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# MEMORANDUM ON DISCLOSURE OF CONFIDENTIAL INFORMATION UNDER RECOMBINANT DNA STATUTE

Requirements for early disclosure of confidential information to a government agency is a common feature of several recombinant DNA bills now before the Congress. While these bills treat recombinant DNA research mainly in terms of public health and safety, their failure to provide positive protection against agency disclosure of confidential information to competitors of the corporate or university innovator would produce serious and unintended consequences.

Such disclosures would occur in the following ways:

1. In applications for licensing of facilities,
2. In registration of research protocols,
3. Through inspection by Federal authorities,
4. Through release of information to Federal advisory committees and their consultants,
5. Through exposure of information in research protocols to non-employee members of biohazards committees, and
6. Through various reporting requirements.

This memorandum addresses the points of primary concern in the disclosure problem and suggests how they can be minimized.

## Effects of Premature Disclosure

Except for their contribution to scientific knowledge, the results of recombinant DNA research are useless standing alone. They require the

investment of significant sums to convert them to products available to benefit the public. This is true whether the initial work is done in university or in corporate laboratories.

Premature public disclosure in present context refers to the disclosure of confidential information, for example, in facility applications and research protocols, to an agency that would then be requested to make the information available to other parties under the Freedom of Information Act. Such release would render virtually impossible the prospects for patenting in the United States, where filing must be done within one year from a public disclosure, for the research protocol would be presented before work was undertaken, and consequently, before patentable subject matter could be reasonably identified. Prospects for patenting abroad would be even more limited, because the laws of many important countries have no such grace period within which to file after public disclosure. The market lead time for the innovator would therefore be denied.

The adverse consequence of the lack of opportunity to patent falls both on university research and commercial laboratory research, whether financed privately or by the government. The virtual identity of interests between the university and the corporation in this regard is often misunderstood.

Where patents can be obtained, they offer a means for safeguarding

the investment of the corporation and the university in their research investments. If the investment is immediately dissipated by premature disclosure of details sufficient to show competitors the route to a successful end, much of the advantage of the innovator is lost and, accordingly, so is much of the incentive to invest in future work. To the extent the corporation enjoys a limited exclusive period, either by patenting its own work or receiving at least a limited exclusive license from government-financed research executed in the corporate laboratory, the corporation secures the necessary lead time and the opportunity for recovering investments and returning profits.

With the university, the prospects for patenting offer the opportunity for the university to interest a licensee of its choice to commercialize the invention. Norman J. Latker, Patent Counsel for the Department of Health, Education and Welfare, outlined the experience at HEW with the disposition of rights to HEW-funded research in testimony before a House subcommittee.[1] In his remarks, Mr. Latker traced the Department's failure to convert the research it sponsored into usable commercial products under the Department's patent practices prior to 1969. He pointed out that the subsequent practice of granting rights to the Department's contractors had produced dramatic

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1. Testimony by Mr. Latker before the Subcommittee on Domestic and International Scientific Planning and Analysis, House Committee on Science and Technology, September 29, 1976.

results in terms of the investment of risk capital in the commercialization of products from Department-sponsored research.

Mr. Latker clearly identified the problem and the necessity for supporting the commercialization of agency-sponsored R&D. In his view "the research and development agencies should be under a heavy obligation to assure availability of patent protection when private resources are needed to achieve commercialization."

In summary, regardless of the source of the capital underwriting the research, the availability of patent protection is of the highest importance if the research is to be productive in the public sense. However, prospects for patenting would be essentially eliminated by premature disclosure of the type that would occur under recombinant DNA legislation that does not specifically provide for the confidential treatment of this information.

Exemptions Under FOIA

It is sometimes mistakenly assumed that subsection (b)(4) of the Freedom of Information Act (FOIA) provides adequate safeguards against disclosure of trade secrets and would operate to protect against the premature public disclosure discussed above.[2] Subsection (b)(4) says, with respect to the requirement for public disclosure of information in agency files, that such requirement "does not apply to matters that are... trade secrets and commercial or financial information obtained from a

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2. 5 U.S.C. 552 (1967) (amended 1974).

person and privileged or confidential." This is the so-called trade secret "exemption" of FOIA.

While the underlying rationale for the Freedom of Information Act may have been laudatory, in practice it has been shown to serve mainly as an avenue by which competitors obtain confidential data indirectly from the originator. The cases and commentaries, as well as the practical problems facing the agencies involved, indicate clearly that the safeguards are illusory.

