

The Rise of Litigation in Human Subjects Research

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Owing to widespread public concern about the adequacy of protections for human research subjects and recent instances of serious injury to subjects at several major research institutions, lawsuits against investigators, institutional review boards, and academic institutions are becoming increasingly common. Several claim-promoting conditions are ripe to promote the further growth of this litigation and raise the stakes for research institutions. While this litigation may serve a valuable compensation function

for injured subjects, it will also have profound effects on institutional review boards, leading to a more legalistic, mechanistic approach to ethical review that does not further the interests of human subjects or scientific progress.

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There is a growing perception that the regulation of research involving human subjects has been inadequate and must change (1). Spurred by deaths of research subjects at leading academic institutions (2, 3), federal legislators are considering sweeping changes in the laws governing human research (4). In the meantime, the Office for Human Research Protections (OHRP) has assumed an activist posture and induced most institutions to bolster their human subjects oversight (5). By all appearances, human subjects research is moving from a very flexible form of self-regulation to a more bureaucratically oriented system of oversight.

The federal government's regulations (6), issued three decades ago in the wake of shocking revelations surrounding the Tuskegee Syphilis Experiment (7), devolve responsibility for reviewing and monitoring human studies to institutional review boards (IRBs). The review calculus prescribed by federal law consists of a rough utilitarian weighing of the risks and benefits of the study and an evaluation of subjects' ability to give meaningful informed consent to participation. In practice, the informed consent inquiry tends to focus heavily on the wording of the consent form (8).

Recent revelations suggest that IRBs have often miscalculated the risk-benefit ratios and failed to ensure the integrity of the consent process. Moreover, evidence indicates that IRBs have been systematically underestimating the importance of a range of factors that bear on the ethical inquiry, from the vulnerability of subjects to the pressures created by financial conflicts of interest (1, 8, 9). These findings have served as the impetus for closer federal monitoring of human studies.

What many involved in research today may not appreciate is that stricter government regulation is not the law's only response to harms from research. Our society also relies on private litigation to deter poor practices and compensate persons injured by substandard conduct. Historically, personal injury lawsuits by research subjects against researchers have been rare. However, both the frequency and stakes of these lawsuits are on the rise, and the lawsuits are now beginning to implicate IRBs. In this report, we trace the evolution of this litigation and explain why we

expect to see more of it. In considering its implications, we conclude that while the litigation may help compensate injured subjects, it has potentially undesirable ramifications for research oversight because it is likely to drive IRBs toward a more legalistic, mechanistic approach to ethical review that does not further the interests of human subjects or scientific progress.

THE EVOLUTION OF LITIGATION IN HUMAN SUBJECTS RESEARCH

Informed Consent Claims

Litigation over injuries to research subjects is not new. For at least two decades, occasional cases alleging a failure to obtain informed consent have been brought against various defendants. The doctrine of informed consent dates to the 1914 case of *Schloendorff v. New York Hospital* (10), in which New York's highest court articulated a patient's right to full information before undergoing treatment.

Informed consent litigation relating to medical treatment blossomed in the 1960s and 1970s (11), when courts in many jurisdictions decided to replace a profession-based disclosure standard with a patient-based standard. In other words, jurors were asked to judge claims not according to what information physicians thought a patient reasonably should be given but rather according to what the patient might reasonably expect to be told (11). Claims alleging a negligent failure to obtain informed consent continue today as a fairly common species of medical malpractice litigation.

These claims have been easily transplanted to the research context. The typical allegation is that the research subject was not given sufficient information to permit meaningful consent to research participation. For example, in *Berman v. Fred Hutchinson Cancer Center* (12), brought by the husband of a patient with breast cancer who died in a chemotherapy trial, the plaintiff alleged that his wife would not have agreed to participate in the trial if she had known that a drug intended to prevent lethal side effects from the chemotherapy was not available in intravenous form. Contrary to what doctors allegedly told her, the drug was available only in tablet form, and she died after vom-

iting the pills. In August 2002, the trial court ruled for the plaintiff on this claim (13).

