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An Overview of the Legal Aspects of Human Experimentation and Research

The early months of 1975 perhaps saw more alarm created within the community of professional persons who involve themselves in healing human beings or in conducting research involving human subjects than ever before. The notorious Boston abortion case [*1*] and the current flap over medical malpractice insurance rates [*2*] are merely illustrative. Throughout the whole realm of activity that may be generically described as research and experimentation on human subjects this controversy ramifies with consequences yet unknown. The purpose of this paper is to provide an overview of the legal aspects of research and experimentation on human subjects, directed somewhat toward behavioral research and particularly behavioral research in nonlaboratory settings.

Examining the legal literature in this field leaves two impressions with the reader. One is that the whole subject is deeply tinged with moralistic connotations, stemming from hard-to-define notions of privacy and human dignity; the other is that the crux of the issue is something known as informed consent. While I harbor very strong concerns about the need for human beings to be secure in their privacy even when in public places, I find that the writings in this field are not very helpful. Most people either agree or disagree on the merits of privacy issues, and the writings themselves add little to resolving the legal problems. In a similar vein, while the writings on informed consent are valuable to legal technicians, they seldom if ever open up the entire field for examination by those who are not lawyers.

Attempting to avoid either the too general or too specific approaches, this paper will examine the underlying issues from the perspective of basic legal precepts. Such an approach will have its own shortcomings in that very specific questions will go unanswered. In partial remedy of that, some particular attention will be given to current problems of informed consent in field observations of human behavior.

The place of law in society is to regulate human behavior. In most situations where criminal or civil sanctions are to be imposed the regulations are narrowly drawn to truncate extreme modes of behavior perceived by the lawmakers as socially undesirable enough to be outlawed in one way or another. The main spectrum of behavior goes undisturbed by the law. Accordingly, when I speak of behavior to be controlled I mean those modes or extremes of human behavior that society has thought warranted legal sanctions. The remainder of the paper is organized in five general sections as follows: a discussion of the behavior sought to be controlled by holding researchers liable, and available means of control; elements of various theories of civil liability; defenses to

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civil liability; special difficulties for field researchers of human behavior; and possible solutions and final thoughts.

Behavior to be Controlled

So far as imposing liability is concerned, the law generally attempts to prevent behavior that causes harm to human beings. Historically, the most obvious sorts of harm guarded against were injuries to the body and direct damage to property. Hence, a typical behavior that leads to liability is an automobile crash that injures people and destroys automobiles. More recent forms of injury that have been given recognition in the law are injury to a person's emotions or psychic well-being in the absence of any direct injury to the physical body, and damage to a person's pecuniary interests in the absence of either bodily or psychic injury or damage to tangible property.

In large part the present unsettled legal status of the human experimentation field is caused by the newer sources of liability. Certainly, both healers and researchers have long been aware of the potential of liability for bodily injuries suffered by human subjects. The whole well-developed subject of informed consent recognizes that fact. Hence, it is mainly the new fields of liability that now define the behavior to be controlled. As shall be seen, the emerging law is insisting that human beings be not unnecessarily and unreasonably exposed to forces that will cause them serious emotional or psychic stress even in the absence of any bodily harm, and the law is beginning to insist that similar exposure to pecuniary damage be avoided even in the absence of damage to tangible property. These are the behaviors to be controlled, and to the extent that human experimentation causes the unwanted consequences it falls within the ambit of controlled behavior.

Societies have numerous means of showing disapprobation for unwanted behavior. Most of them fall far short of legal sanctions. As examples, bad boys are spanked and bad men are not made deacons in their churches. Economic sanctions are often used too, as boycotts of high-priced meats and products of nonunion growers of lettuce and grapes have recently demonstrated. Complete social ostracization is rare in our own culture but may still be prevalent in others. For professional people, such as participants in human research and experimentation are likely to be, the professions themselves have instituted sanctioning systems. Many professions have in a sense created monopolies for persons accredited by them. Behavior seriously deviating from accepted norms of the profession leads to disaccreditation and expulsion from the field. Notable recent illustrations are the disbarments of Dean, Erhlichman, Mitchell, and others of Watergate notoriety. Hence, to the professional person, removal from the field is a formidable source of control. Furthermore, as opposed to practitioners, researchers rarely if ever create the kinds of products that regularly and immediately bring the income needed to support their research activities. Most often, some other entity, usually governmental, must be persuaded to bankroll current endeavors in anticipation of receiving prospective benefits that are not presently saleable on any open market. The threat of losing these sources of support can be as great a control mechanism as any other.

While all of the foregoing sources of control are effective against researchers to some degree, none directly involves the law in either of its two basic modes. One mode is the criminal law that punishes forbidden behavior with jail sentences or fines. Because of the extremely unsavory connotations of criminal convictions, at least for people in professions, subsidiary social ramifications may be equally as dreaded as the criminal sanctions themselves. Nevertheless, because criminal charges are likely to be made only in instances of most egregious behavior, no further consideration will be given to them here [*3*].

