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Review of American and English Literature of Recent Years
(Fourteenth Rheumatism Review)
Charles J. Smyth, M.D., F.A.C.P., Chairman, Editorial Committee

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(Sixteenth Rheumatism Review)
Charles J. Smyth, M.D., F.A.C.P., Chairman, Editorial Committee

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The Changing Mores of Biomedical Research
A Colloquium on Ethical Dilemmas from Medical Advances

The Changing Mores of Biomedical Research
A Colloquium on Ethical Dilemmas from Medical Advances

Held at the Forty-eighth Annual Session of the American College of Physicians, San Francisco, April 12, 1967

Panelists
Hon. Warren E. Burger, LL.D.
Sir Peter Medawar, B.Sc.
Tomas E. Starzl, M.D., F.A.C.S.

Challengers
René Dubos, Sc.D., M.D.
Irving S. Wright, M.D., F.A.C.P.
Walsh McDermott, M.D., F.A.C.P.

Co-chairmen
David Krech, Ph.D.
Joshua Lederberg, Ph.D.
Samuel E. Stumpf, Ph.D.

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When the needs of society come in head-on conflict with the rights of an individual, someone has to play God. We can avoid this responsibility so long as the power to decide the particular case-in-point is clearly vested in someone else, for example, a duly elected governmental official. But in clinical investigation, the power to determine this issue of "the individual versus society" is clearly vested in the physician. Both the power itself and, above all, our awareness that we are wielding it are increasing every day and can be expected to increase much further. It is this inescapable awareness that we are wielding power that has us so deeply troubled, for we are a generation nurtured on the slogan "the end does not justify the means" in matters concerning the individual and his society. Yet as a society we enforce the social good over the individual good across a whole spectrum of nonmedical activities every day, and many of these activities ultimately affect the health or the life of an individual.

Traditionally in our Judeo-Christian culture we have handled this issue by one of two mechanisms. When, as in our racial problem, for example, the conflict contains no built-in contradiction, we publicly and officially subscribe to a set of ideals. We can work privately and publicly toward the attainment of these ideals, and with their attainment would come the solution of the problem. This mechanism works when the forces in conflict are intrinsically reconcilable even though the reconciliation might take many decades or a century. But we use another mechanism when the conflict is head on, when the group interest and the individual interest are basically irreconcilable.

In circumstances like these, such as the decision to impose capital punishment or the selection of only a minority of our young men to become soldiers, the issue is decided by a judgment that is arbitrary as it affects the individual. In short, we play God. When we take away an individual's life or liberty by one of these arbitrary judgments we try to depersonalize the process by spreading responsibility for the decision throughout a framework of legal
institutions. Thus, it is usually a jury, not a judge, that determines the death penalty; a local draft board, not a bureaucrat, that decides who goes to Vietnam. This second type of mechanism works only because there is widespread public acceptance that society has rights too and that it is preferable that the power to enforce these rights over the rights of the individual be institutionalized.

I submit that the core of this ethical issue as it arises in clinical investigation lies in this second category—the one wherein, to ensure the rights of society, an arbitrary judgment must be made against an individual.

This is not to say that all ethical problems in clinical investigation fall into the irreconcilable category. On the contrary, in numerical terms most of them probably do not.

Without question, a considerable portion of the lapses in fully protecting individual rights in clinical investigation can be avoided by more careful and open attention to the subject and by our ingenuity in developing new practices to attain some of the same old ends. This will prove quite costly in financial terms, but what is being accomplished in this way is very much to the good and is to be strongly encouraged. But there remains that hard core of the problem: the kind of situation in which it clearly seems to be in the best interests of society that the information be obtained. It can be obtained only from studies on certain already unlucky individuals, and no convincing case can be made that they can expect much in the way of benefits except those accruing to them as members of society.

Clearly there are three questions here:

[1] From where does society get its rights or interest that makes it imperative to perform biomedical studies on an individual?

[2] How is the individual subject selected?

[3] How are the social priorities decided?

The social priorities are easy; any small group of certified medical statesmen can settle them in an afternoon. As we all know, however, it is the other two questions that are so thorny.

