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WHEN HUMAN EXPERIMENTATION IS CRIMINAL

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Medical researchers engaged in human experimentation commit criminal acts seemingly without consequence. Whereas other actors who violate bodily integrity and autonomy are routinely penalized with convictions for assault, fraud, and homicide, researchers escape criminal punishment. This Article begins to scrutinize this undercriminalization phenomenon and provides a framework for understanding why researchers are not prosecuted for their crimes. It argues that their exalted social status, combined with the perceived social benefit of their research, immunizes them from use of the criminal sanction. Whether these constitute sufficient grounds to give researchers a pass from punishment is a significant question because the state's failure to act creates expressive harms. It displays attitudes towards victims and perpetrators that negatively affect the values of autonomy and dignity in medical research. Moreover, alternative sanctions not only lack the same expressive impact, but may also inadequately police criminal harm. This Article concludes that this implicit immunity is harmful to society and inconsistent with criminal law policy.

I. INTRODUCTION

An unacknowledged problem exists in the realm of human subject experimentation: criminal acts are being committed seemingly without consequence. The individuals escaping punishment are no ordinary individuals; rather, they are medical researchers whose exalted social status

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combined with the social benefits of their research appear to immunize them from punishment. Consider the following examples:[1]

Pregnant women become unwitting guinea pigs in an experiment testing a medication to prevent miscarriages. As a result, their daughters and sons are at higher risk for cancer. The researchers are never prosecuted.[2]

A patient becomes an unwitting participant in an experiment to test the safety and effectiveness of an ocular implant. Before implanting the device, the researcher tells him that it is "quite safe" and a "tried and true method" of vision correction, rather than the truth—that the FDA has not approved the device. The victim suffers permanent damage to his eye.[3] The researcher is never prosecuted.

A healthy twenty-four-year-old woman participates in an asthma study. Doctors ask her to inhale a drug without telling her that this is an experimental use of the drug, previous inhalations resulted in death, and the FDA has not approved the procedure. She dies.[4] The researchers are never prosecuted.

This Article addresses the significant, yet largely unexplored, question of why medical researchers escape criminal punishment.[5] Whereas other

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[1] Other examples of research misconduct also exist. *See, e.g.*, United States v. Stanley, 438 U.S. 669 (1987) (injecting serviceman secretly with chemicals); Barrett v. United States, 689 F.2d 324 (2d Cir. 1982) (unwitting participant in chemical warfare experiment); Heinrich v. Sweet, 49 F. Supp. 2d 27 (D. Mass. 1999) (unwitting subjects in radiation experiments); White v. Paulsen, 997 F. Supp. 1380 (E.D. Wash. 1998) (same); Stadt v. Univ. of Rochester, 921 F. Supp. 1023 (W.D.N.Y. 1996) (same); *In re* Cincinnati Radiation Litig., 874 F. Supp. 796 (S.D. Ohio 1995) (same); Moore v. Regents of Univ. of Cal., 793 P.2d 479 (Cal. 1990) (surreptitious harvesting of tissue); Grimes v. Kennedy Krieger Inst., 782 A.2d 807 (Md. 2001) (testing lead abatement strategies on indigent children without adequately informing parents of risks); Burton v. Brooklyn Doctors Hosp., 452 N.Y.S.2d 875 (App. Div. 1982) (enrolling premature infants in experiment without parental knowledge or consent); Friter v. IOLAB Corp., 607 A.2d 1111 (Pa. Super. Ct. 1992) (implanting experimental device into patient's eye without consent); Complaint, Robertson *ex rel.* Robertson v. McGee, 2002 WL 535045 (N.D. Okla. 2002) (No. 01CV0060H(M)), 2001 WL 34783383 (deceiving patients during cancer vaccine study); John Solomon, *Government Tested AIDS Drugs on Foster Kids*, MSNBC.COM, May 4, 2005, http://www.msnbc.msn.com/id/7736157/ (using children in foster care in seven states as guinea pigs to test HIV drugs without permission).

[2] Mink v. Univ. of Chicago, 460 F. Supp. 713 (N.D. Ill. 1978).

[3] Kus v. Sherman Hosp., 644 N.E.2d 1214, 1216 (Ill. App. Ct. 1995).

[4] *See* Letter from the Office of Human Research Prot. (OHRP) to Dr. Edward D. Miller, Johns Hopkins Univ. Sch. of Med. (July 19, 2001), *available at* http://www.sskrplaw.com/bioethics/letter.html; Warning Letter from Joanne L. Rhoads, Ctr. For Drug Evaluation & Research, FDA, to Dr. Alkis Togias, Johns Hopkins Asthma & Allergy Ctr. (Mar. 31, 2003), *available at* http://www.sskrplaw.com/bioethics/warningletter.pdf.

[5] In recent years, a number of cases have exposed misconduct by researchers in human subject experiments. *See supra* note 1. This has caused many commentators to question

actors who violate bodily integrity and autonomy are routinely punished with convictions for assault, fraud, and homicide, researchers walk away from similar crimes unsanctioned.[6] This Article is meant to begin a conversation that considers why criminal sanctions are not utilized in the context of human subject research and scrutinizes whether criminal punishment is an important, but overlooked, mechanism for protecting the dignitary interests of human subjects. Given the rise in human subject experimentation as a result of biotechnology research, this is a critical and timely question.

This Article examines two forms of intentional misconduct. Each, like the illustrations above, involves a researcher's purposeful and deliberate failure to obtain consent, thereby violating an individual's interest in self-determination and autonomy. The first type of misconduct is that of researchers who conduct experiments on individuals without their knowledge. The second is that of researchers who deliberately fail to disclose to individuals the known and obvious risks of participation in an experiment. This occurs, for example, when a researcher intentionally fails to utilize, or significantly alters, an approved informed consent document. The misconduct involves acts that the criminal law typically punishes: intentional, deceptive, and non-consensual contact with the person of another.[7] These acts are customarily prosecuted because they violate one of

existing policing mechanisms. *See* Alan Meisel, *A "Dignitary Tort" as a Bridge Between the Idea of Informed Consent and the Law of Informed Consent*, 16 LAW MED. & HEALTH CARE 210, 212 (1988); E. Haavi Morreim, *Litigation in Clinical Research: Malpractice Doctrines Versus Research Realities*, 32 J.L. MED. & ETHICS 474 (2004) [hereinafter Morreim, *Litigation in Clinical Research*]; E. Haavi Morreim, *The Clinical Investigator as Fiduciary: Discarding a Misguided Idea*, 33 J.L. MED. & ETHICS 586 (2005) [hereinafter Morreim, *The Clinical Investigator as Fiduciary*]; Grant H. Morris, *Dissing Disclosure: Just What the Doctor Ordered*, 44 ARIZ. L. REV. 313 (2002); Leonard L. Riskin, *Informed Consent: Looking for the Action*, 1975 LAW FORUM 580, 596; Marjorie Maguire Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219 (1985). However, none comprehensively explore the role that the criminal law can play in addressing dignitary and actual harms to individuals in research. *But see* LORI ANDREWS & DOROTHY NELKIN, BODY BAZAAR: THE MARKET FOR HUMAN TISSUE IN THE BIOTECHNOLOGY AGE (1999); James T. O'Reilly, *Elders, Surgeons, Regulators, Jurors: Are Medical Experimentation's Mistakes Too Easily Buried?*, 31 LOY. U. CHI. L.J. 317, 368 (2000) ("If systemic safety problems expose elderly patients to harm, criminal prosecution is a proper response.").

[6] Importantly, new criminal legislation is not necessary to punish the conduct discussed in this Article. The acts constitute criminal conduct under existing statutes. *See infra* note 196.

[7] These crimes include the offenses of fraud, assault, battery, rape, and murder. Fraud has been described as "the very essence of wrong; conduct that has always been and always will be wrong, according to the common judgment of mankind; conduct that cannot be dressed up or manipulated or associated so as to invest it with any element of right." Morris,

our most cherished entitlements—freedom from intentional and non-consensual contacts with our person.[8]

There is no question that informed consent is lacking in these cases.[9] I focus upon these "easy" cases of non-disclosure in order to center full attention on the question I seek to consider: why culpable acts in human experimentation, which eliminate an individual's right to make informed choices about what will be done to her body, are not punished. While other forms of misconduct in human subject research exist,[10] and will be the subject of future articles, the fact that these straightforward cases of misconduct do not result in criminal punishment demonstrates the need to explore the initial question of why the criminal sanction is overlooked.

This Article provides the first framework for understanding why research misconduct in the form of deceit and violations of bodily integrity currently escapes criminal punishment. The framework has two components, which I label "idealization bias" and "social benefit bias."[11] Idealization bias refers to the difficulty individuals may have in viewing researchers, who are often doctors,[12] as criminals deserving of punishment. Social benefit bias refers to the hypothesis that research misconduct is often ignored or forgiven because of the perceived societal value of the research.

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supra note 5, at 322-23 (citing Knox v. Phoenix Leasing Inc., 35 Cal. Rptr. 2d 141, 147 (Ct. App. 1994)).

[8] Albright v. Oliver, 510 U.S. 266, 272 (1994) ("The protections of substantive due process have for the most part been accorded to . . . the right to bodily integrity." (citing Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 847-49 (1992))); Schmerber v. California, 384 U.S. 757, 772 (1966) ("The integrity of the individual person is a cherished value of our society.").

[9] I do not discuss cases that involve material misrepresentations made when seeking approval to conduct an experiment using human subjects. I also do not consider problems attendant to informed consent, such as whether individuals actually understand the document they sign. *See, e.g.*, Diaz v. Hillsborough County Hosp. Auth., 165 F.R.D. 689, 690 693-94 (M.D. Fla. 1996) (involving pregnant women's suit against researchers, in part because the women did not understand the informed consent document they signed). The desirability of utilizing the criminal sanction in these more difficult cases will be discussed in future articles.

[10] For example, human subject researchers often violate the regulations that are meant to protect human subjects. *See infra* note 211.

[11] This Article does not contend that these biases represent the only explanations for the absence of criminal punishment. However, they are sufficiently credible to warrant attention.

[12] Morreim, *The Clinical Investigator as Fiduciary*, *supra* note 5, at 587 ("[M]any volunteers are invited into research by their own physicians . . . . [I]nvestigators [in Phase I drug trials] usually are physicians, but their relationship with volunteers is completely independent of the treatment setting." (citation omitted)); O'Reilly, *supra* note 5, at 321 ("In the face of health care cost reductions elsewhere in their budgets, more physicians and physician practice groups are now practicing some clinical research to boost profits.").

This Article posits that idealization and social benefit bias may affect decision-making in ways that can result in researchers being immunized from criminal punishment. This implicit immunity is harmful because the state's failure to punish researchers creates expressive harms by displaying attitudes towards victims and perpetrators that negatively affect the values of autonomy and dignity in medical research. While sanctions outside the criminal context do exist, these alternatives not only lack the same expressive impact, but also may inadequately police criminal harm.

This Article unfolds in five parts. Part II discusses idealization and social benefit bias. Part III scrutinizes the expressive role of criminal punishment and the shortcomings of alternative sanctions. Part IV discusses the utility of imposing punishment. Part V addresses arguments against use of the criminal sanction and examines considerations that can guide policy. The Conclusion argues that criminal punishment can restore the protection of dignity and autonomy in human subject research.

II. THE TWO BIASES

This Part explores whether cognitive biases can explain why culpable medical researchers escape criminal punishment. It draws from the lessons of social cognition research, which contribute to our understanding of how individuals process information and draw conclusions.[13] The research demonstrates that people regularly employ "schemas" to quickly categorize and assimilate information.[14] A schema can be "conceptualized as a mental structure which contains general expectations and knowledge of the world."[15] It "represents knowledge about a concept . . . , including its attributes . . . ."[16] Stereotypes are the best-known example of a schema.[17]

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[13] For a comprehensive review of this literature, see Ronald Chen & Jon Hanson, *Categorically Biased: The Influence of Knowledge Structures on Law and Legal Theory*, 77 S. CAL. L. REV. 1103, 1125 (2004); see also Jerry Kang, *Trojan Horses of Race*, 118 HARV. L. REV. 1489 (2005) (utilizing social cognition research in the study of implicit racial bias). The approach is different from behavioral law and economics although similarities exist. *See id.* at 1494 n.21 (differentiating between his "behavioral realist" approach and "the cognitive psychological groundings of . . . behavioral law and economics"). For further reading on behavioral law and economics, and related literature, see BEHAVIORAL LAW & ECONOMICS (Cass R. Sunstein ed., 2000); Cass R. Sunstein, *Behavioral Analysis of Law*, 64 U. CHI. L. REV. 1175 (1997); see also Jeffrey J. Rachlinski, *The Uncertain Psychological Case for Paternalism*, 97 NW. U. L. REV. 1165 (2003) (describing cognitive psychological concepts affecting decision-making).

[14] *See generally* Chen & Hanson, *supra* note 13 (summarizing research).

[15] *Id.* at 1133 (citation omitted). The term has been interpreted in different ways. *Id.* at 1131; Kang, *supra* note 13, at 1498 n.39.

[16] Kang, *supra* note 13, at 1498 (citation omitted).

[17] Chen & Hanson, *supra* note 13, at 1126-27. The concept of a schema is closely related to the concept of heuristics—rules of thumb or mental shortcuts—that can cause

Essentially, schemas provide a mechanism for people to make quick predictions, decisions, or judgments about the overwhelming amount of information they encounter.[18]

Despite the necessity of employing schemas, they create the risk of biased decision-making because they "guide what we attend to, what we perceive, what we remember and what we infer."[19] The two subparts that follow delineate two possible biases that may result from the schema we apply to researchers and to the work that they perform. These biases create the risk of faulty decision-making in the human subject research context and, thus, may explain the failure to utilize the criminal sanction to punish culpable medical researchers. The purpose of identifying these potential biases is to call attention to the possibility of their existence and encourage further empirical inquiry. Idealization bias is explored in Subpart A; Subpart B discusses social benefit bias. The words *doctor* and *researcher* are used interchangeably in this Part because the researchers engaged in human subject research are more often than not medical doctors.[20]

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predictable failures to accurately assess risk or result in judgment errors, as is discussed in the behavioral law and economics literature. *Id.* at 1197 (stating that inferential shortcuts include schemas or heuristics); *see, e.g.*, Christine Jolls, Cass R. Sunstein & Richard H. Thaler, *A Behavioral Approach to Law and Economics*, *in* BEHAVIORAL LAW & ECONOMICS, *supra* note 13, at 14 (discussing heuristics).

[18] Chen & Hanson, *supra* note 13, at 1132, 1145 ("Before individuals can draw inferences (that is, before they can apply a chosen schema to the concepts before them), they generally need to categorize or label . . . .").

[19] *Id.* at 1133 (citation omitted).

[20] *See supra* note 12; *see also* Frances H. Miller, *Trusting Doctors: Tricky Business When It Comes to Clinical Research*, 81 B.U. L. REV. 423, 424-25 (2001) ("[T]he boundaries separating medical research from clinical practice are becoming increasingly hard to trace . . . . [S]ome drug and device manufacturers now compensate primary care physicians for enrolling their patients in clinical studies." (citations omitted)). It is important to note that there are important differences between the doctor-patient relationship and the researcher-subject relationship. Some commentators argue that it is inaccurate to claim that a fiduciary relationship exists between researchers and their subjects. *See, e.g.*, E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve*, 4 HOUS. J. HEALTH L. & POL'Y 1 (2003); Morreim, *The Clinical Investigator as Fiduciary*, *supra* note 5; Richard S. Saver, *Medical Research and Intangible Harm*, 74 U. CIN. L. REV. 941, 968 (2006) ("Whether a similar fiduciary relationship exists between investigator and research subject remains subject to vigorous debate."). Although courts have recognized that special duties exist between researcher and subject, the scope of these pronouncements remains unclear. *See, e.g.*, Moore v. Regents of Univ. of Cal., 793 P.2d 479, 485 (Cal. 1990); Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 818 (Md. 2001).

