be the result of cultural rather than ecological factors.

After working with the wooden flaker and producing some acceptable replicas with characteristics similar to aboriginal flake scars, I believe it is entirely possible that the Period 3 Palliaike points were pressure-flaked with a wooden tool. I would suggest, therefore, that the geographic range of the wooden pressure-flaker technique should not be confined to Australia.

References and Notes

1. A. P. Elkin, *Man* **130**, 110 (1948); N. Tindale and H. A. Kubdsay, *Aboriginal Australian* (Angus & Robertson, Sydney, Australia, 1963), pp. 25–46; personal communication.
2. D. E. Crabtree, *Amer. Antiquity* **33**, No. 4, 446–78 (1968).
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4. D. E. Crabtree and B. R. Butler, *Tebiwa* **7**, (1964).
5. D. E. Crabtree, *ibid.* **10**, 60 (1967).
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8. L. S. B. Leakey, *Adam's Ancestors* (Harper & Row, New York, 1960).

9. Supported by National Science Foundation grant GS 1659. I thank Dr. H. Swanson, Jr., for his assistance and for the "General Aspects of Flintworking" section; Dr. J. Bird for conceiving and promoting the experiment, for giving personal advice, for loaning the representative collection, and for furnishing lithic material and wooden flakers; Dr. R. A. Gould for contributing the illustrations and photographs, for loaning Australian cultural material, and for his editorial assistance; J. Bopp for typing; my wife Evelyn for her aid and encouragement; and, particularly, Drs. Bird and Gould for spending their valuable time at my workshop observing, advising, and assisting in the actual experiments.

Compensating Persons Injured in Human Experimentation

Ethical precautions do not guarantee the safety of research subjects; financial protection is also needed.

Clark C. Havighurst

Despite all the attention that has been directed to the ethics of experimentation with human subjects, there is one remarkable omission from the various ethical formulations and from most writing on the matter. Emphasis in such discussion is always on two aspects of the investigator's obligation: (i) the preventive aspect—the need to minimize risks—and (ii) the consensual aspect—the research subject's right to be informed of what use is being made of his person. But ethical discussions seem to stop at this point and to disregard the possibility that, in spite of all ethically prescribed precautions and the procurement of adequately informed consent, the research subject will still suffer harm. It would be startling to conclude that ethical considerations do not enter into the question of what should be done for the research subject who is thus injured, yet expressions of this concern have tended to appear more often in legally oriented discussions than in the ethical literature on human experimentation (*1*).

The notable disproportion in the literature is illustrated in the Spring 1969 issue of *Daedalus* (the proceedings of the American Academy of Arts and Sciences), in which only about six of 386 pages devoted to "ethical aspects of experimentation with human subjects" dealt with compensation of the injured participant (*2*). The matter was touched on only by the lawyers present at the symposium, and the only thorough consideration was the provocative discussion by Guido Calabresi of the Yale Law School, who, in concluding his discussion, anticipated the main point of this article: "Examination and refinement of devices like the compensation fund [for injured research subjects] by people who are involved in medical research seem, to me, to offer considerably more promise than further elaborations on the infinite varieties of consent that are currently the mainstay of symposia on human experimentation" (*3*). In defense of the medical literature, it must be noted that Henry K. Beecher, in an excellent recent piece in *Science* (*4*), has looked beyond the care and consent aspects and has squarely advocated compensation arrangements.

The ethical lacuna noted involves no particular moral shortcoming on the part of the medical profession; rather, it reflects the naturally narrow focus of ethics on the personal responsibility of the clinical investigator himself, to the exclusion of the focus on the responsibility of the medical profession as a whole. When the matter is looked at solely in terms of the investigator's responsibility, no real ethical issue can of course be raised in the absence of some kind of demonstrable fault. But, even given exclusive concern with the researcher's standard of conduct, one might still ask whether the investigator does not have an ethical duty to provide research subjects with advance protection against mishaps, by means of insurance or otherwise. Nevertheless, personal responsibility, like the legal duty, has apparently always been deemed discharged by the exercise of care and the obtaining of consent. This course may have produced responsible behavior on the part of most researchers, but it has left the ultimate ethical problem unsolved and undoubtedly some victims uncompensated.

