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Informed Consent and the Investigational Use of Medical Devices: A Comparison of Common Law Duties with Those Imposed on Researchers Under Section 520(g) of the Medical Device Amendments of 1976*

THOMAS G. FIELD, JR. AND DOMINIC S. PIACENZA**

When the Food and Drugs Act of 1906 was superseded by the Federal Food, Drug and Cosmetic Act, medical devices (and cosmetics) were

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subject to regulatory control for the first time.[1] At least a major part of the pressure for passage of the 1938 Act was generated by the sulfanilamide disaster.[2] As a consequence of that disaster provisions were made that new drugs could not be marketed unless they had first been shown to be safe for human use.[3]

While medical devices and drugs were lumped together for some purposes under the 1938 Act, devices were not subject to such preclearance. Nor, in 1962, when new drugs were subjected to even tighter control as a result of the thalidomide disaster,[4] were devices affected.[5] Not until later did a situation begin to emerge requiring a closer control of device marketing. In the late 1960s, thousands of injuries (many fatal) were attributed to faulty heart valves, pace makers and intrauterine devices.[6] Moreover, not only were there problems with the safety of devices, but the Food and Drug Administration was also spending considerable resources to remove from the market useless devices being fraudulently palmed off on unwary consumers.[7] As a result of both of these developments, in 1969, the Department of Health, Education and Welfare convened a study group, known as the Cooper Committee, to study the problems and make recommendations as to how to deal with them.[8]

In 1970, the Cooper Committee filed its report, making specific legislative recommendations.[9] Among its suggestions was one that at

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[1] *See* STAFF OF HOUSE SUBCOMM. ON PUBLIC HEALTH AND ENVIRONMENT OF THE COMM. ON INTERSTATE AND FOREIGN COMMERCE, 93D CONG., 2D SESS., A BRIEF LEGISLATIVE HISTORY OF THE FOOD, DRUG AND COSMETIC ACT 4 (Comm. Print No. 14, 1974) [hereinafter cited as LEGISLATIVE HISTORY].

[2] *Id.* at 3.

[3] *Id.* at 16, 18.

[4] *Id.* at 15.

[5] *Id.* at 18. *See* 21 U.S.C. § 355 (1977).

[6] *Hearings on H.R. 6073, 9984, 539 and 10061 Before the Subcomm. on Public Health and Environment of the House Comm. on Interstate and Foreign Commerce,* 93d Cong., 1st Sess. 154 (1973) [hereinafter cited as *House Hearings*].

[7] *Id.* at 155. *See also* two cases coming to different conclusions about the authority of the FDA over devices used in the practice of a "religion": Founding Church of Scientology v. United States, 409 F.2d 1146 (D.C. Cir. 1969) and Church of Scientology v. Richardson, 437 F.2d 214 (9th Cir. 1971). In addition to questions of safety and efficacy of medical devices, issues were beginning to develop concerning the distinction between drugs and devices; *see* Weitzman, *Drug, Device, Cosmetic?,* 24 FOOD DRUG COSM. L.J. 226, 320 (1969).

[8] *House Hearings, supra* note 6, at 155.

[9] *Id.*

least some kinds of devices be subjected to clinical tests prior to being marketed.[10] Shortly after receiving the report, the FDA convened expert panels to begin the important and time-consuming work of reviewing and classifying medical devices. By the end of 1973, when Congress began to hold hearings on proposed legislation, these panels had already classified over 3,000 devices according to risk and need for premarket testing.[11]

At least part of the reason that it took six or seven years from the time that the Cooper Committee began its work until passage of the Medical Device Amendments Act of 1976[12] was the difficulty of deciding which kinds of devices would be subject to what kinds of controls. Problems had arisen in regard to premarket clearance of new drugs, and there was no desire to repeat mistakes which had been made in regard to them.[13] Thus arose the need for the complex provisions setting forth the conditions under which new devices could be marketed without preclearance — and the need for time to draft and consider them.[14]

Not only did the amendments set forth detailed provisions for exempting certain classes of devices from preclearance, but they also set forth conditions under which devices otherwise subject to preclearance could be used prior to such preclearance.[15] This paper will deal with the exemption granted for the investigational use of devices subject to premarket testing and, more particularly, with the obligation of an investigator seeking such exemption to secure an informed consent agreement from human subjects (or their representatives) under §520(g) (3) (D)[16] of the Act. It will also consider the relationship

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[10] *Id.* at 156.