The second basic mode is the civil law. Of direct application is the law of civil wrongs,

known as the law of torts in legal parlance. Ordinarily, the sanction of the law of torts is forced recompense in money for harm done. The usual goal is to restore the injured party to status quo, but in extreme cases exemplary damages are levied against a wrongdoer. Although exemplary damages primarily serve a punitive purpose, they are paid to the injured victim and not to the state and do not in other ways carry the extreme stigma of criminal sanctions.

The nature of the various sanctions is shaped by several factors. Two are the odiousness and harmfulness of the controlled behavior. Extremes in either characteristic are likely to be visited with extreme sanctions. The third is the extent that the controlled behavior is not characteristic of the population that makes the rules. The last point can best be illustrated by observing that alcohol drinking offenses are punished little whereas marihuana use offenses are punished much.

Elements of Various Torts

The remainder of this paper is essentially devoted to the potential tort liability of researchers engaged in experimentation with and observations of human beings [*3*, pp. 503–507, *4*] and how such liability might be avoided. Basically, three kinds of injury-producing behavior are recognized in the law, with distinctions among them depending principally on the mental state of the offender. *Intentional torts* are wrongs produced by acts intentionally done. Moreover, it is the doing of the act that is intentional and not the causing of harm. Hence, if a researcher intentionally touches a subject's body with no intention to cause harm, but harm in fact ensues as a consequence of the touching, then an intentional tort has occurred. By contrast, *negligent torts* are wrongs produced by careless acts in situations where ordinary prudence called for more care than was exercised. Finally, *strick liability* torts are wrongs done by behavior that is so dangerous under the circumstances or so reprehensible that the law holds the actor accountable without respect to whether the behavior was intentional, careless, or entirely innocent. Notwithstanding the fact that human experimentation would seem to fit this category, historically it has been reserved for activities connected with the use of land, such as blasting or mining, and actually has little applicability to the subject at hand, except in respect to privacy issues to be discussed.

Intentional Torts

Researchers who directly touch or manipulate the human body in any way need be concerned about liability for intentional torts. Very brief descriptions of the several most applicable torts will be given along with specific illustrations.

A *battery* is an unprivileged and an unconsented to harmful or offensive touching of another person [*5*]. All of the definitions of torts used herein are well within the general scope of the law. The reader must be mindful that cases are rarely decided on general statements but on the nuances and exceptions so typical of the law. Not only does battery give rise to an action for damages actually caused, but owing to its intentional classification, it can also give rise to punitive damages as well. Perhaps more threatening to researchers is the possibility of damages for emotional injury or mental distress caused by the physical touching. Examples of batteries would be an insertion of a hypodermic needle into a person's body against his will and administration of a substance to a subject against his will (or administration with permission if the subject was deceived about the true nature or effects of the substance). Clearly, both healers and researchers must be concerned about the prospects of battery liability.

An *assault* is an intentional setting in motion of forces that create within another person an apprehension of an imminent battery [*5*, § 21]. Hence, assault makes possible

compensation of injuries that stem solely from fright or other emotional distress when there has been no actual harmful and offensive touching. An example of assault would be to approach a person with a hypodermic under circumstances that created the apprehension that an injection was to be made against the will and without the consent of the assaulted person. Assault cases usually arise in more mundane circumstances, however, such as in heated arguments when contestants begin to threaten one another.

False imprisonment is an unprivileged and unconsented to deprivation of the liberty of motion of another person [5, § 35]. Common examples of false imprisonment are the unjustified retention of a patron in a store under accusations of shoplifting or the locking of another person in a room or house as a coercive measure. Researchers of human behavior must concern themselves with this tort when they engage in projects that require confinement of subjects.

Intentional infliction of mental distress is a rather new and fast-developing tort. This tort imposes liability for mental distress caused by intentional and outrageous behavior [5, § 46]. It differs from assault primarily in that the injured person need not have been put in apprehension of an imminent battery. An example of the cases finding liability for intentional infliction of mental distress is one in which a person sought to punish his mistress emotionally by cutting his own throat in her kitchen [6]. This example highlights the outrageous component of the tort. More recent cases have enlarged the scope of outrageous behavior to less extreme situations such as unusual and extreme methods used to collect debts [7]. While most situations involving researchers would involve either assault or battery and not this tort, nevertheless methods used in field experimentation could conceivably give rise to liability under this theory. An illustration would be an intended unobtrusive observation of human behavior that was detected, creating fear or apprehension in the observed person.

To these intentional torts the law has recognized certain defenses. The defense of *privilege* is based on the recognition that certain relationships require relaxation of the severe restrictions on human mobility and interchange that would be imposed by an unbending application of the intentional torts. For example, being jostled on a crowded sidewalk can be an offensive touching. To avoid countless battery actions stemming from such situations the law recognizes a privilege that extends to the usual jostlings that are inherently part of daily life. Privileges also extend to the spanking of children by parents, to good-faith arrests by policeman, and to many other commonplace activities that are not ordinarily harmful but could be construed as offensive. Anytime the offensive behavior becomes more extreme and shades over into harmful behavior, the actor stands the risk of exceeding the privilege and putting himself in the range of tort liability.