The Washington Post reports the unhappiness of former Food and Drug Commissioner Alexander M. Schmidt at the way the FOIA was working at FDA.[3] He said that about 90% of the requests for documents constituted "industrial espionage - companies seeking information about their competitors - and not the public's right to know." To a similar end is an article appearing in the Wall Street Journal.[4] Again the conclusion is expressed that an overwhelming percentage of the requests for information have nothing whatsoever to do with the public's examination of the actions of its government but are directed to legislatively sanctioned industrial spying.

Indeed, there is widespread misunderstanding of the Act itself with respect to the nature of the exemptions that are ostensibly provided by subsection 552 (b)(4). For example, the exemption was never intended to be a true "exemption." In the legislative report accompanying the Senate

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3. Washington Post, July 27, 1976, at A4.
4. Wall Street Journal, May 9, 1977, at 1.

version of the FOIA amendments, there appears the following statement:

> Congress did not intend the exemptions in the FOIA to be used either to prohibit disclosure of information or justify automatic withholding of information. Rather, they are only permissive. They merely mark the outer limits of information that may be withheld where the agency makes a specific affirmative determination that the public interest and the specific circumstances presented dictate... that the information should be withheld.[5] (Emphasis supplied)

While it is true that the Senate version of the FOIA was not adopted by the Congress, there appears a similar interpretation in the House report of its version, which differed little in this regard. The following statement is contained in the House report:

> This milestone law guarantees the rights of persons to know about the business of their government. Subject to nine categories of exemptions, whose invocation in most cases is optional, the law provides that anyone may obtain reasonably identifiable records or other information from federal agencies.[6] (Emphasis supplied)

It is particularly instructive to note the summary of a meeting between Representative John E. Moss and Representative Barry Goldwater, Jr., concerning the exemptions under FOIA. This summary concerns the impact of the exemptions on energy R&D activities in the private sector:

> We agreed that any lack of predictable protection of the private sector's proprietary information

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5. S. REP., 93rd Cong., 2nd Sess. 854.
6. 3 U.S. CODE CONG. & AD. NEWS 6269 (1974).

> under the existing Freedom of Information Act exemption from mandatory disclosure for such information (5 USC 552 (b)(4)) could seriously inhibit private sector cooperation and participation with ERDA to the detriment of the national energy research and demonstration program.
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> Mr. Moss acknowledged Mr. Goldwater's conclusion, based on an independent staff legal analysis, that protection under exemption (b)(4) is neither predictable nor adequate because of recent court interpretations of the exemption.[7]

Representative Moss was the father of the Freedom of Information Act. His observations reflect his serious concern for the interpretation of the exemption as well as a recognition of its inadequacy as a source of reliance on an agency's treatment of confidential information.

The leading case on interpretation of FOIA is National Parks and Conservation Association v. Morton.[8] There the tests as to the application of the exemption are said to be (1) whether the government's ability to obtain information in subsequent inquiries is likely to be affected by the knowledge that it may be made public, and (2) whether release of the information obtained by the government agency might cause substantial harm to a competitive position. Although an argument can be made that the second test would justify retention of trade secrets in confidence against a request under FOIA, the cases and commentators, not the least of whom is Representative Moss, have found this not dependably true in practice.

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7. 121 CONG. REC. H12379 (Dec. 11, 1975).
8. 498 F. Supp. 965 (D. D. C. 1974).

Illustrative of the problem is Petkas v. Staats, a Court of Appeals decision from the District of Columbia, home base for FOIA litigation.[9] There the court overturned an agency assurance of nondisclosure even though the information had been supplied on the condition that it would not be disclosed. The court said the obligation would not be enforced and remanded the case for examination under the tests laid down in the National Parks case.

One commentator examined the law and practice in implementing the FOIA "exemption" and concluded as follows:

> Presently, the status of proprietary information within government possession is uncertain. Prior agreements between the recipient agencies and the supplying businesses, whether formal or informal, statutorily premised or discretionally given, no longer serve as a valid assurance that business interests will be considered. Confidential treatment, determined under the more exacting standards of trade secret law, depends upon an intricate and individual evaluation of data not now covered by existing agency guidelines. A business concerned with safeguarding valuable information has little alternative but to resort to litigation for a judicial determination of the matter. As has been shown, even this avenue may be of limited value. It is apparent, therefore, agencies must develop adequate evaluative procedures which encompass fairness for all interests involved, and give due regard to the property interests protected by due process.[10]

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9. 501 F. 2d 887 (D. C. Cir. 1974).
10. Gazarek, Would Macy's Tell Gimbel's: Government-Controlled Business Information and the Freedom of Information Act, Forwards & Backwards, 6 LOYOLA UNIV. L. J. 594, 621 (1975).

This article also alludes to the varying interpretations of what constitutes a trade secret, a determination that compounds the difficulties encountered in relying on an "exemption." But even if the agency agrees that specific subject matter constitutes a trade secret, the exemption under FOIA is at best fragile.