In recent years, three important innovations have occurred in litigation over research-related injuries. First, the types of legal claims have diversified. Second, as a result the number and types of defendants named in these lawsuits have increased. Finally, plaintiffs' attorneys are increasingly using class action techniques to bring claims on behalf of large groups of research subjects. These developments individually and collectively may have significant implications for the future of human subjects research. We explore these developments in the context of several of the dozen or so high-profile cases filed in the last few years.

The New Legal Claims

Enterprising plaintiffs' attorneys have turned to a daunting array of legal doctrines in framing lawsuits against those who perform and oversee research. A lawsuit that 20 years ago would have been brought as a routine informed consent claim may today include allegations of defective products, fraud, negligent conduct and monitoring of the research, intentional infliction of emotional distress, breach of patients' rights protected by state law, violation of federal regulations, and violation of constitutional rights. This diversification in legal causes of action is not unique to research-related litigation—it is also visible in other tort litigation such as suits brought by health maintenance organization enrollees against health plans that deny them coverage for services (14). However, it is especially pronounced in the human subjects area.

A popular approach in lawsuits alleging injuries in pharmaceutical trials is to combine the traditional informed consent claim with product liability claims against the drug manufacturer (15). For example, the mother of an infant who died in a trial of the heartburn drug Propulsid recently filed suit against the Children's Hospital of Pittsburgh and Janssen Pharmaceuticals, alleging that she was not informed of risks and adverse events associated with Propulsid and that the drug was defectively designed (16). This legal tactic recycles one used in some of the earliest human subjects litigation, claims brought by women whose infants were injured by diethylstilbestrol (17, 18).

Three other recent cases illustrate even greater legal creativity in the drafting of claims. The case of *Gelsinger v. University of Pennsylvania Hospital* arose from the death of 18-year-old Jesse Gelsinger in a phase I gene therapy trial (19). The Gelsinger family coupled the usual informed consent claim with a product liability claim, and then went further: They alleged that the investigators had committed fraud by not revealing that previous subjects enrolled in the protocol had died and that the principal investigator had a financial relationship with the sponsoring biotechnology company (20). The parties reached a confidential settlement in November 2000.

Robertson v. Oklahoma, a state court case that grew out of a federal suit dismissed for lack of jurisdiction (21),

involved injuries to subjects in a phase I/II melanoma vaccine trial at the University of Oklahoma Health Sciences Center at Tulsa. The plaintiffs made three main allegations. First, they alleged a lack of informed consent based on the investigators' failure to reveal that the vaccine had not been subjected to animal studies, their failure to disclose all the relevant risks, and their misrepresentation of the vaccine as a potential cure for cancer. Second, they claimed that the trial itself was negligently run—essentially a claim of investigator “malpractice” in the conduct of research—because the investigators enrolled ineligible patients and failed to monitor the subjects' health appropriately. Third, they alleged that investigators fraudulently misrepresented the purpose, risks, and benefits of the study. Some of the defendants reached a settlement with the plaintiffs in July 2002 (22).

The case of *Wright v. Fred Hutchinson Cancer Center* is another interesting cocktail of legal claims; it incorporates the kind of “research malpractice” and fraud claims used in *Robertson*, includes conflict of interest allegations like those in *Gelsinger*, and adds several new theories (23). In this case, subjects in a trial to prevent graft failure in patients undergoing bone marrow transplantation alleged that the investigators used misleading consent materials and failed to disclose various conflicts of interest. The plaintiffs also claimed that the investigators failed to report deaths appropriately to the IRB and failed to update consent forms as required by the IRB, in essence alleging negligent conduct of the trial. In addition, the plaintiffs in *Wright* posited a “breach of the right to be treated with dignity” under the due process clause of the 14th Amendment to the U.S. Constitution, arguing that international conventions such as the Nuremberg Code and the Declaration of Helsinki substantiated this right. The same group of attorneys have taken these groundbreaking constitutional and international law claims even further in other cases (12, 24), although it is too early to judge their legal sway. The trial court in *Wright* recently dismissed the constitutional and international law claims made in that case (13), while a New York district court allowed similar claims to proceed in a case involving a drug trial in Nigeria (25).