Without too deep reflection it seems to me that society actually having a right here is a relatively new phenomenon that is chiefly derived from the demonstration that knowledge gained by studies in a few humans can show us how to operate programs of great practical benefit to the group. Until the late nineteenth century, as I understand it, most human experimentation expanded knowledge but did not increase the power to control disease. The physicians of that day thus had no problem in maintaining the double ethical charge still preserved in the Helsinki Declaration: to "safeguard the health of the people," on the one hand, and to make the health of "my patient" the first consideration, on the other hand. But starting, I suppose, with the yellow fever studies in Havana, we have seen large social payoffs from certain experiments in humans, and there is no reason to doubt that the process could continue. It is by this demonstration, analogous to the great "invention of invention" of Newton's era, that medicine has given to society the case for its rights in the continuation of clinical investigation. Once this demonstration was made, we could no longer maintain, in strict honesty, that in the study of disease the interests of the individual are invariably paramount.

Yet we are temperamentally incapable of leaving it at that. Our reflex action here is to try to imitate what we do when the same conflict arises in irreconcilable form elsewhere in our society. That is to say, we are willing to concede that some judgments must be arbitrary, but we attempt to clothe them with institutional forms so that at least the judgments are not made solely by one person. We will play God, but we would like to do it by group effort.

I am deeply convinced that such efforts provide no real solution because our culture has not yet faced up to the irreconcilable nature of the conflict at the heart of this particular issue. And until it does so, there exists no recognized consensus or article in the "social contract," if you will, to provide that base on which any law or regulation must rest if it is to be viable.

Conventional juridical procedures including the traditional jury system are too slow to fit the urgent nature of many clinical decisions. Any peer group committee might set us, let us say from law, theology, and medicine, would have credentials that are obviously suspect. It has been chosen neither by the society nor by the individual whose conflicting rights are to be arbitrated; more importantly, it lacks that widespread social consensus that supports trial by jury or your local draft board. Therefore, such a peer committee cannot, in fact, dilute and hence dissipate the ethical responsibility of the clinical investigator although it may give the superficial image of doing so. Thus, by the terms of our culture, as may be seen in the Declaration of Helsinki, no matter who the investigator talks into partnership when he acts, he acts alone.

What can we do to solve this agonizing dilemma? Obviously we cannot convene a constitutional convention of the Judeo-Christian culture and add a few amendments to it. Yet, in a figurative sense, until we can do something very much like that, I believe deeply that the problem, at its roots, is unsolvable and that we must continue to live with it.

To be sure, by careful attention we can cut down the number of instances in which the problem presents itself to us in its starkest form. But there is no escape from the fact that, if the future good of society is to be served, there will be times when the clinical investigator must make an arbitrary judgment with respect to an individual. The necessity for such arbitrary judgments has had tacit social recognition and approval for some time. Because the approval was tacit, however, there was an imbalance of actions and words, in effect, a hypocrisy, that marvelous human invention by which we are enabled to adapt to problems judged to be not yet ripe for solution. By this hypocrisy society had its future medical interests fully protected. At the same time the attitude could be maintained that in medical matters, as contrasted with those in many other walks of life, the sole public interest was in the inviolability of the individual.

Now, most unfortunately, these essentially harmless hypocrisies of our culture have been codified. For both the Helsinki Declaration and the new Food and Drug Administration regulations in effect, a hypocrisy, society had its future medical interests fully protected. At the same time the attitude could be maintained that in medical matters, as contrasted with those in many other walks of life, the sole public interest was in the inviolability of the individual. The future interest of the group and its sometime conflict with the interest of the individual, in effect, are ignored. I believe it has been most unwise to try to extend the principle of "a government of laws and not men" into areas of such great ethical subtlety as clinical investigation.

When in our cultural evolution it has not yet been possible to develop an institutional framework for a particular kind of arbitrary decision that may affect an individual, there is only one basis on which to proceed, and that is on the basis of trust. My position may sound paternalistic, as indeed it is. Making arbitrary decisions concerning an individual in conflicts as yet unsolved by our society is one of the major responsibilities of a parent. Society may not have given us a clear blueprint for clinical investigation, but it has long given us immense trust to handle moral dilemmas of other sorts, including many in which, in effect, we have to play God. Thus, the moral dilemma of clinical
investigation is not something new; what is new about the problem is its rapid increase in size. This rapid increase in size is no help to us now, but it may hasten the day, still far off, when in medical investigations we can institutionalize this making of arbitrary decisions between an individual and his society.