A. IDEALIZATION BIAS

"[D]octors are revered as nearly godlike . . . ."[21]

Role schemas, as the name suggests, help people decide what conduct to expect from those in certain roles.[22] Generally, people do not expect criminal behavior from a doctor, despite substantial documentation of the commercialization of science and medicine[23] and the incentives this creates for misconduct.[24] Instead, doctors are often placed on a pedestal.[25] They

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[21] PriceGrabber.com, How Doctors Think, http://www.pricegrabber.com/search_books2.php/book_id=15061581/search=How%20Doctors%20Think/st=product/sv=title (last visited Feb. 2, 2009) (providing synopsis of JEROME E. GROOPMAN, HOW DOCTORS THINK (Houghton Mifflin 2007)).

[22] Chen & Hanson, *supra* note 13, at 1137 (citation omitted) (stating that role schemas refer to "the set of behaviors we expect[] of a person in a particular social position").

[23] Medical research today is a multi-billion dollar industry. *See* Morreim, *Litigation in Clinical Research*, *supra* note 5, at 474 ("[Clinical trials] have become a huge business."); O'Reilly, *supra* note 5, at 349 ("Clinical research consumes an estimated four billion dollars annually . . . ." (citing OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERV., NO. OEI-01-97-00191, INSTITUTIONAL REVIEW BOARDS: PROMISING APPROACHES at A1 (1998))); Kurt Eichenwald & Gina Kolata, *Drug Trials Hide Conflicts for Doctors*, N.Y. TIMES, May 16, 1999, at A1 (reporting that researchers earn up to one million dollars per year).

[24] The commercialization of science increases incentives and temptations to commit bad acts. As one respected ethicist reports, "In countless discussions with research scientists, I have learned about their tampering with the principle of voluntary consent in order to get research underway, advance science, and obtain research grants for the sake of protecting their laboratories and professional advancement." Jay Katz, *The Consent Principle of the Nuremberg Code: Its Significance Then and Now*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 226, 231 (George J. Annas & Michael A. Grodin eds., 1992); *see also* Michael Baram, *Making Clinical Trials Safer for Human Subjects*, 27 AM. J.L. & MED 253, 268-69 (2001) ("[P]rospects of financial gain are so tempting that researchers and organizations are inadvertently or even deliberately [violating] other FDA and NIH requirements intended to protect human subjects."). Doctors and researchers report that the most frequent causes of research misconduct are pressures to obtain funding, pressures of career advancement, pressure to publish and to produce results, and pressure to succeed in a competitive environment. *See* JAMES A. WELLS, THE GALLUP ORG., FINAL REPORT: OBSERVING AND REPORTING SUSPECTED MISCONDUCT IN BIOMEDICAL RESEARCH 37 (2008), *available at* http://ori.dhhs.gov/research/intra/documents/gallup_finalreport.pdf; O'Reilly, *supra* note 5, at 324 (noting "the patent law advantage of taking a primary position for the innovator who patents a device first"); *see also* Lori A. Alvino, Note, *Who's Watching the Watchdogs? Responding to the Erosion of Research Ethics by Enforcing Promises*, 103 COLUM. L. REV. 893, 906-09 (2003) (discussing incentives that facilitate the erosion of informed consent).

[25] *See* JAMES M. LANG, LEARNING SICKNESS: A YEAR WITH CROHN'S DISEASE 40 (2004) ("Our society assigns doctors especially revered places of authority and respect."); Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 478 (2002) ("[P]atients yearn to have confidence in their doctors, to idealize them, to endow them with superhuman powers." (quoting HERMAN MILES SOMERS & ANNE RAMSAY SOMERS, DOCTORS, PATIENTS, AND HEALTH INSURANCE: THE ORGANIZATION AND FINANCING OF MEDICAL CARE 459 (1961)));

are perceived as healers and altruistic, honest actors who toil tirelessly for the betterment of mankind. Evidence of this schema can be seen in television portrayals and public opinion polls.[26] In 2006, for example, a nationwide public opinion poll found that doctors and scientists are amongst the most trusted of occupations and professions.[27] In fact, doctors are the most trusted occupation and scientists among the top three, above police officers and professors.[28]

The role schema applied to doctors and researchers creates the risk of an idealization bias. This bias may affect how the acts of researchers are judged. Individuals may interpret the culpable acts of researchers as innocent mistakes or, at most, negligence, rather than as criminal. Hence, the idealization of doctors may explain the reluctance to prosecute them when they are involved in research misconduct.

The evolution of tort doctrine in informed consent cases provides some evidence of this bias. Prior to the 1960s, courts strongly protected an individual's autonomy interests by recognizing the torts of assault or battery against doctors who either failed to adequately inform their patients about the risks of treatment or failed to abide by the consent obtained.[29] The attitude of courts during this period is best expressed by Justice Cardozo's oft-quoted language: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body;

Valerie M. Harris, *Being a Doctor: Pros, Cons and What It's Really Like*, MOMMD, http://www.mommd.com/beingadoctor.shtml (last visited Feb. 2, 2009) ("For centuries, the physician has been one of the most respected members of society.").

[26] *See* Michael Pfau et al., *The Influence of Television Viewing on Public Perceptions of Physicians*, 39 J. BROAD. & ELEC. MEDIA 441 (1995). The Emmy and Peabody award-winning drama *House* portrays a drug-addicted doctor who orders ethically problematic medical procedures, often without permission, that he believes are necessary. He is depicted as a medical genius whose acts can be forgiven because he obtains results. *But see* Rebecca M. Chory-Assad & Ron Tamborini, *Television Doctors: An Analysis of Physicians in Fictional and Non-Fictional Television Programs*, 45 J. BROAD. & ELEC. MEDIA 499 (2001), *available at* http://findarticles.com/p/articles/mi_m6836/is_3_45/ai_n25037085/pg_1?tag=artBody;col1 (finding that television portrayals, though still positive, are slightly less so than in 1995).

[27] THE HARRIS POLL, DOCTORS AND TEACHERS MOST TRUSTED AMONG 22 OCCUPATIONS AND PROFESSIONS: FEWER ADULTS TRUST THE PRESIDENT TO TELL THE TRUTH (2006), http://www.harrisinteractive.com/harris_poll/index.asp?PID=688. The poll was conducted by telephone between July 7-10, 2006, among a nationwide sample of 1002 U.S. adults. *Id.*

[28] *Id.* Scientists were trusted to be truthful by 77% of those surveyed, compared with police officers at 76% and professors at 75%. *Id. But see* Tara Parker-Pope, *Doctor and Patient, Now at Odds*, N.Y. TIMES, Jul. 29, 2008, at F6.

[29] *See, e.g.*, Mohr v. Williams, 104 N.W. 12, 15-16 (Minn. 1905); Rolater v. Strain, 137 P. 96, 97-99 (Okla. 1913).

and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages."[30]

By recognizing the torts of assault or battery in informed consent cases, courts placed the individual's right to self-determination at the fore. Doctors were held liable for violations of consent, whether or not the patient suffered any physical harm, because "the essence of the plaintiff's grievance consists in the offense to the *dignity* involved in the unpermitted and intentional invasion of the inviolability of his person . . . ."[31] The doctor's good or bad faith was irrelevant because the injury justifying compensation was to the patient's right to be free from non-consensual contact with her person.[32]

However, in the 1960s and 1970s, courts began to shield doctors from battery liability because they presumed that doctors were acting in good faith and for the benefit of the patient. As one court put it:

> We believe that medical treatment beyond the scope of a patient's consent should not be considered as an intentional tort or species of assault and battery as it has been viewed in the past. The doctor in a malpractice case is ordinarily not an actor who intends to inflict an injury on his patient and any legal theory which presumes that intent appears to be based upon an erroneous supposition. Instead, *the doctor is not one who acts antisocially as one who commits assault and battery, but is an actor who in good faith intends to confer a benefit on the patient.*[33]

Idealizing doctors in this fashion caused courts to view the consequences of battery liability as overly punitive.[34] For example, if found liable in battery, a doctor might be required to pay damages out of pocket because malpractice insurance would not be available for "an arguably 'criminal' act."[35] Additionally, the possibility of an award of punitive

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[30] Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914) (citing Pratt v. Davis, 79 N.E. 562 (Ill. 1906)). Justice Cardozo is often cited as the source of the modern doctrine of informed consent. Morris, *supra* note 5, at 317. *But see* Paul A. Lombardo, *Phantom Tumors and Hysterical Women: Revising Our View of the Schloendorff Case*, 33 J.L. MED. & ETHICS 791, 791 (2005) ("[I]t would be surprising to find a serious commentator who used the Schloendorff opinion as the foundation of an argument about the origins of informed consent.").

[31] RESTATEMENT (SECOND) OF TORTS § 18 cmt. c (1965) (emphasis added). The tort allows for nominal damages for the offensive contact and compensation for emotional distress. *See* W. PROSSER, LAW OF TORTS § 9, at 35 (4th ed. 1971).

[32] RESTATEMENT (SECOND) OF TORTS, *supra* note 31, § 16, at 18; *see* Morreim, *Litigation in Clinical Research*, *supra* note 5, at 483 n.81 ("[B]attery protects the purely dignitary interest in the body that it be free from offensive contact." (citing Meisel, *supra* note 5, at 16)).

[33] Dries v. Gregor, 424 N.Y.S.2d 561, 564 (App. Div. 1980) (citations omitted and emphasis added).

[34] Shultz, *supra* note 5, at 226.

[35] Trogun v. Fruchtman, 207 N.W.2d 297, 313 (Wis. 1973).

damages raised concerns.[36] Since courts presumed that doctors were acting in good faith and for the benefit of the patient, these outcomes seemed unduly harsh. Thus, courts began to treat non-consensual encroachments upon the sanctity of the body as a form of medical malpractice sounding in negligence.[37] The concern for doctors appeared to overshadow considerations of individual dignity, autonomy, and self-determination.

The courts' idealization of the medical profession persists even in cases involving researchers who act in bad faith. For instance, *Heinrich v. Sweet*[38] was a class action lawsuit filed on behalf of terminally ill brain cancer patients who were subjects in radiation experiments without their knowledge.[39] The patients thought they were receiving treatment and were unaware of the deception until a government report uncovering the experiments was published over forty years later.[40] The plaintiffs sued in battery, alleging that the defendants "intentionally injected the class' decedents with toxic substances and irradiated the class' decedents *without consent*."[41] The researchers acted in bad faith. The victims had not agreed to become research fodder, or to be injected with the experimental radioactive substance. However, despite evidence of intentional deceit, the court dismissed the battery claim and held that the action should be treated as a form of medical malpractice or negligence.[42]

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[36] *See, e.g., id.* Other reasons cited by the *Trogun* court include that the failures to disclose do not constitute affirmative conduct and thus should not be conceptualized as an intentional tort, or as the type of contact or touching required for an intentional tort. *Id.*

[37] The claim "is in reality one for negligence in failing to conform to the proper standard, to be determined on the basis of expert testimony as to what disclosure should be made." PROSSER, *supra* note 31, § 32, at 165. *See generally* Cobbs v. Grant, 502 P.2d 1, 7-8 (Cal. 1972) (holding that failure to warn of known risk sounds in negligence).

[38] 44 F. Supp. 2d 408 (1999).

[39] *Id.*

[40] *Id.* at 411.

[41] Heinrich *ex rel.* Heinrich v. Sweet, 49 F. Supp. 2d 27, 38 (D. Mass. 1999).

[42] *Id.* Because the patients had consented to the procedure, but not to the injection of the radiation, the court found that this was an action based upon a lack of informed consent. Many courts utilize a negligence standard in cases involving a failure to obtain informed consent. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772 (D.C. 1972); *Cobbs*, 502 P.2d 1, 7-8; Natanson v. Kline, 350 P.2d 1093 (Kan. 1960); Wilkinson v. Vesey, 295 A.2d 676 (R.I. 1972). A minority of jurisdictions allows medical battery claims for lack of informed consent. *See, e.g.*, Lloyd v. Kull, 329 F.2d 168 (7th Cir. 1964); Mink v. Univ. of Chicago, 460 F. Supp. 713, 718 (N.D. Ill. 1978) (citing Cathemer v. Hunter, 558 P.2d 975, 978 (Ariz. Ct. App. 1976)); Perry v. Shaw, 106 Cal. Rptr. 2d 70 (Ct. App. 2001); Gragg v. Calandra, 696 N.E.2d 1282 (Ill. App. Ct. 1998); Kus v. Sherman Hosp., 644 N.E.2d 1214 (Ill. App. Ct. 1995); Roberson v. Provident House, 576 So. 2d 992 (La. 1991); Duttry v. Patterson, 771 A.2d 1255 (Pa. 2001); Morgan v. MacPhail, 704 A.2d 617, 620 (Pa. 1997); Friter v. IOLAB Corp., 607 A.2d 1111 (Pa. Super. Ct. 1992); Harvey v. Strickland, 566 S.E.2d 529 (S.C. 2002); Shadrick v. Coker, 963 S.W.2d 726 (Tenn. 1998).

Even in negligence cases, glimpses of idealization bias are present. The majority of jurisdictions utilize the "medical custom" standard as the basis for imposing liability.[43] In determining whether the right to informed consent is breached, the focus of the inquiry is on what the medical community believes is reasonable to disclose.[44] Reliance upon medical community standards assumes that the community will always act in good faith and in furtherance of the best interests of the patient.

A growing number of jurisdictions utilize a standard that focuses upon the information a reasonable person would want to receive in determining liability.[45] The question asked is whether a reasonable person would have consented to the procedure if he or she had been given the undisclosed information. The use of the reasonable person standard again reflects a concern for the idealized doctor because the standard was chosen to protect doctors from the vindictive patient by avoiding placing doctors "in jeopardy of the patient's hindsight and bitterness."[46] A subjective standard would recognize that the patient, not the doctor, has the right to decide what is in his or her best interest.[47]

That we idealize doctors, even those acting in bad faith, demonstrates the efficacy of idealization bias. Indeed, such reverence overshadows concern for the patient's right to make informed decisions about what is done to her person and relegates protection of the individual's interests in her bodily integrity to a secondary status.[48] The idealization phenomenon is

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[43] *See, e.g.*, Osborn v. Irwin Mem'l Blood Bank, 7 Cal. Rptr. 2d 101, 124 (Ct. App. 1992) (noting that medical custom standard is the majority rule).

[44] *Id.*

[45] *See* Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 430 (2006) (noting that almost half of jurisdictions utilize the reasonable patient standard).

[46] *Canterbury*, 464 F.2d at 790-91. Only a minority of jurisdictions utilize a subjective test, and do so in order to provide strong protection to individual autonomy and decision-making. *See, e.g.*, McPherson v. Ellis, 287 S.E.2d 892, 897 (N.C. 1982); Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1980); Arena v. Gingrich, 748 P.2d 547, 549 (Or. 1988); Millard v. Nagle, 587 A.2d 10, 13 (Pa. Super. Ct. 1991); Flanagan v. Wesselhoeft, 712 A.2d 365, 370 (R.I. 1998).

[47] *Canterbury*, 464 F.2d at 781 ("[I]t is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie."); *Id.* at 786 ("[T]he patient's right of self-decision shapes the boundaries of the duty to reveal."). Only a few jurisdictions utilize the subjective person standard. *See* Hartke v. McKelway, 707 F.2d 1544, 1548-49 (D.C. Cir. 1983); Korman v. Mallin, 858 P.2d 1145, 1150-51 (Alaska 1993); Lugenbuhl v. Dowling, 676 So. 2d 602, 605-06 (La. Ct. App. 1996); Macy v. Blatchford, 8 P.3d 204, 209-11 (Or. 2000).

[48] Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261, 366 (1999) ("[P]atients can be harmed when they are prevented from making decisions about their own care, even when, or perhaps *especially* when, no physical harm occurs."); *see also* Morreim, *Litigation in Clinical Research*, *supra*

not new. For example, the long-standing therapeutic exception to informed consent allows doctors, in their sole discretion, to withhold information from a patient if they believe the information would cause psychological harm and thus hurt the patient's physical well-being.[49] This exception implicitly assumes doctors acting in good faith and failing to disclose relevant information, not to serve their own ends, but for the benefit of the patient.