The fraud claims in cases like *Wright* are of particular interest because they give the plaintiffs' attorney significant leverage in court. An allegation of fraud is likely to powerfully affect jurors. While the public may be becoming more cynical about business ethics in the wake of several major corporate scandals, the public is used to thinking of researchers as committed to new knowledge and the welfare of research subjects rather than the pursuit of profits that might come from a successful trial. Such a claim, casting investigators as intentionally leading subjects into danger for their own financial gain, can alter the entire tenor of a case.

Fraud allegations also open the door for enormous damages awards. In tort law, damages may have three components: compensation for economic losses, such as lost

wages; damages for pain and suffering; and “punitive” damages. The punitive damages component, which is intended to punish especially blameworthy defendants, usually accounts for a substantial portion of the multimillion-dollar personal injury verdicts that attract media attention. In actuality, punitive damages are rare: They occur in less than 1.5% of medical malpractice verdicts and approximately 5% of plaintiff trial wins overall (26, 27). However, punitive damage awards are exceptionally common among fraud claims, occurring in about one fourth of verdicts for the plaintiff (27, 28). Hence, research subjects who bring successful fraud claims stand a good chance of receiving very large damages awards. This makes research-related litigation very attractive to plaintiffs’ attorneys who work on a contingency-fee basis.

The New Defendants

In addition to the proliferation of different types of claims, plaintiffs’ attorneys have innovated by casting their net across a wider range of defendants, including IRBs. The Gelsingers, for instance, sued the university, the hospital, the investigators, and the biotechnology company that sponsored the trial. The *Robertson* plaintiffs sued the hospital, the principal investigator, the pharmaceutical sponsor, top university officials, the individual members of the IRB, and the university bioethicist who consulted with the IRB. Most recently, a suit brought by the family of a man who died in a trial of the Abiomed artificial heart even named the hospital’s patient advocate (29).

The move to target IRBs has resonated deeply with academic medical centers, their IRB members, and the courts. This strategy formed the centerpiece of the highly publicized decision in *Grimes v. Kennedy-Krieger Institute* (30). The plaintiffs in this case were families enrolled in a study to determine how effectively varying degrees of lead paint abatement procedures protected children from the harmful effects of lead exposure. Although even the highest exposure levels in the study were below those of other low-income housing in Baltimore (95% of which had lead hazards at the time of the study) (31), the plaintiffs argued that the trial should never have been conducted because the ongoing exposure of children to hazardous levels of lead paint was unjustifiable. The IRB at Johns Hopkins had addressed this issue in its deliberations, but had decided that the benefits of the research outweighed the risks.

Maryland’s highest court decided that the IRB’s calculus was flatly wrong and constituted negligence. In essence, the court replaced the expert judgment of the IRB with its own judgment of the risk–benefit ratio, suggesting that neither the parents’ consent nor the IRB’s approval of the protocol would make the researchers immune from liability. In addition, the court chastised the IRB for suggesting revisions to the protocol intended to avoid applying certain federal protections to the children in the control group.

The multiple-defendant strategy used in cases like *Kennedy-Krieger* creates attractive litigation dynamics for

the plaintiffs’ attorney. Most obviously, it increases the pool of money available to pay a judgment. In addition, the naming of top university officials and individual IRB members raises the profile of the case, attracting media attention and prompting concern on the part of officials and IRB members at other institutions about their personal legal exposure. Finally, suing IRB members opens the door for courts to review the procedures and substance of IRB deliberations, rather than confining their scrutiny to the behavior of the investigators. This represents an important change in the scope of judicial review and regulation of human subjects research.

The New Class Actions

The third major innovation in human subjects research litigation is the use of class action techniques. In a class action lawsuit, a large number of individuals who have similar injuries and legal claims sue as a group, seeking a judgment or settlement that will apply to the entire class. The use of class action techniques in product liability claims has exploded over the last 30 years (32). In recent years, class action suits have proven powerful in litigation against drug manufacturers and tobacco companies (27, 33). Pioneering uses of this strategy in research-related litigation date back to the diethylstilbestrol cases (34), and class actions are now becoming the norm in human subjects litigation.