The neglected ethical issue is faced only when one considers the responsibility of the medical profession as a whole (*5*). Indeed, while the ethical impetus has been supplied mainly by the medical profession, ultimate responsibility resides in the entire research "industry," including its educational, corporate, philanthropic, and governmental components. When the situation is viewed in this manner, there can hardly be debate about the basic principle that research costs which take the

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form of injuries to human subjects ought, to the extent possible, to be borne by the research industry, and ultimately by society as a whole, and not by the unlucky subjects themselves.

This principle of societal responsibility makes not only humanitarian but economic sense, for the research industry will undertake fewer projects that are not justified by a balancing of risks (and other costs) against potential benefits if all of the potential costs must be taken into account. Despite all the precautions in experimental design that ethics prescribes, the necessary balancing of risks and benefits lacks needed indices and incentives—and thus sacrifices attainable precision—unless dollar costs must be contended with. Whatever compensation system is devised must not only compensate the unlucky subject but also place the burden on those best able to evaluate and control the risks attending the experiment. Indeed, Calabresi contends that the latter goal, because of its long-run effects of minimizing risk and providing incentives for care, is more important than the humanitarian goal of caring for particular victims. Happily, the two objectives go hand in hand a good part of the way; their twin achievement is the subject of the discussion that follows.

Nonlegal Approaches

The vehicle of progress that is most often invoked in this field is the law. Proposals for legislative change or for judicial formulation of a rule of liability irrespective of fault are, of course, appropriate, but there is reason to doubt that either legislatures or the courts are likely to move quickly to force the research industry to recognize an obligation to compensate all injured research subjects. Lawsuits that might lead to imposition of liability without a demonstration of fault have been at best infrequent in this field, and none has reached the appellate courts for a definitive opinion. Suits against corporate defendants (drug companies or hospitals) are likely to be settled, in part for the purpose of avoiding definitive rulings on the legal points, and cases involving individual investigators alone would not lend themselves to development of a rule of strict (nonfault) liability because, as in the case of ethics, the question seems narrowly focused on personal rather than corporate responsibility. By the same token, the legislative process is not easily stimulated or guided and might produce a more restrictive law than is desirable, especially if action is finally prompted by an event of the magnitude of the thalidomide tragedies. The point is simply that the prospect for legal change by judicial or legislative processes is highly uncertain. A policy—governmental or institutional—that waits on such change is therefore hardly a responsible, or ethical, one.

It appears to me that the means are rather close at hand for accomplishing, without resort to either judicial or legislative processes, practically all the good that would be expected to flow from a change in the law. The ultimate practical result of legal change would be to alter practices in the research industry in ways that would assure fairly systematic compensation of injured research subjects. But this same result can also be achieved by moving the sponsors of research to assume a burden—so far as we know, a relatively slight one—that they may now be allowing the research subjects themselves to bear. Since government itself sponsors a vast quantity of the research with which we are concerned, one line of action is reasonably apparent. Other means are also available.

The attack may be mounted on any or all of three fronts.

1) The Public Health Service could commence a review of its policy on "protection of the individual as a research subject" (*6*) with a view to adding a requirement that investigators make arrangements, in advance of embarking on an experiment, for the compensation of research subjects for such harms as may occur. The present policy requires informed consent, "peer-group" review, and other precautionary measures but takes no notice of the possibility that injury could nevertheless occur or that prudent steps might be taken to minimize the consequences of such an eventuality.

2) The Food and Drug Administration (FDA) could consider imposing similar new requirements in drug testing, the most likely procedure being to have the drug company sponsoring the research contractually indemnify each research subject for harm that might flow from use of the drug. The FDA's authority for issuing such a regulation would not be altogether clear, but it can be convincingly argued that, by encouraging more careful analysis of the possible risks and benefits that each test entails, the regulation would relate to "the protection of the public health," as required by 21 U.S.C. § 355(i). Recent FDA proposals would introduce requirements for peer-group review of clinical trials in institutional settings (*7*), an essential but decidedly modest reform in view of recent disclosures (*8*).