In the meantime we can do no more than carry on under the mantle of the trust we now possess. To continue to receive that trust we must be ever conscious that the issue of the individual vis-a-vis society is always there, and we can try our best to create an environment of awareness of it on our clinical services. For once a moral dilemma has become clearly recognized; whenever each person acts within that dilemma, his act can be seen for what it is, and the extent to which he has seemed to act with acceptable propriety can be picked.

But the hard core of our moral dilemma will not yield to the approaches of "Declarations" or "Regulations": for as things stand today such statements must completely ignore the fact that society, too, has rights in human experimentation. Somehow, somewhere, in this question of human experimentation, as in so many other aspects of our society, we will have to learn how to institutionalize "playing God" while still maintaining the key elements of a free society.

Let us now start our consideration of the views set forth by our panelists with challenges from Drs. Leake and Dubos. Dr. Leake.

It would be presumptuous of me to "challenge" the statements made by any of the distinguished participants in this important symposium on the ethical aspects of experimental studies on human subjects, arranged so well by my long-time friend Dr. Irving Wright. It is less aggressive and more relaxing to venture "comments" in amplification of what has been said so well.

Frequent now are discussions of the moral problems confronting us as a result of our amazing technical achievements. From the awful consequences of nuclear weaponry to the details of human experimentation, we are seeking vigorously to find ways of resolving the ethical confusion that so deeply troubles us. To our chagrin we are discovering that there are no comfortable absolutes on which to rely in our moral dilemma but rather that responsible choices have to be made by each of us as individuals as to an appropriate ethic or way of conduct in the ever-shifting confrontation with the realities of our tension-filled lives.

Recently I commented (1) on opinions already expressed by Drs. Joshua Lederberg (2) and Russell Elkanon (3) on the moral problems raised by organ transplantation and by Dr. Belding Scribner (4) on hemodialysis. At that time I collaborated with Dr. Thomas Starzl (5) in trying to analyze some aspects of these ethical matters. By then many newsmen and popular writers, such as Victor Cohn of the Minneapolis Tribune, Milton Silverman of the Saturday Evening Post, and Albert Rosenfeld and Shana Alexander of Life, were doing their best to call public attention to the moral problems caused by biomedical advances and were emphasizing that it is the responsibility of all people to aid in their solution.
Dr. Leake: Now I come to the questions. I will try to keep one for each panelist as I go down the line unless we get into some kind of an argument, but I don’t think we will.

Dr. McDermott: I must say that in preparing for this Colloquium I had occasion to read all those Declarations as well as the Hippocratic Oath. I was vastly entertained to see that “first things are first” in the Hippocratic Oath in that the first part of it has nothing to do with the patient at all; it has to do entirely with the relationships of physicians to each other.

Dr. Leake: It is important, I think, that we always make sure that we make the distinction between medical etiquette—the subject of the older principles of medical ethics—and the fundamental moral problems with which the public is concerned. We will turn, then, to Dr. Stumpf and his interesting discussion. The point that I’m raising here is in regard to the experimentation that he mentioned; he brought up the point that it is not possible to predict from animal experimentation what drugs will do in humans. Well, I’ve been working in this field for a long while, and my own feeling is that we can get a pretty good idea. But when it comes to experimentation on humans, I could ask, isn’t a therapeutic procedure of any sort undertaken by any physician on any patient a form of experimentation in the sense that we can never predict absolutely what the outcome of the therapeutic procedure may be?

Prof. Stumpf: I agree that there is a distinction between a patient and a subject, and I agree with your point that a physician almost always is experimenting with a drug in relation to the particular patient. But the difference is that a physician is experimenting on the patient with a drug that has been cleared, whereas (and this is the point that I have been raising) the subject is being subjected to a trial with something that has not been cleared. It may be that novel chemicals and drugs are used also in therapy, but the big distinction, I take it, is that, even in the case of using a drug that has not been thoroughly tested, the justification for it is the possible good it will do its patient in the context of a problem; whereas, when you give it to a subject, there is the question as to whether the possible side effects can justify its use.

