

IN THE
SUPREME COURT OF THE STATE OF WASHINGTON

No. 59714-6

PROGRESSIVE ANIMAL WELFARE SOCIETY,
a Washington nonprofit corporation,

Respondent,

v.

UNIVERSITY OF WASHINGTON,
an agency of the State of Washington,

Appellant.

BRIEF AMICUS CURIAE OF
THE AMERICAN PSYCHOLOGICAL ASSOCIATION
IN WHICH THE WASHINGTON STATE PSYCHOLOGICAL
ASSOCIATION JOINS

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STATEMENT OF THE CASE

This case involves an issue of great concern to the American Psychological Association ("APA") and its many members who conduct psychological research. The Progressive Animal Welfare Society ("PAWS"), an organization that aggressively opposes research involving animals, sought access under RCW Chapter 42.17 to an unfunded grant application submitted to the National Institutes of Health ("NIH") by psychologist Dr. Gene P. Sackett, of the University of Washington, and veterinarian Dr. Linda Cork of Johns Hopkins University. Their application contained preliminary hypotheses and research protocols for a proposed study entitled "Effects of Socialization on Forebrain Development."¹ The court below ruled that portions of the application must be disclosed.

The usual procedure for obtaining federal funding is to submit a grant application to a funding agency such as the NIH, which distributes the bulk of federal funds for biomedical research.

¹ The scientists proposed to examine the relationships between developmental brain abnormalities in monkeys who were reared in isolation, and self-abusive behavior. The purpose was to understand and ultimately permit treatment of analogous behavior in children. See Declaration of Linda Cork at 3-7 (CP 250-54); Declaration of Gene P. Sackett at 1-2 (CP 431-32).

The agency then submits the application to a panel of scientists for evaluation of scientific merit. As a result of this review, the application may be approved or disapproved for funding, or deferred for clarification and further review. Approved projects are ranked according to merit. Currently, because of limited resources, only about 20% of projects approved by NIH scientific review groups are actually funded. Projects that do not receive funding are frequently revised and resubmitted by the researcher or submitted to another agency (as occurred in this case).²

As explained below, it has long been NIH policy, based upon important public interests, to provide information contained in grant applications only if and when the proposal receives funding. PAWS, however, sought access to an unfunded application. Although PAWS' request was made pursuant to a Washington statute, the issue raised has national implications. Washington's public records disclosure statute, RCW 42.17.250 et seq., specifically requires the Court to consider the "public interest." This law

² See Declaration of Linda Cork at 6-7 (CP 253-54).

is similar to the federal Freedom of Information Act ("FOIA") and the public records statutes of other states. As set forth below, a proper balancing of the public and private interests at stake overwhelmingly justifies maintaining the confidentiality of unfunded grant applications.

ARGUMENT

The APA supports the current system of peer review for public funding of scientific research, and believes that compelled disclosure of preliminary research ideas would destroy that system. Such disclosure would: (1) compromise the ability to conduct certain research; (2) jeopardize the established intellectual property rights of researchers; and (3) improperly subject scientists who submit applications, and members of scientific review panels, to politically-motivated harassment.

The APA recognizes that there is a legitimate public interest in general information about research that actually is supported by public funds. However, the disclosure of a grant application -- prior to any commitment of public funds -- is premature and could be injurious. The Washington law at issue in this case requires this

Court to balance the public interest in disclosure against the potential harms such disclosure would cause. We submit that the public interest requires this Court to reverse the trial court's ruling, and hold that unfunded grant applications are presumptively non-disclosable.

I. THE POTENTIAL HARMS OF PUBLIC DISCLOSURE OF UNFUNDED GRANT APPLICATIONS FAR OUTWEIGH THE BENEFITS

In the state of Washington, not all government records are available for public examination. Rather, such examination may be enjoined if it "would clearly not be in the public interest and would substantially and irreparably damage any person, or would substantially and irreparably damage vital government functions." RCW 42.17.330. In addition, the State must protect "[v]aluable formulae, designs, drawings and research data . . . when disclosure would produce private gain and public loss." RCW 42.17.310(1)(h). In determining whether to permit disclosure, the Court must always

insure that information disclosed will not be misused for arbitrary and capricious purposes and . . . that all persons . . . will be protected from harassment and unfounded allegations based on information they have freely disclosed.

RCW 42.17.010(11).

In short, the law requires the Court to balance the benefits of disclosure against specific potential harms, and to protect valuable research data. In seeking to discern the public interest, the Court should consider federal law and policy on the subject, as well as established practices in the conduct of research that leads to advances in public health.