Research behavior is not yet recognized as one of the usual risks of normal human intercourse. Consequently, no rule of law requires that researchers' behavior be tolerated by all who choose to engage in the routine affairs of daily life. Consequently, with possible rare exceptions in healing situations, researchers would not be able to claim privilege as a defense to intentional torts stemming from research activities. Nevertheless, the law does not require that researchers proceed at their peril in the absence of a privilege. Fully consistent with the view that human beings ought to be free of unprivileged intentional torts is the law's acknowledgment that people can consent to what would otherwise be harmful or offensive touching and other torts. Hence, the defense of *consent* protects surgeons when they operate and can protect researchers when they experiment.

As was pointed out in the introductory remarks, much of the legal literature in the human experimentation field is given to informed consent [8–11]. The addition of the word "informed" reflects the fact that courts have not erected a shield against liability

on every pretext of consent. The cases clearly indicate that consent obtained through fraud, coercion, and undue influence is not consent at all. Similarly, consent on less than full disclosure of the risks involved is not informed consent. Most of the litigation to date has been concerned with procedures performed by medical practitioners, but the theory is fully applicable to research endeavors.

Strict Liability Torts

Apart from defamation and invasion of privacy, traditional strict liability torts have little applicability to the topic under consideration. Moreover, very recent developments in the law of defamation and invasion of privacy cast substantial doubt on whether or not even these torts may be any longer uniformly treated as strict liability torts [*12*]. Nevertheless, *defamation* is a false statement that damages the reputation of the defamed person. In that absence of truth is an indispensable element of the tort, defamation carries its own best defense as part of its definition. Rarely should the tort arise in research situations.

By contrast, *invasion of privacy* could pose a threat to researchers. This relatively new tort acknowledges that the revelation of private matters, even in the absence of falsehood, can be damaging and ought to be actionable under some circumstances. While the body of cases is somewhat amorphous in form, four major subdivisions have been discerned by courts and scholars.

Owing to its analogy to copyright and patent infringement matters, *appropriation* is perhaps the most uniformly accepted theory of invasion of privacy. Under this theory the unauthorized use of the likeness of a private person can sustain a cause of action for damages. Ordinarily, this tort applies when an advertiser has used a picture in an advertisement without the consent of the subject [*13*].

False light is an invasion of privacy in which true facts used to cast untrue aspersion on the character of another person. In one example, a young child was struck down and badly injured by a carelessly driven automobile. The picture was published as a news item shortly thereafter with impunity because freedom of the press to publish news outweighed any privacy considerations at that point. Several months later, however, the picture was used as a frontispiece for a magazine article entitled "They Ask to be Killed." This was found to be an invasion of privacy in that the child was falsely held in a bad light [*14*]. To the extent that this tort damages reputation, it is closely related to defamation.

Intrusion has been used to control what are at the same time the most outrageous and the least public invasions of privacy. In the prototypic case [*15*] a motel operator bugged a room occupied by newlyweds so as to regale himself with the sounds emanating therefrom. The defendant was held liable for damages for intrusion notwithstanding the fact that he had not made public whatever information he had obtained.

Public revelation of private facts is a mode of invasion of privacy that has been used when quite truthful but secret facts are made public for no good reason. This tort seems on the first glance to be complementary to defamation in that defamation brings liability for damage to reputation caused by false statements, whereas revelation of private facts brings liability for publication of damaging true statements. Revelation of private facts has been used very sparingly, however, and only where extreme damage has occurred under circumstances that could easily have been avoided [*16*]. In sum, it clearly falls drastically short of doing for true damaging statements what defamation does for false damaging statements.

With the exercise of appropriate care, researchers should ordinarily not be concerned about liability under any of the strict liability torts. Appropriate care would include obtaining consent in connection with studies that might otherwise involve intrusions or public revelation of private facts. Perhaps the most genuine concern would be potential

liability for public revelation of private facts when research data were disclosed after a promise of confidentiality had been given. This possibility will be made more evident in later sections examining testimonial privileges.

Negligent Torts

As observed earlier, a negligent tort is injury produced by a permitted act done carelessly. For example, surgery without consent would be a battery even if done with maximum care, whereas consented-to surgery would not be a battery, but if done carelessly would be a negligent tort. Hence, consent of itself is not a defense to a negligent tort and the potential of liability for causing harm carelessly overrides any theory of defense in most circumstances. By far, most of the law in this area has been generated by medical malpractice litigation.

Difficulties for Field Researchers

The present status of the law presents different problems for different kinds of research activities. Classical clinical research under laboratory conditions poses no special legal problems so long as genuine informed consent of the research subjects is received and so long as the procedures are prepared and conducted with reasonable care. Problems arise, however, when an experimental design requires that some subjects be unaware of what is actually being done to them as, for example, when placebos are administered to a control group and an active agent to a test group. A more specific and perhaps more difficult example has arisen in certain field research programs. Studies of the relationship between drug use and traffic crashes can be used to illustrate the difficulty. Sometimes, for example, such a study will require that data obtained in crash situations be augmented with more extensive background information about drug use practices of people involved, including, perhaps, any specific use preceding the crash in question. Obtaining such information from most people would require an absolute pledge of confidentially, if even that would be sufficient.