3) Various medical centers might begin independently to provide protection for research subjects, either by adopting a program of self-insurance or by obtaining commercial group or other insurance.

Insurance or Contractual Indemnity

Each of the foregoing steps involves special problems that must be worked out in detail at some level. The first set of problems involves the potential role of insurance. In many ways, insurance would provide a useful mechanism for carrying out proper compensation arrangements. Thus, a group contract covering all the experimental subjects of a given research institution would provide a ready means of administration. If group insurance were deemed impractical (perhaps because of wide variations in the level of risk associated with different experiments), direct insurance of the individual subjects would be feasible, with the institution acting as the insurer's agent and paying the premiums.

Insurance premiums would be absorbed in the institution's research budget. Experience under group policies would be quickly reflected either in refunds or in higher premium levels. The premiums would thus provide some of the desired incentive for care so long as refunds or added costs were not automatically passed on to, or assumed by, the sponsoring agency, which would be less sensitive than the contracting or grantee institution to either the value of a dollar or the existence of a risk. The best arrangement would combine coinsurance provisions in the insurance policy and insistence by the sponsors of research that each research institution meet its insurance costs out of overhead allowances rather than as a separate cost item in its contracts. Under such arrangements, cost-cutting incentives would persist to whatever

degree they are present in nonprofit enterprises.

A system of contractual indemnity of research subjects, implemented by an institutional compensation fund, might be a more satisfactory alternative than commercially procured insurance. This would be a form of "self-insurance," the risk assumed being for institutional liability under the contractual indemnity rather than under the law of torts for malpractice. For reasons of cost, many larger institutions may prefer the self-insurance plan, leaving insurance primarily to assist the smaller institutions. Most institutions are probably already "self-insuring" important risks to which their research subjects are exposed by standing willing voluntarily to provide care for any of them who suffer adverse effects. It is doubtful that bills would be rendered for such care.

The authority of the granting and contracting agencies of the federal government to pay the costs of insurance covering research subjects constitutes a special legal problem. One report discloses that, in contracting for the testing of rubella vaccine, NIH claimed not to have legal authority to pay insurance premiums covering either the hospital or the subjects (*9*). In that instance the affected hospital incurred an $8000 expense for premiums, which it bore as part of its overhead. This result is consistent with the view expressed above—namely, that, in order not to reduce incentives for care, insurance should be treated as an overhead item. The result also accords with the following statement by the Senate committee that approved a subsequently enacted bill (*10*) authorizing federal indemnification of contractors undertaking "unusually hazardous" research: "So as not to substitute Federal indemnity for the contractor's normal insurance or self-insurance programs, it is the intent of the committee that the governmental indemnity extended to Public Health Service contractors not be substituted for the insurance or self-insurance programs normally maintained by such contractors. Indemnity should not be provided in lieu of available private insurance" (*11*). If the policy behind this statement is not protection of the private insurance industry but preservation of maximum incentive for care, the principle appears to extend to federal payment of private insurance premiums as direct costs incurred under contracts and grants. The better course would be to treat these items as indirect costs, using an industry-wide yardstick and allowing the individual institutions to benefit from refunds and reduced premiums and requiring them to bear the expense of increases in premiums.

The present government policy is not easily ascertained. General contracting regulations appear to treat insurance as just another cost (*12*). The regulation applicable to commercial (as opposed to educational) contractors specifies that insurance coverage shall not exceed legal liability (*13*), a condition which may frustrate the object of compensating injured research subjects in cases where fault cannot be demonstrated. Further, the regulations seem to require that the government receive the benefit of premium refunds (*14*). Whether premiums would be regarded as direct or indirect costs in a grant or contract is not clear, but the question would probably hinge on whether the coverage was under a blanket policy or under a policy procured for the specific project (*15*). Premiums under an institutional group policy covering all research subjects would probably be treated as an indirect cost, presumably with less accountability (at least in the case of educational institutions) and therefore greater incentives for care (*16*).

