplantation, to determine whether “lost potency of aged and ill men could be reinvigorated.” Dr. L.L. Stanley transplanted testes from recently executed prisoners into eleven healthy prisoners. The San Quentin doctors also transplanted ram testes into twenty-three inmates who suffered from various medical issues. Over the course of three years, 500 prisoners had testicular transplants. Needless to say, these transplants were unsuccessful.

World War II sparked a tremendous boom in medical experimentation on the incarcerated. With soldiers dying in Europe and the South Pacific, the demand for human research material increased. In 1942, a variety of risky medical experiments were practiced on state prisoners, including injections of cattle blood as a potential new source of plasma (critical to wounded soldiers), atropine studies, and research involving “sleeping sickness, sandfly fever, and dengue fever.” Inmates in federal prisons took part in an equally wide range of medical experiments, including exposure to sexually transmitted diseases such as gonorrhea, recurring sicknesses like malaria, and induction of gas gangrene.

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135 See HORNBLUM, supra note 8, at 79. In part, the experiments were driven by fear that declining “white, masculine vigor” would result in a degradation of the nation’s moral values. See 1913–1951: Dr. Leo Stanley, AHRP, http://ahrp.org/1913-1951-dr-leo-stanley/ [https://perma.cc/F2BK-HD3A].

136 See LEDERER, supra note 20, at 112.

137 See id.

138 HORNBLUM, supra note 8, at 79.

139 See Allen M. Hornblum, They Were Cheap and Available: Prisoners as Research Subjects in Twentieth Century America, 315 BRITISH MED. J. 1437, 1438 (1997) (noting that the ongoing war sparked the emergence of a “new industry” using “human material”).

140 Atropine is a medication to treat certain types of nerve agent and pesticide poisonings as well as some types of slow heart rate. See Atropine, BRITANNICA, https://www.britannica.com/science/atropine [https://perma.cc/YWU6-Z3XP].

141 See Hornblum, supra note 139, at 1438.

142 The 1944 malaria experiments at Stateville Penitentiary in Illinois were the best known. The tests included “periodic mosquito bites, raging fevers, nausea, vomiting, blackouts,” and various med-
The post-war focus on prison experimentation can also be linked to the immense growth in the pharmaceutical and health care industry.144 A vast wave of prisoner experiments began, with funding coming from both the government and various for-profit corporations.145 After World War II, the United States stood alone in permitting experimentation on prisoners. Europe and the South Pacific, having been far closer to both medical and wartime atrocities, interpreted the Nuremberg Code to ban medical experimentation on prisoners entirely.146

In contrast, American medical researchers, perhaps feeling unburdened by the legacy of wartime history, performed multiple medical experiments on the incarcerated.147 Indeed, researchers used prisoners as subjects in a wide variety of studies, ranging from cancer research to experimental testing of cosmetics.148 Accordingly, “what had once been a small, underfunded, unsophisticated cottage industry” became “a well-financed, broad clinical research program” testing new and innovative medical treatments.149 The post-war expansion of experimentation on prisoners was unprecedented and virtually unregulated.150

So encouraged, scientists in the late 1940s studied the transmission of dangerous intestinal viruses by having New York State Vocational Institution prisoners swallow unfiltered stool suspension.151 This was to test the viral contagion.152 It is unknown whether these prisoners were ever compensated.153

Often prominent universities, hospitals, scientists, and prisons collaborated to perform these medical experiments on the incarcerated. In 1953, University of Chicago and the Argonne Cancer Research Hospital conducted experiments on Illinois State Penitentiary inmates to “determine the hemolytic defect that develops during primaquine administration.”154 Blood-containing chromium-51 was injected into the prisoners, followed by an injection of prima-
quine. Those prisoners who were sensitive to primaquine developed severe anemia, including rapid heartbeat, fatigue, shortness of breath, chest pain, and cramps.

By the 1960s, over half the states permitted prisoners to be used as “medical guinea pigs.” Human experimentation quickly followed. Drs. Carl Heller and Alvin Paulsen, with the explicit permission of the AEC, performed a series of radiation experiments on Washington and Oregon prisoners. The two doctors irradiated prisoner testicles with 8 to 600 rads of radiation, as well as injections with carbon-14, a radioactive tracer. Each dose of radiation was stronger than twenty modern diagnostic X-rays would provide today.

The Washington and Oregon experiments continued until 1971, using 131 inmates as experimental subjects. Additionally, researchers performed numerous biopsies of the inmates’ reproductive organs, vasectomizing them when the studies were over. “Compensation” for these procedures was five dollars a month during the program, ten to twenty-five dollars for each biopsy, and one hundred dollars post-vasectomy. In contrast, Paulsen received $505,000 from the AEC for his work.

After each irradiation session, rashes, peeling, and blistering on inmates’ scrotums soon followed. The long-term side effects reported by the inmates included pain during sexual intercourse, difficulty maintaining erections, and testicle shrinkage. In addition, chromosome damage in testicular cells, potentially caused by the radiation, can cause infertility, increase the possibility of testicular cancer, and raise the odds that children will have birth defects. The surviving participants now have various medical problems likely resulting from the experiments, including prostate cancer, loss of vision, and vascular diseases.

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155 See id.
157 Stobbe, supra note 49.
158 See WELCOME, supra note 50, at 367.
159 See id.
161 See WELCOME, supra note 50, at 367.
162 See id.
163 See id. at 367–68.
164 See id.
165 See id. at 370.
166 See id.
167 See Lee, supra note 160.
168 See id.
Another infamous prisoner medical experiment emerged from a collaboration between the University of Pennsylvania, Holmesburg Prison, and various for-profit laboratories. During the 1950s and 1960s, Dr. Albert Kligman used the inmates at Pennsylvania’s Holmesburg Prison as research subjects for numerous studies on “acres of [prisoner’s] skin.”\textsuperscript{169} Dr. Kligman tested 153 experimental, topical drugs over the span of four years, with approximately seventy-five percent of inmates suffering side effects such as baldness, extreme scarring, and permanent skin and nail injuries.\textsuperscript{170}

Kligman’s research studies included tests with “toothpaste, deodorant, shampoo, skin creams, detergents, liquid diets, eye drops, foot powders, and hair dye,” all applied to the skin, with painful results and frequent biopsies.\textsuperscript{171} Dow Chemical paid Kligman $10,000 to test dioxin, a component of Agent Orange, on inmates’ skin.\textsuperscript{172}

Even more troubling, many of the Holmesburg prison experiments were conducted on individuals who were not yet convicted. More than half of the inmates in Philadelphia prisons at the time were individuals awaiting trial or trying to make bail.\textsuperscript{173} The prisoners were so desperate for money that they signed up for Kligman’s experiments in droves.\textsuperscript{174}

Profits were a common motive in prisoner experiments. In the early to mid-sixties, inmates in Alabama, Arkansas, and Oklahoma prisons\textsuperscript{175} were used in poorly designed blood-plasma trials, which studied transfusions using large amounts of plasma, or plasmapheresis.\textsuperscript{176} In the Oklahoma prison, a unit of blood was removed from each prisoner, the plasma removed, and then the remaining cells reinjected.\textsuperscript{177} Proper sanitary measures were not kept and, at one institution, twenty-eight percent of the subjects developed hepatitis.\textsuperscript{178} Instances of transfusions of the wrong blood types were reported and an undetermined number of other inmates died from these procedures.\textsuperscript{179} Although the plasma experiments eventually ceased, Dr. Austin Stough, who oversaw the

\textsuperscript{169} HORNBLOM, supra note 8, at xx (quoting Kligman’s initial reaction to seeing so many captive subjects for his dermatological experiments).
\textsuperscript{170} See WASHINGTON, supra note 96, at 249.
\textsuperscript{171} See HORNBLOM, supra note 8, at xv.
\textsuperscript{172} See GRAHAM DUKES ET AL., PHARMACEUTICALS, CORPORATE CRIME AND PUBLIC HEALTH 48 (2014).
\textsuperscript{173} See HORNBLOM, supra note 8, at 23–24.
\textsuperscript{174} See id.
\textsuperscript{176} See WASHINGTON, supra note 96, at 253.
\textsuperscript{177} See Rugaber, supra note 175.
\textsuperscript{178} See id.
\textsuperscript{179} See id.
research, personally profited to the tune of over $2 million.180 The prisoners were a critical part of both industry profitability and scholarly achievement.181

By the 1970s, the types of human medical experiments that took place in correctional facilities were divisible into three general categories: “behavior modification research conducted by prison officials; biomedical research, often supported or directed by federal agencies; and pharmaceutical research, largely funded and controlled by private drug companies.”182 In 1972, officials from the U.S. Food and Drug Administration (FDA) estimated that over ninety percent of investigational drugs were tested on prisoners as a first step,183 whatever the level of consent.

Following the 1972 media exposure of the Tuskegee syphilis experiment,184 Congress passed the National Research Act in 1974.185 The Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was tasked to develop guidelines for the ethical conduct of research.186 The Commission essentially forbade medical research on prisoners, with two main concerns in mind: (1) whether prisoners bear an equitable share of the burdens arising from the research, and (2) whether prisoners have the capacity to give their full and free consent.187 In theory, the only research that is now permitted in correctional facilities is that deemed minimal-risk.188

Under current FDA regulations, all research involving human subjects must go through an Institutional Review Board (IRB).189 An IRB190 is an appropriately constituted group that has been formally designated to review and

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180 See WASHINGTON, supra note 96, at 253.
181 See HORNBLUM, supra note 8, at xvi.
182 See Reiter, supra note 9, at 510.
183 See ADVISORY COMM. ON HUMAN RADIATION EXPERIMENTS, supra note 59, at 437.
184 The Tuskegee study, initiated by the U.S. Public Health Service in 1932, studied the significant effects of untreated syphilis, in part to encourage development of new treatments for the disease. See Barbara E. McDermott, Coercion in Research: Are Prisoners the Only Vulnerable Population?, 41 J. AM. ACAD. PSYCHIATRY & L. 8, 10 (2013). In the study, 600 African-American sharecroppers from Alabama were provided with medical care, meals, and burial insurance. Id. Of those 600 men, 399 were already infected with syphilis and 201 were healthy. Id. The participants believed that they were receiving treatment for “bad blood,” but were never told they had syphilis; none of them gave any informed consent. Id. Even after the discovery of penicillin in the 1940s, the treatment was withheld. Id. The study continued until 1972, at which point 128 of the original participants had died, 40 of their wives had been infected, and 19 children had been born with congenital syphilis. Id.
185 Id.
186 Id.
187 Id.
188 Id. at 11. “[F]or prisoners, minimal risk is defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.” Id.
189 See 45 C.F.R. §§ 46.101–.124.
190 21 C.F.R. §§ 56.101–.114 (2019); 45 C.F.R. §§ 46.107–.111.
monitor biomedical research involving human subjects. In reality, however, modern human experimentation is regulated haphazardly by a “crazy-quilt of hortatory codes and maxims, scattered federal laws and regulations,” and IRBs. Indeed, “IRBs as currently constituted do not protect research subjects but rather protect the institution and the institution’s investigator.”

Our standard history of human medical experimentation traditionally ends in the 1970s, particularly for non-therapeutic human subject experimentation. My research illustrates, however, that this narrative is incomplete. As I explore in the next Part, medical research on captive, vulnerable populations continues in the twenty-first century.

II. EUGENICS, MEDICAL EXPERIMENTATION, AND DRUG TESTING IN THE 21ST CENTURY

Why does the captive subject remain such a popular body upon which to practice medical experiments? As discussed in Part I, the history of experimenting on the incarcerated and institutionalized arose at the same time that both the institution and the correctional facility were born. Those individuals incarcerated in correctional facilities were “vulnerable, stigmatized, and expendable,” frequently poor, uneducated, and largely belonging to minority groups. All of these captive, vulnerable individuals have continued to prove irresistible to doctors and researchers hoping to perform human subject research.

Some minimal federal oversight over human subject research is provided by the Policy for the Protection of Human Subjects, 45 C.F.R. § 46, which regulates the type of experiments that may be performed upon vulnerable populations. In most general terms, the policy applies to all research involving human subjects that is conducted, supported, or otherwise subject to regulation by any federal department or agency.