Dr. Leake: You have brought up a point, namely whether the drug has been cleared. It is my opinion that judgment with regard to the use of any chemical agent for any purpose in medicine should be made by members of the qualified health professions and not by a group of bureaucrats. When we talk about clearance, I realize of course that it is necessary to have some consensus of judgment, but I believe that that consensus of judgment should be from the health professions.

Prof. Stumpf: I’m not aware that people who are unqualified are making judgments with respect to clearance. Now, I speak obviously as a philosopher who spends most
of his time in a very delightful ivory tower, but the logic of it is rather clear. Two things have to be said here, and I don't mean it to come out quite as abrasively as it will. In the first place, I'm not sure there would have had to be a bureaucracy if the issues hadn't provoked it; and, in the second place, I have a feeling that Dr. Goddard is, in fact, a doctor.

**Dr. Leake:** He is, and he is an excellent man. But he is attempting, in my opinion, to regulate what I believe is an unsatisfactory law or statute for this reason: that the law or statute implies that there is an absolute effectiveness or an absolute safety to every drug. There is no such thing.

**Prof. Stumpf:** No, but the implicit drift of your argument would be that there should be no controlling of any kind; and I don't think anyone in this room would want that.

**Dr. Leake:** No, I didn't say that. I acknowledged the necessity for social control.

**Prof. Stumpf:** Well, then, the goodness or the badness of it is yet a different question, but I think the issue that you have raised is whether there really should be any other human being except ourselves always. And I might say that in the experimentation in our laboratory we've kept from coming to any use on any other human being except ourselves those drugs that did show in ourselves undesirable effects. I think self-experimentation is pertinent for those who are going to develop a new drug. Now to go on with my questioning. Turning to Judge Burger, may I ask a question that I think is of interest at the present time? Am I right in saying that in the experimentation in our laboratory we've kept from coming to any use on any other human being except ourselves those drugs that did show in ourselves undesirable effects? I think self-experimentation is pertinent for those who are going to develop a new drug. Now to go on with my questioning. Turning to Judge Burger, may I ask a question that I think is of importance to all of us. What is the real significance of consent—whether informed or not? My point is this: Does consent absolve the clinical experimenter from liability for malpractice or for injury to either his subject or his patient?

**Prof. Stumpf:** Are you suggesting that the government, as the government, ought not to have anything to do with this even though the government bureaucracy is staffed by physicians?

**Dr. Leake:** No.

**Prof. Stumpf:** Then what is the issue?

**Dr. Leake:** I feel that there is a reasonable way in between where it can be worked out without the difficulties that are arising now, especially in experimentation. But let me go on, if I may. How about self-experimentation?

**Prof. Stumpf:** That's a rather interesting thing in that the only code that I know of that touches on this is, to the best of my recollection, the Helsinki Declaration in which it says—I think in Section 5—that certain very dangerous experiments ought not to be undertaken except in those cases where the experimenter himself is the subject.

**Dr. Leake:** Remember, I tried to point out this is my own field, and, when one is dealing with chemicals for the first time, there is always a danger. I've had a lot of experience in this. In our laboratories we've developed five useful drugs: diethyl ether for anesthesia, carbamazepine for amebiasis, Violaform® (iodochlorhydroxyquinoline) for amebiasis and bacterial enteritis, the amphetamines, and nalorphine, the antagonist to morphine. In each case, no one of those drugs was ever used on anyone else first—on ourselves always. And I might say that in the experimentation in our laboratory we've kept from coming to any use on any other human being except ourselves those drugs that did show in ourselves undesirable effects. I think self-experimentation is pertinent for those who are going to develop a new drug. Now to go on with my questioning. Turning to Judge Burger, may I ask a question that I think is of importance to all of us. What is the real significance of consent—whether informed or not? My point is this: Does consent absolve the clinical experimenter from liability for malpractice or for injury to either his subject or his patient?