Defining Coverage

Regardless of whether insurance or contractual indemnification of the subject (self-insurance) is chosen as the preferred mechanism, decisions will have to be made concerning the extent of coverage. In the case of the Public Health Service or the FDA, a standard indemnity contract might be developed in cooperation with private research institutions or the drug industry, or a standard insurance policy might be worked out with the assistance of the insurance industry (*17*). Some of the questions that would have to be answered in developing an insurance policy or indemnity scheme would be these.

1) Would pain and suffering be compensable, or might the subject's "informed consent" be appropriately deemed a waiver of damages for such subjective injury?

2) Are there legal or practical objections to drafting a group accident insurance policy to provide benefits based on loss of wages and earning capacity rather than a fixed amount?

3) If loss of wages were considered compensable, would this influence the choice of research subjects in unfortunate ways, or should a minimum death benefit and per diem hospitalization benefit be provided as a means of reducing any tendency to exploit prisoners and the poor?

4) Would a ceiling on damages be appropriate, or might it serve merely to encourage malpractice litigation to recover what a jury might be willing to award?

5) Could or should the subject's consent be framed as an acceptance by him of insurance or indemnity as his exclusive remedy, or might the subject's right to judicial relief be confined to cases where he could show "gross" negligence?

Special administrative problems would occur in cases where the research subjects were persons who were already sick, rather than healthy volunteers. This situation is likely to be encountered most often in the later stages of drug experimentation, since in other sponsored research it is common for healthy volunteers to be employed. The added problem in compensating subjects who were previously ailing is to distinguish harm that is properly a cost of research from side effects the risk of which is tolerable in view of the therapy's probable beneficial results. The patient's resulting condition cannot be compared with his healthy state, as is appropriate in the case of healthy volunteers, but must be matched against the probable outcome of other therapies. A compensation scheme requiring such a judgment might be altogether impossible to administer because of the guesswork involved, but the FDA might be able to find a means of requiring compensation for the net detriment caused by those unanticipated drug-associated side effects about which the prescribing physician was not warned by the manufacturer. For example, the actual amount of the indemnity might be determined by a panel of doctors, who would be able to prevent windfalls to a patient who ended up actually better off despite the side effects. Similarly, the Public Health Service or private institutions might find it possible, on such a basis, to extend an indemnity or insurance protection to patients enlisted in

experimentation as well as to healthy volunteers.

Thus, while one can anticipate serious problems in meeting the need to protect sick persons from bearing the net losses resulting from their use as subjects in experimentation, an effort to overcome these problems in a reasonable manner should be made. The need for having the costs of research efforts borne by the research sponsors and not subsidized by individual research victims is particularly acute in the case of drug experimentation. Because the drug companies are profit-making enterprises, their awareness of costs should be greater than that of the nonprofit institutions in which most other research is carried on. By the same token, failure to make the drug industry bear the true costs will lead to overly dangerous experimentation, as subsidization of drug development by research victims continues to occur.

Removing the Stigma from Experimentation

Systematizing compensation of injured research subjects will have the salutary effect of alleviating much of the suspicion with which the law now seemingly regards human experimentation. This suspicion has been commented on by both Beecher (*4*) and Delford L. Stickel (*18*). Both writers have also stated explicitly the desirability of providing protection for research subjects by a mechanism that does not inculpate the physician. Stickel's comments sum up much of what has been said here.

> Insurance for healthy subjects of human experimentation . . ., if widely used, would accomplish the same result [that is, assured compensation] as would the judicial evolution of a legal principle of "liability without fault" for harm resulting from experimentation.

He goes on,

> Such strict liability might be accomplished by carrying out the implications of the widely stated but unfortunate principle that "the physician experiments at his peril." . . . But, while the object of shifting the burden of losses suffered by research subjects to those supporting the research is a valid one . . ., the medical profession would have good reason to resent the achieving of this result by a process imputing blame to the experimenters in every case. Insurance of a nonmalpractice variety would seem to be the more desirable way of providing the needed protection for research subjects. Perhaps a legal doctrine imposing liability on the experimenter for failure to provide such insurance, enabling the injured subject to recover even in the absence of other negligence, would ultimately be appropriate; however, the availability and widespread use of such insurance would be prerequisites to such a legal rule, unless a duty to provide such insurance were created by legislation or regulatory action.