The policy is divided into four subparts: subpart A, also known as the “Common Rule”; subpart B, additional protections for pregnant women, human fetuses, and neonates; subpart C, additional protections for prisoners; and sub-

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194 See supra notes 15–193 and accompanying text.
195 WASHINGTON, supra note 96, at 246.
196 Id. at 247.
198 Id.
part D, additional protections for children.199 The policy, however, only applies to those federal agencies that choose to adopt it.200 In addition, the Common Rule does not apply to any research not funded or conducted by specified federal sources.201 As detailed below, this leaves substantial room for some very questionable human subject research.

A. Correctional Facilities

Medicine has always claimed a “special provenance” over crime and the criminal,202 a provenance that is tightly intertwined with the history and practice of eugenics.203 Given that such a despised, overlooked set of subjects sits captive in an easily accessed institution, it should be of no surprise that prisoners remain the most popular set of individuals upon which to test various medical theories, dangerous materials, and pharmaceuticals.

Today’s inmates are still desirable for medical experimentation due to the structure of the federal regulation of most medical therapies.204 At the most basic level, federal regulations require that any medical experimentation on humans take place in three formal phases: Phase I, which asks about the safety of treatment; Phase II, which continues to evaluate safety while also asking about effectiveness of the treatment; and Phase III, which compares the treatment to the standard treatment.205 Phase I requires healthy subjects to test both the safety and efficiency of any treatment, whether pharmaceutical or interventional, and accordingly is the most dangerous, due to side effects and unknown results.206 Because of the difficulties of Phase I testing, most medical researchers prefer that their subjects be in closed facilities, where they can be carefully tracked and monitored.207 Accordingly, those individuals who are incarcerated long term—whether in alternative correction locations or formal correctional facilities—remain the medical researcher’s ideal subject, despite the regulations that currently surround prison research.208

200 See id.
202 WASHINGTON, supra note 96, at 247.
203 See id. (providing examples where scientists justified their experiments on prisoners on the basis of racial distinctions).
204 Id. at 246.
205 Id.
206 Id.
207 Id.
208 Id.; see 45 C.F.R. §§ 46.301–.306.
The list of medical experiments currently occurring in correctional facilities is long, and I discuss only a representative subset below. These experiments are not confined to prisons; such research takes place in all sorts of correctional control facilities, including drug addiction treatment centers. These human medical experiments are overseen by private contractors and are frequently just beyond the reach of governmental regulation. Such research all too often manages to elude regulation.

Indeed, the majority of research involving prisoners occurs outside the purview of the requirements of 45 C.F.R. § 46.303, subpart C. Research involving vulnerable populations applies only to research that includes “any individual involuntarily confined or detained in a penal institution.” Accordingly, any prisoner studies that do not take place in a formal correctional facility are being conducted without review or approval by an IRB.

1. Alternative Corrections

Both public universities and drug companies regularly use prisoners and other incarcerated individuals as subjects in medical experiments. More than one-third of these medical experiments take place in alternative corrections facilities, which include probation, residential drug treatment programs, parole, community corrections, home confinement, and boot camps for first-time drug users and sellers.

Most recently, in both 2006 and 2008, the drug company Hythiam entered into contracts with five different states to recruit addicted prisoners into an experimental drug addiction treatment program. State courts diverted defendants with drug charges into an experimental treatment program called Prometa, which included thirty days of three different experimental drugs prescribed off-label. The pharmaceuticals consist of gabapentin, an anti-seizure medication; flumazenil, which is used as an antidote in the treatment of benzodiazepine-
pine overdose; and hydroxyzine, an antihistamine.\footnote{See Deborah L. Shelton, *Marketing Hype or a Miracle Cure?*, CHI. TRIB. (Dec. 9, 2007), http://articles.chicagotribune.com/2007-12-09/news/0712080301_1_meth-addiction-hythiam-protocols [https://perma.cc/N4DR-HBHC].} The Prometa protocol costs approximately $15,000 per participant, and has been touted as a revolutionary cure-all for a myriad of addictions.\footnote{See id.} Prometa, however, is not FDA-approved as an addiction therapy, nor has it undergone extensive scientific testing.\footnote{See id.}

In 2006, Prometa was used in a forty-person pilot program in a Pierce County, Washington felony drug court through a nonprofit treatment center.\footnote{See Kari Huus, *Setbacks Plague Drug Addiction Remedy*, NBC NEWS (Jan. 11, 2008), http://www.nbcnews.com/id/22315918/ns/health-addictions/t/setbacks-plague-drug-addiction-remedy/#.W3M83n4nab8 [https://perma.cc/3SN7-BHF9].} Initially, officials reported very promising results.\footnote{Id.} Due to the pilot program’s success, Pierce County was able to obtain $800,000 for Prometa funding in both the state and county correctional facilities in 2007.\footnote{Id.} The Pierce County Council ended the Prometa funding, however, after a report by auditors concluded there was no evidence it actually worked.\footnote{See Shelton, supra note 219.}

Prometa’s manufacturer, Hythiam, aggressively marketed the drug combination to the numerous drug courts that offer treatment to offenders as an alternative to going to jail.\footnote{See Huus, supra note 222.} But a number of its pilot programs in various state and county drug courts, while deemed successful initially, had mixed results when further scrutinized.\footnote{See id.} In Pierce County, for example, the nonprofit clinic administering the drug combo made its results look far better than they were, often by failing to count the probationers who dropped out of the program or were imprisoned.\footnote{See Is This Meth Treatment Too Good to Be True?, LAS VEGAS SUN (Dec. 9, 2007), https://lasvegassun.com/news/2007/dec/09/is-this-meth-treatment-too-good-to-be-true/ [https://perma.cc/68SN-GVMM].} Ultimately, those given Prometa treatment did not have better outcomes than those given a placebo in terms of reducing methamphetamine use, retention in treatment, or reducing methamphetamine cravings.\footnote{See id.}

Another drug addiction treatment, Vivitrol (extended release naltrexone), is currently being tested on pre-release and released prisoners through a study
sponsored by the Friends Research Institute. Vivitrol is a prescription injectable medicine used to treat opioid and alcohol dependence after detoxification. As a non-opioid-based treatment for opioid addiction, Vivitrol is popular for use in prisons and drug courts, and has been repeatedly tested in criminal justice settings. Vivitrol is produced and marketed by a for-profit drug company, Alkermes Inc.

In 2011, Alkermes initiated a three-year clinical research study on the efficacy of Vivitrol. Over a period of six months, the company injected it monthly into prisoners scheduled for release in three Maryland prisons. Out of the twenty-seven parolees enrolled in the study, seven had serious, adverse effects from the injections, including anaphylactic reactions and abscess at the injection site. Twenty-six out of twenty-seven participants had other side effects, including blood and lymphatic system disorders, gastrointestinal disorders, and urinary tract infections.

The issues with testing Vivitrol on inmates are multi-fold. First, using Vivitrol requires that the patient be fully opioid-free for at least two weeks before beginning treatment. Thus, any relapse of drug use while taking Vivitrol can be very dangerous, as there is the possibility of accidental overdose, serious injury, coma, or death. Additionally, other serious side effects include severe reactions at the injection site, such as tissue damage necessitating surgery or tissue death, and suicidal thoughts.

Because Vivitrol is such a new drug, there is little empirical evidence that supports its use. There have only been five trials testing Vivitrol’s impact on


235 See id.

236 See id.

237 See VIVITROL, supra note 231.

238 See id.

239 See Alec MacGillis, The Last Shot, PROPUBLICA (June 27, 2017), https://www.propublica.org/article/vivitrol-opiate-crisis-and-criminal-justice [https://perma.cc/V84M-8PE9] (asserting that Vivitrol does not have the same evidence supporting its use that methadone and buprenorphine have).
opioid addiction, most of which have been small and industry-funded.\textsuperscript{240} Although Vivitrol has been approved by the FDA for opioid treatment, the approval was based on a single trial in Russia, where the requirements for drug efficacy and safety are far looser.\textsuperscript{241} The one existing study comparing buprenorphine versus Vivitrol concluded that both are equally effective in preventing relapse—that is to say, not very effective.\textsuperscript{242} There have been studies showing high dropout rates, as well as ones finding that the subjects returned to opioid use while taking Vivitrol or after going off it.\textsuperscript{243} Thus, prisoners or convicted offenders participating in drug court programs are literally experimental subjects for Vivitrol’s maker.

Alkermes has been heavily lobbying criminal justice policymakers to make their treatment the only one available to pre-release and released prisoners who need addiction treatment.\textsuperscript{244} This would mean that prisons, jails, and drug courts could force addicts to take Vivitrol as their only alternative to incarceration.\textsuperscript{245} Alkermes has been extremely active at the state level, where most decisions about drug treatment and alternate corrections are made.\textsuperscript{246} In 2016 alone, the company spent $4.4 million on federal lobbying; not coincidentally, 2016 sales for Vivitrol were $209 million, and Alkermes predicts that sales could reach $1 billion by 2021.\textsuperscript{247}

Alkermes has marketed directly to drug court judges and correctional facilities, including halfway houses, to push its product.\textsuperscript{248} For example, at least eight drug courts in Indiana only allow Vivitrol as an opioid addiction treat-

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\textsuperscript{241} Id.
\textsuperscript{243} See Goodnough & Zernike, supra note 232.
\textsuperscript{245} Szalavitz, supra note 240.
\textsuperscript{246} See MacGillis, supra note 239.
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ment, excluding any other medication. Vivitrol is two to three times as expensive as other, generic treatments, such as methadone and buprenorphine.

The multiplicity of problems with Vivitrol makes it unsuitable for use in medical research studies or as a required medication for pre-release prisoners, parolees, individuals on probation, and residents in drug court-ordered halfway housing. Nonetheless, Vivitrol has been routinely and repeatedly tested on inmates, and its use is sometimes required for individuals to be eligible for participation in certain drug courts. Given the serious side effects, expense, and uncertain efficacy of the drug, this kind of medical experimentation with those in the state criminal justice system is unacceptable.

2. Modern Medical Experiments in Prisons

Despite the federal rules and regulations in place, a surprisingly large amount of medical research takes place in correctional facilities, involving both children and adults. Medical experimentation on the incarcerated is alive and well.

As the corrections population has increased to almost 7 million individuals, this captive group has offered an irresistible subject pool to drug companies and medical test clinics. In prisons and jails alone, the number incarcerated has expanded to approximately 2.1 million, with the rest of the growth taking place during probation, parole, and other correctional alternatives.

The majority of research involving prisoners occurs outside the purview of 45 C.F.R. § 46, subpart C, which regulates the type of experiments that may be done to vulnerable populations. Subpart C regulations protecting prisoners do not extend to the vast majority of prison research participants. In addition, many prisoner experiments are being conducted without either review or approval by an IRB. The primary protection prisoners have from abusive medical research “hangs on a single thread, on a single federal regulation in

249 See id.
250 See Lopez, supra note 244.
251 Szalavitz, supra note 240.
252 See Gordon et al., supra note 230 (explaining one recent experiment conducted on prisoners).
253 INST. OF MED. OF THE NAT’L ACADS., supra note 212, at 58.
254 See id.
255 Under 45 C.F.R § 46.306(a)(2), prisoners may only be included as subjects when the research involves one of the following four categories: (i) a study of criminal behavior and studies of possible causes and effects; (ii) a study of prisons as institutional structures or of prisoners as incarcerated persons, with only minimal risk allowed; (iii) research on conditions particularly affecting prisoners as a class (permitted only after consultation with the Secretary of the Department of Health and Human Services (DHHS)); (iv) research on practices to improve the health and well-being of the subject (permitted only after consultation with the DHHS Secretary).
256 See INST. OF MED. OF THE NAT’L ACADS., supra note 212 at 30, 66.
257 Id. at 30.
federally funded research only.”

There have been numerous clinical trials and experimental therapies that not only violate the law but also subject inmates to inhumane medical risks. Indeed, conducting research on individuals has become an enterprise, and the incarcerated, now as always, present a perfect confined set of subjects.