Human experimentation injuries are quite amenable to the class action approach. The basic requirements for obtaining court permission to pursue a class action are that the group of plaintiffs is sufficiently numerous, that the commonalities among the plaintiffs outweigh the differences, that the named plaintiffs are typical of the rest of the class, and that the plaintiffs’ attorneys can adequately represent the class (35). The requirement of numerosity is usually met since research protocols involve multiple subjects. Satisfaction of the commonality and typicality requirements tends to follow in cases involving a defectively designed protocol because subjects will probably feel the effects of the defect in similar ways. The representativeness requirement no longer poses a significant barrier because plaintiffs’ attorneys have become very skilled in class action techniques and can ably represent large groups of plaintiffs.

The use of class actions has several advantages for plaintiffs’ attorneys. With dozens to thousands of plaintiffs, the potential award to plaintiffs becomes much higher, making for higher contingency fees. Indeed, at least one firm has found clinical trials litigation so lucrative that it is marketing a specific practice niche in this area (36). Plaintiffs’ firms can also combine forces and achieve economies of scale in litigation that would otherwise be too costly and cumbersome to pursue.

In summary, the new human subjects litigation is more aggressive than ever, featuring a greater diversity of claims, more defendants, and more plaintiffs. In the current climate of concern about human subjects safety,

courts, juries, the media, and the public are greeting the claims sympathetically. The prospects for the growth of tort litigation in human subjects research are extremely favorable.

LITIGATION PROSPECTS

Several claim-promoting conditions are ripe to promote the further growth of this emerging litigation. Plaintiffs' lawyers will benefit from researchers' relatively poor historical compliance with federal regulations; the widespread public concern with the safety of research subjects (37); research institutions' risk-averse attitude toward litigation and surrounding publicity; the unsympathetic intersection of product liability, conflicts of interest, and potential research fraud; and the contingency-fee multiplier presented by potential class action claims.

While medical malpractice litigation has long been one of the bread-and-butter practice areas of personal injury attorneys, there are reasons to think that research-related litigation may be even more attractive to plaintiffs' attorneys than traditional malpractice cases. One consideration is that in a medical malpractice case, there is usually little dispute that the physician's intention was to help the patient, which tends to make the physician a sympathetic defendant for the jury. In a research-related case, there is a much greater potential for arguing that the researcher's motives and the subject's good are not aligned, especially if there are apparent financial conflicts of interest. The fact that so many investigators have financial relationships with commercial study sponsors (38)—indeed, some have direct financial stakes in the success of the technology being tested (39)—creates fertile ground for allegations of fraud and perceptions of conflicts of interest to take root with juries.

A second factor relates to the applicable standard of care. Whereas garden-variety medical malpractice cases traditionally have applied a standard that is grounded in customary medical practice, the standard of care in research-related litigation is set by federal regulations, international conventions, and what a "reasonable" IRB would require. The use of a reasonableness standard gives judges and juries wider leeway than a custom-based standard in determining what should be required of IRBs and investigators. In practice, this standard is tougher on defendants, who cannot invoke an "everybody does it" defense. The *Kennedy-Krieger* decision is the first—but surely not the last—instance of a court's substituting its own, stricter standards for those of an IRB. As public concern about human subjects protection continues to intensify, what is considered "reasonable" is bound to push further in a direction that favors plaintiffs.

Another major factor that will impel more litigation in the research area is defendants' responses to lawsuits. Most research institutions are not accustomed to dealing with lawsuits over research studies. Their first impulse will be to

settle the matters quickly and quietly so as to limit disclosure of sensitive details. However, rapid settlements will probably lead to more litigation, as word travels among the relatively small group of plaintiffs' attorneys who handle these claims that good returns are available on relatively small pretrial investments.

IMPACT OF LITIGATION

This litigation has potentially significant implications in both the legal and research arenas. Trial-court and appellate judges, through their written opinions, create formal legal precedent that is applied in future cases. Because the recent spate of clinical trials cases is still working its way through the courts, there are few published opinions that allow us to gauge the evolution of the common law in this area. Some of the appellate opinions issued to date—such as *Kennedy-Krieger*—indicate that courts are receptive to the kinds of claims being brought by plaintiffs, but defendants have prevailed in other cases.