[11] *Id.*

[12] Act of May 28, 1976, Pub. L. No. 94-295, 90 Stat. 539.

[13] *See generally House Hearings, supra* note 6, at 364-97.

[14] *See generally* § 513 (a) (1), 21 U.S.C. § 360c (a) (1).

[15] §§ 520(b) and (g), 21 U.S.C. §§ 360j (b) and (g). § 520 (b) exempts custom devices ordered by a health care professional for a *named* patient. § 520 (g) exempts devices for investigational use with humans subject to application being made by "experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices." § 520 (g) (2) (A), 21 U.S.C. 360 j (g) (2) (A).

[16] 21 U.S.C. 360j (g) (3) (D). This paragraph requires that the Secretary of Health, Education and Welfare promulgate regulations pursuant to paragraph (2) (A) requiring an assurance that, in the absence of extraordinary, life-threatening circumstances, informed consent will be obtained from the patient or his representative. *But see* discussion in note 54, *infra,* regarding the difficulty of meeting the proposed duty.

between the statutory obligation and that which might be imposed by the common law of negligence.

The Duty Under the Statute

It will be necessary to review, briefly, the overall organization of the Federal Food, Drug and Cosmetic Act.[17] Only then can the full implications of the device amendments be understood. First, there is a section which defines words used in the Act; §201 (h) defines a "device," with certain exceptions, to be an article which is:

> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.[18]

There is also a lengthy section which sets forth "Prohibited Acts." These include the introduction into interstate commerce[19] or the receipt in interstate commerce[20] of an adulterated or misbranded device — as well as the failure to comply with the conditions of investigational exemption under §520(g) or the filing of a false or misleading report with respect to a device.[21]

Lest someone seize upon the words "interstate commerce," it should also be noted that a provision buried in a rather unexpected place in the Act creates a presumption of interstate commerce. It is interesting that this presumption applies only to medical devices (as opposed to foods, drugs or cosmetics). Further, this presumption of sufficient involvement with interstate commerce to enable federal regulatory jurisdiction

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[17] 21 U.S.C. §§ 321 *et seq.* (1977).

[18] *Id.* § 321 (h). For a discussion of the significance of this section as amended, *see, e.g.,* Weigel and Raubicheck, *How to Comply with the New Medical Device Law,* 31 FOOD DRUG COSM. L.J. 312, 312-3 (1976) and Geller, *The Medical Device Amendments of 1976* . . . . , 31 FOOD DRUG COSM. L.J. 424, 425-6 (1976).

[19] 21 U.S.C. § 331 (a). *See also* Geller, *supra* note 18, at 443.

[20] *Id.* § 331 (d).

[21] *Id.* § 331 (q).

would seem to have particular impact on the investigational use of medical devices.[22]

One might wonder about the consequences of non-compliance with the Act or the doing of something prohibited under it. Sanctions are set forth in §§ 302-304[23] and include injunction,[24] criminal penalties[25] and seizure of offending devices.[26] In regard to criminal penalties, it ought to be noted that it has been long held that a *knowing* violation of the act is not necessary for prosecution.[27]

As noted above, traffic in adulterated or misbranded devices is prohibited. The conditions which cause a device to be adulterated or misbranded, respectively, are set forth in §§ 501 and 502 of the Act.[28] The former seems to be most relevant here, and § 501 (f) provides that a device subject to preclearance[29] (a class III device) which has not been precleared and does not have an investigational exemption under § 520 (g) is adulterated.[30] Moreover, § 501 (i) provides that a device is adulterated if "any investigator who uses such device [under § 520(g)] . . . fails to comply with a requirement . . . under such section."[31] One of those requirements is that the investigator secure informed consent from each human subject, and § 520(g) (3) (D) requires the Secretary of Health, Education and Welfare (or his delegee, the FDA) to promulgate regulations governing the securing of such consent.[32] In this respect, it is interesting to note that in the bill which was passed by the Senate, detailed provisions were set forth governing this matter, but the House bill lacked them.[33]

This discrepancy was taken up by the conference committee, and its report indicates why the specific provisions of the Senate bill were

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[22] *Id.* § 379a. *See* Geller, *supra* note 18, at 426-7. It is expected that this provision could be especially significant with respect to 21 U.S.C. 331 (q) and through it to § 520 (g) of the Act.