In 2000, for example, the federal Office of Human Research Protections (OHRP) called off a variety of federally funded human experiments, all run by the University of Texas. The university had failed to follow federal regulations aimed at protecting research-study volunteers. Of the roughly 300 experiments suspended at the time, 195 involved Texas prisoners, with most testing HIV/AIDS drugs.

Universities often pair up with prisons to run experiments. In 1997, Dr. Hans Steiner, a Stanford psychiatrist, conducted an experimental drug trial on juvenile offenders held by the California Youth Authority (CYA). Steiner administered Depakote, a seizure disorder medication, to sixty-one young men, aged fourteen to eighteen, to see if the drug would reduce tendencies toward violent behavior. The Stanford IRB approved the research, allowing the CYA to consent for any children whose parents could not be reached after thirty days. Like all psychotropic medications, Depakote can have serious side effects, including serious liver damage, inflammation of the pancreas, bleeding, high blood ammonia levels, and suicidal thoughts and actions.

The Stanford CYA Depakote experiment illustrates the problem with relying on state statutes and various regulatory bodies to regulate such medical experimentation on children. In California, a “tangled, contradictory web of state and federal laws govern[s] medical research on prisoners and chil-

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258 Id. at 64.
259 Id.
261 See id.
262 WASHINGTON, supra note 96, at 269.
263 Id.
264 Id.
265 See Reiter, supra note 9, at 524 (noting the doctor’s testing of a drug on children for an off-label purpose).
267 See Reiter, supra note 9, at 524.
One state statute directs that “[b]iomedical research shall not be conducted on any prisoner in this state.” But another statute, passed to allow inmates access to experimental HIV and AIDS medications, allows prisoners to be prescribed “investigational new drug[s]” that are only available through treatment protocols if it is in “the best medical interest of the patient . . . .” These loopholes mean improper human subject research can flourish unnoticed. Given the multiple cracks in the system for oversight of prisoner research, we need stronger, more absolute controls on such medical experimentation on inmates.

B. Children

Children, whether imprisoned or otherwise captive, are another tempting target for human medical research. This is especially true when parental consent concerns are either abrogated or diminished.

1. Wards of the State

Medical research on infant state wards is minimally regulated. Most wards of the state are children who have been removed from their parents due to mistreatment or abandonment, when legal custody of the child reverts to the state. These children primarily live in foster family homes, although approximately nineteen percent live in institutions or group homes. The abuse and neglect already suffered by wards of the state should not be further exacerbated by inappropriate medical research experimentation.

The medical research conducted by the National Institutes of Health (NIH), testing AIDS drugs on foster children, shows the harms that can arise without careful oversight. For fifteen years, beginning in the 1990s, various scientific researchers tested AIDS drugs on hundreds of foster children in stud-
ies funded by the NIH. The research studies were administered in seven states—Illinois, Louisiana, Maryland, New York, North Carolina, Colorado, and Texas—and involved more than forty-eight separate experiments. The ages of the foster children enrolled ranged from infants to the late teens.

Several of the experiments using enlisted foster children were very risky, involving early Phase I and Phase II research to determine side effects and safe dosages, so children could begin taking adult AIDS medicine cocktails. Many of the children had to be forced to take the medicines, which routinely caused vomiting and diarrhea, and those who refused were often put on stomach tubes to force the medications.

Due to the toxicity and strength of the drugs, several of the foster child experiments reported serious side effects such as “rashes, vomiting and sharp drops in infection-fighting blood cells,” particularly when the children took experimental antiretroviral drugs in the hopes of suppressing AIDS, or tried other experimental medicines to treat secondary infections. One experiment, which administered high doses of an experimental drug to the children, had a disturbingly high death rate. A safe and effective dose was never determined.

Very few of these foster care children received advocates or independent monitors to oversee their needs, despite the research institutions’ promise to provide them. Moreover, NIH failed to track whether children were appointed advocates, leaving the decision up to volunteer medical review boards at each research study location. Some of the experimenters believed that children as young as five were old enough to provide their consent. In addition,

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278 Id.
279 Id.
280 Phase I testing is usually to determine a drug’s toxicity. See Vera Hassner Sharav, AIDS Drug/Vaccine Experiments on Foster Children, AHRP (Sept. 8, 2005), http://ahrp.org/aids-drug-vaccine-experiments-on-foster-children/ [https://perma.cc/8WGT-7GA4].
281 Id. Phase II testing is typically used to assess whether a drug has any impact on the intended disease. See id.
282 See Solomon, supra note 277.
284 See Solomon, supra note 277.
285 Id.
286 Id.
287 Id.
288 Id.
289 Id.
the foster and/or biological parents were not always consulted before the treatments were prescribed.  

At the end of these experiments, only some of the drugs were approved for children, while others were rejected due to their toxicity and troubling side effects. In one research experiment testing dapsone, for example, “at least ten children died from a variety of causes, including four from blood poisoning.”

Further, the funding from the NIH was premised on testing experimental AIDS drugs and vaccines on a wide range of children in foster care, including infants and children who were only “presumed” to be HIV-infected. This was justified on the basis of one researcher’s finding that “[t]he incidence of transmission of HIV from an infected mother to her offspring is estimated to be in the range of 5%–40%.” Accordingly, foster children who may never have developed AIDS were given drugs that had fatal risks and severe adverse effects, all for non-therapeutic purposes.

Finally, several HIV vaccines were tested on children without HIV. One of the reports resulting from the study of an experimental AIDS vaccine noted that 125 immunized children were not infected with HIV. Another study, testing two experimental vaccines, acknowledged that 157 newborn infants were sought and utilized.

Clinical trials testing brand new pharmaceuticals on foster children continue to take place today. In 2009, seven-year-old Gabriel Myers, who had been prescribed Vyvanse and Symbyax, took his own life in his Florida foster home. Gabriel was among a number of Florida foster children enrolled in pharmaceutical clinical trials by his doctor, Dr. Sohail Punjwani.

Neither informed parental consent nor judicial authorization for administering psychotropic medications was obtained for the foster children participat-

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290 See id.
291 Id.
292 See Sharav, supra note 280.
293 Id.
294 Id.
295 Id.
296 See id.
297 See id.
ing in the drug trial. Following an investigation into the death, Florida banned the use of foster children in clinical drug trials, over the protest of the FDA. Despite the ban, however, Psychiatric Solutions, a Florida residential treatment programs operator, successfully added an amendment to the ban allowing the administration of “mental-health drugs to young foster children for three days without the consent of a parent or judge.”

Policies for enrolling foster children into clinical drug trials vary by state and county. Many child psychiatrists who treat foster children have close ties to the pharmaceutical industry and have received serious financial inducements to prescribe mood-altering pharmaceuticals, especially antipsychotic drugs. There are tremendous amounts of money available to pediatric drug researchers, and with industry funding comes great pressure on the researchers to speedily produce results.

Between 2010 and 2013, for example, pharmaceutical companies gave $14 million to psychiatrists treating California foster children. California’s foster care doctors received double the payment of the average California doctor during that time. Unsurprisingly, the doctors who prescribed the most antipsychotics and other psychotropic medication received the most money. Between 2010 and 2013, one doctor in southern California, Bhatia Prakash, received over $2.58 million for “research,” and another, Steven Volk, received over $2.18 million for the same. A large portion of this “research” money went to funding clinical trials to test psychotropic drugs on foster children.

Seven of the twenty-five California doctors with the highest prescription count in this period were conducting research for psychotropic drug compa-

306 See id. (noting the results of an investigation conducted by Mercury News).
307 See id.
308 See id. (displaying a map of payments to doctors in California).
309 See id.
Many of these drugs have severe side effects. For example, Zyprexa, a common psychiatric medication created to treat severe mental illness, which is often prescribed for child behavior problems, can lead to weight gain, exacerbation of diabetic conditions, and tardive dyskinesia, which can be irreversible.

This use of foster children as unwitting participants in clinical trials is particularly disturbing, given that almost twenty-five percent of California foster care adolescents are prescribed psychotropic medications. Often these medications are prescribed to control unwanted behavior instead of severe mental illness, the only condition for which the drugs are approved. Foster children do not have to consent to the use of these medications. These children are viewed as “the bottom of the ladder in our society,” so it is unsurprising that “[t]he experimentation, the drug cocktails, the first-line drugging typically starts with the group that’s the least protected.”

Over the past five to ten years, investigations in five states have uncovered that hundreds of foster children were prescribed excessive doses of various psychotropic drugs. These prescriptions were also given to younger children, even though there is no evidence to support such a use. These foster children represent attractive subjects to drug companies because they are a “captive audience:” either the foster parent or staff member ensures that the child takes the pills, thereby eliminating any compliance issue in long-term testing or research.

Many powerful anti-psychotic drugs are prescribed to foster children to treat behavior problems, which is an off-label use not approved by the FDA.
The majority of these psychotropics comes with serious side effects, including “breast growth in boys, cardiac arrest, extreme weight gain and diabetes.”\textsuperscript{321} Often one anti-psychotic is prescribed in tandem with another, and for long durations of time, not just as emergency short-term measures.\textsuperscript{322} These antipsychotics are prescribed to children in foster care at a disproportionate rate, frequently for children diagnosed with attention deficit and hyperactivity disorder (ADHD), instead of schizophrenia or bipolar disorder, for which these psychotropics are specifically designed.\textsuperscript{323} There is little evidence supporting the use of antipsychotics for treatment of ADHD in children.\textsuperscript{324}

Overall, both the NIH and its OHRP have worked to create “greater participation of children in research, despite general concerns regarding human subjects’ protections more generally.”\textsuperscript{325} This is a reversal of the traditional government policy of “children last.”\textsuperscript{326} When applied to highly vulnerable and captive children, this new policy is untenable—there is seemingly no one standing at the helm.

2. Extreme Poverty and Critical Illness

Children who are in extreme poverty or suffering from critical illness should also have scrupulous regulation overseeing any medical research performed on them, as they also consist of a captive population: captive in either their hospital or impoverished/dangerous surroundings. Like foster children, these vulnerable children need special protection from medical research that uses them in non-therapeutic ways.

a. Extreme Poverty

In 1992, the New York State Psychiatric Institute and Mt. Sinai Medical School enrolled approximately 150 young minority boys for a clinical trial testing the effect of a drug on children with ADHD.\textsuperscript{327} Some of the boys were younger siblings of children adjudicated as juvenile delinquents.\textsuperscript{328} These chil-

\textsuperscript{321} See id.

\textsuperscript{322} See Meredith Matone et al., \textit{Antipsychotic Prescribing to Children: An In-Depth Look at Foster Care and Medicaid Populations}, POLICYLAB EVIDENCE TO ACTION 6 (2015).

\textsuperscript{323} See id. at 7, 9.

\textsuperscript{324} See id. at 11.


\textsuperscript{326} Coleman, \textit{supra} note 304, at 544.

\textsuperscript{327} Nina Bernstein, \textit{2 Institutions Faulted for Tests on Children}, N.Y. TIMES, June 12, 1999, at B5.

\textsuperscript{328} Id.
Children were identified through court records from the New York Department of Probation, as well as by interviews of parents to find those who used “adverse rearing practices.” The parents were paid $125 for their children’s participation. The boys were given fenfluramine, and they had their neurochemical responses recorded in an effort to prove a theory linking aggression to a biological marker. After an outcry, federal medical ethics researchers criticized Mt. Sinai and the Research Foundation of City University of New York, but no charges were filed.

The Kennedy Krieger Institute (KKI), a Johns Hopkins-associated facility for disabled children, was similarly accused of exposing poor black children to “dangerous lead hazards” during a housing study. KKI promised to help parents find “lead-safe housing” for their lead-poisoned children, and simultaneously enrolled them in a research study. Yet researchers knew that the housing in which the families were placed by KKI was itself imbued with poisonous lead. As the class action lawsuit charged:

Children were enticed into living in lead-tainted housing and subjected to a research program which intentionally exposed them to lead poisoning in order for the extent of the contamination of these children’s blood to be used by scientific researchers to assess the success of lead paint or lead dust abatement measures . . . . These children’s health was put at risk in order to develop low-cost abatement measures that would help all children, the landlords, and the general public as well.

