COMMENTS OF NORMAN J. LATKER, PATENT COUNSEL, DHEW, ON "LEGAL ANALYSIS OF PUBLIC DISCLOSURE REQUIREMENTS RELEVANT TO APPLICATIONS FOR BIOMEDICAL RESEARCH GRANTS"

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Outside of a generally adequate review of the relevant laws which may be brought into question by the Congressional charge to this Commission, the resulting analysis and recommendations by the Wallace paper on the policy of managing research information are seriously defective.

Certainly no thinking person can categorically oppose "public participation" or "openness" in the development of public policy in the abstract, especially in the climate created by the abuse of trust by some Government agencies whose need to meet assigned objectives required higher degrees of privacy than available to most Government agencies such as N.I.H. Notwithstanding the need to correct abuses in these situations, it is also clear that if "openness" at the discretion of any person is to be the rule in all situations, some other societal values may well suffer or be defeated. Thus, in every situation where the question of "public participation" arises, the human and economic values to be gained or lost must be objectively evaluated and a determination made on whether the result sought by the program in question is enhanced, unchanged, or defeated by random public participation.

In this regard, the handling of this assignment is a failure in that the paper insists throughout without supporting data that this is a situation between "conflicting interests" requiring a compromise position which appears to be administratively unworkable and impairs the objectives of the program.

From opening to conclusion, the paper repeatedly assumes a need to balance "public participation" and "private deliberations" while shifting the burden of proofs to those who argue that private deliberation should prevail. Substantially, all the arguments supporting "openness" are generalizations based on the belief that the public's right to know (which is erroneously ascribed to be a first amendment guarantee) will necessarily enhance the protection of those human subjects involved in 40% of NIH's research proposals, and that further, the free exchange of scientific ideas (whether supported by clinical evaluation or not), will result in their swiftest development. Whether such generalizations are correct can only be determined when examined against fact.

The Wallace presumption that random public participation is inherently useful is in direct conflict with the following findings of the President's Biomedical Research Panel:

1) "There does not appear to be any direct, necessary, or inherent connection between disclosure of such information and protection of human subjects in research under the present system of Federal regulations and review bodies, nor did testimony before the Panel argue for such full disclosure." (See page 3 of Panel Report.)

2) ". . . uncontrolled disclosure of research information seems to offer neither compelling grounds nor a convincing record that it serves the aim of protecting human subjects of research." (See page 3 of Panel Report.)

But most important, the Panel did conclude on the basis of its study (including review of all requests to DHEW for research proposals) that private deliberation of peer review groups and release at the discretion of investigators of their research proposals and its results clearly outweighed in terms of identifiable human values the need for random public participation.

Thus, the Panel found:

> ". . . clear evidence that the existence of a licensable patent right, which is contingent on protection of intellectual property rights, is a primary factor in the successful transfer of research innovation to industry and the marketplace. In light of the effect of disclosure of research information on intellectual property rights, and in light of the importance of such rights to the transfer of research innovations to the delivery of health care, it is clear that the present mechanism of complete 'openness' ensures public accountability at the cost of sacrificing protection of intellectual property rights of demonstrable potential benefit to the Nation."

Further,

> "The Panel is concerned that the failure to protect and define such right may fatally affect a transfer of a major health innovation. (See pages 8-14 of the Panel's report.)

I support these findings and hope others here today will amplify on how the "public participation" thesis will seriously affect if not defeat the successful technology transfer function developing and carefully nurtured between Government, non-profit organizations, and industry in answering human needs.

Even the Wallace paper makes clear the jeopardy that intellectual property rights are placed in, if before a peer review group that is open to random public scrutiny. I think it should be emphasized that this jeopardy is not removed in situations where public participants chose not to be present at peer review meetings.

The paper's failure to understand the need to assure optimum transfer of innovation from the bench to the patient is illustrated on page 49:

> ". . . a researcher may prefer to develop his commercial ideas with public money, and thus be able to negotiate with private parties only after the utility of his idea has been proven. While this is obviously in the researcher's interest, as it would give him more bargaining power, it is not necessarily in the interest of the public." (Emphasis added.)