Another illustration could involve interviews of surviving drivers in fatal automobile crashes. The researcher might ask for a blood sample, fully disclosing the medical procedure and risks, but failing to disclose the risk that the chemical test results might be used against the subject in either civil or criminal litigation. Failure to inform of this risk may be held to invalidate the consent.

In most states, however, the researcher cannot be sure that information obtained by pledge of confidentiality can be withheld in court should a subpoena for its production be issued. This may then mean that genuine informed consent requires that the subject be told of this risk. It seems certain that such a disclosure would promptly end the cooperativeness of the subject and undermine the experiment.

While there appear to be no cases dealing with pecuniary or penal damages suffered by inadequately informed subjects, researchers clearly would be risking suit if they chose to proceed without informing their subjects of potential risks and the subjects' revelations were later damagingly disclosed in court. In addition, the most recent guidelines on informed consent issued by the Department of Health, Education and Welfare fully comprehend that complete disclosure of such risks be made to research subjects in experiments of this sort.

The HEW guidelines for protection of human subjects and informed consent are perhaps the most important present source of authority in the area because so much public funding is tied directly to their satisfaction. It is becoming increasingly evident that all sources of federal research funds are beginning to demand adherence to HEW guidelines

even though they are specially applicable only to funds provided under the Public Health Service Act as amended by the National Research Act, P.L. 93-348, §212(a). As defined in recently promulgated HEW guidelines [*17*], informed consent has the following meaning:

> (c) "Informed consent" means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent include:
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> (1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;
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> (2) a description of any attendant discomforts and risks reasonably to be expected;
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> (3) a description of any benefits reasonably to be expected;
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> (4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;
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> (5) an offer to answer any inquiries concerning the procedures; and
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> (6) an instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.

Clearly, the potential for liability in research situations represents an extension of the basic concepts of liability discussed earlier. Nevertheless, in times of enhanced desire to protect the integrity of human privacy and increased alarm about insidious and pervasive governmental invasions of it (note that much if not most research is either funded or conducted by government), it is not unduly timid to give great weight to the potential risks faced by researchers if they ignore the fullest requirements of informed consent.

Research Privilege as a Possible Solution

Clearly, the existing law poses a researcher's enigma. Genuine informed consent will invalidate experimental design, whereas failure to inform poses liability, nonfunding, and other hazards for the researchers.

One of the most spontaneous reactions to unconsented to behavioral research somewhat fittingly involved lawyers as researchers. In the Chicago jury project a research plan was devised to study the deliberations of injuries in the secrecy of the jury room. Consent was received from the judges and all lawyers involved in every case to listen in to the deliberations, but the jurors themselves were not informed. Notwithstanding the fact that important knowledge derived from the studies, many people were shocked at the unconsented to intrusion into the privacy of the individuals involved. Legislatures acted quickly to control such research behavior. New York created a special crime of "eavesdropping" as it relates to injuries [*18*], and Congress outlawed knowingly and willfully recording or attempting to record or listen to or observe the proceedings of United States juries of which the person so acting is not a member [*19*]. While the Chicago jury studies themselves were funded by the Ford Foundation and not by the federal government, it should go without saying that nonfunding is somewhat milder than the action taken in this instance.

Any solution would seem to require a state of affairs that would not punish researchers for being silent about the possibility that data might be used against the subject in court, or that would allow the researcher to say unequivocally and accurately that the data could never be so used. To be valid either position would require a legal basis for excluding the researcher's data from the reach of courts' subpoena powers.

Presently, courts very strongly resist measures that inhibit the "search for truth" in the courtroom. In our legal culture there is a deep-seated policy that every person has a duty to come to court, bearing his evidence and testimony. This duty is compellable by the subpoena power of the courts with refusals punishable by contempt citations, fines, and jail. Therefore, under the law in most states researchers can be compelled to disclose

relevant data obtained in experimentation. Whether or not the data are relevant and admissible under the complex rules of evidence are separate issues that will not be examined here.

The historical evolution of the duty to testify reveals its present strength. United States law stems from the common law of England, and in the very early common law witnesses not only could not be compelled to testify but were actually unwelcome in the courts [*20*]. Such people were seen as fomenters of litigation or meddlers in other people's affairs. Times changed, however, and in Elizabethan times of 1562–1563 a statute was enacted to *permit* witnesses to testify [*20*, p. 17]. Rather quickly the nature of the adversary system changed so that by the 1600s the duty to testify had become well established in English and American colonial courts [*20*]. When the American revolution came and the Constitution was adopted, the right to compel testimony was acknowledged as an element of fair trials. Consequently, one can argue that the right to compel testimony is a fundamental constitutional right [*20*, §2191] of litigating parties guaranteed by the sixth and seventh amendments to the United States Constitution for criminal and civil trials, respectively.