The lawsuit alleged that no medical treatment was provided for the children in the study, and exposure to the lead caused permanent neurological injuries in some of the children.

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330 Id.
331 Id. Fenfluramine was also known as now-banned diet drug Fen-Phen, which causes heart valve defects. See id.
332 See Diana Zuckerman, The Ethics of Inclusion and Exclusion in Clinical Trials: Race, Sex, and Age, in THE PENN CENTER GUIDE TO BIOETHICS 243, 255 (Vardit Ravitsky et al. eds., 2009).
333 See Bernstein, supra note 327.
335 See id.
Additionally, as the class action argued, the consent agreements signed by
the parents did not contain a full explanation of the research, which was specif-
ically designed to test the lead abatement process by checking how much the
children’s blood continued to be contaminated.338 “Lead-safe” was never de-
fined in the consent form, but a reasonable person would have likely inferred
that the housing provided was safe from lead threats to children.339 In 2001, the
Maryland Court of Appeals analogized KKI’s role in the lead-poisoning study
to the Tuskegee syphilis study.340 Lawsuits are still pending against the Kenne-
dy Krieger Institute for its actions.

b. Critical, Life-Threatening Illness

Medical experiments have also been performed on severely premature in-
fants without proper parental consent. In 2013, the U.S. Department of Health
and Human Services investigated a research study involving blood transfusions
for very premature infants.341 The study tested when blood transfusions should
be given to treat anemia. Premature babies were randomly assigned to either
one group receiving transfusions for mild anemia, or a second group receiving
transfusions only for severe anemia.342 The point of the study was to determine
the best method for preventing deaths and brain damage.343 The study was
conducted by the Neonatal Research Network, a collaborative effort between
academic medical center neonatal intensive care units across the United
States,344 and funded by NIH.345

Public Citizen, a consumer advocacy organization that reviews human
medical experiments,346 found two problems with the study. First, the research-
ers failed to inform parents of the risks inherent in pursuing an alternative meth-
od of treatment, as opposed to the standard care procedures.347 The parental con-

338 Complaint, supra note 336, ¶ 2.
339 See Harriet A. Washington, Limning the Semantic Frontier of Informed Consent, 4 J.L. MED.
& ETHICS 381, 388–89 (2016).
341 See Richard Knox, Another Study of Preemies Blasted Over Ethical Concerns, NPR (Aug. 23,
2013), https://www.npr.org/sections/health-shots/2013/08/23/214800726/another-study-of-preemies-
blasted-over-ethical-concerns [https://perma.cc/X9K6-P946].
342 See id.
343 See id.
345 Letter from Gregory P. Weaver et al., Pub. Citizen Health Research Grp., to the Hon. Kathleen
Sebelius, Sec’y of the Dep’t of Health & Human Servs., re: Transfusion of Prematures (TOP) Trial:
Does a Liberal Red Blood Cell Transfusion Strategy Improve Neurologically-Intact Survival of Ex-
346 See Ethics and Clinical Trials, PUB. CITIZEN, https://www.citizen.org/our-work/health-and-
safety/ethics-and-clinical-trials [https://perma.cc/S7MF-XNTC].
347 See Knox, supra note 341.
sent form also failed to disclose that the restrictive transfusion group—where blood was only transfused at the danger point—was riskier than being in the other group.\textsuperscript{348} In addition, all the consent forms contained misleading information that equated participation in the study with receiving customized care for the infant, with most forms indicating that the trials had no risk.\textsuperscript{349} In other words, the parental consent forms did not allow the signers to make a truly informed decision.\textsuperscript{350}

Second, the design of the infant blood transfusion study failed to set up a comparison group receiving the typical customized care, a standard aspect of most modern research trials.\textsuperscript{351} The study also failed to provide a clear description of the standard transfusion practices at the participating hospitals.\textsuperscript{352} Public Citizen argued that these failures made adequate safety monitoring impossible, and accordingly, the risks to the premature infants were neither minimized nor reasonable.\textsuperscript{353}

These deviations from the regular standard of care and proper use of informed consent in infant research studies are not uncommon. From 2005 through 2009, a research study known as SUPPORT (Surfactant, Positive Pressure, and Oxygenation Randomized Trial) was performed on 1,316 premature infants who had breathing problems due to their early arrival.\textsuperscript{354} The infants were divided into two groups: one group provided with high blood oxygen levels, which can increase the risk of blindness, and one group provided with lower blood oxygen levels, which can increase the risk of neurodevelopmental disorders and death.\textsuperscript{355}

The researchers used “experimental measuring devices” with the intention of blinding the caregivers from knowing the babies’ actual oxygen levels. Moreover, the parents were never informed.\textsuperscript{356} This was done in the name of making the study more “rigorous.”\textsuperscript{357} The experiment’s researchers also told

\textsuperscript{348} Weaver et al., supra note 345, at 2. The restrictive transfusion group consisted of the group of infants who only received blood transfusions when their hemoglobin levels became exceptionally low. Id.

\textsuperscript{349} See id. For example, consent forms made no mention of the results of two earlier studies of the when-to-transfuse question. Knox, supra note 341. Both of these studies indicated that later transfusions had a higher rate of mortality, brain injury, and need for emergency transfusions. Id.

\textsuperscript{350} See Weaver et al., supra note 345, at 2.

\textsuperscript{351} See Knox, supra note 341.

\textsuperscript{352} Weaver et al., supra note 345, at 2.

\textsuperscript{353} See id.

\textsuperscript{354} See Editorial, Subject to Question, 500 NATURE 377, 377 (2013).

\textsuperscript{355} See id.

\textsuperscript{356} Alice Dreger, You Might Be in a Medical Experiment and Not Even Know It, DISCOVER MAG. (Jan. 31, 2017), https://www.discovermagazine.com/health/you-might-be-in-a-medical-experiment-and-not-even-know-it [https://perma.cc/MJ8E-XR8T].

\textsuperscript{357} Id.
the patients’ parents that the study did not have any special risk, because all the procedures carried out represented standard care.\footnote{Id.} This was untrue.\footnote{Id.}

Despite this serious failure in transparency for the participants, the issue-laden consent forms were reviewed and approved by all twenty-three medical center ethics committees involved, including those from Stanford, Yale, Duke, and Tufts.\footnote{Richard Knox, Feds Fault Preemie Researchers for Ethical Lapses, NPR (Apr. 10, 2013), https://www.npr.org/sections/health-shots/2013/04/10/176811809/feds-fault-preemie-researchers-for-ethical-lapses [https://perma.cc/X7TU-NX2E].} The parents of the 1,316 infants were never informed that the study carried increased risks of blindness, brain damage, and death to their newborn children.\footnote{See id.}

Recurring abuses of the most vulnerable populations of children illustrate how the current loose set of regulations and oversight are insufficient to protect the defenseless, particularly when there is more than a minimal risk of harm. The scientific and medical community is simply not able to police itself when it comes to medical experimentation on vulnerable children.\footnote{See Coleman, supra note 304, at 577–78 (explaining that even where researchers are well intentioned, children in families with limited means may still be harmed).}

\section*{C. Psychiatric Institutions}

Despite the variety of laws and statutes theoretically preventing the use of the mentally ill in medical experimentation, the practice still continues. Many psychiatric researchers “mistreat mentally ill [patients] in ways that would . . . provok[e] outrage . . . in other areas of medicine.”\footnote{See Carl Elliott & Emma Bedor Hiland, Exploiting Vulnerable Citizens, in BIOCITIZENSHIP: THE POLITICS OF BODIES, GOVERNANCE, AND POWER 133, 142 (Kelly E. Happe et al. eds., 2018).}

Some of the most troubling experiments have been the “symptom provocation” or “challenge” studies, where previously stable mentally ill patients were given amphetamines, ketamine, or other psychoactive drugs to provoke a psychiatric episode.\footnote{See id.} These experiments typically had a long-lasting, negative effect on the patients, because after a relapse—particularly a first relapse following an initial psychotic break—some patients never return to the same level of mental health.\footnote{See Robert Whitaker & Dolores Kong, Testing Takes Human Toll, BOS. GLOBE, Nov. 15, 1998, at A1.} In addition, schizophrenic patients tend to suffer significantly higher rates of self-harm and suicide during a relapse.\footnote{Id.} Repeated psy-
chotic relapses for a schizophrenic patient very frequently lead to a worse long-term outcome.367

The sole purpose of these challenge experiments was to induce psychosis in the patients for the benefit of the researchers.368 These researchers, in pharmaceutical experiments conducted nation-wide, have repeatedly failed to inform their mentally ill patients of the risks inherent in these studies, thus keeping their patients in the dark as to the true purposes of the research.369 Consequently, the researchers cannot possibly obtain proper consent.370 The symptom-provocation experiments at the University of Maryland, University of California Los Angeles, and the National Institute of Mental Health have used similarly faulty informed consent mechanisms.371

Likewise, Yale University researchers performed experiments that subjected stable schizophrenia patients to psychotic relapse in an amphetamine provocation experiment, in conjunction with a Veterans Affairs (VA) hospital.372 The men, in one instance, were injected with m-chlorophenylpiperazine to induce psychosis.373 These injections exacerbated the patients’ delusions and hallucinations374 Yale also recruited schizophrenic patients for experiments where the individuals were hospitalized, their medications halted, and they were then given infusions of “tetrahydrocannabinol, the psychoactive ingredient in marijuana.”375

As a whole, medical experiments on the mentally ill, particularly those who are confined, are underregulated, and often veer into the unethical. In Georgia, for example, Drs. Richard Borison and Bruce Diamond tested multiple psychiatric drugs on schizophrenic patients, using all sorts of inducements to get them to agree to testing.376 Dr. Borison, who was the chief of psychiatry for the Augusta VA Hospital, hired mainly female staffers to coax schizophrenic patients into consenting to the trials by, for example, offering cigarettes to patients in locked wards in exchange for participation.377 Such a travesty of informed consent has no place in modern medical research.

Similarly, in 1995, a New York state trial court ordered the New York State Health Department to cease conducting hundreds of experiments on vul-

367 Id.
368 See Elliott & Hiland, supra note 363, at 142.
369 Whitaker & Kong, supra note 365.
370 See id.
371 Id.
372 Id.
373 Elliott & Hiland, supra note 363, at 142.
374 Whitaker & Kong, supra note 365.
375 Id.
377 See id.
nerable patients deemed to be incompetent to give consent. The 400 ongoing New York psychiatric experiments, costing roughly $52 million, were overseen by the New York Office of Mental Health and involved hundreds of institutionalized psychiatric patients who were undergoing experimental drug treatments for a variety of mental illnesses.

In many of these cases, it was the relatives and friends of the patients who had given their consent, not their parents or guardians. The court order halted all experiments on adult psychiatric patients who were unable to give consent, nontherapeutic experiments on children, and experiments where the child’s parents had not given consent.

The New York appellate court upheld the trial court’s order, holding the regulations allowing such medical experimentation without proper consent to be invalid. The court made clear that New York could no longer administer “experimental antipsychotic and psychotropic drugs, which are capable of causing permanent harmful or even fatal side effects[, or use] highly invasive painful testing procedures on subjects,” particularly when the experiments lacked therapeutic benefit.

In addition, the court found that the preparation phase of the research study was untenable. Several of the studies involved required a medication-free or placebo phase, where the subjects swapped their current medication for an experimental medication, frequently causing relapse and adverse symptoms. The court specifically noted the “cost in human pain and suffering to those subjects who are not capable of expressing either their consent or objection to participation[.]”

Using mentally ill patients in medical research studies continues. Between 2002 and 2005, three anti-psychotic drugs were tested out on psychiatric inpatients, at least one of whom was enrolled in the trial involuntarily or without consent. Known as the Comparison of Atypicals in First Episode of Psycho-

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379 Id.
380 Id.
381 Id.
383 See id. at 98.
384 See id.
385 See id.
386 Id. at 100.
sis, or CAFE study, the medical experiment was funded by AstraZeneca, the manufacturer of Seroquel, and done in partnership with the University of Minnesota. The research trial required 400 patients in the midst of their first psychotic episode to take an assigned anti-psychotic drug for a complete year.