While the effects of the litigation on case law are just beginning to emerge, other effects are already visible. Particular developments in the litigation have signaled to other potential plaintiffs and plaintiffs' attorneys what litigation tactics may prove successful. For example, courts have generally ruled favorably on plaintiffs' motions to certify a class action. They have in some cases granted defendants' motions to dismiss particular causes of action or defendants, but in other cases plaintiffs have been allowed to proceed with their innovative claims. Furthermore, the wide publicity surrounding this litigation, including news of settlements, appears to have inspired additional suits. Thus, while the ultimate impact of this litigation on the law itself remains to be seen, the growing momentum will, at the very least, result in more cases and more settlement activity over the next few years.

Viewing the tort system as a form of regulation, litigation against researchers should create incentives for more careful research and greater human subjects protection. Researchers and institutions who have been sued, or who have heard about others being sued, will want to avoid future suits. They can do so by being clear about conflicts of interest, paying special attention to the processes through which subjects' informed consent is obtained, designing and conducting trials carefully, monitoring studies closely for injuries to subjects, and ensuring that proper steps are taken when injuries occur. If one believes that tort litigation effectively deters substandard behavior, then litigation can simply be seen as filling the gaps left by inadequate IRB oversight and the lack of strong direct government regulation.

In addition, the tort system provides a means for injured individuals to obtain compensation. The current system of research regulation offers no mechanism for compensating human subjects who suffer adverse events. Although tort law is an inefficient mechanism of compen-

sation (27), it nonetheless provides some relief in a system that otherwise would lump injured subjects with the cost of research-related injuries.

There are, however, significant disadvantages to the growth of tort litigation in research. First, litigation will inevitably increase the costs of research. The damages paid to injured subjects may be enormous, especially if punitive damages are involved. Moreover, the administrative costs of investigating and trying a personal injury claim with complicated issues of liability and causation can be high—indeed, these costs are a key factor driving the use of class action techniques. Where research institutions are made to bear these costs, the effect will be to make clinical research more expensive, as liability insurers adjust insurance premiums to guard against these new and uncertain risks. One could argue that these increases merely represent the true costs of undertaking research. However, many research institutions will be ill prepared to bear them.

Second, decisions like *Kennedy-Krieger* may have a serious chilling effect on individuals' willingness to serve on IRBs. While most IRB members should be covered by the institution's professional liability insurance, the threat of being named in a lawsuit joins onerous workloads, lack of compensation, and other disincentives for IRB service. As the legal threat grows, it will further stress the pool of human capital on which our peer review–based system of research regulation relies.

Perhaps most significantly, we fear that the combination of more bureaucratic regulatory oversight and significant exposure to litigation could lead to worse, not better, decision making about the ethics of research studies. Once courts begin to second-guess IRBs' decisions, the natural tendency for IRBs will be to become more conservative. They may be pushed into a legalistic mode in which slavish attention to regulatory detail crowds out reviewers' ability to ask real questions about the risks and benefits of research studies. Some research that has long been considered acceptable in terms of risk–benefit ratio may no longer be approved.

In some instances, such recalibration will be a welcome and valuable change. The revelations of deficiencies in the approval processes at leading universities indicate that IRBs are failing to meet public expectations (3). However, the impact will be destructive if IRBs feel compelled to adopt requirements that are of marginal or no benefit to human subjects for the primary purpose of avoiding legal exposure—just as physicians have felt compelled to practice “defensive medicine” in response to the growth of medical malpractice litigation. As we have argued elsewhere, the courts are not always adept at risk–benefit analysis (40). While few would argue that IRBs have always gotten the balance right in the past, we doubt that replacing their expert opinion with the ex post views of judges and juries represents an improvement.

CONCLUSION

As a result of the many claim-promoting conditions we have outlined, researchers are likely to be visited by tort litigation to an extent heretofore unknown. The sunny view of this trend is that the best aspects of the current regulatory regime—that is, self-regulation driven by professional integrity—will be preserved, but litigation will promote more attention to detail and increased public accountability (41). However, we doubt this will be the case. More likely, as litigation increases, the future of human subjects research will feature a more grinding regulatory approach.

We have little to offer to prevent this outcome beyond exhortation. We hope that investigators will continue to volunteer their time on IRBs, with a renewed sense of responsibility. The challenge that lies ahead for IRBs is to respond to the very real concerns that have given rise to lawsuits and heightened government scrutiny without damaging the professional integrity and thoughtful deliberation that constitute the best aspects of our peer review system of governance.

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