Importantly, idealization bias can be overcome in individual cases.[50] After all, some doctors are prosecuted for criminal conduct. However, when these prosecutions occur, there is usually an explanation for why the role schema was conquered. In some cases, the person's role as a doctor was merely coincidental to the conduct.[51] In others, alternative schemas were more salient. For example, the so-called War on Drugs likely "primes" prosecutors and law enforcement to be ever vigilant for evidence of improper drug distribution.[52] Hence, doctors are prosecuted for allegedly improperly prescribing narcotic painkillers to patients.[53] In these cases, the power of the War-on-Drugs prime can explain the ascendance of the drug-dealer schema over the doctor schema. In sum, when doctors are prosecuted, it appears that alternative schemas are more salient and thus defeat idealization bias.[54]

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note 5, at 480 ("Because standard informed consent doctrine limits recovery to cases featuring a physical or other separate injury, it can fail to honor human autonomy in cases where someone's right to choose has been abused without demonstrable physical damage." (footnote omitted)).

[49] *See, e.g.*, Salgo v. Leland Stanford Jr. Univ. Bd. of Trs., 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957). In *Salgo*, the court held that a risk which was remote did not have to be disclosed if, in the doctor's sole judgment, the patient would become so terrified that she would fail to obtain the surgery the doctor thought was necessary. *Id.* This is known as the "therapeutic exception" to informed consent. Because the doctor's duty is to "place the welfare of [the] patient above all else," the patient's right to autonomy in decision-making could be limited. *Id.*; *see also Canterbury*, 464 F.2d at 788-89 (upholding the therapeutic exception).

[50] Chen & Hanson, *supra* note 13, at 1175-77.

[51] This occurs when a doctor is prosecuted for rape or murder, for example.

[52] Priming "'refers to any experiences or procedures that bring a particular concept (or any other knowledge structure) to mind.'" Chen & Hanson, *supra* note 13, at 1180 (citation omitted).

[53] *See* Press Release, U.S. Drug Enforcement Admin., Doctor Charged with Illegal Drug Distribution (July 2, 2007), *available at* http://www.usdoj.gov/dea/pubs/states/newsrel/atlanta070207.html.

[54] In the social cognition field, this is often referred to as "subtyping." Subtyping allows individuals to avoid reconceptualizing a schema, but rather create exceptions to the general rule. Chen & Hanson, *supra* note 13, at 1205 ("When confronted with disconfirming information individuals can carve out a special subschema for that evidence in a way that preserves more general schema—like an 'exception that proves the rule.'").

B. SOCIAL BENEFIT BIAS

Another explanation for the failure to prosecute culpable researchers is that they are engaged in socially beneficial research.[55] Researchers perform a service that society believes is worthy, beneficial, and important. Generally, our society accepts the practice of human subject research, despite the fact that serious injury and death can result,[56] because it may lead to cures or treatments for devastating diseases.[57] The desire to foster research that holds the promise of substantial potential benefits may create a willingness to turn a blind eye to intentional misconduct or an unawareness that one's interpretation of conduct is influenced by the motivation to encourage research.[58] This is what I refer to as social benefit bias.

Social cognition research establishes that an individual's motivations can play a significant role in determining "which concepts, beliefs, and rules we apply to a judgment; we may be especially likely to apply those that are congruent with our goals."[59] In fact, motivations may be the most important factor affecting the schema an individual adopts.[60] The failure to punish culpable researchers may stem from fear that punishment would stymie medical research that we are motivated to promote. This desire to

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[55] Researchers have been prosecuted for falsifying data. *See infra* note 98. But these prosecutions make sense since in neither instance is society benefited. Results based upon falsified data will not result in knowledge that helps develop cures or treatments for diseases, for example.

[56] Experiments involving human subjects can be therapeutic or non-therapeutic. Whitlock v. Duke Univ., 637 F. Supp. 1463, 1467 (M.D.N.C. 1986). Therapeutic experimentation provides a benefit to the subject, while non-therapeutic experimentation does not. *Id.* Many subjects in non-therapeutic research are healthy. *Id.*

[57] OFFICE OF TECHNOLOGY ASSESSMENT, OTA-BA-337, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS 56 (1987) ("There are nearly 350 commercial biotechnology firms in the United States actively engaged in biotechnology research and commercial product development and approximately 25 to 30 percent appear to be engaged in research to develop a human therapeutic or diagnostic reagent . . . . Most, but not all, of the human therapeutic products are derived from human tissues and cells, or human cell lines or cloned genes."). Already, tests and treatments for diseases such as leukemia, cancer, diabetes, hepatitis-B, and infertility exist as a result of this important research. ALAN M. RUSSELL, THE BIOTECHNOLOGY REVOLUTION: AN INTERNATIONAL PERSPECTIVE (1988), *cited in* Thomas P. Dillon, Note, *Source Compensation for Tissues and Cells Used in Biotechnical Research: Why a Source Shouldn't Share in the Profits*, 64 NOTRE DAME L. REV. 628, 628 n.1 (1989).

[58] Individuals also may underestimate the possibility that they will become the victims of research misconduct. Psychological studies reveal that individuals have an inclination to be overconfident or overly optimistic when it comes to making risk assessments for themselves. Rachlinski, *supra* note 13, at 1172, 1191; Sunstein, *supra* note 13, at 1183 (discussing systematic overconfidence in risk judgments).

[59] Chen & Hanson, *supra* note 13, at 1183 n.341 (citation omitted).

[60] *Id.* at 1183 (citation omitted).

advance research may affect how decision-makers interpret researchers' conduct and victims' harm.

Perhaps the best example of social benefit bias, and its close relationship to idealization bias, is *Moore v. Regents of the University of California*, a case involving surreptitious research.[61] Mr. Moore had a rare and deadly cancer known as hairy-cell leukemia in his spleen.[62] He sought treatment from Dr. David Golde, a prominent cancer specialist at the UCLA Medical Center. He gave Dr. Golde permission to conduct a splenectomy (the surgical removal of his spleen) to treat his leukemia. After the successful procedure,[63] Moore moved to Seattle.[64]

When Dr. Golde asked Moore to return for follow-up treatments, Moore was not suspicious. For the next seven years, Moore dutifully flew from Seattle to California every few months, and underwent sometimes painful medical procedures that included withdrawing samples of "blood, . . . skin, bone marrow aspirate, and sperm."[65] He made the trek because Dr. Golde asserted that the procedures were medically necessary[66] and that only he could perform them.[67] Neither assertion was true.

What Moore did not know was that prior to his surgery, Dr. Golde had developed research and financial interests in Moore's cells.[68] The procedures Dr. Golde performed after the successful surgery had nothing to do with treating Moore's leukemia, which was in remission. Instead, Dr. Golde was actively conducting research on Moore's cells solely for financial gain and commercial advantage. Dr. Golde exploited the doctor-patient relationship to ensure that he had exclusive access to Moore's cells.[69] When Moore specifically asked Dr. Golde whether there was any possible research interest or financial benefit in his bodily substances, Dr. Golde repeatedly told him no and "actively discouraged such inquiries."[70] In fact, Dr. Golde went so far as to say that "there was no commercial or financial value" in Moore's tissue.[71]

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[61] 793 P.2d 479 (Cal. 1990).

[62] *Id.* at 481.

[63] *Id.*

[64] Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES MAG., Apr. 16, 2006, at 39, 41 *available at* http://www.nytimes.com/2006/04/16/magazine/16tissue.html.

[65] *Moore*, 793 P.2d at 481 (internal quotation marks omitted); Skloot, *supra* note 64, at 2.

[66] *Moore*, 793 P.2d at 481.

[67] *Id.*

[68] *Id.*

[69] *Id.*

[70] *Id.* at 486 (internal quotation marks omitted).

[71] *Id.* (internal quotation marks omitted).

Dr. Golde never asked Moore for express consent to the removal of his blood and tissue.[72] However, at the close of seven years, Dr. Golde asked him to sign a consent form giving UCLA permission to use the withdrawn tissue for research purposes.[73] Dr. Golde presented the consent form as a mere formality and Moore signed.[74] However, Moore became suspicious when, after he later declined to sign a similar consent form, Dr. Golde offered to pay for his airfare and accommodations at a ritzy Beverly Hills hotel.[75]

Moore hired a lawyer.[76] During his investigation, the lawyer discovered that Dr. Golde had obtained a patent on the cell line developed from Moore's cells.[77] He learned that Dr. Golde had a contract with a biotechnology company that gave Dr. Golde stocks and financing worth more than $3.5 million to "commercially develop" and "scientifically investigate" the cell line.[78] The market value of the cell line was predicted to reach $3 billion.[79] Upon learning of the deception, Moore said that he felt "violated for dollars," "invaded," and "raped."[80] Moore sued Dr. Golde for conversion.[81] His lawsuit was dismissed by the trial court, reinstated by the court of appeals, and finally made its way to the California Supreme Court.

Over strongly worded dissents, the majority refused to extend conversion liability to Moore's situation. It acknowledged that the tort of conversion would protect individual autonomy.[82] However, the court

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[72] Michelle J. Burke & Victoria M. Schmidt, *Old Remedies in the Biotechnology Age: Moore v. Regents I*, MAG. INTELL. PROP. & TECH., Oct. 27, 2006, *available at* http://www.piercelaw.edu/risk/vol3/summer/moore.htm.

[73] *Id.*

[74] *Id.*

[75] *Id.* During that trip, Moore told Dr. Golde that he no longer had a place to stay in Los Angeles. *Id.* Moore became suspicious because Dr. Golde seemed "overeager" to pay for his accommodations, Dr. Golde made numerous attempts to obtain his signature on the consent form, and Dr. Golde was evasive when asked about any commercial use of his tissue. *Id.*

[76] ANDREWS & NELKIN, *supra* note 5, at 27.

[77] *Id.* at 28. The lawyer discovered this by reading an article published by Dr. Golde in *Science* describing the patent. *Id.*

[78] Skloot, *supra* note 64, at 2.

[79] *Id.*

[80] ANDREWS & NELKIN, *supra* note 5, at 28.

[81] His complaint stated thirteen causes of action, including lack of informed consent and breach of fiduciary duty. Burke & Schmidt, *supra* note 72.

[82] *See* Moore v. Regents of Univ. of Cal., 793 P.2d 479, 494 (Cal. 1990) ("To be sure, the threat of liability for conversion might help to enforce patients' rights indirectly. This is because physicians might be able to avoid liability by obtaining patients' consent, in the broadest possible terms, to any conceivable subsequent research use of excised cells.").

decided against extending the theory to the medical research context because recognition would "create[] disincentives to the conduct of socially beneficial research" that was "of importance to all of society . . . ."[83] In so holding, the court touted protection of "innocent researchers" despite the fact that Dr. Golde was not an innocent researcher acting in good faith.[84]

Invocation of the innocent researcher ideal demonstrates the sometimes intimate relationship between the social benefit and idealization biases. The entire court agreed that Dr. Golde deliberately failed to obtain consent in order to mine Moore's body for cells in furtherance of Dr. Golde's financial interests. Despite this, the majority's primary concern was to avoid stymieing socially useful conduct.[85]

The *Moore* decision marks an unwillingness to recognize insults to human dignity that result from intentional fraud. What appears to distinguish the *Moore* case from a typical assault or fraud case,[86] customarily subject to the criminal sanction, is the potential social benefit of the researcher's conduct and a fear that recognition of Moore's interests would stymie future research.

Researchers engaged in intentional misconduct have taken advantage of social benefit bias, intentionally or unintentionally, to deflect attention

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[83] *Id.* at 494, 487. *See also id.* at 499 (noting that the majority was concerned that "the imposition of liability for conversion will impede medical research by innocent scientists who use the resources of existing cell repositories" but that this was "a factual setting not presented here . . . .") (Broussard, J., concurring and dissenting); *see also id.* at 513 n.14 (Mosk, J., dissenting) ("On this record the majority's solicitude for the protection of 'innocent parties' seems ironic. The complaint is replete with factual allegations . . . to the effect that defendants repeatedly lied to Moore about their commercial exploitation of his tissue."). For further commentary on the *Moore* case, see Michelle Bourianoff Bray, *Personalizing Personalty: Toward a Property Right in Human Bodies*, 69 TEX. L. REV. 209, 233-239 (1990); Dillon, *supra* note 57, at 631-32.

[84] *Moore*, 793 P.2d at 497.

[85] The court did allow Mr. Moore to proceed on his claim of violation of informed consent. However, this remedy is illusory for individuals, such as Moore, who do not suffer actual harm. *See* Krause, *supra* note 48, 366-67; Morreim, *Litigation in Clinical Research*, *supra* note 5, at 480 ("[A] number of scholars have recommended that serious deficiencies of informed consent be deemed a distinct dignitary tort."); Morris, *supra* note 5, at 330-31; Shultz, *supra* note 5, at 225. *But see* Nancy Levit, *Ethereal Torts*, 61 GEO. WASH. L. REV. 136, 152 (1992) ("Courts are beginning to compensate for infringements of the decisionmaking process, even if the tangible injury is not one that the law recognizes.").

[86] No criminal charges were ever brought against Dr. Golde. Dr. Golde's actions are similar to routinely prosecuted assaults. To make this determination, this Article refers to the Model Penal Code because state statutes differ in their definitions of crimes. An "assault" occurs when an actor "knowingly . . . causes bodily injury to another . . . ." MODEL PENAL CODE § 211.1 (1962). "Bodily injury" includes physical pain. *Id.* § 210.0(2). When Dr. Golde performed medical procedures on Mr. Moore for seven years without his permission, he caused physical pain, and he was aware that physical pain was practically certain to occur. *Id.* § 2.02(2)(b)(ii) (defining "knowingly").

away from their bad acts, demonize the victim, and shape public opinion. They have become "availability entrepreneurs"[87] who can package events to benefit from social benefit bias. For example, in defending against accusations that his surreptitious mining of Moore's body was for his own financial benefit, Dr. Golde stated: "If there is economic gain, it will be to the people of California."[88] Dr. Golde's attorney described Moore to others as "an ingrate."[89] "Golde saved Moore's life . . . . 'Most people would embrace the doctor with all the gratitude they have.'"[90] One newspaper reported, "Moore's suit has raised the passions of the scientific community, which warns that if he is successful he will strike a blow against future medical research."[91] It is not surprising, then, that the general public, who stand to reap the benefits of research, are affected. As one letter to the editor stated:

> While I am not given to emotional outbursts over the numerous atrocities we humans seem hellbent on committing against one another, I was compelled to comment on the article "Medical Community Rocked by Tissue-Ownership Battle" [Jan. 8]. Instead of hoping the medical community might one day save a life with their research, it appears John Moore and his lawyers have regressed to the ultimate in greed and self-degradation. While not always a staunch supporter of many of today's medical advances and research tactics, I nonetheless believe these advances will ultimately benefit mankind in the long run. The only hope I was left with after reading this article was that the research conducted on Mr. Moore's spleen would one day prove vital and essential to extending the lives of Mr. Moore and his lawyers, and that they would be denied this life-extending help solely for financial reasons.[92]

Hints of social benefit bias can also be seen in the failure to acknowledge systematically and consistently the history of research misconduct that accompanies many important medical advances, procedures, and products. For example, Dr. James Marion Sims is recognized as the "father of American gynecology" and revered as a benefactor of women, having opened the first hospital in the nation for the care of women in New York City and dedicated his career to the treatment

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[87] Christine Jolls, Cass R. Sunstein & Richard Thaler, *A Behavioral Approach to Law and Economics*, *in* BEHAVIORAL LAW AND ECONOMICS, *supra* note 13, at 13, 38.

[88] Robert Reinhold, *Ruling Raises Fear of Research Curbs*, N.Y. TIMES, July 24, 1988, at 15.

[89] Frank Swoboda, *It Was My Spleen, and Now It Could Be Anywhere*, WASH. POST, Jan. 26, 1988, at HE10 (statement of Anthony Murray, attorney).