The CAFE study had serious risks. It required patients to stay on their assigned drug, regardless of its therapeutic success or lack thereof. In addition, the experiment strictly limited access to drugs needed to ease the very serious side effects and symptoms of the trial drugs.

At least one of the patients was enrolled in the anti-psychotic study without proper consent. On November 12, 2003, Dan Markingson was involuntarily hospitalized for psychosis and mood disorder by Dr. Stephen Olson, and was judged unable to make decisions about his medication. On November 20, 2003, however, Dr. Olson changed course and asked the court to temporarily suspend the involuntary commitment of Markingson. The next day, Markingson was enrolled in the CAFE study by a social worker. Dr. Olson was one of the lead researchers in the study.

Markingson was now judged capable of consenting to a clinical trial of antipsychotic medications. The consent form was read to Markingson out loud, and he allegedly consented.

Clinical trials of antipsychotic drugs do not typically allow patients with a risk of suicide or violence to participate, in order to reduce the likelihood that...
they will harm themselves or others during the experiment.399 Here, however, the CAFE trial did allow patients who presented such risks to enroll.400 This included Markingson.401 The study had poor enrollment numbers and was facing probation, so it is likely there was some pressure to recruit questionable patients.402

Despite Markingson’s mother’s protestations about her son’s enrollment in the clinical trial, she was unable to remove him from the experiment, or change his medication protocol.403 No surrogate decisionmaker was ever appointed for Markingson.404 Approximately six months later, when he was still part of the CAFE medication trial, Markingson died by suicide in his halfway house.405

By the time the CAFE medical trial concluded, there were eighteen “serious adverse events” reported from the 400 patients, including an alleged homicide, three suicide attempts, and two deaths by suicide (both by patients taking Seroquel).406 As part of the clinical trial, AstraZeneca paid the University of Minnesota Psychiatry Department $15,648 for every patient who completed the CAFE study. This amounted to $327,000 in revenue for the Department.407 Minnesota also required the study coordinator for the CAFE study to do eighteen hours of continuing education as part of a “corrective action” for enrolling patients without full consent.408 In 2015, the University of Minnesota halted patient enrollment in all psychiatric drug studies after being criticized in a state report for its handling of the Markingson suicide.409

Clinical trials continue on both adult and adolescent inpatients with severe depression and suicidal ideation. Janssen Laboratories, a subsidiary of Johnson & Johnson, is currently running research studies using intranasal esketamine (aerosolized ketamine) on inpatient adolescents and adults who are

400 See id.
401 See id.
402 See Stone, supra note 393.
403 See id.
405 See Elliott, supra note 387.
406 See id.
407 See id.
408 Elliott, supra note 395.
suffering from severe, treatment-resistant depression and are at imminent risk for suicide. In one clinical trial currently being performed at Yale University, adolescents between twelve and seventeen are testing intranasal esketamine, comparing the reactions to adolescents taking a psychoactive placebo (oral midazolam). The intranasal esketamine will be compared to the midazolam to determine which is better at reducing the symptoms of major depressive disorder, including suicidal ideation, for those teenagers who are assessed to be at imminent suicidal risk.

Notwithstanding the promotional efforts of pharmaceutical companies, however, it is unclear whether using esketamine instead of the standard anti-depression drugs to relieve treatment-resistant depression really makes a significant difference. In addition, the side effects of long-term ketamine use for depression are essentially unknown. Common side effects of repeated ketamine use include urinary tract symptoms, liver toxicity, cognitive changes, ulcerative cystitis, neurocognitive deficits in working and episodic memory, and dependence.

Testing such a potentially addictive drug on inpatient mentally ill adolescents is questionable, particularly because their level of depression may make their parents or guardians desperate to try any new treatment, even one with significant potential side effects and the possibility of long-term dependence. Suicidal teens are another vulnerable population that should be prohibited from participating in any human medical experimentation.

Despite all of these dangers in conducting experiments testing anti-psychotics and other anti-depressants, such clinical research trials continue, particularly when the drugs in question are patented, name-brand medications. The financial pressure to test and bring to market new mental illness drugs is
intense, given that anti-psychotics are the top-selling class of drugs by revenue. 416 “Successful clinical trials are the lifeblood of biotech companies,”417 because profits depend on the development of new drugs, which require human medical experimentation. The strong industry desire to experiment on the seriously mentally ill should not be permitted, however, particularly when the subjects are captive and vulnerable.

D. Residential Centers for the Disabled

In November of 2019, the Department of Justice (DOJ) started investigating whether caretakers at the Glenwood Resource Center, an Iowa residential home for the intellectually disabled, had been performing experiments on hydration and sexual arousal upon their patients.418 Many of the residents at the residential home are unable to walk, speak, or feed themselves.419 The residents are medically fragile, and they include both children and adults who are physically and/or intellectually disabled.420 “Harmful and uncontrolled human subject experiments” are alleged to have taken place at the Glenwood center, including one study on sexual arousal of patients and one study on “optimal hydration” in treating pneumonia.421 According to reports from guardians of residents at the center, Glenwood has not requested permission from parents or guardians to perform any such experiments on the residents.422 The DOJ is also investigating “inadequate medical, nursing . . . and behavioral health care, harmful restraint practices and incidents of needless physical injury.”423 Even

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422 Id.
in the 21st century, it seems, performing human medical experiments upon the captive and vulnerable is still within the bounds of acceptable.

III. CAPTIVE MEDICAL EXPERIMENTATION GOING FORWARD: INFORMED CONSENT, PRIVACY, AND PROFITS

The severe restrictions on freedom and liberty, as well as the complicated role of the medical and drug industries in clinical research, mean that any potential medical research involving vulnerable, captive subjects has tremendous challenges.  

A. Informed Consent

A patient’s informed consent is required for any medical treatment or procedure. The main goal of informed consent is to protect the autonomy of those patients receiving medical treatment or acting as research subjects. Essentially, informed consent requires medical professionals and researchers to adequately disclose material information of the proposed treatment so that patients can make knowledgeable choices. More specifically, informed consent requires a wide-ranging disclosure of comprehensive information about risks, benefits, and alternative forms of treatment. Since the 1970s, voluntary informed consent has been a prerequisite to enrolling human subjects for medical experimentation. The purpose of informed consent is to ensure that potential participants have adequate information, relayed in layman’s terms so that the subject can voluntarily choose whether to participate.

The doctrine of informed consent has been a failure in many ways. Although attractive in theory, informed consent has not truly allowed patients to make informed decisions about their diagnoses and treatments to match their preferences. The failure rate for actually understanding informed consent

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424 See INST. OF MED. OF THE NAT’L ACADS., supra note 212, at 55.
425 Cummings, supra note 298, at 363.
428 See id. at 1081.
forms is greater than ninety percent.432 Patients cannot express their preferences if they do not fully comprehend the potential procedures,433 thereby obviating the “informed” aspect of their consent. As Dr. Jay Katz famously noted, “informed consent in today’s world is largely a charade which misleads patients into thinking that they are making decisions when indeed they are not.”434

If attaining true informed consent from human subjects is challenging, it is even more difficult in institutional, correctional, or foster care settings. Many prisoners have poor reading and communication skills;435 many institutionalized subjects do not have complete cognitive abilities; and foster parents are often not fully cognizant of what they are signing.

Despite the difficulty of obtaining true informed consent, informed consent documents frequently require a college-level reading comprehension.436 The writing is loaded with medical jargon and frequently uses unfamiliar drug terminology, further confusing readers.437 In addition, the extreme length of many informed consent forms makes it unlikely they are comprehensively read and understood, even by sophisticated readers.438

There tends to be a communication barrier between medical researchers and their subjects, especially when these experiments are non-therapeutic, as many drug studies tend to be.439 The potential dangers and risks to the individual are often unclear, and people too often “trust institutions they know or are blinded by hope that they will benefit.”440

Moreover, when the research results are published, readers of the study will take the authors at their word when they assert that the subject consented or an IRB approved, even when the validity of that consent is questionable.441 There is little accountability for the researchers and doctors involved in medical experiments on vulnerable populations, because there is minimal follow-up

432 *Id.* at 12.
433 *Id.* at 12–13.
436 See INST. OF MED. OF THE NAT’L ACADS., supra note 212, at 38.
437 See Washington, supra note 339, at 388–89.
438 See id.
440 See id.
on whether patients have truly granted informed consent.442 Further, “what researchers believe to be ethical might not actually fulfill the basic requirements of informed consent or ethical research.”443

The question of informed consent is doubly complicated for those in correctional facilities. Prisoners tend to have lower levels of education than the general population, and are frequently unfamiliar with medicine and health care in general.444 In addition, a high percentage of inmates suffer from serious infectious diseases and major psychiatric disorders, both of which might make the comprehension of a complicated informed consent form extremely difficult.445 Any of these aspects individually prevents an inmate from fully comprehending the information relevant to deciding to participate in medical research; serious illness, whether physical or mental, can limit the capacity of the individual subject.446 Taken all together, it makes truly informed consent to such experiments virtually impossible.

Further, even when technically granted, an inmate’s consent should not be regarded as truly voluntary.447 The structure of life in both jail and prison leads to circumstances that erase any ability to realistically consent. In the world of correctional facilities, inmates are continually under the threat of duress, and thus must always be on alert to comply with directions and follow the rules.448 Inmates’ physical safety and well-being relies on their ability to listen to those who have authority over them.449 Because of their imprisoned status, inmates, who by law have many fewer rights, are frequently under “direct or subtle coercion, including risks, threats, or acts of physical and even sexual assault.”4450 This constant coercive pressure limits inmates’ ability to make their own decisions about medical experiments or drug trials because of their powerless position.451

In addition, lack of adequate health care can create a “coercive influence.”452 Many offenders join investigative trials because it is the only way to access medical care.453

442 See id. at 366.
443 Id.
445 See id.
446 See id.
447 See id.
448 Id.
449 Id.
450 Id.
451 See id.
452 INST. OF MED. OF THE NAT’L ACADS., supra note 212, at 56.
Patients in mental health institutions also may not be able to fully comprehend to what they have consented. The strong likelihood of impaired capacity within this group renders the population especially vulnerable. True informed consent can be extremely elusive in such circumstances. Often patients are asked to sign a stack of consent forms all at once, without sufficient time to read or digest them. The sheer volume of the materials raises the question of whether any individual, let alone one with serious mental illness, could know and understand the contours of the research.

The difficulty with obtaining true informed consent persists even with less vulnerable populations. A recent study, focused on adult participants in cancer clinical trials, found that many subjects “had poor understanding of essential elements of their trial,” despite reading and signing often-elaborate informed consent forms. In particular, at least eighty percent of patients were not able to respond correctly to three key types of questions in the consent form: (1) questions that addressed the experimental nature of their trial therapy; (2) questions about the trial’s purported efficacy; and (3) the potential risks relative to alternative treatments. This was despite the fact that most of the patients were “white, native English speakers,” with half having at least some college education.

Such low levels of comprehension raise serious questions about the quality of informed consent in many clinical trials, given that these particular patients should have been able to answer the questions. Part of the problem often is the length and complexity of the informed consent forms, because the content is frequently shaped with the intent of shielding the research institution and/or trial sponsor from liability, rather than focusing on the needs of actual human subjects. The attempts to shorten and simplify the informed consent forms have not really improved comprehension of key elements or associated risks, however, despite higher patient satisfaction.

In response to these problems, some researchers have advocated getting rid of informed consent forms entirely and replacing them with in-person medi-

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453 See id.
454 Lamkin & Elliott, supra note 9, at 1058.
456 See id.
458 See id.
459 See id. at 4.
460 See id. at 2.
461 See id. at 8.
tical counseling.\textsuperscript{462} This would involve in-person discussions about the relevant risks and benefits inherent in the experimental treatments, as well as the alternatives.\textsuperscript{463} Although in-person discussions would take more time and money, this may be one of the few ways to obtain truly informed consent from non-vulnerable populations. Given the costs, however, such in-depth medical counseling is unlikely to replace consent forms any time soon.