Summary and Conclusion

Without disparaging the ethical importance of informed consent or of care and supervision in research design, it is possible to assert that ethics requires also that the investigator furnish financial protection to research subjects. Lacking mechanisms for providing this protection, investigators have seldom made such provision in the past, and have left research subjects to rely on the institution's sense of moral obligation or on poorly defined legal rights. Research institutions and research sponsors, especially the federal government and the drug industry that it regulates, could provide for insurance or indemnification through mechanisms yet to be developed. In pursuit of this goal, serious study should begin on the problems of implementing compensation arrangements for all injured research subjects. The Public Health Service and the FDA have not fully discharged their responsibility in the direction of creating conditions under which clinical research can proceed with adequate regard for the subjects' rights.

I expect some disagreement regarding the importance that I attach to preserving financial incentives for risk reduction by researchers and research institutions, and to resisting the temptation simply to spread the cost of these injuries by assigning them automatically and entirely to insurers and sponsors of research. Such disagreement might stem from a sense that, in this area, ethical impulses are of greater overall significance than economics in generating maximum safety. While this impression is generally valid, reliance on ethics alone would neglect the small but critical class of cases at the margin, where ethics may be weak and peer groups inattentive but where economic instincts may be especially acute. Much drug experimentation probably falls within this category, and so, probably, does a great deal of other research that may seem, on the surface, to be inspired by altruism alone (*19*).

A second objection to my stickling about preserving research institutions' financial incentives for risk reduction concerns the possibility that the research deterred by such an arrangement might not be limited to that in which the costs, including the risks foreseen, exceed the social value of the research. This is of course a real risk: because researchers are generally unable to reap much of the profit from their useful discoveries, we cannot be confident that the potential social value of the discovery will induce the researcher or research organization (the primary decision maker) to undertake the research whenever the costs are outweighed by social benefits. Still, the benefit-cost decisions on which the support of medical research is largely based will not be improved by taxing insurance premiums directly to the funding agency. In short, I see no grounds for freeing the primary decision maker, who is seldom wholly free from at least some economic temptation, from the need to consider these potential costs in actual rather than hypothetical terms. The possible gains from cost reduction induced by proper allocation of incentives for risk reduction are too great to be squandered by focusing only on the need to shift these risks from individual victims to society as a whole.

Finally, I have a sense, for whatever it is worth, that ethical considerations alone require that these costs not be passed on to the sponsors of research. It seems to me that each research institution and drug company should bear them willingly in recognition of its ethical obligation to the individuals enlisted in its enterprises and as a token of its fulfillment of that obligation.

References and Notes

1. See, for example, I. Ladimer, *J. Chronic Dis.* **16**, 1229 (1963). This pioneering proposal suggests coverage under a scheme similar to workmen's compensation.
2. *Daedalus* **98**, No. 2 (1969).
3. G. Calabresi, *ibid.*, p. 387.
4. H. K. Beecher, *Science* **164**, 1256 (1969). See also ———, *Research and the Individual: Human Studies* (Little, Brown, Boston, 1970), pp. 39–42.
5. This is not the first time the medical profession has been reminded that individual relationships should not be emphasized to the exclusion of broad social considerations. There may be an instructive analogy to the profession's reluctance to acknowledge the social dimensions of the delivery of health care.
6. Public Health Service, *Protection of the Individual as a Research Subject* (Government Printing Office, Washington, D.C., rev. ed., 1969).