[90] *Id.*

[91] *Id.*

[92] Diane M. Burrows, Letter to the Editor, *John Moore's Spleen*, WASH. POST, Jan. 14, 1989, at A22.

of women's disorders.[93] Hospitals carry his name, and marble monuments bearing his likeness and accolades stand in prominent locations.[94]

Very rarely, however, does anyone acknowledge the history of his abuse of female slaves, which formed the basis of his extensive knowledge. In the 1840s, Dr. Sims performed surgeries on enslaved girls and women in an attempt to perfect an operation to treat white women suffering from a painful vaginal condition. He performed excruciatingly painful surgery on his captives to create the condition, without the use of anesthesia, and forced them to take turns restraining each other as he made incisions, since other doctors could not stomach their "bone-chilling shrieks."[95] This is how he perfected the procedure, published his results in a prestigious medical journal, and became known as the "father of American gynecology."[96] Importantly, this observation is not meant to condemn the use of the knowledge he gained (this Article offers no opinion on that question), but rather to point out that the silence regarding his methods is perhaps the result of a desire to enjoy the fruits of his labor without the constant reminder of the methods used to obtain them. A similar phenomenon is present in the ongoing debate over the morality of utilizing the medical knowledge obtained from the torture of concentration camp victims by the Nazis.[97]

In conclusion, both idealization bias and social benefit bias may explain why researchers engaged in misconduct escape punishment.[98] They

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[93] HARRIET A. WASHINGTON, MEDICAL APARTHEID: THE DARK HISTORY OF MEDICAL EXPERIMENTATION ON BLACK AMERICANS FROM COLONIAL TIMES TO THE PRESENT 1, 61 (Doubleday 2006) (2006).

[94] *Id.* at 1.

[95] *Id.* at 65.

[96] *Id.* at 66.

[97] George J. Annas & Michael A. Grodin, *Introduction* to THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 24, at 3, 5 (citations omitted); *see also* Alan C. Nixon, *If the Data's Good, Use It—Regardless of the Source*, THE SCIENTIST, Nov. 14, 1988, at 8 (defending the use of Nazi data).

[98] Researchers are often prosecuted for filing false claims with the government under the mail and wire fraud statutes. *See* 18 U.S.C. § 1001 (2006) (false claims); 18 U.S.C. § 1343 (2006) (wire fraud); 18 U.S.C. § 1341 (2006) (mail fraud); *see, e.g.*, United States *ex rel.* Cantekin v. Univ. of Pittsburgh, 192 F.3d 402 (3d Cir. 1999) (same); United States *ex rel.* Berge v. Univ. of Ala., 104 F.3d 1453 (4th Cir. 1998) (same); United States *ex rel.* Chandler v. Hektoen Inst. for Med. Research, 118 F. Supp. 2d 902 (N.D. Ill. 2000) (same); United States v. Univ. of Cal., 912 F. Supp. 868 (D. Md. 1995) (same); United States v. Breuning, No. K-88-0135 (D. Md. Sept. 19, 1988) (*cited in* Bratislav Stankovic, *Pulp Fiction: Reflections on Scientific Misconduct*, 2004 WIS. L. REV. 975, 985 (2004)) (false claims); United States. v. Keplinger, 776 F.2d 678 (7th Cir. 1985) (mail fraud). These prosecutions present further evidence of the social benefit bias. Some of these prosecutions occur in cases where researchers falsify efficacy data during the course of research. *See, e.g.*, United States v. Smith, 740 F.2d 734 (9th Cir. 1984) (involving researchers who made false statements

are not viewed as criminals deserving of punishment. In Part III below, this Article begins a discussion on whether criminal punishment is appropriate for researcher misconduct. It does so by exploring the expressive harms that can result when an identifiable group of culpable actors are not punished through use of the criminal sanction.

III. THE IMPORTANCE OF CRIMINAL PUNISHMENT

Punishing culpable researchers would send a clear message: violations of autonomy and dignity are wrong whether or not they take place in the context of socially beneficial research.[99] But that begs the question—what is punishment? This Article subscribes to the familiar view that what distinguishes punishment from other penalties is that punishments express moral condemnation.[100] According to philosopher Joel Feinberg's well-known formulation, punishment is a "*conventional* device for the expression of attitudes of resentment and indignation, and of judgments of disapproval and reprobation, on the part either of the punishing authority . . . or of those 'in whose name' the punishment is inflicted."[101] Under this definition, a necessary condition of punishment is that it expresses censure, judgment, and disapproval in a socially conventional manner.

Viewed in this way, punishment is not necessarily limited to the criminal sanction. If other penalties are understood to carry similar messages of denunciation and disapproval, they too could constitute punishment. Subpart A scrutinizes the expressive meaning of criminal punishment. Subpart B then considers whether alternative sanctions carry the same expressive meaning as the criminal sanction, and concludes that they do not.

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concerning efficacy of investigational drugs); Beverly Merz, *Many Address Task of Preventing Research Fraud*, 260 J. AM. MED. ASS'N 2011, 2011 (1988) (discussing the case of Dr. Breuning, Ph.D., who plead guilty to providing false efficacy data to the National Institute of Mental Health). Such misconduct places society at risk because the tested product may be, in fact, unsafe. However, the failure to prosecute cases in which individuals are injured can be explained by the fact that the harm to the individual subject arguably leads to better data, resulting in a safer product.

[99] Galanter and Luban refer to this as "norm projection." Marc Galanter & David Luban, *Poetic Justice: Punitive Damages and Legal Pluralism*, 42 AM. U. L. REV. 1393, 1429 (1993). They argue that "an important aim of punishment is to dramatize publicly that legal norms are seriously intended. That is, punishment prevents offenses by norm projection and norm reinforcement as well as by deterrence." *Id.*

[100] *See, e.g.*, JOEL FEINBERG, *The Expressive Function of Punishment*, *in* DOING & DESERVING: ESSAYS IN THE THEORY OF RESPONSIBILITY 98 (1970); Henry M. Hart, Jr., *The Aims of the Criminal Law*, 23 LAW & CONTEMP. PROBS. 401, 404 (1958).

[101] FEINBERG, *supra* note 100, at 98 (emphasis added).

A. WHAT CRIMINAL SANCTIONS EXPRESS

How a society conventionally expresses censure is important. For example, Dan Kahan argues that verbally castigating a wrongdoer could be considered punishment if social norms within the community make it appropriately condemnatory.[102] In our society, the criminal sanction[103] is viewed, uncontroversially, as *the* most serious statement of moral blameworthiness. In his famous treatise, Henry Hart asserted that what differentiates criminal punishment from the civil remedy is "the judgment of community condemnation which accompanies and justifies its imposition."[104] The criminal sanction is the socially conventional method for expressing public censure,[105] and is well understood in this society as a way for the state to condemn an act and to disavow it.[106] Use of the criminal sanction may not be the only way to punish, or the best way, but in our society, it is the usual way.[107]

One feature of the sanction that makes it a unique method of expressing moral censure is the stigma that attaches to the individual. As one commentator describes it: "In modern criminal law, the stigma of a criminal sanction has become a special kind of remedy because of its burdensome and sometimes destructive consequences for the individual."[108] The stigma is not limited to a conviction. The state's decision to charge an individual also carries meaning, for it expresses that the accused probably deserves moral censure because his acts justify placing him at risk of a conviction and its attendant consequences. This explains the feelings of shame and humiliation that often accompany a criminal charge.

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[102] Dan M. Kahan, *What Do Alternative Sanctions Mean?*, 63 U. CHI. L. REV. 591, 600 (1996).

[103] In this Article, the phrase "the criminal sanction" or "criminal punishment" are used to refer to the act of charging someone with an offense as well as any resulting conviction and consequences, including imprisonment, fines, probation, or community service.

[104] Hart, *supra* note 100, at 404. Others have also recognized the special nature of criminal punishment. *See, e.g.*, Kenneth Mann, *Punitive Civil Sanctions: The Middleground Between Criminal and Civil Law*, 101 YALE L.J. 1795, 1808 (1992) ("The principal paradigmatic purpose of the criminal law—the reason for invoking criminal law rather than some alternative sanctioning system—is punishment.").

[105] FEINBERG, *supra* note 100, at 98.

[106] *Id.* at 102.

[107] I have paraphrased Hugo Bedau here. *See* Hugo Adam Bedau, *Feinberg's Liberal Theory of Punishment*, 5 BUFF. CRIM. L. REV. 103, 125 (2001) ("'Punishment . . . might be deserved by the criminal only because it is the customary way of expressing the resentment or reprobation he 'has coming.' Not, mind you, the only way, or the best way—just the usual way.").

[108] Mann, *supra* note 104, at 1809.

Furthermore, the criminal brand continues to express condemnation long after it is imposed. Except in rare circumstances,[109] a person convicted of a crime must, for the remainder of his life, inform others of his culpability and blameworthiness by disclosing his conviction on employment, education, housing, and licensing applications. A conviction also has political, economic, and social consequences.[110] In many instances, it results in the loss of the rights to vote and to carry a weapon, and of the ability to obtain public benefits, live in certain neighborhoods, and engage in certain types of employment. These are just a few collateral consequences of a conviction.

When the state utilizes the criminal sanction, it "goes on record" and "testif[ies] to the recognition" that the conduct in question is wrong and the offender is deserving of condemnation and reprobation.[111] The use of the sanction "tells the world that [the offender] had no right to do what he did, that he was on his own in doing it, that his government does not condone that sort of thing."[112] Through criminal punishment, the state vindicates the victim's value or worth.[113] The victim has been wronged, and the state is stepping up to defend her honor, so to speak.[114]

The state's failure to utilize this powerful method of condemnation is also expressive. "What a community chooses to punish and how severely tells us what (or whom) it values and how much."[115] When the state permits an identifiable group to commit criminal acts without punishment, it sends a message of official complicity and solidarity with the offender,[116]

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[109] Juvenile adjudications and expungements are exceptions, although even these protections are not always perfect. *See* Carrie T. Hollister, *The Impossible Predicament of Gina Grant*, 44 UCLA L. REV. 913 (1997) (discussing sealed-record statutes for juveniles and their problems); Margaret Colgate Love, *Starting Over with a Clean Slate: In Praise of a Forgotten Section of the Model Penal Code*, 30 FORDHAM URB. L.J. 1705 (2003) (discussing expungements).

[110] DOUGLAS HUSAK, OVERCRIMINALIZATION: THE LIMITS OF THE CRIMINAL LAW 6 (2008) (citing Nora V. Demleitner, *Preventing Internal Exile: The Need for Restrictions on Collateral Sentencing Consequences*, 11 STAN. L. & POL'Y REV. 153 (1999)).

[111] FEINBERG, *supra* note 100, at 103.

[112] *Id.* at 102.

[113] *See* Jean Hampton, *An Expressive Theory of Retribution*, *in* RETRIBUTIVISM AND ITS CRITICS 1, 15 (Wesley Cragg ed., 1992).

[114] Lawrence Friedman, *Essay in Defense of Corporate Criminal Liability*, 23 HARV. J.L. & PUB. POL'Y 833, 842 (2000) ("[T]he commission of an act the community, through its laws, deems wrong should be met with disapprobation for the sake of the victim and the sake of the community.").

[115] Dan M. Kahan, *Social Meaning and the Economic Analysis of Crime*, 27 J. LEGAL STUD. 609, 615 (1998).

[116] JEFFRIE G. MURPHY & JEAN HAMPTON, FORGIVENESS AND MERCY 131 (1988) ("[W]e would be accomplices in the crime if we failed to punish its perpetrator, because we would

approval of the conduct,[117] and disassociation from the victim. As a result, wrongdoers may believe that they are entitled to act as they did. Punishment is meant to humble the offender, to make him feel some inner experience of humiliation and shame,[118] in order to "annul or counter" the message sent by his conduct.[119] Letting the offender "get away with it" may lead to further bad acts as offenders and potential offenders come to believe that their treatment of the victim or class of victims is permissible.[120]

The problems associated with failing to punish are apparent in the treatment of a well-known and respected researcher and professor, Dr. Albert Kligman. In 1951, Dr. Kligman, a professor of dermatology at the University of Pennsylvania School of Medicine, was called to Holmesburg Prison to treat an outbreak of athlete's foot.[121] Describing how he felt when he first arrived at the prison, Dr. Kligman exclaimed, "All I saw before me were acres of skin. It was like a farmer seeing a fertile field for the first time."[122] For the next twenty-five years, Dr. Kligman conducted experiments on prisoners[123] for the benefit of at least thirty-three major pharmaceutical and cosmetic companies, including Merck, DuPont, and Johnson & Johnson.[124] He also created his own company to personally profit from his research[125] and became a millionaire after he created the anti-acne medication Retin-A as a result of his research.[126]

The prisoners were not fully or accurately informed about the nature of the experiments conducted on them.[127] As one explained, "We were never

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be condoning the evidence it gave us of the relative worth of victim and offender . . . we would be acquiescing in the message it sent about the victim's inferiority.").

[117] FEINBERG, *supra* note 100, at 101-03.

[118] Hampton, *supra* note 113, at 1, 15.

[119] MURPHY & HAMPTON, *supra* note 116, at 124-28, 130. "To inflict on a wrongdoer something comparable to what he inflicted on the victim is to master him in the way that he mastered the victim. The score is even. . . . Hence the *lex talionis* calls for a wrongdoer to be subjugated in a way that symbolizes his being the victim's equal." *Id.* at 128.

[120] *See also* Hampton, *supra* note 113, at 6 (explaining how crime demeans a victim's worth); *cf.* Jean Hampton, *Correcting Harms Versus Righting Wrongs: The Goal of Retribution*, 39 UCLA L. REV. 1659, 1679 (1992) (explaining that allowing the propagation of books that assert the superiority of one race or sex can be dangerous because people may "come to believe [their] assertions of superiority" and act on those beliefs).

[121] WOLFGANG WEYERS, THE ABUSE OF MAN: AN ILLUSTRATED HISTORY OF DUBIOUS MEDICAL EXPERIMENTATION 426 (2003).

[122] WASHINGTON, *supra* note 93, at 249.

[123] WEYERS, *supra* note 121, at 427.

[124] WASHINGTON, *supra* note 93, at 249.

[125] WEYERS, *supra* note 121, at 543-44.

[126] WASHINGTON, *supra* note 93, at 249.

[127] WEYERS, *supra* note 121, at 435.

told what was going on. We never had [a copy of] anything we signed."[128] One of Dr. Kligman's students acknowledged that "uninformed patients were the rule,"[129] and Dr. Kligman admitted, "It was years before the authorities knew that I was conducting various studies on prisoner volunteers . . . . No one asked me what I was doing. It was a wonderful time."[130]

Dr. Kligman faced no lasting repercussions for his conduct, even after the U.S. Food and Drug Administration (FDA) discovered his questionable practices. The FDA initiated an investigation after Dr. Kligman published an article that described covering inmates' torsos with an industrial solvent that the FDA had banned from human tests.[131] The FDA investigation revealed additional questionable practices.[132] Consequently, the agency banned Dr. Kligman from receiving and testing investigational drugs on human subjects.[133] This was only the second time in its history that the FDA used this sanction.[134] However, prominent doctors and researchers spoke out in his defense and pressured the FDA to reverse its decision.[135] Less than a month later, the FDA gave in to the pressure.[136] The agency's capitulation sent a clear message to Dr. Kligman and the research community that his actions were condoned.

Dr. Kligman received that message. He recently stated, "My view is that shutting the prison experiments down was a big mistake . . . . I still don't see there having been anything wrong with what we were doing."[137] He is still praised for his prison work[138] and currently sits on the ethics

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[128] WASHINGTON, *supra* note 93, at 245 (quoting Jesse Williams's statement during a 2004 interview with Washington).

[129] WEYERS, *supra* note 121, at 435.

[130] WASHINGTON, *supra* note 93, at 251. Problematically, at the time of these experiments, the United States had already adopted guidelines for research that required informed consent. *See* WEYERS, *supra* note 121, at 381.