Vulnerable, captive populations—those people who are incarcerated, institutionalized, in foster care, living in extreme poverty, or suffering severe illness—should not be able to consent to human medical experimentation. Many of these patients are viewed as “sickly, unproductive, and unhappy,” and thus clinical researchers might see little value in their lives and health.\textsuperscript{464} The patients themselves may nonetheless understandably feel quite differently, even if they cannot communicate fully due to cognitive or psychological impairments. We must be especially careful to protect the autonomy and bodily integrity of these individuals, along with all other vulnerable, captive subjects.

B. Privacy and Confidentiality

Maintaining confidentiality during clinical research and experimentation is a critically important component of research ethics.\textsuperscript{465} Confidentiality and privacy require maintaining the anonymity of human research subjects, both as a matter of respect to the patient and as a matter of the patient’s comfort in disclosing their information when anonymity is promised.\textsuperscript{466}

The maintenance of confidentiality in research is encouraged by numerous federal research guidance regulations.\textsuperscript{467} The Health Insurance Portability and Accountability Act (HIPAA)\textsuperscript{468} and the Common Rule govern the information collected in clinical trials. The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes.\textsuperscript{469} As discussed above, the Common

\textsuperscript{462} See id. at 1–2.
\textsuperscript{463} See id. at 10.
\textsuperscript{464} See Schwartz, supra note 426, at 123.
\textsuperscript{466} See id. at 336.
\textsuperscript{467} See Deven McGraw et al., Privacy and Confidentiality in Pragmatic Clinical Trials, 12 CLINICAL TRIALS 520, 522 (2015).
\textsuperscript{468} The federal Medical Privacy Rule, authorized by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), limits how covered physicians may use and disclose protected health information (PHI) for any purpose.
\textsuperscript{469} See 45 C.F.R. §§ 164.501, 164.508, 164.512(i) (2018). Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances.
Rule governs the ethical conduct of human research in circumstances in which the research is federally supported or being conducted by an institution that has agreed, in an assurance agreement, to be bound by federal research rules.\textsuperscript{470} Under the Common Rule, IRBs have the responsibility for ensuring that federally funded research adequately protects the privacy of the research subjects and maintains the confidentiality of patient data.\textsuperscript{471}

Violators of the HIPAA Privacy Rule may be subject to civil and criminal penalties. These penalties, however, fall primarily on covered entities, such as health plans and health care providers.\textsuperscript{472} The individual researchers themselves are not covered by the Privacy Rule,\textsuperscript{473} and thus may follow it less strictly.

In addition, patient dignity suffers harm when medical information is shared without specific consent.\textsuperscript{474} This is all the more true for vulnerable, captive populations, who often are unable to fully grant their consent, or may even be seen as not needing or deserving such protection and autonomy.

Maintaining privacy for a vulnerable, captive subject can be extremely difficult. In correctional facilities, confidential health information can often be deduced from an inmate’s routine, a cell search, or regular visits.\textsuperscript{475} In addition, any health or medical information that would normally be kept private may have to be shared with correctional officials to avoid danger or the spread of disease.\textsuperscript{476}

For those individuals who are being treated for mental illness in facilities, whether prisons, psychiatric hospitals, or long-term care homes, the sharing of private medical information might disclose data that they do not wish to be exposed, particularly if their files contain sensitive and/or upsetting diagnoses.

Beyond that, patients who have their sensitive medical information exposed can suffer harm in the employment and health insurance markets, in addition to reputational harm.\textsuperscript{477} Although people from all backgrounds can face these problems, it is a particular issue for those who rely on public benefits, such as those in nursing homes, foster care, and psychiatric institutions, be-

\textsuperscript{470} The “Common Rule” was jointly promulgated by twenty-eight federal entities to implement the provisions of the Federal Research Act, creating a uniform set of standards and procedures. \textit{See generally} 45 C.F.R § 46. The Common Rule also requires the creation of oversight bodies such as IRBs. \textit{See id.} §§ 46.107–.109.

\textsuperscript{471} \textit{See id.} § 46.107.

\textsuperscript{472} \textit{See} 42 U.S.C. §§ 1320d-5 to -6 (2012).


\textsuperscript{475} \textit{Inst. of Med. of the Nat’l Acads.}, \textit{supra} note 212, at 56.

\textsuperscript{476} \textit{See id.}

\textsuperscript{477} \textit{See Konnoth, supra} note 474, at 1319–20.
cause regulations have increasingly facilitated the collection and public use of this particular data.478

An increasing amount of health information is collected from individuals in public benefits programs such as Medicaid and Medicare. These patients tend to be poorer, sicker, older,479 and more vulnerable to breach of private health information damages—particularly those in captive settings. Vulnerable patients should not be subjected to potential extra violations of confidentiality, because their privacy and autonomy are already at risk.

Finally, similar to informed consent, many patients are confused about the “basic ethical, legal, and practical limits on medical confidentiality.”480 In particular, the word “confidential” is not always understood, and many patients seem confused over which aspects of their medical information are protected.481 If this is true of a great many patients in general, how much truer will it be of those individuals who are vulnerable, captive subjects?

There are simply too many problems with privacy and confidentiality to allow vulnerable, captive populations to participate in human research. Even if these individuals do agree to share their private medical records and information, it is often without full understanding. Although sometimes the guardians or parents of these vulnerable, captive populations might consent to waiving medical confidentiality, the individual does not always agree (or was never asked).

Finally, IRB committees, which are the primary regulatory bodies concerned with patient privacy and confidentiality, were largely designed with the intent to “review trial design, risk-benefit ratios, and informed-consent document” compliance, not to safeguard human privacy and autonomy.482 As I discuss in Part IV, we need much stronger controls and oversight over all human medical experimentation, but particularly over vulnerable populations.483

C. Profits

The profit motive intertwines with modern human medical experimentation. Pharmaceutical companies have tremendous financial incentive to test

478 See id. at 1320.
479 See id. at 1325.
481 See id. at 664.
482 See Carl Elliott & Roberto Abadie, Exploiting a Research Underclass in Phase 1 Clinical Trials, 358 NEW ENG. J. MED. 2316, 2317 (2008).
483 See infra notes 521–599 and accompanying text.
new or patented drugs on a variety of captive subjects.484 Clinical research has transformed from an academic endeavor to a massive industry, where numerous enterprises work in tandem with private doctors, hospitals, and university research centers.485 Due to the pressure from the drug companies to finish their studies as quickly as possible, doctors who are financially invested in clinical research sometimes persuade patients to take medications that are inappropriate or even unsafe on an experimental basis.486 Patient rights can be lost in the hustle.487

Physicians who conduct full-time commercial drug research routinely report earning over $1 million in revenues every year, booking profits of $300,000.488 The development of psychiatric drugs is particularly big business. Although new antipsychotic drugs have revolutionized the lives of people living with schizophrenia and other psychiatric illnesses, the clinical testing of these medications often results in a conflict between the pursuit of money and proper patient care.489 This tension between financial incentives and proper care has created “a landscape tarnished by the greed of some rogue investigators and repeated instances of patients being harmed.”490

To take a recent example of the power of the drug and medical industry, it is instructive to look at the Best Pharmaceuticals for Children Act (BPCA).491 The BPCA was passed in 2002 through an aggressive lobbying push that targeted various pediatric research interests, including industry executives, government enterprises, and “industry supported organizations such as the American Academy of Pediatrics.”492

Although safe and ethical clinical testing of pediatric medications is a laudable goal, there is frequently a conflict of interest when the drug maker sponsors the research. When industry funds the research, the medical journal

486 See id.
487 See id.
488 See Whitaker, supra note 376.
489 See id.
490 Id.
491 The BPCA was enacted into law in 2002, reauthorized in 2007 under the FDA Amendments Act, again in 2012 under the FDA Safety and Innovation Act, and most recently in 2017 through the FDA Reauthorization Act. Its goals are: (1) “[t]o encourage the pharmaceutical industry to perform pediatric studies to improve labeling for patented drug products used in children, by granting an additional 6 months patent exclusivity”; and (2) for the “NIH to prioritize therapeutic areas and sponsor clinical trials and other research for off-patent drug products that need further study in children.” BPCA, NICHD, https://bPCA.nichd.nih.gov/Pages/default.aspx [https://perma.cc/8MC7-EPUT].
492 See Sharav, supra note 484, at 19.
findings are often biased in favor of the sponsor’s interests. Research sponsored by nonprofit organizations do not exhibit such a bias.

The intimate ties doctors have with the drug industry span all corners of medical research. Recently, Dr. José Baselga, the chief medical officer of Memorial Sloan Kettering Cancer Center, resigned from the hospital and as an editor of a prestigious medical research journal. Baselga had failed to disclose millions of dollars he had received from drug and health care companies in his multiple publications detailing his cancer research findings. The doctor consistently omitted his close financial ties to Swiss pharmaceutical company Roche and a variety of biotech startups in his medical journal publications. This in turn led to questions about his neutrality in presenting his research findings. Further, Baselga served as a director on the boards of various drug companies—roles that imposed fiduciary duties to the companies on him—while he simultaneously stewarded Sloan Kettering’s medical operations.

In addition, in 2017, Baselga extolled the virtues of two unsuccessful Roche-sponsored clinical trials, all the while failing to disclose his connection to Roche. Although Baselga ultimately resigned from Sloan-Kettering, he quickly gained employment at AstraZeneca, a sign of his extremely strong industry ties.

As ethicists have argued, failing to disclose such intimate financial company relationships, like Baselga’s, “can shape the way studies are designed and medications are prescribed to patients, allowing bias to influence medical practice.” The reporting requirements for disclosing such ties are very weak, however, and for the most part, leave the decision up to the submitting re-

494 See id.
496 See id.
497 See id.
499 See id.
501 See Thomas & Ornstein, supra note 495.
This failure to disclose industry funding can result in biased clinical trial publications. These publications ultimately end up forming the basis of FDA approvals and clinical practice guidelines.\textsuperscript{503} The boundaries between industry and academic research remain remarkably porous, often to the patient’s disadvantage.\textsuperscript{504} A recent study found that 67.2% of industry-funded research favored new treatments, compared to 49.0% of nonprofit-funded research.\textsuperscript{505} The difference was even more dramatic for medical research using pharmaceutical drugs—65.5% of the industry-sponsored studies showed the positive results of new treatment, compared to the 39.5% of nonprofit-sponsored studies favoring the new treatment.\textsuperscript{506} In addition, industry-sponsored clinical studies may cherry-pick certain analyses of research data to better sell the benefits of certain drugs.\textsuperscript{507}

The pharmaceutical industry pays doctors a staggering amount of money for their “consulting” services. In a report studying the three years between 2013 and 2016, ProPublica discovered that pharmaceutical companies such as Genentech, Pfizer, AstraZeneca, Allegan, and GlaxoSmithKline paid doctors millions of dollars to test, promote, and use their products.\textsuperscript{508} Given how payments or rewards given to doctors make them more likely to prescribe differently,\textsuperscript{509} the sheer amount of money given to doctors to test and use experimental drugs raises serious concern.