It is pertinent, for example, that the legislative history of the Government in the Sunshine Act notes in a discussion of the FOIA exemptions that the Freedom of Information Act "permits but does not require the withholding of information."[11] This, indeed, is consistent with both precedents and practice under FOIA.

The same conclusion, as well as reference to the adverse effects thereof, with respect to the problems of the university in seeking grants and in soliciting commercial interest for university-developed inventions likewise emerges strongly from a pair of congressionally-sponsored studies.[12] The President's Biomedical Research Panel expressed its concern in this manner:

> The Panel is seriously concerned that the unpredictability of government protection for intellectual property rights, owing to the uncontrolled and unconditioned disclosure of research information under current court interpretation of the Freedom of Information Act, is likely, in the Panel's view, to stifle industry interest in developing potentially important research innovations.[13]

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11. 3 U.S. CODE CONG. & AD. NEWS 2191 (1976).
12. Commissioned under Title III of the Health Research and Health Services Amendments of 1976 (P. L. 94-278).
13. DHEW Publication (OS) 76-513, at 16.

Similarly, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, a group of entirely different composition, examined the question independently and urged that information "the disclosure of which would adversely affect future patent or other valuable commercial rights" be protected from disclosure under FOIA.[14]

Much of the concern of these groups arose from the Court of Appeals' decision in Washington Research Project, Inc. v. Department of Health, Education and Welfare.[15] There the court placed the burden of demonstrating the trade secret character of the information requested on the agency. The information was contained in research protocols submitted as part of requests for grants from HEW. The lower court had ordered release of the grant applications which included the research protocols. In affirming, the Court of Appeals declared that the exemption relied upon applied to trade secrets and that there were no trade secrets in a "noncommercial scientist's design." The court said further that "it defies common sense to pretend that the scientist is engaged in trade or commerce."

The basis for the court's decision was therefore on the ground that the appellant had failed to bring himself within the FOIA exemption by virtue of his employment rather than the nature of the subject matter - and despite

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14. DHEW Publication (OS) 77-0003. at 37.
15. 504 F. 2d 238 (D. C. Cir. 1974).

the fact that the interests of his university employer in preserving confidentiality were fully as legitimate as would have been those of a corporate employer.

Practical Difficulties Under FOIA

Finally, there are the practical aspects of the handling of trade secrets under FOIA in the face of requests for disclosures. Whether or not the exemption from disclosure is regarded as permissive, the agency in possession of the information submitted by companies or universities engaged in recombinant DNA research would inevitably find it impossible to comply fairly with the administrative requirements of FOIA. The threshold question of determining what information constitutes a trade secret poses a problem in itself. Additionally, this decision must be made within ten days of the request for disclosure.[16] Accordingly, within ten days the agency must locate the material requested, evaluate it for trade secret content, advise the originator of its decision to disclose (if it had previously agreed to do so, possibly as a condition of disclosure to the agency) and advise the requester of its decision.

It must be remembered as well that the determination of trade secret status in this field of high technology should be made by individuals in the agency who are trained in the technology and who would, therefore, be removed from more productive duties for this undertaking. The

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16. 5 U.S.C. 552 (a)(6)(A).

burden on the agency would be, in the usual case, virtually an impossible one to discharge justly within the time allowed.

The agency is, in fact, in the middle. It stands subject to suit from the requester if it denies access to information and suit from the originator if it discloses trade secret information. Of course, once the information is disclosed to a requester, usually a competitor of the originator, the harm to the originator has been done; whatever might be gained by litigation would inadequately compensate for the loss of the originator's trade secrets.

It is, of course, possible for the originator who learns in time of the prospective delivery of his information to a requester under FOIA to go to court to prevent disclosure. He could try to persuade the court that the documents are, indeed, entitled to trade secret status. But for the court to reach its decision it would need the time, patience and expertise to evaluate the documents in camera, one by one. The likelihood of a fair disposition of the issue by this route is understandably small. If the suit was initiated by a disappointed requester to whom the agency had refused to give up information, the agency-defendant could not be expected to discharge the defense of its position with the greatest vigor, for it has nothing more at stake than the enmity of the originator. And if the originator intervened in the litigation, the issue is still at the mercy of an overburdened court.