[131] WASHINGTON, *supra* note 93, at 250; WEYERS, *supra* note 121, at 556. The results were published in the *Journal of the American Medical Association* in 1965. WEYERS, *supra* note 121, at 556.

[132] His experiments included burning his captives with radiation, immersing their body parts in tanning chemicals, and applying acid to their scrotums until the skin fell away. WASHINGTON, *supra* note 93, at 244. Many of the victims still bear physical scars. *Id.*

[133] WASHINGTON, *supra* note 93, at 250; WEYERS, *supra* note 121, at 558.

[134] WEYERS, *supra* note 121, at 558-59.

[135] *Id.* at 559-60.

[136] *Id.* at 558, 560; WASHINGTON, *supra* note 93, at 250.

[137] Ian Urbina, *Panel Suggests Using Inmates in Drug Trials*, N.Y. TIMES, Aug. 13, 2006, at 1, *available at* http://www.nytimes.com/2006/08/13/us/13inmates.html.

[138] WEYERS, *supra* note 121, at 616.

committee at the University of Pennsylvania medical school[139] where he is an emeritus professor of dermatology.[140]

The failure to punish creates expressive harms. "A person suffers expressive harm when she is treated according to principles that express negative or inappropriate attitudes toward her."[141] When researchers are permitted to commit criminal acts against individuals without punishment, it sends the message that research subjects can be harmed to serve the ends of research. The state's failure to act makes this message all the more powerful because "the state is—or at least purports to be—an impartial agent of morality, with greater capacity to recognize the moral facts than any involved individual citizen."[142] To paraphrase John Braithwaite, what is needed is punishment that maximizes the sense of shame and communicates the message that crime in human experimentation "is as abhorrent to the community as crime in the streets."[143]

B. SCRUTINIZING THE ALTERNATIVES

If punishments are "sanctions . . . expressing public reprobation and moral censure of the harm-causing wrongdoer,"[144] then civil liability and institutional penalties may not constitute punishment. This Subpart argues that these commonly used alternatives to the criminal sanction in the human experimentation context are not conventionally understood as expressing moral condemnation as dramatically and unequivocally as does criminal punishment.[145]

1. Civil Liability

Generally, civil liability is viewed as a means to compensate an injured victim and return her to the status quo *ante*, as opposed to a punitive

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[139] *Id.*

[140] *See* Urbina, *supra* note 137.

[141] Elizabeth S. Anderson & Richard H. Pildes, *Expressive Theories of Law: A General Restatement*, 148 U. PA. L. REV. 1503, 1527-28 (2000). Expressive harms can occur whether or not communication is intended. *Id.* at 1529-30. "An expressive harm . . . results from the ideas or attitudes expressed through a governmental action, rather than from the more tangible or material consequences the action brings about . . . . [T]he very meaning they convey demonstrates inappropriate respect . . . ." Richard H. Pildes & Richard G. Niemi, *Expressive Harms, "Bizarre Districts," and Voting Rights: Evaluating Election-District Appearances After* Shaw v. Reno, 92 MICH. L. REV. 483, 506-07 (1993).

[142] Hampton, *supra* note 113, at 1693.

[143] JOHN BRAITHWAITE, CRIME, SHAME AND REINTEGRATION 143 (1989).

[144] JOEL FEINBERG, HARMLESS WRONGDOING 12 (1988).

[145] Kahan, *supra* note 102, at 593. My only argument is that *today*, these alternative sanctions do not carry the same expressive message as criminal punishment. I do not express an opinion about whether other sanctions, such as shaming, are better alternatives.

device.[146] Unlike criminal punishment, tort liability is not reserved for culpable actors; even accidental conduct can result in a compensatory damages award.[147] Setting aside the issue of punitive damages for a moment, compensatory damages do not express moral censure in the same way as criminal punishment, and thus do not carry the same stigma. Whether a harm is the result of an accident, negligence, or an intentional act, the amount of compensatory damages remains the same.

Additional factors explain why the social meaning of civil liability is different from that of the criminal sanction. First, criminal defendants are afforded constitutional procedural protections such as proof beyond a reasonable doubt and the right to counsel. The absence of such procedural protections in civil proceedings expresses the seriousness of criminal punishment relative to civil liability.[148] Second, a finding of civil liability is not accompanied by the risk of imprisonment or the collateral consequences of a criminal conviction. Accordingly, civil defendants are not humbled to the same extent as are criminal defendants. Criminal punishment expresses blame and reprobation, a message that is largely absent from an award of

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[146] *See* Mann, *supra* note 104, at 1799 (stating that the paradigmatic distinction between the criminal and civil law is that "the criminal law is distinguished by its punitive purposes, its high procedural barriers to conviction, its concern with the blameworthiness of the defendant, and its particularly harsh sanctions. In contrast, the civil law is defined as a compensatory scheme, focusing on damage rather than on blameworthiness, and providing less severe sanctions and lower procedural safeguards than the criminal law."). This is not to say that the civil remedy can never result in opprobrium. Rather, the criminal conviction results in stigma more often than the civil remedy. *See, e.g.*, Lawrence Friedman, *In Defense of Corporate Criminal Liability*, 23 HARV. J.L. & PUB. POL'Y 833, 854 (2000) ("Notwithstanding the retributive character of some aspects of civil liability (a punitive damage award, for example), only criminal liability is understood against the background of social norms, codified by the criminal law, as conveying the particular moral condemnation that expressive retribution contemplates."); *see also* J. Morris Clark, *Civil and Criminal Penalties and Forfeitures: A Framework for Constitutional Analysis*, 60 MINN. L. REV. 379, 407 (1976) ("One might conceptualize the difference between civilly and criminally labeled penalties by stating that most people see in civil penalties an element of deterrence, but not a very strong element of retribution or moral condemnation."). *But see* Galanter & Luban, *supra* note 99, at 1404-07 (arguing that the public often associates the civil sanction with punishment). There are other civil remedies such as injunctions, forfeitures, and specific performance. However, this Article only discusses compensatory and punitive damages because they are most often sought in cases involving mistreatment of human subjects.

[147] One instance in which tort liability carries a stigma is when it is brought in response to a failure to convict the defendant of a crime. However, even in such cases, the stigma is connected to the criminal sanction and is viewed as a substitute for the failure to obtain the desired criminal conviction. For example, to the extent that there was a stigma attached to the award of civil (wrongful death) damages against O.J. Simpson, it is likely associated with the failure to convict him in his criminal murder trial.

[148] *See* Carol S. Steiker, *Punishment and Procedure: Punishment Theory and the Criminal-Civil Procedural Divide*, 85 GEO. L.J. 775, 808 (1997).

compensatory damages. In fact, far from being humbled or stigmatized, compensatory damages express to wrongdoers that they are privileged to act, subject only to possible payment later in the form of damages.[149] Thus, the compensatory damages remedy allows wrongdoers to convert property rules into liability rules at will.[150] Finally, even the players in the criminal justice system recognize the symbolic—and practical—difference between a judgment of guilt and a finding of liability.[151] Although compensatory damages may sometimes express condemnation, they are not the socially conventional way of doing so.

The bulk of my discussion thus far has addressed the compensatory damages component of tort liability. However, an award of punitive damages is also possible. Punitive damages have been described as quasi-criminal punishment and are reserved for culpable actors.[152] The Supreme Court recognized that "[u]nlike compensatory damages, . . . punitive damages are specifically designed to exact punishment in excess of actual harm to make clear that the defendant's misconduct was especially reprehensible. Hence, there is a stigma attached to an award of punitive damages that does not accompany a purely compensatory award."[153]

Punitive damages are a conventional device for expressing condemnation. However, the relative strength of that condemnation is weak compared to the condemnation expressed by the criminal sanction. Punitive damages carry neither the possibility of imprisonment nor the collateral consequences of criminal punishment. Moreover, punitive damages are the subject of negative portrayals in the media as a result of the tort reform movement.[154] The archetype stories of frivolous lawsuits that are rewarded by out-of-control juries paint punitive damages awards as

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[149] *See* Robert Cooter, *Prices and Sanctions*, 84 COLUM. L. REV. 1523, 1550 (1984) ("[I]f crimes were priced, rather than sanctioned, people would be permitted to commit crimes provided that they paid the price.").

[150] Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1124-27 (1972).

[151] As a criminal defense lawyer, I often attempted to negotiate a civil settlement in lieu of criminal prosecution.

[152] Unlike compensatory damages, punitive damages require proof of a culpable mens rea, such as malice. *See* Galanter & Luban, *supra* note 99, at 1407; Dan Markel, *Retributive Damages: A Theory of Punitive Damages as Intermediate Sanction*, 94 CORNELL L. REV. 239 (2009).

[153] *See* Pacific Mut. Life Ins. Co. v. Haslip, 499 U.S. 1, 55 (1991) (O'Connor, J., dissenting); *see also* WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS § 2, at 9 (5th ed. 1984) (describing punitive damages as an "anomalous" situation demonstrating that "the ideas underlying the criminal law have invaded the field of torts").

[154] *See, e.g.*, Am. Tort Reform Ass'n, Punitive Damages Reform, http://www.atra.org/show/7343 (last visited Feb. 2, 2009) (discussing problems with punitive damages awards from the perspective of an organization advocating tort reform).

abuses of the legal system.[155] In other words, public perception of punitive damages as disproportionate punishment has diluted their condemnatory power. Finally, courts can reduce punitive damages awards at their discretion.[156] If reduced, the resulting damages may no longer humble and shame the offender. Indeed, the reduction may even vindicate the wrongdoer.[157]

Assuming that punitive damages do constitute punishment, there remains an important use for criminal sanctions. Culpable acts injure potential victims as well as actual victims.[158] Potential victims may fear being subjected to future harms.[159] Unlike criminal sanctions, punitive damages cannot be awarded to protect future victims.[160] Criminal sanctions, on the other hand, punish wrongdoers for injury to actual victims as well as injury to society as a whole.

In sum, compensatory damages do not express punishment, and the social meaning of punitive damages is at best ambiguous. Use of the civil sanction, as opposed to criminal punishment, expresses that the offender's behavior does not deserve denunciation by the state. Thus, the state's failure to charge researchers for crimes expresses an inappropriate attitude towards the victim and the offender when compared to its willingness to charge people with crimes for committing similar acts outside of the medical research context. Arguably, these messages are exacerbated by the

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[155] *See, e.g.*, Galanter & Luban, *supra* note 99, at 1409-11; Legalzoom, Top Ten Frivolous Lawsuits, http://www.legalzoom.com/legal-articles/top-ten-frivolous-lawsuits.html (last visited Feb. 2, 2009) ("We've all heard the one about the woman who spilled scalding coffee and successfully sued McDonald's.").

[156] *See, e.g.*, BMW of N. Am., Inc. v. Gore, 517 U.S. 559 (1996) (finding punitive damages award with a 500:1 ratio to compensatory damages excessive). Although the Court has not placed constitutional limits on the ratio between actual and potential harm, it has indicated that punitive damages awards that exceed a single-digit ratio with compensatory damages will likely offend due process. State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408 (2003). Punitive damages awards have been reduced by courts in medical research cases. *See, e.g.*, Heinrich v. Sweet, 308 F.3d 48 (1st Cir. 2002).

[157] *See* Hampton, *supra* note 120, at 1687-89 (discussing how the reduction in large punitive damages awards may express the relative superiority of the offenders over those injured).

[158] *See* MURPHY & HAMPTON, *supra* note 116, at 125 n.19 (stating that some moral wrongs injure not only one individual, but society as a whole); Jerome Hall, *Interrelations of Criminal Law and Torts: II*, 43 COLUM. L. REV. 967, 969 (1943) ("[I]n torts, 'effects' almost invariably include actual damage to some person, whereas in crimes, damage is not essential—instead the notion of a 'social harm,' supplies the requirement there." (citation omitted)).

[159] *See* ROBERT NOZICK, ANARCHY, STATE, AND UTOPIA 58-71 (1974) (arguing that the state is justified in establishing public institutions of criminal justice with respect to acts which create a generalized sense of fear affecting persons other than actual victims).

[160] *See, e.g.*, Philip Morris USA v. Williams, 549 U.S. 346 (2007).

too-frequent use of the criminal sanction as a normative response to wrongful conduct. I do not advocate overcriminalization. However, legislative eagerness to propose and pass new criminal laws and the use of tough-on-crime rhetoric sends a message that the criminal sanction is the only means of expressing societal condemnation. Consequently, overcriminalization has constructed a social reality that only criminal sanctions are capable of truly punishing offenders and vindicating victims.

2. Institutional Sanctions

Institutional sanctions also provide a means for protecting against misconduct in human experimentation. Both the FDA and the National Institutes of Health (NIH) play a role in protecting human subjects.[161] FDA regulations govern clinical trials of drugs and devices for FDA approval. Researchers who fail to comply with FDA regulations, such as informed consent requirements,[162] may lose their entitlement to work with investigational drugs.[163]

The NIH protects human subjects by conditioning its coveted research grants. Recipients of NIH funds must sign an assurance of compliance with human subject protection rules, including mandatory informed consent procedures.[164] Failure to comply with these requirements can result in withdrawal of current funding and ineligibility for future grants.[165]

Institutional sanctions can cause embarrassment, stigmatization, reputational losses, and even affect a researcher's ability to work in his chosen field. However, as serious as these consequences may be, they do

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[161] "Compliance with these parts is intended to protect the rights and safety of subjects involved in [such] investigations . . . ." 21 C.F.R. § 50.1 (2008). For a general history of existing regulations protecting human subjects, see Alvino, *supra* note 24, at 895-909.

[162] 21 C.F.R. § 50.20.

[163] 21 C.F.R. § 312.70 (2008). This revocation can be permanent, but is rarely employed. *See* O'Reilly, *supra* note 5, at 345. The FDA can also issue a temporary or lifetime bar from participating in the drug industry. 21 U.S.C. §§ 335a, 335b (2006) (applying debarment only after a researcher has a qualifying conviction for a felony). The FDA maintains a list of individuals and firms barred from participating in the drug industry, and publishes this list in the federal register. FDA, Disqualified/Restricted/Assurances List for Clinical Investigators, http://www.fda.gov/ora/compliance_ref/bimo/dis_res_assur.htm (last visited Feb. 2, 2009); *see also* Tamar Nordenberg, *Inside FDA: Barring People from the Drug Industry*, FDA CONSUMER MAG., Mar. 1997, http://www.fda.gov/fdac/features/1997/297_debar.html (discussing debarment).

[164] Public Health Service Act (PHSA), 42 U.S.C. §§ 201-300 (2000). The PHSA establishes uniform regulations on informed consent, 45 C.F.R. § 46.101 (2008), and delineates oversight responsibilities to Institutional Review Boards, 21 C.F.R. § 56.101 (2008); *see also* 45 C.F.R. § 46.103 (regulating the National Institutes of Health (NIH), the Department of Health and Human Services, and the FDA).