Unfortunately, there is little that health systems can do to require their doctors to behave ethically, outside of standard conflict-of-interest policies.\textsuperscript{510} Although transparency about any ties to industry or drug companies is a goal, it often is neglected or brushed aside out of ignorance or laziness.\textsuperscript{511} Other

\textsuperscript{502} See id.
\textsuperscript{504} See Ornstein & Thomas, supra note 498.
\textsuperscript{505} See Jalees Rehman, Can the Source of Funding for Medical Research Affect the Results?, SCI. AM. (Sept. 23, 2012), https://blogs.scientificamerican.com/guest-blog/can-the-source-of-funding-for-medical-research-affect-the-results/ [https://perma.cc/ZAB9-VV5X].
\textsuperscript{506} See id.
\textsuperscript{507} See id.
\textsuperscript{511} See id.
times, doctors do not even recognize that their professional neutrality has been skewed by their financial interests, and they are unaware that social psychology—in particular, reciprocity norms—are unconsciously at work in their prescribing and medical practice.\footnote{512}{See Faye Flam, Opinion, Doctors Like to Think Big Pharma Doesn’t Sway Them. It Does., BLOOMBERG (Oct. 25, 2018), https://www.bloomberg.com/opinion/articles/2018-10-04/doctors-often-don-t-see-conflict-of-interest-in-drug-company-cash [https://perma.cc/F3T6-MNZD].}

Further, industry-funded studies tend to demonstrate that a product is effective more often than independent studies, even when the researchers involved fail to see any conflicts.\footnote{513}{See id.} Even when doctors do see conflicts, they often feel that simply disclosing them wipes the slate clean in terms of bias.\footnote{514}{See id.} The existence of conflicts is now the status quo in medicine and research.\footnote{515}{See id.} Moreover, clinical trials sponsored by the drug industry tend to give more favorable results to the specific drug tested.\footnote{516}{See Ben Goldacre, Trial Sans Error: How Pharma-Funded Research Cherry-Picks Positive Results, SCI. AM. (Feb. 13, 2013), https://www.scientificamerican.com/article/trial-sans-error-how-pharma-funded-research-cherry-picks-positive-results/ [https://perma.cc/RKR2-K5KY] (excerpt from BEN GOLDACRE, BAD PHARMA: HOW DRUG COMPANIES MISLEAD DOCTORS AND HARM PATIENTS (2013)).}

This strong collaboration between medicine and industry distorts both medicine and clinical trials.\footnote{517}{See Barbara Perkins, Industry Has Too Much Influence in Medicine. It’s Time to End That., WASH. POST (Oct. 4, 2018), https://www.washingtonpost.com/outlook/2018/10/04/industry-has-too-much-influence-medicine-its-time-end-that/?utm_term=.fb3397896f0a [https://perma.cc/DD9S-HZ5C].} This should be a familiar narrative at this point, as our history of human medical experimentation on the vulnerable is rife with troubling industry-science-medicine collaborations that primarily benefited commerce, not patients.\footnote{518}{See id.} For example, radiation treatments for cancer were primarily driven by the partnership between industry and medicine, where hospitals felt they needed to purchase increasingly powerful X-ray devices simply to appear modern in the eyes of patients and improve their finances, rather than improve the therapeutic success of their treatments.\footnote{519}{See id.} Similarly, as discussed in Part I, the history of testing radiation on captive subjects was not focused on helping patients; instead, the military-medical-industrial complex used these individuals for their own benefit.\footnote{520}{See id.; supra notes 15–193 and accompanying text.}
that may not be particularly effective. Given such bias, industry trials should not be allowed to enroll those who are already vulnerable in other aspects.

IV. SAFEGUARDS AND SOLUTIONS

A. Nomenclature: Disguising Human Medical Experimentation

Naming is powerful. What we call a practice can greatly shape how it is perceived and accepted. Human medical experimentation is a prime example. As Dr. Carl Elliott has pointed out, what used to be known as medical experiments on humans has now been recast as the far more anodyne “research studies” or “clinical trials.”\(^{521}\) Patients have become “research test subjects,” no longer human beings. The change in language reflects the effort to deflect concerns about the treatment of research participants.\(^{522}\)

The research and medical industries are extremely motivated to use language presenting their experiments as “safe, carefully regulated, and socially beneficial.”\(^{523}\) Indeed, the push to recast human medical experimentation from an ethically questionable to a socially beneficial practice has been very useful to those recruiting for pharmaceutical studies, because willing volunteers are always desired. The most recent change in phrasing, from “research subject” to “research participant,” casts the individual in an active, positive light—no longer passively being experimented upon, but instead choosing to participate in beneficial research.\(^{524}\)

The secrecy and obfuscating role of nomenclature in human medical experimentation goes further. As Harriet Washington contends, “the naming problem even impinges upon the acronyms by which clinical trials are known because they can undermine objectivity about the appropriateness of and expectations from the research.”\(^{525}\) Creating acronyms or nicknames such as CURE (Clopidogrel in Unstable Angina to Prevent Recurrent Events Trial Investigators) or HOPE (Heart Outcomes Prevention Evaluation) may give potential subjects falsely high expectations for the results of the research trial.\(^{526}\) These names give the research a positive connotation, making implicit promises with little to back it up.\(^{527}\)

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\(^{521}\) See Carl Elliott, Whatever Happened to Human Experimentation?, 46 HASTINGS CTR. REP. 8, 8 (2016).

\(^{522}\) See id. at 9.

\(^{523}\) Id.

\(^{524}\) Id. at 10.

\(^{525}\) Washington, supra note 339, at 383.

\(^{526}\) Id. at 384.

\(^{527}\) See id.
In addition, research studies that use clever acronyms find it far easier to attract recruits, receive higher methodological study scores,\(^{528}\) and get more funding from major drug companies.\(^{529}\) For the average potential research subject, the use of acronyms to title research trials can border on the coercive, giving subconscious hope or encouragement to join the study.\(^{530}\)

Even calling research subjects “patients” can blur the realities of human medical experimentation, because there is no actual therapeutic relationship between the researcher and the subject, as there is between doctor and patient—what Dr. Katz called the “therapeutic illusion.”\(^{531}\) Nor do any of the typical rights of patients accrue in research scenarios.\(^{532}\) Research is not treatment, yet our language obscures and elides this crucial difference, resulting in “human subjects . . . being recruited to serve the interests of others.”\(^{533}\)

All of this opaque, misleading, or psychologically manipulative nomenclature makes it extremely difficult for the average, non-medically trained adult to properly understand and appreciate the full magnitude of human medical experimentation. How much more is this true for vulnerable, captive populations, who tend to have much more severe challenges comprehending the proposed contours of the human medical experiments?

### B. The Movement for Increased Participation by Captive Subjects

Despite the many problems with using captive, vulnerable individuals for experimental medical research, there has been a renewed demand to expand federal and state limitations on human subject research. In particular, medical researchers, doctors, and the medical/pharmaceutical industry seek to widen their experimental access to prisoners and children.

Some scientists and doctors believe that the current regulations banning most research in correctional facilities are too restrictive: first, because they unfairly limit prisoners’ ability to participate in medical trials; and second, they are an overreaction to the particular abuses in the 1960s and 1970s.\(^{534}\) They

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\(^{528}\) See id. at 385.


\(^{530}\) See id. at 158.


\(^{532}\) Id.

\(^{533}\) Id. at 10.

argue that racial and ethnic minorities are already underrepresented in biomedical research, and given their overrepresentation in correctional settings, excluding inmates from clinical research trials creates serious concerns for longitudinal, participatory studies.535

Proponents of expanding prison medical research contend that the inability to include inmates in surveys and following up with participants in correctional facilities may jeopardize the validity of scientific conclusions.536 Specifically, the loss of minority men from medical research due to incarceration may result in “biased, underpowered estimates” when studying health disparities.537

Women, African-Americans, and Latinx are underrepresented in medical research, which adversely impacts the universality of the data.538 This underrepresentation may also harm future patients as well as the scientific community.539

Prisoners are currently not permitted to take part in experimental treatments, which can provide desperately ill subjects a last chance at therapy.540 Because many inmates are HIV positive, granting prisoners access to experimental HIV research could be beneficial to the inmates and to society as a whole.541 Researchers in favor of loosening restrictions argue that the increasing numbers of individuals in correctional facilities, who disproportionately suffer from HIV and hepatitis C, offer a useful possibility to control such diseases if research access was increased.542 Similar benefits could accrue to inmates suffering from cancer, hepatitis, tuberculosis, and other diseases common in correctional facilities.543

In response to these concerns, the Institute of Medicine (IOM) recommended that the government loosen regulations on using prisoners for human medical research, particularly for testing pharmaceuticals.544 The IOM report concluded that riskier prison experiments should be permitted if they could


535 See Huang et al., supra note 534, at 162.

536 See Emily A. Wang & Christopher Wildeman, Studying Health Disparities by Including Incarcerated and Formerly Incarcerated Individuals, 305 J. AM. MED. ASS’N 1708, 1708 (2011) (explaining the likely impact of incarceration on the Coronary Artery Risk Development in Young Adults Study).

537 Id.


539 See id. at 510.

540 See id. at 498–99.

541 Id.


543 See Hoffman, supra note 534, at 498.

544 See Urbina, supra note 542.
potentially benefit inmates, so long as there was an independent review to oversee the process. In doing so, the IOM’s framework for analyzing prison medical experimentation shifted from emphasizing protection and fairness to a more procedural mechanism focusing on inmate representation in research studies.

Concerns about underrepresentation and access to human research studies are genuine. That being said, using captive populations for medical experiments is simply too risky. First, much of the push for widening the pool of potential experimental volunteers to prisoners stems from industry. Biotech and pharmaceutical companies look at prisons and see a “deep pool of captive subjects with limited rights, housed in inherently coercive environments.” Such a convenient assembly of research subjects is incredibly appealing, given the routine difficulties of finding participants for medical research. And using prisoners or other captive populations is particularly tempting for medical researchers, who gain the ability to easily control the subject’s diet, stimuli, environment, and routine interactions, thus ensuring fewer external influences interfering with the experiment.

The call to expand the pool of experimental subjects to vulnerable or captive populations is not limited to prisoners. There is a similar argument to allow more human medical experimentation on children, despite the potential of their being “exploited as commodities for commercial ends.”

There are serious problems, however, with increasing child participation in medical research. Many of the children recruited to participate in such medical research are economically disadvantaged minority children. In the face of their more limited access to quality health care, they and their families are more vulnerable to inducements to participate. These families, therefore, are

545 See id.
548 See id.
550 See Sharav, supra note 484, at 12.
far more willing to enroll their children in medical research studies, something that is exploited by many major research centers.\textsuperscript{552}

Second, much of the desire to loosen restrictions on children and medical experimentations results from the dramatic rise of prescribing psychopharmaceuticals\textsuperscript{553} and behavioral drug treatments\textsuperscript{554} for children. Obtaining enough participants for pediatric clinical trials is difficult; pediatric patients comprise approximately twenty to twenty-five percent of the world’s population, and only a small subset of children suffers from the medical issues being studied.\textsuperscript{555} This means that there is a real shortage of subjects for pediatric research.

This shortage of available pediatric research subjects, however, makes the concomitant trend of medicating foster children with psychotropic drugs\textsuperscript{556} very troubling. The vast majority of psychotropic drugs are FDA-approved only for adults, not children, leading to much off-label prescribing.\textsuperscript{557} Widespread off-label prescribing results in a lack of clinically definitive data about the safety, dosage, and side effects of the drugs used on children.\textsuperscript{558} And the general lack of oversight for foster children’s health care means that frequently the most disadvantaged children participate in human medical experiments, particularly those testing psychotropic medication use in children. Foster children provide a perfect captive, vulnerable population upon which to experiment.

Institutionalized patients suffering from mental illness are likewise viewed as grist for the clinical research mill. Certainly, mental illness is a condition that deserves more dedicated research. Nevertheless, the relentless pressure for rapid enrollment in clinical trials—particularly pharmaceutical trials for psychiatric drugs—has led to a focus on institutionalized patients for participation.\textsuperscript{559} Psychiatric medications are one of the most frequently prescribed drugs in the world and in turn, make billions of dollars for their makers.\textsuperscript{560} As the Belmont Report noted, “the institutionalized may continually be sought as

\begin{footnotes}
\item[552] See id. at 1216.
\item[556] See Camp, \textit{supra} note 553, at 373.
\item[557] See id. at 379.
\item[558] See id. at 380.
\item[559] Lamkin & Elliott, \textit{supra} note 9, at 1067.
\item[560] Id. at 1068.
\end{footnotes}
research subjects, owing to their ready availability in settings where research is conducted.”\(^{561}\)

Complicating the situation, there are currently no specific legal protections protecting the mentally ill with impaired capacity.\(^{562}\) Although current U.S. regulations recognize the importance of providing ethical treatment of research subjects with mental disorders,\(^{563}\) there are no particular guidelines for IRBs and investigators.\(^{564}\) This makes using institutionalized, mentally ill patients in human medical experiments very tempting for the medical and pharmaceutical industries.