Legislative Solution

The criminal statute prohibiting disclosure of confidential information by Federal employees, 18 U.S.C. 1905, is of uncertain comfort with respect to disclosure under FOIA. Indeed, section 1905 would, if involved at all, apply only after disclosure and after the damage had been done. Also, section 1905 only applies "unless otherwise provided by law." Since FOIA is another law, it is an easy interpretation to find that section 1905 does not prevent disclosure under FOIA. Indeed, in M. A. Shapiro and Company v. Securities and Exchange Commission the court explicitly held that section 1905 "does not prevent disclosure of information that is authorized to be disclosed under other laws" and that, accordingly, "there is nothing in Section 1905 of Title 18 that prevents the operation of the Freedom of Information Act" - -i.e., disclosure under FOIA.[17]

On the other hand, there are many such "other" statutes that prohibit disclosure of confidential information;[18] and where they do, the penalties of 18 U.S.C. 1905 can be invoked for unauthorized disclosure by federal employees. Subsection (b)(3) of FOIA similarly provides an "exemption" against disclosing information protected by another statute.

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17. 339 F. Supp. 467, 470 (D. D. C. 1972).
18. Atomic Energy Act of 1954, 42 U.S.C. 2011, 2161-2166; Civil Rights Act of 1964, 42 U.S.C. 1971, 2000e-5(b) and 8(e); Federal Election Campaign Act, 2 U.S.C. 431, 437g(a)3; Consumer Product Safety Act, 15 U.S.C. 2051, 2055(a)(2); Occupational Safety and Health Act of 1970, 29 U.S.C. 651, 664.

A good example is the Federal Nonnuclear Energy Research and Development Act of 1974.[19] The inclusion of protection for confidential information was intended specifically to circumvent the unpredictability of the protection ostensibly afforded by the fourth "exemption" of FOIA. Indeed, Senator Fannin stated in connection with the House-Senate Conference Committee's action on the bill:

> The conferees took this action because... under existing law, primarily the Freedom of Information Act, "holdings" have made government protection of trade secrets and other proprietary information completely unpredictable... Out action here is intended to remedy that situation for ERDA.[20]

Again, in the Federal Aviation Act of 1958, as amended, there is specific language prohibiting release under FOIA where the Administrator has determined the information contains trade secrets, privileged information or confidential commercial or financial information.[21]

In approaching a statutory solution, however, attention should be given Robertson v. Butterfield, a 1974 Court of Appeals decision from the District of Columbia.[22]

In that case appellees had requested certain reports in the files of the Federal Aviation Administration. These reports consisted of analyses

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19. 42 U.S.C. 5901, 5916.
20. 121 CONG. REC. H12379 (Dec. 11, 1975)
21. 49 U.S.C. 1301, 1357(d)(2).
22. 498 F. 2d 1031 (D.C. Cir. 1974).

made by employees of FAA with respect to the operation and maintenance performance of airlines. The FAA Administrator had denied disclosure as being "not required in the interest of the public." The lower court referred to the Federal Aviation Act of 1958, in which there is provision for withholding such reports.[23]

The Court of Appeals interpreted the lower court's decision as relying on subsection 552 (b)(3) of FOIA, although the decision did not specifically so state. This exemption goes to the disclosure of matters "specifically exempted from disclosure by statute." The issue before the Court of Appeals, therefore, was whether the Federal Aviation Act of 1958 was, under these circumstances, such a "statute" as to bring the denial for disclosure within subsection (b)(3).

The Court of Appeals held that it was not. The court reasoned that the exemption of subsection (b)(3) applied only where the statute that was asserted to exempt disclosure "[specified] the documents or categories of documents it authorizes to be withheld from public scrutiny." This, declared the court, the Federal Aviation Act failed to do.

Accordingly, a statute affording positive protection for confidential information associated with recombinant DNA, whether submitted as part of a voluntary request for approval of facilities and projects or as mandatory

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23. See note 21.

compliance with other provisions of a recombinant DNA statute, should denominate with care the categories of information to be withheld from disclosure under FOIA. Such a categorization, for example, might generally take the form of the several types of information enumerated at the beginning of this Memorandum. It would also state, of course, that any such statutory exemption would be subject to overriding considerations of the public health and safety.

In summary, there is strong precedent and sound rationale for including statutory language in a recombinant DNA bill that would give positive and dependable protection for research and development information submitted pursuant to requirements of a statute. The public interest will not be served by leaving the matter to the vagaries of an FOIA exemption, particularly where the agency responsible for the decision concerning disclosure would have to expend high priced and precious talent to make reasonable judgments required by the FOIA approach. But, more important, FOIA has been shown to be inadequate and undependable; reliance on the trade secret "exemption" will not inspire full disclosure.

The concerns about premature disclosure affect both the commercial organization and the university. Specific statutory language that would qualify the statute under subsection (b)(3) would avert much litigation from both requesters of information and originators of information that would otherwise be invited by any decision the agency might make. Only

through such a positive declaration in the statute will the prospects for patenting by industry and universities be preserved and the essential step of commercialization be encouraged in this advancing frontier of medical science.

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