[165] *See* 45 C.F.R. § 46.123.

not necessarily express moral condemnation. Although an offender may feel punished when his privilege to work in an industry is withdrawn, institutional sanctions are not unambiguously punishment and can even be understood as purely remedial.[166]

The following hypothetical illustrates the notion that institutional sanctions are not punitive. Imagine a doctor who rapes his patient while she is under anesthesia. Rather than prosecuting this doctor, the state revokes his license. Most people would not consider this sanction a sufficient expression of moral blame. Furthermore, wrongdoers in many professional fields are simultaneously prosecuted and debarred from their chosen field. For example, the state often prosecutes lawyers who have already been disbarred. Thus, the failure to impose both criminal sanctions and professional sanctions sends the message that researchers' misconduct is undeserving of the most serious sanction.[167]

3. An Example of the Expressive Failures of Alternative Sanctions

The death of Jesse Gelsinger during his participation in human subject research provides an example of how civil liability and institutional sanctions fail to send equivalent messages of blameworthiness and moral culpability as criminal sanctions. Jessie died as a result of misconduct by the head researcher in the experiment. Despite the existence of criminal statutes prohibiting his conduct, the researcher was not prosecuted.[168] This

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[166] *See* Mann, *supra* note 104, at 1839 (arguing that monetary civil penalties over and above compensation are unambiguously punishment, while nonmonetary penalties are largely remedial). Some courts hold that the withdrawal of the privilege to work in a field is simply remedial. *See, e.g.*, Hudson v. United States, 522 U.S. 93, 104 (1997) ("We have long recognized that 'revocation of a privilege voluntarily granted,' such as a debarment, 'is characteristically free of the punitive criminal element.'" (quoting Helvering v. Mitchell, 303 U.S. 391, 399 (1938))); Flemming v. Nestor, 363 U.S. 603, 617 (1960) (explaining that while the individual is prohibited from further participation in the health care industry, this is "certainly nothing approaching the 'infamous punishment' of imprisonment"); United States v. Bizzell, 921 F.2d 263, 267 (10th Cir. 1990) ("It is the clear intent of debarment to purge government programs of corrupt influences and to prevent improper dissipation of public funds. Removal of persons whose participation in those programs is detrimental to public purposes is remedial by definition."); Manocchio v. Sullivan, 768 F. Supp. 814, 817 (S.D. Fla. 1991) ("Disqualifying a person from participating in a social program or practicing a profession because of offensive activity is not punishment, if the past activity is such that the public would have an interest in excluding the offender.").

[167] The loss of federal funds or debarment may not prevent researchers from continuing to work in the same field. An additional shortcoming with NIH and FDA sanctions is that they only cover trials that are regulated by the FDA or receive federal funds. O'Reilly, *supra* note 5, at 335-36. Half of the trials currently conducted in the United States are funded privately. *Id.* at 337. Legislation proposed in 1997 that would have called for the regulation of all clinical trials affecting interstate commerce failed to pass. *Id.* at 351 n.219.

[168] *See infra* note 196.

case provides a useful lens through which to examine the expressive meaning of the failure to use criminal punishment.

Eighteen-year-old Jesse Gelsinger suffered from a mild form of a rare metabolic disorder that affects the body's ability to break down ammonia.[169] He was diagnosed at age two and for the remaining sixteen years of his life successfully controlled his disease with a low-protein diet and drugs.[170] Jesse's treating physician told him about gene therapy trials conducted by the Institute for Human Gene Therapy at the University of Pennsylvania (IHGT).[171] Dr. James Wilson, director of the IHGT, was the trial's sponsor, which made him responsible for ensuring compliance with the regulations governing human subject research, including informed consent.[172]

Jesse and his father met with researchers at the IHGT to determine whether Jesse was an appropriate candidate for the study and to give informed consent.[173] The researchers told the Gelsingers that the IHGT had achieved a "certain efficacy" with respect to the treatment of the disease.[174] Due to the efficacy information and the informed consent document, Jesse and his father believed that the risks of joining the study were minimal.[175] Jesse enrolled in the trial in September of 1999. Four days later, he died.

After Jesse's death, the FDA conducted an investigation that revealed that researchers had enrolled Jesse in the trial despite the fact that he did not properly qualify to participate in it.[176] The FDA further determined that the researchers "repeatedly or deliberately violated regulations governing the

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[169] Complaint ¶ 2, Gelsinger v. Trs. of the Univ. of Pa., http://sskrplaw.com/links/healthcare2.html (last visited Feb. 2, 2009).

[170] *Id.* ¶¶ 55-57.

[171] Gene therapies use specially created genetic material that is inserted into target cells with the intent to cure a genetically-based disease. Baram, *supra* note 24, at 255. There are currently approximately 500 gene therapy trials involving over 4000 human subjects with funding from the NIH. *Id.* There are also some privately-financed studies approved by the FDA. *Id.*

[172] News Release, United States Attorney's Office, *available at* http://www.upenn.edu/almanac/volumes/v51/n21/gts.html [hereinafter USAO News Release].

[173] Complaint, *supra* note 169, ¶¶ 59-60.

[174] *Id.* ¶ 61. According to the plaintiff's complaint, defendant Dr. Arthur Caplan, an ethical consultant to the research team, admitted after Jesse's death that "there was never any chance that anybody would benefit from these experiments. They [were] safety studies . . . . If you cured anybody, you'd publish it in a religious journal. It would be a miracle. [But t]he researchers wouldn't say that." *Id.* ¶¶ 43-44.

[175] *Id.* ¶ 62.

[176] Jesse's blood ammonia levels on the day before he received the gene transfer exceeded the limit set out in the FDA protocol, but the researchers enrolled him anyway as a substitute for another volunteer who had dropped out. *FDA Suspends Trials at Gene-Therapy Lab*, CNN.COM, Jan. 22, 2000, *available at* http://archives.cnn.com/2000/HEALTH/01/22/gene.therapy/.

proper conduct of clinical studies."[177] These violations included modifying the FDA-approved informed consent document. For example, the researchers had removed information that monkeys injected with the virus had become ill or died.[178] Dr. Wilson and his research team had also ignored an FDA request to revise the informed consent document so that participants would be aware of serious side effects suffered by previous subjects.[179] As a result, neither Jesse nor his father was aware of these risks. According to Jesse's father:

> Jesse and I were told . . . that a prior patient, the patient before him, had shown a clinical improvement of [fifty] percent in her ability to eliminate ammonia from her system . . . . [After Jesse's death] I discovered that no efficacy was achieved at all in this patient. I had no idea there was no success in gene therapy before my son's participation in this. Nobody relayed that information to me. I was under the impression this worked . . . . I found out it was an experiment.[180]

The FDA found numerous additional violations, including failures to make required disclosures to the FDA, which may have brought the trial to a stop before Jesse enrolled.[181] Upon completing its investigation into Jesse's death, the FDA commenced administrative proceedings to disqualify Dr. Wilson from conducting further clinical studies.[182] The

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[177] Letter from Steven A. Masiello, Dep't of Health & Human Serv., to James M. Wilson, Inst. for Gene Therapy 1 (Nov. 30, 2000), *available at* http://www.fda.gov/foi/nidpoe/n12l.pdf [hereinafter Initiation Letter] (providing "Notice of Initiation of Disqualification Proceeding")

[178] WEYERS, *supra* note 121, at 605; Complaint, *supra* note 169, ¶ 61.

[179] WEYERS, *supra* note 121, at 605 (citation omitted). Dr. Wilson failed to maintain adequate case histories of subjects tested with the investigational drugs. *Id.*

[180] *Gene Therapy: Is There Oversight for Patient Safety?: Hearing Before the Subcomm. on Public Health of the S. Comm. on Health, Education, Labor and Pension*, 106th Cong 28, 31 (2000) [hereinafter *Gene Therapy Hearing*].

[181] According to the Chief of the FDA's Center for Biologics, "We probably would have made them stop the trial until we figured out what was going on." *Id.* Although the study's approved protocol required termination of the trial "if a single subject develops Grade III or higher toxicity," Dr. Wilson failed to terminate the study despite knowledge that five subjects had exhibited Grade III toxicity. Initiation Letter, *supra* note 177, at 2-4. In fact, he even failed to document toxicity levels for numerous subjects. *Id.* Dr. Wilson failed to exclude people from the trial who did not meet the criteria for subject selection. *Id.* at 5-8. A total of four ineligible people were entered into the study. *Id.* Dr. Wilson failed to monitor all the subjects as required by the protocol, *id.*, and he frequently submitted misleading and inaccurate information to the independent overseeing body charged with ensuring compliance with the approved protocol. He also did not report that two subjects had suffered serious reactions. *FDA Suspends Trials at Gene-Therapy Lab*, *supra* note 176. Furthermore, Dr. Wilson modified the trial's approved protocols without obtaining approval. Initiation Letter, *supra* note 177, at 8-12.

[182] *See* Initiation Letter, *supra* note 177, at 1.

Government eventually settled a civil suit with the University of Pennsylvania for violations of the civil False Claims Act.[183]

The settlement with the Government imposed a number of sanctions upon Dr. Wilson that may, upon cursory inspection, appear to express punishment. For five years, the settlement prohibits Dr. Wilson from serving as a sponsor in any FDA clinical trial and from conducting human subject research without the supervision of a monitor.[184] Additionally, for three years, the settlement prohibited him from conducting more than one experiment at a time.[185] It also required him "to lecture and author an article on the lessons learned from this study [and] . . . to advocate for inclusion of any statements from those affected by the study, e.g., the Gelsinger family."[186]

Closer scrutiny of these responses to his misconduct, however, leads to the conclusion that they likely do not constitute punishment. The settlement does not permanently bar Dr. Wilson from serving as a trial sponsor or from conducting human subject research. Rather, during the period of restriction, the settlement not only allows him to serve in other capacities, but also permits him to conduct research on humans as long as a monitor is present.[187] The requirement of a monitor may bruise the ego of someone of his stature. However, its insufficiency as punishment is demonstrated if we imagine similar treatment of the more common criminal. Imagine that a bank employee is guilty of embezzlement. Would

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[183] USAO News Release, *supra* note 172 (announcing that the University of Pennsylvania had agreed to pay $517,496). There was also an industry-wide response that could arguably protect future victims. The FDA and NIH jointly announced a new initiative, the Gene Therapy Clinical Trial Monitoring Plan, designed to increase the level of scrutiny by adding reporting requirements for study sponsors, and a series of Gene Transfer Safety Symposia designed to allow researchers to communicate with each other, share results about unexpected problems, and ensure that everyone knows the rules. *See* Larry Thompson, *Human Gene Therapy: Harsh Lessons, High Hopes*, FDA CONSUMER MAG., Sept.-Oct. 2000, *available at* http://www.fda.gov/fdac/features/2000/500_gene.html. The FDA launched random inspections in more than two dozen gene therapy trials nationwide and instituted new reporting requirements. *Id.* Finally, President Clinton announced more "new actions designed to ensure that individuals are adequately informed about the potential risks and benefits of participating in research . . . and steps designed to address the potential financial conflicts of interest faced by researchers." *Id.* President Clinton also stated in May 2000 that he was sending a proposal for new legislation to Congress that would authorize civil sanctions for researchers and institutions found to be in violation of regulations governing clinical trials, which would give the FDA the power to fine researchers up to $250,000 and their institutions up to $1 million. *Id.*

[184] USAO News Release, *supra* note 172.

[185] *Id.* Dr. Wilson is also required to have a special monitor when conducting animal research that could influence the safety of human research participants. *Id.*

[186] *Id.* This Article does not deal with the other researchers involved.

[187] *Id.*

we believe that he was punished if, rather than facing criminal prosecution, he was assigned a monitor to work with him for the next few years to ensure that he does not attempt to embezzle more funds during that time period? A limitation on research functions more as a deterrent, or as a way to incapacitate, rather than as true punishment with its attendant message of moral blameworthiness.[188] Finally, the settlement did not require Dr. Wilson to admit to any wrongdoing or accept any blame for Jesse's death, which makes the requirement that he lecture on the lessons learned from the experience seem somewhat empty of expressive content. Unlike criminal punishment, these responses to Dr. Wilson's misconduct do not carry the collateral consequences of criminal punishment, and thus do not appear to express the same condemnation and moral blame. Once the time period of the FDA sanctions expires, Dr. Wilson is free to continue his work without restriction.[189]

Dr. Wilson has never apologized to the Gelsinger family.[190] He still conducts research[191] and remains a tenured professor at the University of Pennsylvania School of Medicine and chairman of its Molecular and Cellular Engineering Department.[192] Furthermore, Dr. Wilson lost none of his profits despite the fact that at the time of Jesse's death, he had financial interests in the study that may explain the motive behind his misconduct.[193]

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[188] Nothing prevents Dr. Wilson from profiting from conducting human subject research, even during the period of the restrictions. Arguably, in order to punish him for causing the death of another, he should no longer be able to profit from his research, similar to the way in which other offenders cannot profit by publishing a book about their crimes.

[189] He did resign from his position as the head of the Institute for Human Gene Therapy, but the Dean of the University of Pennsylvania Medical School made clear that his resignation had "nothing to do with the Gelsinger case." Emily Sanders, *Researcher Wilson to Step Down as IHGT Head*, DAILY PENNSYLVANIAN, Apr. 23, 2002, http://media.www.dailypennsylvanian.com/media/storage/paper882/news/2002/04/23/News/Researcher.Wilson.To.Step.Down.As.Ihgt.Head-2157651.shtml.

[190] *See* Paul Gelsinger & Adil E. Shamoo, *Eight Years After Jesse's Death, Are Human Research Subjects Any Safer?*, 38 HASTINGS CTR. REP. 25 (2008), *available at* http://www.sskrplaw.com/publications/gelsinger-april-08.pdf ("The federal government charged the researchers and their institutions with fraud. The defendants entered into settlement agreements involving fines and other penalties. But there was no acknowledgment of responsibility, let alone wrongdoing, nor was there even a hint of remorse in the form of an apology.").

[191] *See* Univ. of Pa. Health Sys., Research/James Wilson, http://www.uphs.upenn.edu/penngen/research/wilson.html (last visited Feb. 2, 2009) (describing Wilson's research).

[192] Sanders, *supra* note 189.

[193] Dr. Wilson was the founder of a biotech company, Genovo, in which both he and the University owned shares of stock. WEYERS, *supra* note 121, at 618. Contributions from Genovo made up one-fifth of the $25 million annual budget of the Institute. *Id.* at 618-19 (citation omitted). In fact, the University's conflict-of-interest rules were altered to permit Wilson to own 30% of the company's stock. *See* Diana L. Bush, *Gene Therapy Trials: The Role of the National Institutes of Health and Conflicts of Interest*, 19 BIOTECH L. REP. 576,

Although the Gelsinger family sued Dr. Wilson and the University,[194] the case was settled, and only the University paid an undisclosed sum.[195]

Dr. Wilson was not prosecuted, although he could have been.[196] The use of alternative sanctions resulted in Dr. Wilson receiving better treatment than similarly situated offenders; the failure to utilize criminal punishment expresses that Dr. Wilson is entitled to different or special treatment from the average offender because he is a well-respected and talented doctor conducting socially beneficial research. While he may have suffered some short-term humiliation, the state treated him very differently than it does

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586 (2000). The University also gave Wilson the exclusive right to license patents derived from the IHGT to Genovo and its corporate sponsors. *See* WEYERS, *supra* note 121, at 618-19 (citation omitted). A year after Jesse's death, Targeted Genetics Corporation acquired Genovo. Marie McCullough, *Human Guinea Pigs on the Frontiers of Medicine*, PHILADELPHIA INQUIRER, May 5, 2002, at D1, *available at* http://www.sskrplaw.com/publications/5-20guinea.html. Dr. Wilson received $13.5 million in Targeted stock, and the University received $1.4 million. *Id.* Researchers from other university hospitals who failed to abide by the regulations also held equity interests in the companies sponsoring their trials. Richard A. Knox, *Physicians Deny Deaths Unreported*, BOSTON GLOBE, Nov. 4, 1999, at C1.

[194] The Gelsinger family sued Dr. Wilson and other researchers and institutions involved in the gene therapy trial for, among other things, wrongful death, intentional assault and battery, fraud, lack of informed consent, and fraud on the FDA. *See* Complaint, *supra* note 169. The plaintiffs sought compensatory as well as punitive damages. *Id.*

[195] The civil suit settled with the University paying an undisclosed amount to the Gelsinger family. *See Family Settles Suit over Patient's Death Following Gene Therapy Clinical Trials*, 15 TOXIC L. REP. 1227 (2000).