Notwithstanding the sanctity of the right to have testimony produced, no right, including constitutional rights, is absolutely inviolable. Acknowledging that the right to compel testimony is sometimes overbalanced by competing values, the courts have recognized exceptions to it in some circumstances. These deviations from the duty to testify are carefully couched in exemptions known in the laws as privileges. (Note that the term privilege is used both to describe the exemption from the duty to produce evidence and also to describe a defense to intentional torts. Hence, the earlier use of the term must be distinguished from the present use, which is markedly different.) So far as the common law is concerned, the lawyer-client relationship constitutes the only universally recognized privilege. Historically, in the mind of the judges it is a better policy to enable persons to disclose fully their situations to their lawyers without fear that the lawyer will later be required to disgorge the information under court order than it is to produce every grain of evidence every time. Applying the same kind of policy balance, legislatures in some states have created a doctor-patient privilege, a penitent-priest privilege, and more rarely news reporter-news source [*21–23*], and even researcher-subject [*25*] privileges. A Kentucky statute [*21*] is illustrative of reporter-source privileges:

> No person shall be compelled to disclose in any court, or before any grand or petit jury, or before the presiding officer of any tribunal, or his agent or agents, or before the General Assembly, or any committee thereof, or before any city or county legislative body, or any committee thereof, or elsewhere, the source of any information procured or obtained by him, and published in a newspaper or by a radio or television broadcasting station by which he is engaged or employed, or with which he is connected.

(For a listing of other statutes granting news reporter privileges, see Ref *22*. As to the effectiveness of state statutes in preventing the compulsion of testimony in federal courts, one court has said that they are not "conclusive" but gave them weight in determining the issue on policy grounds [*23*]. Another has said, "Federal courts exercising diversity jurisdiction generally recognize state created privileges" [*24*].)

In each instance, a decision has been made that society at large is better off if the confidentiality of given relationship can be absolutely secured against the compelling powers of the state than if it cannot.

These decisions are made primarily by judges, lawyers, and legislators, but it cannot be gainsaid that their judgments largely reflect intuitions and instincts seeping in from the social body at large. In passing, it is worth noting that the scope of the influential community is growing broader and tending toward greater coincidence with the entire community. In many respects, there is no more noblesse oblige. In a sense, the times are tending toward everyman's day and, therefore, it is everyman's sensibilities that will determine whether or not the researcher-subject relationship deserves protecting.

In recent years both newsmen and social researchers have sought to establish testimonial privileges based on the freedoms of speech, press, and association guaranteed by the First Amendment to the United States Constitution [*26*]. Under this theory compelled testimony in court represents governmental interference with guaranteed liberties to speak, to publish, and to associate with others absolutely free from governmental infringement. Balanced against this argument is the historically steeped duty to appear in court and testify notwithstanding the source of the information or the relationship that gave rise to it.

In a series of recent cases federal courts have balanced the relative weights of these competing interests in the context of some rather important public issues. *Caldwell v. United States* [*27*] involved a contempt citation entered against a black New York Times reporter who refused to honor a subpoena to appear and testify before a grand jury investigating alleged criminal black panther activities. Caldwell defended on the basis that his unique position of trust and confidence had gained the public an important news link to the black panthers and that such a relationship was protected by the First Amendment. Agreeing with Caldwell's claim of First Amendment freedoms, a federal circuit court of appeals held that Caldwell could not be compelled to testify unless the state showed a compelling state interest outweighing the public's right to be informed [*27*, p. 89]. Note the subtle distinction between the public's right to be informed and a reporter's right to find out. The court's exact holding was as follows:

> In light of these considerations we hold that where it has been shown that the public's First Amendment right to be informed would be jeopardized by requiring a journalist to submit to secret Grand Jury interrogation, the Government must respond by demonstrating a compelling need for the witness' process before judicial process properly can issue to acquire attendance.

Not wanting to announce a sweeping reporter's privilege, the court noted as special facts the sensitivity of the news source and the unique position of trust and confidence that had been achieved by Caldwell. What the court did in effect was to recognize a conditional privilege that could be outweighed if other considerations were given more weight.

Although *Caldwell* lined up with the policy stance approved by some legal scholars [*25*, p. 243, *28*, *29*], it was not given a warm reception by the United States Supreme Court. Weighing the balance differently in *Branzburg v. Hayes* [*22*], the Supreme Court held that no reporter-source privilege existed in respect to information about sources of criminal conduct that the reporter had either seen [*22* at 2662] or been told about [*22* at 2662] in respect to criminal conduct of other persons [*22* at 2664]:

> It is apparent ... from our history and that of England, that concealment of crime and agreements to do so are not looked upon with favor. Such conduct deserves no encomium, and we decline now to afford it First Amendment protection by denigrating the duty of a citizen, whether reporter or informer, to respond to grand jury subpoena and answer relevant questions put to him.

Furthermore, the court suggested that even if a conditional privilege did exist, which it had already denied, then the state clearly could establish a compelling need to obtain information necessary to prosecute illegal behavior [*22* at 2666, *23*]. A federal circuit court of appeals referred to *Branzburg v. Hayes* as a limited case and recognized a conditional reportorial privilege on the facts of the case before it. In that case (*Baker*, Ref *23*) plaintiffs in a civil action sought to compel divulgence by a reporter of his sources of information for an article about racial "block busting" that had appeared in the Saturday Evening Post years earlier. Refusing to compel testimony, the court commented that

> ... [T] hough a journalist's right to protect confidential sources may not take precedence over that rare overriding and compelling interest, we are of the view that there are circumstances, at the very least in civil cases, in which the public interest in non-disclosure of a journalist's confidential sources out-weighs the public and private interest in compelling testimony. The case before us is one in which the First Amendment protection does not yield.