7. 34 Federal Register 13552 (22 Aug. 1969).
8. See, for example, *New York Times* (29 July 1969), p. 1.
9. *Medical Malpractice: The Patient Versus the Physician, A Study by the Subcommittee on Executive Reorganization of the Senate Committee on Government Operations, 91st Congress, 1st Session* (Government Printing Office, Washington, D.C., 1969), pp. 467–468.
10. 42 U.S.C. [U.S. Code] § 241(h) (Supp. I, 1965); 10 U.S.C. § 2354 (1964).
11. S. Rep. 367, 89th Congress, 1st Session (1965).
12. 41 C.F.R. [Code of Federal Regulations] §§ 1–15.205–16, .309–15.
13. 41 C.F.R. § 1.205–16.
14. 41 C.F.R. §§ 1–15.201–5, .303–5.
15. 41 C.F.R. §§ 1–15.202, .203; 42 C.F.R. §§ 52.31, .32.
16. 42 C.F.R. § 52.41 (grants); 41 C.F.R. §§ 1–15.307–3, –4.
17. The Atomic Energy Commission has developed a standard-form policy for nuclear accidents (10 C.F.R. § 140.91). Precedents developed in the field of atomic energy will be useful in carrying out the recommendations made herein, especially since some clinical experimentation may require protection against disaster. The protection of research institutions against the consequences of public disasters should be integrated with protection of research subjects against the consequences of private ones.
18. D. L. Stickel, *Law & Contemporary Problems* **32**, 597 (1967).
19. See R. S. Merrill, in *The Rate and Direction of Inventive Activity: Economic and Social Factors* (National Bureau of Economic Research, Special Conference Series No. 13) (Princeton Univ. Press, Princeton, N.J., 1962), pp. 420–26.
20. This article was written in conjunction with work performed pursuant to contract No. HSM 110-69-214 with the Public Health Service, Department of Health, Education, and Welfare.

South Africa (I)

Booming Nation's Research and Industry Benefit from Close Ties with the United States

South Africa occupies a unique position in the world today. It is unique in that it bases its entire constitution, legislative system, and practically every other phase of life on differential treatment of different sections of its population. Rightly or wrongly, these different groups of people are spoken of as "races." Every single aspect of our life has come to be dominated by the thought: to what group or race does that *man belong? . . . The idea of race has gained a tenacious grip on the minds of South Africans and, especially, our political leaders. It has become a national neurosis of obsessional variety.*—From a lecture, "The Meaning of Race," by Phillip V. Tobias, head of the Department of Anatomy, University of the Witwatersrand (1961).

South African Prime Minister B. J. Vorster returned in June from a visit to Europe, and told his countrymen, "We are not as isolated as our enemies try to make out." It was appropriate that this should be among his first remarks because, for two intertwined reasons, concern about isolation ranks high among those who are categorized as white in this economically booming and most prosperous of African nations. First, South Africa is at least some 5000 miles from the nations with which the whites have important affinities—cultural, economic, familial, and of other sorts. Aviation and telecommunications are reducing the effects of that distance. But, with an almost unanimously hostile Black Africa between them and Europe, and with the Portuguese battling to hold on to nearby Mozambique and Angola, South Africa's nearly 3.6 million whites—living among some 15 million persons classified as "nonwhite"—feel very far away from the rest of the white world. Which makes it all the more painful as well as infuriating for them to know that, within that white world, revulsion toward South Africa's *apartheid* policies has led, often successfully, to attempts at boycotts and octracism. For example, of grievous hurt to many whites in this sports-loving country, Britain—South Africa's leading trading partner—recently invoked opposition to *apartheid* as grounds for refusing to receive a South African cricket tour. Several years ago, the same reason led to South Africa's ouster from the World Health Organization (WHO). Many nations have invoked arms embargoes against South Africa, in accord with a U.N. resolution, and attempts at boycotts of South African goods regularly take place around the world.

Against this background, and despite the WHO ouster, which seems to have had little effect on South African medicine, public health, or access to foreign expertise and information, it is worth noting that one of the least affected areas for white South Africans is that embracing science, technology, and medicine. These are fields in which South Africa has built considerable strength—outstandingly so in some areas—and which, with few exceptions, continue to benefit from close and fruitful relations with leading research centers in Western Europe and especially the United States. These relations are mainly on an individual basis, but U.S. government research organizations are also involved, most notably the National Aeronautics and Space Administration, the National Institutes of Health, and the Atomic Energy Commission. But even when the relationship is formally on a man-to-man basis, it is very often that U.S. government funds support the American share of activity.

There are exceptions to the theme of cordiality. South African scientists now and then tell of hostile encounters in the United States and elsewhere. One told of recently being challenged at a professional meeting, and another, who frequently visits the United States,