[196] For instance, Dr. Wilson's failure to abide by the mandatory regulations governing the conduct of human subject experiments and thereby causing the death of Jesse Gelsinger is comparable to routinely prosecuted homicides. A person is guilty of murder when "it is committed recklessly under circumstances manifesting extreme indifference to the value of human life." MODEL PENAL CODE AND COMMENTARIES § 210.2(1)(b) (1962). A person acts recklessly when he "consciously disregards a substantial and unjustifiable risk" that his acts will cause a particular result. MODEL PENAL CODE AND COMMENTARIES § 2.02(2)(c). Here, Dr. Wilson consciously disregarded a substantial and unjustifiable risk that death would result from his failure to comply with the regulations. The regulations are mandatory and consist of reporting requirements that are meant to ensure the rights and safety of human subjects. 21 C.F.R. § 50.1 (2008) ("Compliance . . . is intended to protect the rights and safety of subjects involved in investigations . . . ."). The reporting of adverse events, for example, is required so that an independent body can continuously determine whether, at any point, the risks to an individual's welfare outweigh the benefits of the research. 21 C.F.R. §§ 56.108, 56.109, 56.111(a)(2) (2008). Dr. Wilson's "repeated and deliberate" failure to report adverse events prevented the independent review body from performing its functions and ending the trial, as the FDA indicated it likely would have done. *See supra* note 189. Hence, his failure to abide by the mandatory reporting requirements created a substantial risk that a human life would be put at risk of death. The risk he took was unjustifiable because there was no justification for his failure to abide by the mandatory reporting requirements. *Id.* The mail fraud and wire fraud statutes could also provide sources of liability. *See* 18 U.S.C. § 1343 (2006) (wire fraud); *id.* § 1341 (mail fraud).

other offenders who have caused the death of another individual.[197]

The criminal brand has symbolic, practical, and expressive significance that other sanctions do not. It is rife with notions of censure and blameworthiness,[198] and justifies the imposition of punishment, which includes not only the potential loss of liberty, but also a host of collateral consequences. The use of any sanction short of criminal punishment risks causing expressive harm because the message is that what was done to the victim does not deserve criminal punishment and its collateral consequences. In other words, it is acceptable for this offender to treat this victim in this manner.[199]

IV. THE UTILITY OF DESERT[200]

Criminal punishment expresses moral condemnation in a way that alternative sanctions do not. This Part argues that imposing criminal punishment will also further instrumentalist goals, such as deterrence[201] and moral education, as a "happy consequence."[202] How criminal punishment can serve these additional goals of punishment in the human experimentation context is discussed next.

A. DETERRENCE

Punishment can deter by vindicating the value of the victim through protection.[203] This protective function works by issuing a "sting" that the

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[197] In fact, according to their attorney, the Gelsinger family is "surprised and disappointed at the seeming lack of any consequence to Wilson for the misdeeds that led to the death of Jesse Gelsinger." Sanders, *supra* note 189 (statement of Alan Milstein, Attorney for Jesse Gelsinger).

[198] Harry V. Ball & Lawrence M. Friedman, *The Use of Criminal Sanctions in the Enforcement of Economic Legislation: A Sociological View*, 17 STAN. L. REV. 197, 216 (1965).

[199] FEINBERG, *supra* note 100, at 102-03.

[200] The title of this Part is borrowed from Paul H. Robinson & John M. Darley, *The Utility of Desert*, 91 NW. U. L. REV. 453 (1997).

[201] MURPHY & HAMPTON, *supra* note 116, at 140 (explaining that the "retributivist's notion of desert is *derived from* punishment's role as a deterrent but is quite different from deterrence").

[202] MICHAEL S. MOORE, THE MORAL WORTH OF RETRIBUTION, RESPONSIBILITY, CHARACTER, AND THE EMOTIONS: NEW ESSAYS IN MORAL PSYCHOLOGY 179-82 (Ferdinand Schoeman ed., 1987); *see* MURPHY & HAMPTON, *supra* note 116, at 129-30 & n.26 (distinguishing the retributive motive, which is to annul the appearance of superiority of the wrongdoer, from other non-retributive motives, such as deterrence and moral education). This is not to say that deterrence is not an appropriate part of any just punishment scheme, but it is not the goal of retribution. Hampton, *supra* note 120, at 1659 & n.2.

[203] MURPHY & HAMPTON, *supra* note 116, at 138.

offender feels upon engaging in a prohibited act.[204] The desire to avoid this pain in the future is how deterrence is achieved.[205]

Determining how best to deter misconduct in human subject research is important because the protection of human subject autonomy essentially falls upon the individual researcher. In theory, institutional bodies such as the FDA, NIH, and Institutional Review Boards (IRB)[206] police misconduct by approving research protocols and conducting periodic audits. In practice, resource constraints make any consistent effort to ensure that human subjects are protected illusory.[207] Since these institutions cannot audit even a small subset of human subject research, they rely upon researchers to provide truthful information in the study protocol when seeking approval to conduct research, to comply with follow-up reporting

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[204] *Id.* at 140.

[205] *Id.*

[206] The role of the Institutional Review Board (IRB) is to review and approve research protocols and informed consent documents, ensuring that the safety of individuals will be adequately protected and that the benefits outweigh the risks. O'Reilly, *supra* note 5, at 331 & n.93 (citing OFFICE OF INSPECTOR GEN., *supra* note 23, at 3. Some companies have their own IRBs, and other IRBs operate independently, being hired by contract to study any management organization or researcher who wants their services. O'Reilly, *supra* note 5, at 100. Their composition and duties are set forth by statute. *See* 21 C.F.R. §§ 56.101, 56.103, 56.109 (2008) (FDA); 45 C.F.R. §§ 46.103, 46.109 (2008) (NIH). Members usually consist of lay volunteers and members from the researcher's institution. *See, e.g.*, 21 C.F.R. § 56.107 (FDA).

[207] *See also* Gelsinger & Shamoo, *supra* note 190, at 25-27 ("Last year, a report by the inspector general of the Department of Health and Human Services found that the FDA, the agency responsible for overseeing most clinical trials, inspected just 1 percent of study sites. Small wonder, since it has a mere two hundred investigators and there are 350,000 sites." (citing OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERV., NO. OEI-01-06-00160, THE FOOD AND DRUG ADMINISTRATION'S OVERSIGHT OF CLINICAL TRIALS (2007); THE BALT. CONFERENCE ON ETHICS, ETHICS IN NEUROBIOLOGICAL RESEARCH WITH HUMAN SUBJECTS (Adil E. Shamoo ed., 1997)). IRBs are often overwhelmed with the amount of work they are required to do, and they are typically under-resourced. *See* Jonathan Moreno et al., *Updating Protections for Human Subjects Involved in Research*, 280 J. AM. MED. ASS'N 1951, 1956 (1998); *see also* O'Reilly, *supra* note 5, at 336-37 & n.131 (noting that IRBs are overworked and underfunded (citing 1 NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING PERSONS WITH MENTAL DISORDERS THAT MAY AFFECT DECISIONMAKING CAPACITY 71 (1998))). The shortcomings of IRBs are frequently studied and discussed. *See, e.g.*, O'Reilly, *supra* note 5, at 330 n.91. As one commentator recognized, "[I]t is now widely accepted that IRBs are overwhelmed by trial oversight responsibilities and documentation, are easily misled or ignored by researchers, and are unwilling to challenge institutional colleagues." Baram, *supra* note 24, at 267-68; *see also* Kus v. Sherman Hosp., 644 N.E.2d 1214, 1216-17 (Ill. App. Ct. 1995) (involving a researcher that changed the informed consent form from the one that had been approved by the FDA by removing language that the intraocular lens was experimental. The defense expert testified that if the IRB had audited the researcher's charts, it would have discovered the discrepancy).

requirements, and to follow informed consent requirements.[208] Thus, the lack of consistent and reliable institutional oversight of human subject research fails to provide adequate deterrence incentives.[209]

Researchers are essentially left to police themselves, and historically, they have failed in their efforts. It took a law student to bring an end to the Tuskegee syphilis experiments,[210] the FDA to stop Dr. Kligman's experiments at Holmesburg Prison, the suspicions of a patient and his

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[208] Although the FDA and the NIH do perform periodic inspections and audits, and IRBs have obligations to continue monitoring the research protocol subsequent to approval, all three bodies simply cannot monitor every human subject trial conducted. Site visits and audits are conducted by investigators for the FDA and NIH. O'Reilly, *supra* note 5, at 332; *see* U.S. Dep't of Health & Human Serv., Office for Human Research Protections, http://www.hhs.gov/ohrp/ (last visited Feb. 2, 2009) (NIH procedures); U.S. Dep't of Health & Human Serv., U.S. Food and Drug Administration Home Page, http://www.fda.gov (last visited Feb. 2, 2009) (FDA procedures). Very few trials are audited. O'Reilly, *supra* note 5, at 345. The FDA simply does not have the resources to meet its workload. *Id.* at 346 n.183 (citing Frances O. Kelsey, *The Bioresearch Monitoring Program*, 46 FOOD DRUG COSM. L.J. 59, 60-61 (1991)). In fact, the FDA's supervision of trials is a "discretionary function" depending on government priorities. O'Reilly, *supra* note 5, at 346 (citing 28 U.S.C. § 2680(a) (1994)). The NIH also requires each institution to maintain its own audit system and to report problems in patient protection to the NIH. 45 C.F.R. § 46.103(b)(5) (2008). IRBs frequently fail to continue review of approved studies. *See* O'Reilly, *supra* note 5, at 332 (citing NAT'L BIOETHICS ADVISORY COMM'N , *supra* note 207, at 71).

[209] *See* O'Reilly, *supra* note 5, at 333 ("The repercussions of embarrassment and cost would be a real deterrent if enforcement occurred more frequently and was more efficient than the slow process now in place.").

[210] The Tuskegee syphilis study was the longest experiment involving human subjects in United States history, running for forty years from 1932 until 1972. Katz, *supra* note 24, at 230. During the now infamous study, researchers deliberately deceived 400 African-American men with syphilis, leaving the disease untreated in order to study the natural course of the disease. *Id.* Some men were not told that they had syphilis and were told that they were receiving routine medical treatment, while others were told that they were receiving treatment for the disease. *Id.* The experiments continued even after the government put regulations in place to protect human subjects and after an effective treatment for syphilis had been discovered. WASHINGTON, *supra* note 93, at 165-66. Articles detailing the experiments had been published in medical journals, and the results from the study had been shared at a 1936 American Medical Association meeting. *Id.* at 166; WEYERS, *supra* note 121, at 498-99. But it took a law student to put an end to it. WEYERS, *supra* note 121, at 582. When he learned of the experiments, he complained to public health service officials. *Id.* at 500. But the blue ribbon panel it assembled in response concluded that the unwitting subjects should continue to remain untreated. *Id.* Frustrated, he told a friend at the Associated Press, and on June 26, 1972, an article appeared in the New York Times. *Id.* at 502. As a result of public outrage, the Department of Health, Education, and Welfare terminated the study shortly thereafter. *Id.* By then, only seventy-four of the original 400 test subjects were still alive. *Id.* Many doctors expressed the view that there had been nothing wrong with the study. *Id.* at 608. Some doctors argued that they had done nothing wrong because African-Americans suffering from syphilis would not have voluntarily sought treatment anyway. WASHINGTON, *supra* note 93, at 161. None of the individuals involved were ever criminally prosecuted.

lawyer to discover Dr. Golde's mining of Moore's body, and a death to expose the actions of Dr. Wilson. These are only a few instances of ineffective self-policing.[211] Another example is the recent discovery that for over sixty years, researchers at the State University of Iowa (now Iowa University) concealed experiments performed on unwitting orphans. A professor at the University led experiments on children to test his hypothesis that stuttering was conditioned in children as the result of overly critical parents.[212] With the University's knowledge and agreement, he tested his hypothesis at an orphanage, telling the orphanage that he was conducting a study to improve children's speech.[213] During the course of the experiment, his research assistant very successfully made non-stuttering children into stutterers.[214] After the experiment was over, very little effort was made to correct the stuttering they had induced in the children,[215] and the efforts they did make were largely unsuccessful.[216]

Those involved in the study acknowledged that they were engaged in a "'monster experiment' that would, if discovered, be compared to the World War II experiments and ruin the careers of the scientists and researchers involved."[217] Thus, they decided to conceal it. The experiment was discovered in 2001 only after the research assistant suffered an attack of conscience and alerted the press.[218]

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[211] Concerned with the lack of compliance, after Jesse Gelsinger's death, the NIH reminded other gene therapy researchers of their reporting obligations. Bush, *supra* note 193, at 576. Researchers responded with 691 adverse events that had not been disclosed as required. *Id.* The FDA and NIH investigations of other gene therapy trials confirmed that many human subjects had suffered from "adverse effects," many of which had not been reported by the researchers or organizations involved. *Id.* For example, medical researchers at Cornell University and Tufts University failed to report six deaths to NIH. *See* Deborah Nelson & Rick Weiss, *Earlier Gene Test Deaths Not Reported: NIH Was Unaware of 'Adverse Events,'* WASH. POST, Jan. 31, 2000, at A1; Deborah Nelson & Rick Weiss, *Gene Therapy Deaths Disclosed*, BOSTON GLOBE, Nov. 3, 1999, at A10. Although some, if not all, of the deaths were the result of the subjects' underlying illnesses, researchers were still required to report the deaths to the oversight agencies. Nelson & Weiss, *Gene Therapy Deaths Disclosed*, *supra*. The FDA "suspended gene therapy trials at St. Elizabeth's Medical Center in Boston, a major teaching affiliate of Tufts University School of Medicine, . . . because scientists there failed to follow protocols and may have contributed to at least one patient death." Thompson, *supra* note 183.

[212] *See* Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 839 n. 32 (Md. 2001).

[213] *Id.*

[214] *See id.*

[215] *Id.*

[216] *Id.*

[217] *Id.*

[218] *Id.*

The threat of criminal punishment would likely have important deterrent effects on researchers.[219] Currently, a researcher engaged in calculated risk-taking knows that if he violates human subject protections, the likelihood of discovery is minimal and even if discovered, he will not be prosecuted. At most, he may pay compensatory damages[220] or face temporary restrictions on his research.[221] The "sting" of criminal punishment, including the stigma of being branded a criminal, risk of imprisonment, and message of disapproval, denunciation, and reproach, is more serious than that provided by alternative sanctions. The fear of being labeled a criminal will likely be felt strongly by researchers because they are a class that is prone to view themselves as different from the common criminal.[222] Hence, the consequences of criminal punishment can be expected to deter more effectively than other sanctions even if the possibility that culpable acts will be discovered remains equally small.[223]

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[219] John C. Coffee, Jr., *Does "Unlawful" Mean "Criminal"?: Reflections on the Disappearing Tort/Crime Distinction in American Law*, 71 B.U. L. REV. 193, 193 (1991) (arguing that criminal punishment operates "as a system of moral education and socializing"); Hampton, *supra* note 113, at 17 ("The use of punishment may be particularly desirable if a person or legal institution wants to take advantage of the deterrent value of retributive suffering.").

[220] The tort system has often proved inadequate to protect human subjects. Issues such as whether a researcher owes a duty of care to the subject remain an open question. *See* Alvino, *supra* note 24, at 910-12. Furthermore, subjects must demonstrate cognizable injury prior to recovery, and actual physical injury may not result from a violation of informed consent. Although most jurisdictions allow recovery without physical injury for negligent infliction of emotional distress, *id.* at 913 n.140, "damages . . . may be difficult to prove in the absence of physical harm . . . ." Saver, *supra* note 20, at 226, *cited in* Alvino, *supra* note 24, at 913 n.140.

[221] *See supra* notes 186-212 and accompanying text (discussing the sanctions faced by Dr. Wilson as a result of his role in Jesse Gelsinger's death). In fact, even when misconduct is demonstrated, fellow researchers tend to rally around the accused. *See supra* note 183 and accompanying text (discussing the response of researchers to Dr. Kligman and Dr. Wilson).

[222] *See* HERBERT L. PACKER, THE LIMITS OF THE CRIMINAL SANCTION 356 (1968) ("People who value their standing in the community are likely to be especially sensitive to the stigma associated with a criminal conviction."); Ball & Friedman, *supra* note 198, at 216-17 ("Business abhor the idea of being branded a criminal . . . . [B]usinessmen, after all, form a large, respectable, and influential class in our society."); Arthur L. Liman, *The Paper Label Sentences: Critiques*, 86 YALE L.J. 630, 630-31 (1977) ("To the businessman, . . . prison is the inferno, and conventional risk-reward analysis breaks down when the risk is jail.").