While the court's opinion seems to be at odds with *Branzburg v. Hayes*, its own protestations to the contrary notwithstanding, several factors mentioned by the court may distinguish the two: (1) *Baker* involved civil rights questions, a very sensitive area; (2) *Baker* was a civil as opposed to a criminal action; (3) the reporter was not a party to the main action; (4) other sources of information had not been exhausted; (5) the information was not essential to the cause of action.

Dashing the hopes for a reporters' privilege as it did, the Supreme Court left little room for gaining such a privilege for researchers on First Amendment grounds.

Moreover, a later case, *United States v. Doe* [*30*] explicitly rejected the contention that the First Amendment required such a privilege. In that case a Harvard social scientist was held in civil contempt for refusing to answer grand jury questions in the course of investigation of criminal conduct surrounding the unauthorized release of the "Pentagon Papers." The researcher was questioned about his sources for various scholarly articles he had written about the Viet Nam war. In a limited holding, the court held that no privileges existed in respect to conversations between scholars. It was not necessary for the court to delve into the more general question as to whether the relationship between the scholar and primary data source would be protected by the First Amendment. Presumably, *Branzburg v. Hayes* [*22*] answers that negatively. The researcher case did afford some slight relief for the researcher in upholding his right to refuse to give his opinion about general matters related to his studies. The Supreme Court refused to review the case [*31*].

In sum, the Supreme Court ended hopes that a constitutional reportorial privilege would be recognized, and the Court urged that proponents of privileges lay their arguments before legislatures who are, according to the Court, better able to balance relevant factors and delimit any privilege that they might see fit to grant [*22* at 2669]. Presumably, if legislatures choose to act they will heed the advice of Professor Wigmore, who set forth the most widely recognized criteria to be met in recognizing privileges as follows [*20*, section 2185]:

1. The communications must originate in a confidence that they will not be disclosed.
2. The element of confidentiality must be essential to the relation between the parties.
3. The relation must be one which in the opinion of the community ought to be assiduously fostered.
4. The injury that would injure to the relation by the disclosure of the communication must be greater than the benefit gained by its contribution to the disposition of the litigation.

Other writers have reviewed the status of the law in various states as it pertains to privilege for researchers [*25, 28, 32*]. Rather than repeat that information here, attention will be given to illustrating the nature of the protection that can be given the researcher-subject relationship if a legislative body is persuaded to do it. In recent years national alarm has arisen concerning the increase in the use of illicit drugs, and the federal government has responded by sponsoring research for drug abuse prevention and drug offender's rehabilitation. In enacting the comprehensive Drug Abuse Prevention and Control Act of 1970 [*33*] Congress recognized that this research would be greatly hampered if the research subjects' identities and data about them could be produced in court. Accordingly, the 1970 Act empowered the secretary of the Department of Health, Education and Welfare (HEW) to authorize a researcher-subject privilege to protect the individuals involved in "research on the use and effect of drugs" [*34*]. This drug research privilege is absolute in that it has no exceptions. Moreover, it excludes use of the privileged information in actions of all kind, administrative as well as judicial and criminal as well as civil [*34*].

In the 1970 Act Congress also authorized the Attorney General of the United States "to carry out educational and research programs directly related to enforcement of the laws of his jurisdiction concerning drugs" [*35*] and empowered him to grant identical researcher-subject privileges [*35*] to those available to HEW as needed to meet the requirements of the act. Congress later extended a conditional privilege to the doctor-

patient relationship in treatments of drug users made available under the Drug Abuse Office and Treatment Act of 1972 [*36*]. Under the drug treatment Act records of the "identity, diagnosis, prognosis, or treatment of any patient" are confidential, subject to disclosure under only narrowly prescribed circumstances.

In full, the qualified privilege is stated as follows [*36*]:

> (a) Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function authorized or assisted under any provision of this shall be confidential and may be disclosed only for the purpose and under the circumstances expressly authorized under subsection (b) of this section.
>
> (b) (1) If the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed
>
> (A) to medical personnel for the purpose of diagnosis or treatment of the patient, and
>
> (B) to governmental personnel for the purpose of obtaining benefits to which the patient is entitled.
>
> (2) If the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, does not give his written consent, the content of such record may be disclosed as follows:
>
> (A) To medical personnel to the extent necessary to meet a bona fide medical emergency.
>
> (B) To qualified personnel for the purpose of conducting scientific research, management or financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.
>
> (C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

An identical qualified privilege has been provided by the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974 for programs conducted under its aegis [*37*].

A court may balance the need for disclosure against "the injury to the patient, to the physician-patient relationship, and to the treatment services" and find the gains of disclosure the more important value under the circumstances. The fact that the court has discretion to select between confidentiality and disclosure is what makes the drug treatment privilege a conditional privilege as opposed to the absolute drug research privilege that is beyond the exercise of discretion by the courts.

In essence, the legislatively created drug treatment privilege is very closely akin to the researcher-subject privilege that the courts were asked to acknowledge in the series of cases leading up to *Branzburg v. Hayes* [*22*]. For a follow-up on *Branzburg* see Ref *38*.