[23] 21 U.S.C. §§ 332-4.

[24] *Id.* § 332.

[25] *Id.* § 333.

[26] *Id.* § 334.

[27] *See, e.g.,* United States v. Park, 421 U.S. 658 (1975).

[28] 21 U.S.C. §§ 351 and 352, respectively.

[29] *See generally* 21 U.S.C. § 360 (e).

[30] 21 U.S.C. § 351 (f).

[31] *Id.* § 351 (i).

[32] 21 U.S.C. § 360j (g) (3) (D).

[33] H.R. CONF. REP. No. 94-1090, 94th Cong., 2d Sess. 64 (1976) [hereinafter cited as CONF. REP.].

dropped from the conference bill.[34] The main reason seems to be that a blue ribbon panel has been convened to consider research on human subjects.[35] If specific provisions for informed consent had been in the Act, it would take Congressional action to modify them to be consistent with whatever the panel comes up with. If, on the contrary, it were left to the FDA to promulgate specific provisions, these could be more easily and quickly amended.

Thus the Act gave the FDA (Secretary of HEW) 120 days from the date of passage of the amendments to promulgate rules covering informed consent and other conditions under which one might obtain an investigational exemption for doing clinical evaluation of a new Class III device.[36] Although the Act as passed appears to give the FDA considerable discretion, it is quite clear from the conference report that Congress intended the adoption of the specific provisions dropped from the Senate bill, pending the adoption of whatever recommendations which might come forth from the above mentioned study panel.[37]

Since the 120 days are long past, one might wonder what has become of the rules governing investigational exemptions. As of this writing none is in effect, but proposals were made quite some time ago — in August of 1976.[38] Interested parties were given until October 19, 1976 to provide written comments on them.[39] One is left to speculate on whether the delay has been caused by comments received or by the need to attend to more pressing business.

In spite of the fact that the rules are still only proposals, it is worthwhile to consider them in some detail. Prior to their publication, one writer suggested that: "It would seem logical that the investigational device regulations would be patterned after . . . regulations . . . already promulgated [for similar regulated products]."[40] However, not only do the

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[34] *Id.*

[35] *Id.* The National Commission on the Protection of Human Subjects of Biomedical and Behavioral Research.

[36] 21 U.S.C. § 360j (g) (2) (A).

[37] CONF. REP., *supra* note 33.

[38] 41 Fed. Reg. 35, 282 (1976). There were a number of specific rules implementing the provisions of § 520 (g), 21 U.S.C. 360j (g) generally. In regard to informed consent, specifically, elements which were to appear in an agreement with the patient or his representative appear at 41 Fed. Reg. 35, 313 (1976).

[39] 41 Fed. Reg. 35, 313 (1976). Further action is expected shortly.

[40] Geller, *supra* note 18, at 439, referring to previous regulations covering food additives, new drugs and new animal drugs.

proposals go well beyond those in force (*e.g.*, in regard to new drugs),[41] but it is also likely that *final* regulations will do likewise.

While regulations in effect for new drugs require investigators to certify that informed consent will be sought, they do not require, as do the device proposals, submission to the FDA of the form being used to obtain it.[42] Nor do the regulations in effect for new drugs set forth in detail what the contents of an agreement with a subject shall be.[43] Thus, not only do the device proposals go well beyond similar ones for other products, but it is also doubtful that they could differ much from their present form and be consistent with the legislative aims earlier noted.[44]

First, the proposals provide that each subject shall be given:

> (1) A full and fair explanation of procedures to be followed, including an identification of any which are experimental.
>
> (2) A full explanation of the nature, expected duration and purpose of the administration of the investigational device.
>
> (3) A description of any attendant discomforts and risks reasonably to be expected.
>
> (4) An explanation of the likely results should the procedure fail.
>
> (5) A description of any benefits reasonably to be expected.
>
> (6) A disclosure of any appropriate alternative procedures that might be advantageous for the subject.
>
> (7) A description of the scope of the investigation, including number of patients involved in the investigational study.
>
> (8) An offer to answer any inquiries concerning the investigational study.
>
> (9) An instruction that the subject, or his legal representative, is free to decline entrance into the investigational study or to withdraw his consent and to discontinue participation in the study at any time without prejudice to the subject.
>
> (10) A statement that the investigational device is being used for research purposes.[45]

Moreover, the proposals provide that:

> (b) The agreement entered into by such person or his legal representative shall include no exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights or to release the institution or its agents, or the sponsor, or the investigator from liability for negligence.[46]

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[41] 21 C.F.R. § 312.1 (a) (12) and (13) (1977).

[42] 41 Fed. Reg. 35, 288 (1976). *See also* 41 Fed. Reg. 35, 313 (1976).

[43] 21 C.F.R. § 312.1 (a) (12) and (13) (1977); 41 Fed. Reg. 35, 282 (1976).

[44] *See* discussion corresponding to notes 33-37 *supra*.

[45] 41 Fed. Reg. 35, 313 (1976).

[46] *Id.*

Finally, it is provided that the contents of the consent document be approved by an institutional review committee and that copies of the form be provided to the subject or his legal representative.[47]

In considering these requirements, one might wonder about the extent to which they change obligations which might already be imposed by the common law of negligence. That law obviously is enforced with sanctions considerably different from those noted above and applicable under the regulatory statute, but from the perspective of an investigator, their impact may be far more serious.

This is because seizure or injunction is not likely to have much of an effect on an individual investigator (as contrasted with the sponsor).[48] Nor, if an effort is seriously made to comply with the law, is it likely that the criminal sanctions need to be considered as much of a threat to such a person.[49] Rather, the most significant implications seem to arise in regard to potential civil liability which might attach as a result of following the procedures for informed consent set forth in the proposed regulations.

An effect on civil liability can only result if the proposals change the nature of the preexisting duty of research clinician to a human subject. For that reason, it is necessary to consider the common law and attempt to assess what that duty might be in the absence of regulatory alteration.

The Duty Under the Common Law

There are several things that need to be said at the outset of this discussion of the common law. Most important is that any such discussion must be, of necessity, general. There are fifty-one different

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[47] *Id.*

[48] This is a matter of speculation. It just seems unlikely that the ordinary investigator is going to have enough of an economic investment for either of those to have much of an impact.

[49] No record of prosecutions of such a person have been found in the literature, *but see* United States v. Park, 421 U.S. 658 (1975). A more likely sanction would be for the FDA to refuse to allow an investigational exemption where an investigator was proposed who had a record of misconduct. In FDA practice no record of such an action has been found, *but see* Hamlin Testing Laboratories Inc. v. AEC, 337 F.2d 221 (6th Cir. 1964) and River Forest Pharmacy, Inc. v. Drug Enforcement Adm'n., 501 F.2d 1202 (7th Cir. 1974). *See also* Rheingold, *The Mer/29 Story – An Instance of Successful Mass Disaster Litigation,* 56 CAL. L. REV. 116, 120-1 (1968), indicating that the Grand Jury returned indictments against the company and three scientists. All pleaded *nolo contendere.* The scientists received suspended sentences. Indictment was under 18 USC 1001 *not* 21 USC. *See also* O'Keefe, *Criminal Liability: Park Update,* 32 FOOD DRUG COSM. L.J. 392, 400 (1977).

jurisdictions, counting the District of Columbia, and each is free to develop and apply its own law of negligence. Another thing that should be noted is that the need for informed consent does not arise only in regard to experimental procedures. Rather, experimental procedures tend to involve more risk, and it seems safe to say that as the degree of risk goes up, the need to inform goes up. Also, it seems safe to say that if there is a traditional treatment available with a known risk and an experimental treatment with an unknown, and perhaps higher risk, the need to inform probably becomes absolute. Indeed, in the last situation, more than the law of negligence may be involved.[50]

Finally, it may be useful to distinguish those situations where an injury results from an unavoidable risk in the procedure from those where the injury arises as a result of use of inadequate skill in the procedure. Both of those problems seem to be affected by the proposed regulations[51] and will be discussed here.