[223] *See, e.g.*, JOEL FEINBERG, *Crime, Clutchability, and Individuated Treatment*, *in* DOING AND DESERVING, *supra* note 100, at 252, 263 (claiming that punishment is appropriate for rational risk-takers); Mary M. Cheh, *Constitutional Limits on Using Civil Remedies to Achieve Criminal Law Objectives: Understanding and Transcending the Criminal-Civil Law Distinction*, 42 HASTINGS L.J. 1325, 1355 (1991) ("[T]he theory is that humans, as rational weighers of the risks and benefits of their actions, will risk being penalized if the worst they face is having to pay market value for their illicit gains."); Steven Shavell, *Criminal Law and the Optimal Use of Nonmonetary Sanctions as a Deterrent*, 85 COLUM. L. REV. 1232, 1237-

B. MORAL EDUCATION

Punishment can also be an effective moral educator.[224] The infliction of pain serves an educative function because it "interferes with the offender's pursuit of his interests, draws his attention to the crime and society's condemnation of it, and conveys to him that certain actions are 'fenced off in virtue of what we take to be their immoral character.'"[225] The criminal law's educative and socializing role is arguably necessary to teach researchers that violations of autonomy and dignity are wrong despite the potential utility of the research.

There is evidence that research community norms may serve to facilitate misconduct. First, researchers have been resistant to attempts to place mandatory limits on their research. For example, many researchers objected to the binding nature of the Nuremberg Code as an appropriate guide for their behavior. The Code was created in response to the atrocities committed by Nazi doctors during the Second World War and forms the basis for the protection of human subjects in the United States today.[226] It establishes a set of mandatory, explicit, and uniform ethical guidelines and standards to govern the conduct of medical research on humans.[227] Its ten principles seek to attain two broad goals. First, it aspires to protect autonomy by giving human subjects the absolute right to decide whether to participate in experiments and to end their participation at any time.[228] Second, it aims to protect the welfare of human subjects either by prohibiting certain risky research from being conducted at all or by

38 (1985) ("Nonmonetary sanctions may be helpful of course because their threatened use might deter parties who could not be deterred by monetary sanctions alone.").

[224] Some philosophers do not believe that moral education is a legitimate goal of punishment. *See, e.g.*, JOEL FEINBERG, *in* THE MORAL LIMITS OF THE CRIMINAL LAW, *supra* note 144, at 295.

[225] Hampton, *supra* note 113, at 21.

[226] The Code forms the basis for the protection of human subjects in the United States today. Michael A. Grodin, *Historical Origins of the Nuremberg Code*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 24, at 139. In the 1950s, the NIH adopted guidelines providing that "[t]he rigid safeguards observed at NIH are based on the so-called 'ten commandments' of human medical research which were adopted at the Nuremberg War Crime trials after the atrocities performed by Nazi doctors had been exposed." Leonard H. Glantz, *Influence of the Nuremberg Code on U.S. Statutes*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 24, at 185. An integral feature of the laws governing human subject research is the protection of the autonomy and dignity of human subjects. *See* 45 C.F.R. §§ 46.101-46.409 (2008).

[227] Grodin, *supra* note 226, at 121; WASHINGTON, *supra* note 93, at 258.

[228] *See* Office of Human Subjects Research, Nat'l Insts. of Health, Directives for Human Experimentation: Nuremberg Code, provisions 1, 9, http://ohsr.od.nih.gov/guidelines/nuremberg.html (last visited Feb. 2, 2009).

requiring researchers to terminate an experiment at any stage if its continuation is "likely to result in injury, disability, or death."[229]

Researchers rejected the Code as "a good code for barbarians but an unnecessary code for ordinary physicians."[230] They thought that the Code's "legalistic" demands were unnecessary and unduly burdensome to research.[231] As a former Dean of the Harvard Medical School put it:

> [T]he Nuremberg Code was conceived in reference to Nazi atrocities and was written for the specific purpose of preventing brutal excesses from being committed or excused in the name of science. The code, however admirable in its intent, and however suitable for the purpose for which it was conceived, is in our opinion not necessarily pertinent to or adequate for the conduct of medical research in the United States.[232]

Second, the research community appears to resist efforts to effectively investigate allegations of misconduct. For example, after Dr. Kligman's actions at Holmesburg Prison came to light, attempts were made by the American Academy of Dermatology to discover more information about his research at the prison. The Academy created a task force that sent letters to the researchers involved in the experiments asking for comments. The letters referenced the atrocities at Nuremberg. When Academy officers learned of this, they were furious.[233] They not only immediately informed the task force that it had not been authorized "to suggest that [the] experiments may have been in violation of the Nuremberg Code,"[234] but

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[229] Glantz, *supra* note 226, at 184 (referring to provisions 2-8 and 10 of the Nuremberg Code); Grodin, *supra* note 226, at 121.

[230] Katz, *supra* note 24, at 228.

[231] A Harvard researcher, Henry Beecher, described the Code as "a rigid act of legalistic demands . . . a legalistic document . . . . Until recently the Western world was threatened with the imposition of the Nuremberg Code as Western credo." *See* George J. Annas, *The Nuremberg Code in U.S. Courts: Ethics Versus Expediency*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 24, at 201, 201-05. This researcher rejected rigid rules, stating in 1959 that "the problems of human experimentation do not lend themselves to a series of rigid rules. In most cases, these are more likely to do more harm than good." WEYERS, *supra* note 121, at 377 (citing H.K. Beecher, *Experimentation on Human Beings*, 169 J. AM. MED. ASS'N 461-78 (1959)).

[232] WEYERS, *supra* note 121, at 401. Courts have not utilized the Code as a basis for liability. *But see* Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 834 (Md. 2001). Courts have cited the Nuremberg Code with approval. *See, e.g.*, United States. v. Stanley, 483 U.S. 669, 686 (1987) (O'Conner, J., dissenting); *id.* at 686-87 (Brennan, J., dissenting); Heinrich *ex rel.* Heinrich v. Sweet, 62 F. Supp. 2d 282, 321 (D. Mass. 1999); White v. Paulsen, 997 F. Supp. 1380, 1383-84 (E.D. Wash. 1998) Hoover v. W. Va. Dep't of Health & Human Serv., 984 F. Supp. 978, 978 (S.D. W. Va. 1997), *aff'd*, 129 F.3d 1259 (11th Cir. 1997); *In re* Cincinnati Radiation Litig., 874 F. Supp. 796, 821-22 (S.D. Ohio 1995); Whitlock v. Duke Univ., 637 F. Supp. 1463, 1470-71 (M.D.N.C. 1986), *aff'd*, 829 F.2d 1340 (4th Cir. 1987).

[233] WEYERS, *supra* note 121, at 612.

[234] *Id.* (citation omitted).

they also immediately sent apologies to each researcher who had received the letter.

Finally, the research community tends to defend culpable researchers and downplay the harm. For instance, with respect to Dr. Wilson and the death of Jesse Gelsinger, some members of his community stated that the sanctions against him were unwarranted. When the University of Pennsylvania restricted Dr. Wilson's ability to conduct experiments on humans[235] and decided to stop manufacturing genetically-altered viruses, a leading scientist in the field said that the University's move was an overreaction. "This is throwing the baby out with the bath water .... It basically eliminates the gene therapy program if you can't run trials."[236] Another prominent and well-respected professor, ethicist, and director of the gene therapy program at the University of California, San Diego stated that Jesse's death was "[a]t worst, ... another pothole in the road."[237]

Comments such as these underscore that research norms are in need of modification—a need that can be well addressed by criminal sanctions. The criminal sanction can shape or even change norms or preferences within a community because people in part learn what is morally blameworthy through what is punished.[238] The sanction teaches people, both potential offenders and the community at large, what the public morality is, whether or not they fully internalize it.[239] Criminal punishment can be used self-consciously "to change beliefs, attitudes, and personal values and goals [and] can effectuate policy considerations by influencing what a person thinks he ought to do or what he wants to do in a particular situation."[240] Some scholars even argue that the criminal category is not about public

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[235] Sheryl Gay Stolberg, *Institute Restricted After Gene Therapy Death*, N.Y. TIMES, May 25, 2000, at A20. He was required to restrict his work to the study of molecules and cells, and to experiment only on animals. *Id.*

[236] *Id.*

[237] *See* Stephen S. Hall, *A Death in Philadelphia*, MIT TECH. REV., Jan. 2000, at 2, *available at* http://www.technologyreview.com/biomedicine/12015/page1/ (statement of Theodore Friedmann, Director, Program in Human Gene Therapy, University of California).

[238] *See* Kenneth G. Dau-Schmidt, *An Economic Analysis of the Criminal Law as a Preference-Shaping Policy*, 1990 DUKE L.J. 1, 24 (noting that the criminal sanction is a particularly powerful tool to shape the preferences of the individual defendant and of society at large).

[239] Ball & Friedman, *supra* note 198, at 217, 222; Coffee, *supra* note 219, at 223.

[240] Ball & Friedman, *supra* note 198, at 220. "Often law tries to redefine roles." Cass R. Sunstein, *Social Norms and Social Roles*, 96 COLUM. L. REV. 903, 923 (1996). "For example, the law has said that husbands may not rape their wives .... All of these measures can be seen as attempts to create new or better norms to define the relevant roles." *Id.*; *id.* at 913 ("A good deal of governmental action is self-consciously designed to change norms, meanings, or roles, and in that way to increase the individual benefits or decrease the individual costs associated with certain acts."); Ball & Friedman, *supra* note 198, at 220.

morality at all, but "[r]ather, . . . a set of techniques to be manipulated for social ends."[241] Changing social norms can, in turn, "influence choices . . . by altering the effects of reputational incentives and consequences for self-conception."[242] If the criminal sanction is successful in shaping social norms, then behaving in a manner inconsistent with them will result in "public disapproval," which in turn will produce "embarrassment or perhaps shame and a desire to hide."[243]

To the extent that idealization bias and social benefit bias affects public views about researcher misconduct,[244] criminal punishment can help "rekindle in the public a sense of the immorality of the defendant's acts."[245] Its power to express moral condemnation may more effectively deter misconduct and change both researchers' and society's views concerning bad acts. Criminal punishment can help overcome the idealization bias and social benefit biases that currently appear to exist in the context of human subject experimentation.

V. SCRUTINIZING CRIMINAL PUNISHMENT

I have argued that criminal punishment may be the only sanction that can punish culpable medical actors engaged in intentional misconduct that violates individual rights to autonomy, dignity, and self-determination. I have considered this question in the context of bad acts involving the lack of consent. I end by considering some preliminary questions and concerns that use of the criminal sanction may raise, although I do not intend to resolve them here.[246]

Punishment raises the specter of over-deterrence. With regard to the forms of misconduct discussed in this Article, there exists little difficulty in distinguishing bad acts from good ones. However, if use of criminal punishment will be extended to police other forms of research misconduct, this question of over-deterrence will require further scrutiny. If mistaken or negligent acts cannot be consistently and accurately distinguished from wrongful ones before imposing punishment, the fear of erroneous

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[241] Ball & Friedman, *supra* note 198, at 211; *see also* Mann, *supra* note 104, at 1807 (acknowledging that punishment can be viewed as a means of social control).

[242] Sunstein, *supra* note 240, at 916. Cass Sunstein defines norms as "social attitudes of approval or disapproval, specifying what ought to be done and what ought not to be done." *Id.* at 914.

[243] *Id.* at 915.

[244] *See* Burrows, *supra* note 92.

[245] Ball & Friedman, *supra* note 198, at 222; *see also id.* at 217 (explaining that criminal punishment can make "the proscribed conduct illegitimate in the eyes of a potential actor, even when the actor disagrees with the purpose of the law").

[246] These will be discussed in future Articles.

identification as a culpable actor may keep well-intentioned actors from engaging in research.[247] Additionally, if the line between good and bad acts in medical research is a fine one, researchers may become excessively cautious in order to avoid wrongful exposure to criminal punishment. The argument against criminal punishment, then, is that when there exists difficulty distinguishing between acts we want to encourage and those we do not, it is more appropriate to price rather than to prohibit the behavior.[248]

Another concern with criminal punishment is that vigorous enforcement and stringent penalties may make it difficult to discover unlawful acts in human subject research. Recent work in the area of system justification theory posits that these responses may cause system justifying behaviors—behaviors amongst actors in the system that inhibit detection and prevention efforts.[249] Empirical research into the culture and practices of the research community will be necessary before any prediction can be made about the effect punishment will have on researcher motivations. However, if criminal punishment will result in increased difficulty in ferreting out research crime, this is an important question to consider.

If criminal punishment is deserved in appropriate circumstances, then serious thought must be given to the amount of punishment necessary to humble the wrongdoers. If researchers are prosecuted under existing criminal statutes, do the sentencing schemes map well with what the appropriate sentence should be? In some cases, the punishment provided by existing criminal statutes may be too severe, and in others, too lenient.

If new crimes or sentencing schemes are appropriate, then there are institutional problems to consider. The existence of idealization bias and social benefit bias creates a chicken-and-egg problem. The biases may result in the failure to impose punishment, but imposing punishment may be necessary to change the existing biases. Punishment can reduce the efficacy of these biases, but the existence of them may make prosecutors unwilling to proceed with criminal prosecutions. Additionally, the biases may also affect legislators' willingness to pass criminal legislation or sentencing schemes to punish researchers, especially because one can expect significant resistance from the medical profession to criminal sanctions

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[247] *See generally* Craig S. Lerner & Moin A. Yahya, *"Left Behind" After Sarbanes-Oxley*, 44 AM. CRIM. L. REV. 1383, 1384 (2007) (arguing that "soaring penalties for corporate crimes and dilution of a mens rea requirement . . . could have the paradoxical consequences of creating *more* corporate crime" as people with high moral standards choose to leave the field).

[248] Cooter, *supra* note 149, at 1524 ("If lawmakers can identify socially desirable behavior, but are prone to error in assessing the cost of deviations from it, then sanctions are preferable to prices.").

[249] Gary Blasi & John T. Jost, *System Justification Theory and Research: Implications for Law, Legal Advocacy, and Social Justice*, 94 CAL. L. REV. 1119, 1160 (2006).

directed specifically at them.[250] How do we address this? Perhaps the first step is to at least recognize the problem.

VI. CONCLUSION

The fact that human subject research is socially beneficial should not mean that culpable acts go unpunished. Criminal punishment in appropriate instances would send a clear, expressive message that doctors are not privileged to treat human subjects in a manner inconsistent with their inherent value as human beings. Punishment can reassert acknowledgement of the victim's worth in the face of a denial. Proper punishment will cause suffering in the offender and demonstrate to researchers that their actions are worthy of stigma, ridicule, and shame, and in this way, perhaps change the attitudes of the relevant community. This, in turn, will restore the proper balance between protecting human dignity and autonomy, and allowing socially beneficial research to continue. It will also likely make the self-policing nature of the existing regulations more effective. Punishment will help change the existing biases, which can in turn change the existing norms and place the protection of individuals front and center instead of allowing individuals to be used as guinea pigs in favor of broader societal goals. If we are serious about protecting individual autonomy and dignity in research, consideration of criminal punishment is an important step.

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[250] For example, in 2002, two representatives introduced the Human Research Subject Protection Act of 2002 which would increase protections for human subjects. H.R. 4697, 107th Cong. (2002), *available at* http://thomas.loc.gov/cgi-bin/bdquery/z?d107:h.r.04697:. As of 2005, however, the bill has not come up for a vote. *Id.* Sherman, Silverstein, Kohl, Rose & Podolsky, Chronology, http://www.sskrplaw.com/articles/pdf/biochron6.pdf (last visited Feb. 2, 2009). Similarly, Senator Kennedy's bill, the Research Revitalization Act of 2002, which would also increase human subject protections, has not yet come up for a vote. S. 3060, 107th Cong. (2002), *available at* http://thomas.loc.gov/cgi-bin/bdquery/z?d107:s.03060.