Many other examples of either absolute or conditional privileges could be given, but these two sufficiently demonstrate the two modes for the purposes of this paper. It should be observed that these congressionally created privileges have universal application in that they prevail throughout the geographic jurisdiction of the United States and in both state and federal courts as well as in administrative proceedings. If the privileges are indeed effective in keeping the protected information confidential, then their only shortcoming is in the limited scope of the types of research included. This brings up the question of how binding legislatively created privileges will be on the courts.

People v. Newman [*39*], a recent case decided by the highest court in the state of New York, well illustrates how each of these privileges may be expected to function. Newman was the director of the New York City Methadone Treatment Program, a drug research and treatment project that automatically fell under a conditional doctor-

patient privilege because of its funding under the 1972 treatment act. Moreover, both the Secretary of HEW and the Attorney General had designated Newman's project for the absolute researcher-subject privilege under the 1970 drug abuse research act. Newman's troubles began when a female patient of his clinic witnessed a shooting on a New York City street and recognized the killer as a black male patient of the methadone treatment program. Upon receiving that information, the district attorney subpoenaed photographs and identifying data concerning all black males between ages 21 and 35 who were in Newman's clinic. Newman refused to produce the material and was held in contempt by the trial court. On appeal Newman's defense centered primarily [*39*] on the application of the absolute privilege of the 1970 act and particularly on whether the conditional privilege of the 1972 act had the effect of repealing the earlier absolute privilege. If the latter act did repeal the earlier absolute privilege provision, then the only privilege left to Newman was the conditional privilege in the 1972 act. Application of the New York physician-patient privilege was a subsidiary issue in the case. The Court of Appeals ruled against privilege on grounds that the evidence sought was obtained as an administrative part of the project and not in the confidential physician-patient relationship [*40*].

Although the Court of Appeals did not express its views on how effective the qualified privilege would have been had it been the sole privilege available to Newman, the posture of the arguments raised to the court strongly suggest that the lower courts believed that the need for disclosure in this murder investigation outweighed the possible damages that disclosure might cause to the physician-patient relationship and the treatment program. Hence, this kind of egregious situation appears to establish a line beyond which courts, as they balance competing interests case by case, are not likely to go in honoring a conditional privilege of the kind embodied in the 1972 act.

The Court of Appeals rejected the contention that the 1972 act repealed the earlier law and held that the absolute privilege properly applied to Newman's situation. Once having so decided, the court without further comment vacated the contempt order and invalidated the subpoena issued to obtain Newman's records. This result firmly demonstrates the effectiveness of an absolute privilege: if it applies, it applies notwithstanding the egregiousness of the behavior that is being shielded or the merits of the case that is being shunned. In essence, the legislature's value judgment that a given area is deserving of unconditional privilege rules out any exercise of judicial discretion on a case by case basis.

Final Thoughts

In a general way this article has examined the various theories of liability that researchers engaged in experimentation with and observation of human subjects need recognize in designing their projects. It also examines protective defenses including privilege, informed consent, and ordinary care.

Highlighted is the special dilemma posed by the seemingly irreconcilable duties to assure subjects of complete confidentiality as an element of informed consent and to produce all one's testimony and evidence in court. As has been seen, the dilemma can be resolved by granting a researcher-subject testimonial privilege. While some courts appear to be searching for a rationale to reexamine the issue, the United States Supreme Court refused to acknowledge that the United States Constitution required such a privilege in the closely related news reporter-news source relationship.

Further relief, if it is to be forthcoming, appears to be up to legislatures. While state legislatures can and have created researcher-subject privileges for certain purposes, these privileges apply with certainty only in state courts and only within the jurisdiction of a given state. These limitations alone do not negate the value of state privileges in

promoting research objectives, of course, especially in respect to aspects of human behavior that are totally unrelated to locale. Nevertheless, universal privileges such as those created by Congress in the 1970 drug research and the 1972 drug treatment acts have greater advantage, particularly in respect to research undertaken in the interest of national goals. It follows that researchers in making their pleas for testimonial privileges must carefully evaluate the factors to which legislatures respond. So far as Congress is concerned, nationwide interest is one factor. Intense interest is another. A belief that research documentation is needed badly enough to justify withholding research data from the prosecution of a few crimes or the litigation of a few claims is another.

The recent past shows that drug abuse research qualifies under all counts. Whether or not other research areas will be afforded equivalent treatment may turn largely on the temper of the times. For researchers involved in the special field of the effect of drug and alcohol use on highway safety, it would appear that a strong case could be made based on the national interest both in controlling drug use and in preventing highway losses.

References

[1] "Faculty Voices Mixed Reaction to Edelin Trial," *Harvard Law Record,* Vol. 60, No. 1, 1975. The 1975 manslaughter abortion conviction of Boston physician Kenneth C. Edelin has created quite a stir in the legal world. The ramifications of the case are just beginning to appear. While the case has not yet to received scholarly treatment in print, it has not failed to produce scholars' comment, as in the cited article.

[2] *Trial,* Vol. 11, No. 3, May–June 1975. The joint issues of increasing numbers of medical malpractice actions, skyrocketing judgments, and escalating malpractice insurance rates have gained quick prominence in the winter and spring of 1975. The cited magazine issue has been devoted to this topic.