Let us first consider the question of need to inform as to unavoidable risks. Traditionally, the medical profession has been held to a somewhat subjective standard of care. In short, physicians tend to be held to the standard of conduct prevailing among physicians in the community. In the past this standard has been imposed not only in regard to the skill used in the treatment of a patient, but also to determine whether there was an obligation to inform a patient as to risks involved in a treatment.[52]

Consider blood transfusions, for example. In every transfusion there is some unavoidable risk of serum hepatitis. Should the physician be liable if a patient contracts hepatitis when he had not been warned of the risk? It seems clear that no liability would attach if the transfusion was given in a life-threatening or other situation where a patient could be said to have no choice. What if the patient had a choice (or might have had a choice)? The traditional view has been that the physician is liable only if other physicians in the community would ordinarily warn a patient of such a risk.[53]

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[50] *See, e.g.,* Canterbury v. Spence 464 F.2d 772, 783-5 (D.C. Cir. 1972).

[51] 41 Fed. Reg. 35, 282 (1976); 41 Fed. Reg. 35, 313 (1976).

[52] *See, e.g.,* Canterbury v. Spence, 464 F.2d 772, 783 (D.C. Cir. 1972).

[53] *See, e.g.,* Fischer v. Wilmington Gen. Hospital, 51 Del. 554, 149 A.2d 749 (1959). Note that in many jurisdictions this risk (blood transfusions) is regulated by statute. *See* FRUMER AND FREIDMAN PRODUCTS LIABILITY § 16.04 [3] [b] (Cum. Supp. 1976), listing states which have by statute eliminated liability. MASS. GEN. LAWS ANN. Ch. 106 § 2-316 (5) (1965) is typical.

More recently, courts have come to apply a more objective standard. In a well written, leading case discussing the need to warn of the 1% risk of paralysis from a laminectomy, the D.C. Court of Appeals observed:

> It is the settled rule that therapy not authorized by the patient may amount to a tort — a common law battery — by the physician. And it is evident that it is normally impossible to obtain a consent worthy of the name unless the physician first elucidates the options and the perils for the patient's edification. Thus, the physician has long borne a duty . . . to make adequate disclosure . . . . The evolution of the obligation to communicate . . . has hardly involved an extraordinary restructuring of the law.
>
> Duty to disclose has gained recognition in a large number of jurisdictions, but more largely on a different rationale. The majority of courts dealing with the problem have made the duty dependent on . . . custom . . . in the community . . . . We agree that the physician's nonconformance with . . . custom . . . may give rise to liability . . . . We do not agree that the patient's cause of action is dependent upon the existence and nonperformance of a relevant professional tradition.
>
> There are, in our view, formidable obstacles to acceptance of the notion that the physician's obligation to disclosure is either germinated or limited by medical practice.
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> . . . .
>
> We hold that the standard measuring performance of that duty by physicians, as by others, is conduct which is reasonable under the circumstances.[54]

In another leading case, coming out of Rhode Island two years later, there was occasion to discuss what is "reasonable under the circumstances." There, the court observed:

> It is not necessary that a physician tell the patient any and all of the possible risks and dangers of a proposed procedure . . . . As we noted earlier, materiality is to be the guide . . . . Materiality may be said to be the significance a reasonable person, in what the physician knows or should know is his patient's position, would attach to the disclosed risk or risks in deciding whether or not to submit to . . . treatment.[55]

This was further refined in a pair of cases handed down by the Court of

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[54] Canterbury v. Spence, 464 F.2d 772, 783-5 (D.C. Cir. 1972). Establishing a duty to warn is easy, but meeting that duty may be difficult, indeed. *See, e.g.*, Herbert, *Acquring New Information While Retaining Old Ethics,* 198 SCIENCE 690, 692 (1977); addressing the question of "Is there any such thing as informed consent?," the author cites, *inter alia:*

> a recent study [which] . . . demonstrated that a majority of surgical patients denied after surgery that they had been told about all the possible undesirable outcomes prior to surgery, even though discussion . . . ran for an hour and a half . . . and was tape recorded.