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**Judge Burger:** Well, I think what you're really saying is, does it prevent someone from suing you? The answer is no; nothing ever prevents anybody from suing you.

**Dr. Leake:** I just wanted to make that clear, because a lot of physicians and a lot of hospitals think that once they have a consent signed by a patient everything is in order and they are not going to be sued; and they are surprised when they are.

**Judge Burger:** This is a common attitude in the medical profession. But let me emphasize that there is nothing to prevent some of the ladies in the audience from suing anyone of us for breach of promise if we've smiled at them during the course of this session. You can always sue, but the adequately obtained consent with informed judgment—with the disclosure factor—will generally be an adequate defense in most of those situations.

**Dr. Leake:** The point is that we should do everything we can to promote mutual trust and mutual confidence.

**Judge Burger:** Right.

**Dr. Leake:** This, then, is a matter of extreme importance in interpersonal relations. I wish to turn now to Prof. Krech. If I may. He had a wonderful appeal to the hippy mystique, it seems to me. I think it's important to consider this enriched psychological environment. We are certainly in a tension-filled world. This does bring up plenty of problems. We all should get brains that will expand all over with this psychologically enriched environment that we're getting into. But I am interested in particular in some of the experiments that were quoted. I know something about experiments of this sort with rats and mice in maze learning. We did a lot of it when we were studying the amphetamines which are central nervous system stimulants, as are pentylentetrazol and caffeine. The central nervous system-stimulating effects of many of these drugs have been studied quite exhaustively. I frequently used to tell my students, Certainly, caffeine is a central nervous system stimulant; it will promote association of ideas, but there is no guarantee that this association is ever more correct or accurate than that due to chance. One can say that coffee or caffeine tends to promote a diarrhoea of words and a constipation of ideas. Now, when we were studying the amphetamines, we used pentylentetrazol as controls, and we could find no significant increase in rate of maze learning either with pentylentetrazol or with amphetamines or caffeine. All that I am pointing out is that one can use all sorts of experiments, but one must evaluate those experiments. As has been brought out very clearly in this discussion, what applies at an animal level can be carried over to the human level only with careful consideration.

**Dr. Krech:** I venture to take the risk. I agree that man—and his brain—is bigger and perhaps even better than a mouse. The experiments that I cited were just two of McGaugh's experiments—only two out of a whole series of about 10 years of experimentation over a whole range of drugs. But, despite his very positive and very exciting results (and, of the controls that you indicated should be taken, many have been taken), despite all the progress, I suspect that we are still in the Stone Age of this kind of experimentation. Add to that all
the experimentation on the deleterious effects of inhibitors of protein synthesis, the ribonucleic acid (RNA) experiments, and so on, and I think you can't avoid the feeling that we are close to the verge of an important breakthrough (awful word!). I just want to try to anticipate what we're going to do when the breakthrough comes.

I know that already several of the pharmaceutical houses have on clinical trial a number of drugs intended to speed up or facilitate memory. These trials are being made on patients who are mentally retarded or senile. What the results will be, no one knows. But I would not bet against the project.

**DR. LEAKE:** This is all very important. In general, insofar as the central nervous system is concerned, it is much easier to find chemical agents that will inhibit in one way or another the activity of the central nervous system than ones that will improve or accelerate its activity. But very recently, as you know, magnesium pemoline was introduced by a former student of mine for the purpose of increasing RNA formation. It works, apparently, in experimental animals; it has been tried in humans, not too satisfactorily.

**DR. KRECH:** It doesn't work too satisfactorily in animals either. I might make just one point here. I find in general that physicians are familiar with mood drugs—they have been on the front pages. Physicians are not familiar with what might be termed "intellectual" drugs, and most of the exciting experimental work that is going on (as far as I am concerned) is with intellectual drugs. Now, it is important to understand that, to evaluate the significance of the current work with these drugs, one has to be sophisticated about psychology and behavioral measurement as well as about pharmacology. And I regret to say that most physicians and most pharmacologists are naive and ignorant about the sciences of behavior.

**DR. LEAKE:** Surely I will admit all this, but I also want to remind you that I did emphasize the distinction between mood and behavior; nothing exemplifies it more fully than the attitude or the way in which our hippies go about—their mood is excited and wonderful, you can judge their behavior.