This latter sentence requires explanation, since it directly conflicts with the announced intent of the Government's patent policy covering innovations arising from Government sponsored research at non-profit institutions and the need to expedite their utilization and the constitutional intent to promote the arts and sciences through the guarantee by Congress of rights to creators. (See Art. I, Sec. 8.)

While there are many statements in the Wallace paper of a policy and administrative nature which should be equally challenged, time does not permit full analysis. Notwithstanding, I do wish to speak to a few statements with the clear intent of questioning the drafters' objectivity;

1) In support of "public participation" the drafters imply that the possibility of public surveillance is necessary to insure that another "CIA" situation does not occur at NIH (see page 53). No analogy exists. Even after discovery of these alleged abuses, to my knowledge the CIA was not restructured to permit random public participation on CIA advisory groups, since privacy is still an element necessary if CIA is to meet its objectives, just as it is perceived necessary for peer review.

   The analogy with city councils is equally erroneous, since such councils do not ordinarily deal with intellectual property matters as does NIH.

The drafters' implication that NIH's continued world renowned excellence is dependent on the fear of media exposure fails to consider its past performance and is hardly conducive to attracting high-level participation on peer review groups.

2) On page 54 of the paper Wallace indicates that some of the Panel's contentions are "based on its fallacious survey results." How they are "fallacious" is not explained, though on page 51 the paper indicates "while the Panel's survey showed that only three groups interested in protecting human subjects had made FOIA requests, we have been informed that these three requesters accounted for a significant portion of the total requests." (Emphasis added.) The "we have been informed" language seems to imply that Wallace discovered the truth from sources other than the Panel and/or the Government and implies the basis for the "fallacious survey results" comment.

The Panel on page 17 clearly states ". . . the request of one public interest group for appreciable numbers of research applications raises the prospect of large-scale multiple requests under a short deadline for reply." (Emphasis added.)

Further, the same data made available to the Panel by NIH and other information clearly indicating the source and number of requests on human subjects was available to the drafters through the Commission, Panel, and NIH for their review.

The handling of this matter raises the spector of a less than zealous investigator ready to accept the current climate of institutional conspiracy without justification. It is also clear that the drafters made no separate review of the public requests that both the Commission and the Panel were charged to review, but have chosen to critique the position of the Panel on the data without an independent review. Accordingly, if the paper is intended to respond to the Congressional charge of reviewing these requests, it fails.

3) Most important is the paper's misinterpretation of the Panel's recommendation. First, the Panel advised that peer review be a private deliberation. Second, it recommended legislation be passed to protect intellectual property rights. In support of the latter, the Panel discussed at length the Energy Research and Development Agency (ERDA) precedent wherein Congress created an Exemption 3 amendment to ERDA legislation returning to

the ERDA Administrator the authority to protect technical information without regard to the standards or procedures of FOIA (see page 13 of the Panel Report).

The only sensible implication to be drawn from the Panel Report was to amend the PHS Act in a similar manner. The Wallace report touches on this recommendation on page 63 by merely indicating that amending "the Federal patent laws" cannot entirely resolve the problem of protecting intellectual property.

While the Wallace statement is correct, it ignores the clear intent of the Panel to follow the very important ground already plowed by ERDA in Congress in protecting intellectual property rights in similar situations, through amendment of the Agency's implementing statutes.

As noted above, I believe the Wallace recommendation unworkable (as well as unjustified), since the idea portion of a proposal cannot be realistically separated from the totality of the scientific discussion in the proposal and its disposition. The Commission may well wish to examine situations where patentable inventions occurred in order to determine whether it would have been possible to segregate the licensable result from the research proposal at the time the proposal was first received. Further, it is well known that secondary or tertiary leads not presumed to be the idea for which funding is sought may emerge as the real values of a proposal and could be lost through failure to make

appropriate efforts to segregate. If the segregation of ideas is not possible, it serves little purpose to discuss the remainder of the recommendation in detail. However, there can be little doubt that it carries with it a heavy administrative load also unjustified, unless some value is derived from random public access.

My unhappiness with this paper leads me to wonder whether consideration should be given to opening this question -- if this was not done -- to proposals from other legal and scientific scholars with appropriate credentials to speak to this immensely important problem.