[55] Wilkinson v. Vesey, 110 R.I. 1606, 295 A.2d 676, 689 (1972).

Appeals of Washington State in 1974.[56] In one of them, that court observed, after a lengthy discussion of exceptions to the doctrine of informed consent:

> The precepts which have been discussed dictate that the elements which must exist to impose liability upon a physician under the informed consent doctrine are the existence of (a) a duty to inform, (b) a failure to inform, (c) evidence that, if informed, the patient would have chosen a different course of treatment, and (d) injury resulting from the treatment followed.[57]

This last case is probably an adequate summary of the law of informed consent for present purposes. However, before considering what effect the proposed regulations have on the common law, it will be worthwhile to discuss the other aspect of liability noted above.

A question of an inadequate exercise of skill may be as apt to arise as one of the duty to apprise a patient of hazards inherent in a therapy. Again, traditionally the standard of care was related to the skill prevailing in the community within which the physician practiced. However, this subjective requirement has also been superseded by a more objective one.[58]

Assuming that experimental evaluations are apt to be conducted in a teaching and research hospital, the question then becomes, what is the standard of care in such an institution? Moreover, there is the question of what effect, if any, a waiver of liability would have in that setting. Both of these questions were addressed in a 1963 California decision.[59]

After holding that a waiver of liability is of no effect in a tort suit by an injured patient for pressing reasons of public policy,[60] the court went on to state:

> ... defendant urges that... the funds of the research hospital may be deflected from the real objective of the extension of medical knowledge to the payment of claims for alleged negligence. Since a research hospital necessarily entails surgery and treatment in which fixed standards of care may not yet be evolved, defendant says the hospital should in this situation be excused from such care. But the answer lies in the fact that possible plaintiffs must *prove negligence;* the standards of care will themselves reflect the

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[56] Miller v. Kennedy, 11 Wash. App. 272, 522 P.2d 852 (1974) and Holt v. Nelson, 11 Wash. App. 230, 523 P.2d 211 (1974).

[57] Holt v. Nelson, 11 Wash. App. 230, 523 P.2d 211, 219 (1974).

[58] *See, e.g.,* Canterbury v. Spence, 464 F.2d 772, 785 (D.C. Cir., 1972). There the D.C. court notes that it has generally held that "prevailing medical practice... does not itself define the standard." In general, *see* 1 LOUISELL AND WILLIAMS MED. MALPRACTICE Para. 8.06 (Cum. Supp. 1976). For a decision indicating a contrary inclination, *see* Holton v. Pfingst, 534 S.W.2d 786 (Ky. 1976).

[59] Tunkl v. Regents of U. Cal., 32 Cal. Rptr. 33, 383 P.2d 441 (1963).

[60] *Id.* at 40, 383 P.2d at 447.

> research nature of the treatment; the hospital will not become an insurer or guarantor of the patient's recovery. To exempt the hospital completely from any standard of due care is to grant it immunity by a contractual clause exacted of the patient. We cannot reconcile that technique with the [previous holdings of this court].[61]

Summary and Conclusions

It thus appears that, outside of a few jurisdictions,[62] the proposed investigational use regulations under § 520(g) (3) (D) will have little effect on the tort liability of medical researchers. While they *do* require informed consent and forbid the use of waivers, both of these appear to be consistent with the common law as presently developing in most jurisdictions.

Moreover, as earlier discussed, while a failure to conform may give rise to possible statutory sanctions, the risk of these seems much lower than the risk of tort liability.[63] For that reason the proposals do not seem to be the basis for alarm — and, indeed, may result in researchers being better informed than they might otherwise be of their obligations to human subjects.

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[61] *Id.*, 383 P.2d at 448.

[62] 1 LOUISELL AND WILLIAMS, *supra* note 58, at Para. 17.07-57, for example, lists Oregon, Virginia and West Virginia as currently recognizing a contract waiving a right to sue for negligence.

[63] *See* discussion corresponding to note 48 *supra*.