[3] Ladimer, I., "Ethical and Legal Aspects of Medical Research on Human Beings," *Journal of Public Law,* Vol. 3, No. 2, 1954, pp. 467–502. This article has additional discussion of criminal liability.

[4] Freund, P., "Is the Law Ready for Human Experimentation?" *American Psychologist,* Vol. 22, No. 5, 1967, p. 394.

[5] Restatement, Second, Torts, §13 (1965).

[6] *Blakeley v. Shortal's Estates,* 236 Iowa 787, 20 N.W. 2d 28 (1945).

[7] *Delta Finance Co. v. Ganakas,* 93 Ga. App. 297, 91 S.E. 2d 383 (1956).

[8] Fletcher, J., "Human Experimentation Ethics in the Consent Situation," *Law and Contemporary Problems Series,* Vol. 32, No. 4, 1967, p. 620.

[9] McCoid, A. H., "A Reappraisal of Liability for Unauthorized Medical Treatment," *Minnesota Law Review,* Vol. 41, No. 4, 1957, p. 389.

[10] Plant, M. L., "An Analysis of 'Informed Consent'," *Fordham Law Review,* Vol. 36, No. 4, 1968, p. 639.

[11] Waltz, J. R. and Scheuneman, T. W., "Informed Consent to Therapy," *Northwestern University Law Review,* Vol. 64, No. 4, 1969, p. 628.

[12] *Gertz v. Robert Welch, Inc.,* 94 S.Ct. 2997 (1974).

[13] *Flake v. Greensboro News Co.,* 212 N.C. 780, 195 S.E. 55 (1938).

[14] *Leverton v. Curtis Pub. Co.,* 192 F.2d 974 (3rd Cir. 1951).

[15] *Hamberger v. Eastman,* 106 N.H. 107, 206 A.2d 239 (1964).

[16] *Melvin V. Reid,* 112 Cal. App. 285, 297 P.91 (1931). This is the prototypical case of public revelation of private facts. The lurid past of a reformed prostitute was made into a motion picture. While her true identity could easily have been hidden, the subject's real name was used, causing her great embarrassment within the community where she had established a new life.

[17] *Federal Register,* 45 C.F.R. §46.3(c), Vol. 40, 1975, p. 11851.

[18] N.Y. Penal Law §738, replaced by N.Y. Sess. Laws 1965, ch. 1030, §250.05.

[19] 18 U.S.C.A. §1508 (1964).

[20] 8 Wigmore on Evidence §2190 (McNaughton 1961).

[21] Ky. Rev. Stat. §421.100.

[22] *Branzburg v. Hayes,* 408 U.S. 665, 92 S.Ct. 2646, at 2660, n. 27, (1972).

[23] *Baker v. F. & F. Investment,* 470 F.2d 778, 782 (2d Cir. 1972), cert. denied, 411 U.S. 966, 36 L.Ed. 2d 686, 92 S.Ct. 214, 1975.
[24] *Karp v. Cooley,* 493 F.2d 408 (5th Cir. 1974).
[25] "The Researcher-Subject Relationship: The Need for Protection and a Model Statute," *Georgia Law Journal,* Vol. 62, 1973, pp. 243, 245, 250.
[26] *Amendment 1, United States Constitution,* "Congress shall make no law ... abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble...."
[27] *Caldwell v. United States,* 434 F.2d 1081 (9th Cir. 1970).
[28] Tyler, R. M. and Kaufman, D., "The Public Scholar and the First Amendment: A Compelling Need for Compelling Testimony," *George Washington Law Review,* Vol. 40, No. 5, p. 995.
[29] Nejelski, P. and Lerman, M. J., "Research-Subject Testimonial Privilege," *Wisconsin Law Review,* Vol. 1971, No. 4, 1971, p. 1085.
[30] *United States v. Doe,* 460 F.2d 328, 334, 335 (1st Cir. 1972).
[31] Cert. denied, sub, nom., *Pokin v. United States,* 411 U.S. 909, 93 S.CT. 1527, 36 L.Ed. 2d 199 (1973).
[32] "Social Research and Privileged Data," *Valparaiso Law Review,* Vol. 4, No. 2, p. 368.
[33] P.L. 91-513; 84 Stst. 1236.
[34] 42 U.S.C.A. §242a(a) (2), as amended by P.L. 91-513, Title 1, §3.
[35] P.L. 91-513, Title II, §502(a) and (c).
[36] P.L. 92-555, §408; U.S.C.A. §1175.
[37] P.L. 93-282, §122; 88 Stat. 125.
[38] Nejelski, P. and Finsterbusch, K., "The Prosecutor and the Researcher: Present and Prospective Variations on the Supreme Court's *Branzburg* Decision," *Social Problems,* Vol. 21, Summer 1973, p. 3.
[39] *People v. Newman,* 298 N.E. 2d 65, 32 N.Y. 2d 379 (1973), cert. denied, 414 U.S. 1163, 94 S.Ct. 2d 61 (1973).
[40] 298 N.E. 2d at 653, 654.

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