The difficulty in obtaining enough patients for clinical trials—estimated to take up to thirty percent of clinical research study time\(^{565}\)—is an insufficient reason to allow vulnerable, captive subjects to participate in medical experimentation. The patient recruitment problem costs pharmaceutical companies millions, and it slows down the pace of drug development.\(^{566}\) Accordingly, this recent desire to increase the use of captive subjects for clinical research trials is questionable. As an industry-sponsored news site observed, “the 2.3 [million]-strong U.S. prison population remains an untapped resource for patients who are perfect for clinical trials, including racial minorities, women, as well as people with mental illness and communicable diseases such as HIV/AIDS, hepatitis C, and tuberculosis.”\(^{567}\) This call for greater prisoner participation in research studies from the medical industry is hardly altruistic.

Although local or institutional review boards are supposed to provide strict oversight for any research performed on vulnerable populations, their monitoring is often haphazard and half-hearted. Review board members are required to follow the ethical principles from the 1947 Nuremberg Code and the 1964 Helsinki Declaration, but in reality, these boards are frequently under-


\(^{563}\) See 45 C.F.R. § 46.111(b) (2018) (requiring consideration of additional protections where “some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons”); NAT’L BIOETHICS ADVISORY COMM., supra note 562.

\(^{564}\) See NAT’L BIOETHICS ADVISORY COMM., supra note 562.

\(^{565}\) See Kirsty Barnes, Prisoners May Be Used to Fill Clinical Trial Patient Shortage, OUTSOURCING-PHARMA (July 19, 2008), https://www.outsourcing-pharma.com/Article/2006/08/17/Prisoners-may-be-used-to-fill-clinical-trial-patient-shortage [https://perma.cc/36LV-HJS5].

\(^{566}\) See id.

\(^{567}\) See id.
trained and overworked.\textsuperscript{568} Further, many of the academic research centers running these clinical research studies are funded partially by commercial enterprises, including the very pharmaceutical companies manufacturing the drugs being tested, as well as other interested parties.\textsuperscript{569} Our current oversight system is undermined by a systemic and continual conflict of interest.\textsuperscript{570}

To make matters worse, the Office for Protection from Research Risks (OPRR), which oversees all the local review boards, is itself part of the NIH, which has both conducted and funded much of the human medical research performed on captive subjects.\textsuperscript{571} If and when the OPRR discovers an institutional failure to follow the rules, it has no ability to fine or discipline. Instead, the OPRR can merely request changes in order for the institution to comply with OPRR’s primary tool, the “assurance” document, which is the institution’s pledge to follow federal research regulations.\textsuperscript{572}

Despite the variety of reasons to continue restricting medical experimentation on prisoners, the premise of unfettered research access to captive human subjects persists. In 2018, a group of medical researchers, looking to conduct a long-term, wide-ranging study on how salt intake affects heart disease, selected inmates as the best set of captive subjects, proposing to use a randomized controlled trial with varying salt intakes for several years.\textsuperscript{573} The researchers rejected various other sets of captive populations, including nursing home inhabitants (because it was too difficult to alter their diets), and military recruits (because they were generally too young to be able to see the results on heart disease in a timely fashion).\textsuperscript{574} The salt intake plan would begin with a pilot project involving prisoners aged fifty-five and over, followed by a five-year trial involving 10,000 to 20,000 older prisoners.\textsuperscript{575}

There are myriad problems with this proposal. Although generally it may be useful to know the optimal amount of salt to ingest, “[p]rivileging the potential public health benefits of a study over protections for vulnerable persons, even when risks are judged as minimal, is a gateway to future decisions priori-

\textsuperscript{569} See id.
\textsuperscript{570} See Sharav, \textit{supra} note 484, at 15.
\textsuperscript{571} See Kong, \textit{supra} note 568.
\textsuperscript{572} See id.
\textsuperscript{574} See id.
tizing majority health over individual rights.” Additionally, prisoners demographically are overwhelmingly male and minority, with higher rates of HIV, tuberculosis, and hepatitis C, a fact that does not make them like an average test subject.

Proponents of reinstating prisoner research have argued that this study will help the inmates themselves, in that it will provide them the extra health benefits as well as a psychological benefit of having “agency and representation.” These arguments are both flawed. The fact that inmates’ health might benefit from participating in medical experiments simply highlights the very low level of health care that they normally receive in correctional facilities. Performing human medical experiments on inmates is not the proper solution to poor prison health care.

As for the argument that inmates may gain psychological utility from the agency and representation of participating in a medical experiment, this, too, is dubious. First, the inmates may be coerced to participate because the prison may obtain money or other incentives for their participation in the research. Also, it is unclear how many prisoners would wish to participate in a possibly long or arduous study just to improve the percentage of minority participants in scientific research.

Finally, the very limited ability of inmates to obtain any legal remedy if a medical experiment goes wrong or is performed unethically should give us great pause. In general, prisoners have extremely restricted legal rights due to the qualified immunity of prison officials. As we have seen from past lawsuits of prisoners severely injured in medical experiments, such as the skin experiments.

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578 See Feng, supra note 577.

579 See Laura I Appleman, Cashing in on Convicts: Privatization, Punishment, and the People, 2018 UTAH L. REV. 579, 596–600 (noting the low quality of health care that prisoners tend to receive).

580 See Feng, supra note 577.

at Holmesburg Prison, the ability of inmates to obtain any meaningful remedy or recompense after abusive or unethical behavior is very limited.\footnote{Hornblum, \textit{supra} note 8, at XX.}

In short, inmates, foster children, the institutionalized, and nursing home patients should not be seen as human medical experiment material simply because they “represent a sample of convenience.”\footnote{Kevin Knight & Patrick M. Flynn, Editorial, \textit{Clinical Trials Involving Prisoners: A Bioethical Perspective}, 2 \textit{Clinical Investigation} 1147, 1148 (2012).} At minimum, we should protect our most vulnerable, captive individuals by maintaining the current restrictions.

\section*{C. New Guidelines for the 21st Century}

\"[R]evisiting guidelines does not mean eliminating restrictions.\"\footnote{Id.}

So how can we best encourage clinical research and the testing of new medications without abuse or exploitation? Below I sketch out a few safeguards that would continue to protect our most vulnerable populations from exploitation and abuse, while still allowing medical research to continue with other, less fragile groups.

1. \textbf{Maintain Current Restrictions on Experimental Prison Research}

There are important reasons why federal restrictions on human medical experiments in correctional facilities are still in place, notwithstanding the periodic attempts to loosen them made by various interest groups. Despite the admitted need for better minority male representation in clinical research, using inmates as convenient laboratory specimens is not a solution. Given the problems with duress, inducement, lack of privacy, and compromised informed consent, as discussed above, there is no way to properly oversee medical experiments or make up for the coercive nature of incarceration. Accordingly, any attempt to recruit the individuals currently imprisoned by the criminal justice system for clinical trials should be halted.

2. \textbf{Tightly Restrict Research on Foster Children, the Institutionalized, and Long-Term Care Residents}

These three vulnerable, captive populations—foster children, the mentally compromised, and long-term care patients—should have very limited opportunity to participate in clinical research trials. All three groups frequently must rely on other individuals to make decisions for them, and often family mem-
bers or guardians are too uninformed, overworked, or confused to give proper informed consent.

Foster children, who already suffer from the disruption of family removal and, too frequently, a revolving array of doctors, caseworkers, and foster parents, should not be allowed to enroll in any clinical research trials unless their health depends on it. In addition, all foster children should have an extra layer of oversight when long-term medications or treatments are prescribed.585

Long-term care residents should also have substantial restrictions on clinical trial participation, particularly because they often possess limited cognitive abilities. Complicating matters, their proxies or guardians do not always realize the full implications of participating in medical research and the side effects or negative aspects of the experiments.

Obtaining consent to perform medical research at long-term care facilities frequently requires two levels of consent: first, from the facility managers and staff, and then, if possible, from the residents or their proxies.586 Although responsible researchers are supposed to ensure the patient’s competency to consent, the onus truly lies on the individual clinician.587 This discretion can lead to abuse. The ethical recruiting, retaining, and obtaining of informed consent from long-term residents is often quite difficult,588 particularly when residents have dementia or other comprehension problems. In addition, many residents are unwilling to participate, as they do not trust the researchers’ motives or dislike their daily routine’s interruption.589 As such, there is a danger of coercion to participate.

Further, most long-term care homes do not have an internal IRB or other oversight body and require an external board for supervision,590 a fact that only exacerbates the problem of insufficient oversight and control of medical research. Given our long and shameful history of conducting medical experiments on the aged and terminally ill,591 we should bar any clinical research on those long-term care residents unless the object is entirely safe and therapeutic.

Similar restrictions on medical research should apply to those individuals who are civilly committed, particularly for psychiatric reasons. Like prisoners, the involuntarily committed are captive populations, “isolated and dependent

585 Establishing Psychotropic Review Boards to oversee the general prescribing of psychotropic drugs would be a minimum safeguard. See Camp, supra note 553, at 400.
587 See id.
589 See id.
590 See id. at 246.
591 See Katz, supra note 9, at 407.
on institutional authorities,” and thus present a high barrier for obtaining voluntary informed consent. Worse, the Common Rule, which covers much federally funded medical research, excludes the civilly committed by defining prisoners very narrowly, recognizing only those incarcerated within the criminal justice system. Any set of meaningful restrictions on medical research must include this particular group of captive individuals.

3. Technology to the Rescue

Can future technological innovations protect captive, vulnerable populations while encouraging future medical research?

Given the fast pace of technological change, it is entirely possible that artificial cells and synthetic cadavers could replace the use of humans in medical experiments if used creatively. For example, synthetic cadavers are already being used in medical device studies, obviating the use of human cadavers. If synthetic humans can be used to replace human cadavers for simulation and medical device studies, there is no reason that they cannot be developed in the future to replace humans entirely in clinical research trials. In fact, one synthetic human company, SynDaver, notes that this prototype is in development already: “a synthetic autonomic nervous system (real-time human physiology computer) for the SynDaver Synthetic Human platform—essentially a full body that can move, breathe and bleed autonomously.”

Similarly, a Swiss company, Empa, has created a synthetic skin that can simulate the characteristics of human skin, reproducing “its frictional behaviour against textiles in dry and hydrated conditions.” The plan is to use this synthetic skin in place of clinical trials with human skin to avoid any risk of harm. Synthetic bone is also in development, and hopes are that this bone substitute can be used in the human body alongside natural bone. Obviously, this kind of synthetic bone could also be used for clinical research and testing, thus sparing humans. This kind of biotechnological development has the po-

592 See Lamkin & Elliott, supra note 9, at 1042.
593 See id.
594 See FAQs, SYNDAVER, http://syndaver.com/about/frequently-asked-questions/ [https://perma.cc/FV8L-E2CA].
595 Id.
597 Id.
tential to replace the human element of human subject research, eliminating
the risk and coercion inherent in much clinical research.

The ability to grow replacement organs and spare parts outside the body
also shows potential to replace some forms of human subject research. If
synthetic organs can be created, then there will be a whole world of possibility
opened to those doctors and researchers who want to test various procedures,
medicines, and devices on human body parts. The expanding world of bio-
material may someday negate the need to use human bodies at all.

Until that day comes, however, we must continue to protect the poor, the
imprisoned, the developmentally disabled, the young, the mentally ill, and the
elderly from medical experimentation that can be highly coercive and under-
regulated. Although regenerative engineering gives us hope for the future, it is
important to protect the vulnerable of today, particularly those in captivity.

CONCLUSION

It is all too easy for us to decry the barbarity of the past with human med-
ical research, whether we reach back to former centuries or focus on more re-
cent experiments, such as the Tuskegee Study or the Atomic Energy Commis-
sion’s radiation experiments. In many important ways, however, our use of
captive, vulnerable populations in today’s medical experimentation continues
down the same path. Although the underlying motivations may be different, we
continue to improperly experiment on the incarcerated, the institutionalized,
wards of the state, and the extreme poor, far too often in furtherance of indus-
try profit. Current federal guidelines and legislation have failed to stem the tide
of unethical clinical research. Until the promise of biotechnology can remove
humans entirely from clinical medical research, we must restrict such experi-
mentation to those who freely and knowingly consent.

GUARDIAN (July 8, 2015), https://www.theguardian.com/science/2015/jul/08/laboratory-grown-
organs-transform-lives [https://perma.cc/B2NR-FKN9].