**DR. KRECH:** By the way, we seem to be of the happy opinion that we can't do any self-experimentation on mental retarded patients.

**DR. LEAKE:** No. Speak for yourself, Dr. Krech; I can't.

**DR. MCDERMOTT:** Order!

**DR. LEAKE:** Now I'd like to ask Dr. Lederberg an important question. This has to do with the matter of voluntary abortion and the right to die. Let me ask, if infanticide justified in the case of monstrous birth?

**DR. LEBERGEB:** What I spoke to was not a moral judgment about the consequences of reforms in our law or in our attitude but to plead that they be examined in terms other than so-called "absolutes" with respect to the objects in question. The question of whether infanticide is morally justified, I think, can only be answered by an inquiry as to the consequences of the introduction of this practice into contemporary society. I think it is possibly true—and this is the point that I believe should be debated—that to make it easier to kill a live-born infant may knock down other important barriers to misbehavior on the part of our population. I think that before I would advocate killing even monstrous births, I would want to inquire what the effect might be on the standards of care of other infants, on the attitude towards child beating, and so forth. I hope I did not leave the impression that I regarded our traditional attitudes or our traditions of care for human life in any casual fashion.
testing new drugs. They came to us; we didn't go to them.

Dr. Starzl: I didn't mean to suggest that we had ever used a penal donor who was not to our advance knowledge a legitimate volunteer. I think they were all strongly motivated, most for the very high-minded social reasons you have suggested. We knew for certain that there were certain others, or at least one other who was proved to be motivated by the thought that he would be able to more easily escape from the hospital than from the prison. This, in fact, he did. I think that the problem is not that there aren't legitimate volunteers in prisons but that in the absence of their civil liberties they might not be really free to make a choice. I think a 16-year-old minor who donates a kidney to his identical twin also probably wants to do so, but he does not have the requisite legal protection to be able to make his decision freely. I think we made a mistake in accepting prison volunteers, and I suspect that you probably did so also when you were in Ohio.

Dr. Leake: No, I deny that; we did pretty well on it, and I think the prisoners enjoyed it. But, Mr. Chairman, might I take the opportunity here to thank the members of the panel for responding so directly and so clearly to these nasty questions that I have raised. The panel is an excellent one.

Dr. McDermott: And may we thank you. We will now turn to Dr. Dubos for his challenge.

Individual Morality and Statistical Morality

RENÉ DUBOS, Sc.D. (HON.), M.D. (HON.)

In most human situations we soon become involved in operations that we start without knowing too well what the consequences will be, operations that we do not know how to stop. Many of our ethical problems come from this inability to foresee the consequences of our actions. I am sure that our genial President, Dr. Wright, when he organized this conference, had no sense of what was going to come out of it. If he had had enough foresight, he would have recognized that there have been two entirely different issues before us throughout the morning; I would summarize with the phrase "individual morality" and one I would express as "statistical morality." Now, the persons capable of discussing these two entirely different aspects of ethical problems should have come from entirely different backgrounds. I believe that for individual morality it might have been best to have had a practicing physician who is also a philosopher and a theologian. For statistical morality we should have had a sociologist concerned with the effects of any intervention on the community as a whole. Since here I stand, I shall act in both capacities.

Individual morality is the problem that is easiest to talk about and most difficult to say anything worthwhile about. Individual morality concerns all those ill-defined problems of the relation of the physician to his individual patient. Each and every one of you in this room meets this problem every day and knows far better than I do how to deal with it practically. I would only question the assumption that there are some permanent values involved here, that individual morality—a man-to-man relationship—is something that was determined many thousands of years ago on the basis of some kind of platonic values. In reality we all know, even with very little awareness of history, of differences in attitude in different parts of the world or even in different social groups within a given country. We know that our values in this regard are very different and that they change continually. I offer as an illustration one that was given by Dr. Lederberg, namely, how our attitudes towards contraception have changed and changed so profoundly and how unquestionably our attitudes towards abortion will change within a very short time. I am told by my friends who are physicians in practice that even our views towards euthanasia are changing; certainly they are changing in the general