A. Federal Law Construing the Public Interest

Under the federal FOIA, 5 U.S.C. § 552 et seq., as well as federal policy, the Public Health Service and the NIH expressly exempt information in unfunded grant applications from disclosure.³ This policy was supported by a Congressionally-mandated study. Pursuant to P.L. 94-278, tit. III, § 301 (1976), the President's Biomedical Research Panel studied the implications of disclosing research protocols, hypotheses, and designs contained in federal grant applications.

³ See 45 C.F.R. Part 5, App. (1986); Public Health Service, Grants Policy Statement, at 4-11 (1991); Public Health Service Manual, D.H.S. Pub. No. (OASH) 90-50,000, Part 155.4(c) (1991); NIH Manual, Ch. 4201, at 4 (1983); NIH Grants Peer Review Study Team, NIH, Grants Peer Review: Report to the Director, NIH at 116 (Dec. 1976); Declaration of JoAnne Belk, Acting NIH Freedom of Information Officer (CP 203).

The Panel concluded unequivocally that such disclosure would deter important technology development, violate valuable intellectual property rights of researchers, and severely compromise the nation's peer review system.⁴ The Panel's conclusions were reaffirmed by a subsequent NIH study. See NIH Grants Peer Review Study Team, supra n.3, at 116. These conclusions remain valid, and continue to represent the proper balance between the public and private interests at stake in this case.

To our knowledge, there are only two reported judicial opinions addressing access to information contained in grant applications. In the first case, Washington Research Project, Inc. v. Department of Health, Education and Welfare, 504 F.2d 238 (D.C. Cir. 1974), cert. denied, 421 U.S. 963, 95 S. Ct. 1951, 44 L. Ed. 2d 450 (1975), the Court permitted access to certain information contained in funded grant applications. This is, as we pointed out, a very different matter.

⁴ See Report of the President's Biomedical Research Panel, Disclosure of Research Information (June 30, 1976) (hereinafter Disclosure of Research Information).

The second case involved access to information about unfunded grant applications. See Kurzon v. Department of Health and Human Services, 649 F.2d 65 (1st Cir. 1981). Kurzon, however, involved disclosure of only the names and addresses of unsuccessful applicants; it did not involve access to confidential scientific ideas, methods and techniques as to which the researchers have important proprietary interest.

In Kurzon, the Court concluded that the names and addresses of grant applicants did not fall squarely within the FOIA's exemption (that protects "medical", "personnel" or "similar" files) because "[t]he degree of intrusion is limited . . . by the slight informational content of the requested material." Id. at 69. Indeed, the Court noted the very different process the NIH applies to the substantive content of research proposals, in that "'[i]nitial research or [a] research training grant application on which award is not made' is 'generally not available to the public." Id. (quoting 45 C.F.R. Part 5, App. (1980)) (emphasis in original). Thus, Kurzon is

contrary to the decision below and supports the position urged by the University.⁵

B. Premature Disclosure Would Destroy Valuable Intellectual Property Rights

Ideas are the scientist's sole stock-in-trade, and these valuable assets are protected by the law of intellectual property. However, these protections (such as patents and copyrights) cannot be obtained once an idea has been publicly disseminated.⁶ And patents and copyrights are not the only intellectual property rights of importance to researchers. In the field of psychology, for example, research conducted in corporations and other large organizations often

⁵ Indeed, as the Supreme Court indicated in Forsham v. Harris, 445 U.S. 169, 100 S. Ct. 977, 63 L. Ed. 2d 293 (1980), it is questionable whether unfunded grant applications would even be considered "agency records" under the federal FOIA. In Forsham, the Court noted that only those documents that are "preserved or appropriate for preservation" by an agency are considered "records" under the statutory definition. Id. at 183 n.14.

⁶ See, e.g., 35 U.S.C. § 102 (1988) (no patent will issue if the invention is described in a printed publication more than one year before patent application is filed); Harper & Row Publishers, Inc. v. Nation Enterprises, 471 U.S. 539, 551, 105 S. Ct. 2218, 2225-26, 85 L. Ed. 2d 588, 601 (1985) (right to determine timing and forum of first publication is integral component of copyright protection).

generates data that are valuable trade secrets, which must necessarily remain confidential. Likewise, psychological research on how to design technical equipment so that people can operate it optimally also contains trade secrets.

Thus, it is vital for the scientist to retain control over the timing, method, and forum for disclosure of research ideas and preliminary data. But under the ruling below, scientists who apply for public funding must relinquish that control before even beginning their research, thereby jeopardizing intellectual property rights -- before their value can ever be known. This, in turn, will deter the corporate funding that supplements federal grants and enhances transfer of the fruits of research to the marketplace.

These dangers, as well as other factors, have led the federal government to maintain the confidentiality of unfunded research proposals. As the President's Panel concluded, there is simply "no question" that premature disclosure "sacrifice[s] protection of intellectual property rights of demonstrable potential benefit to the nation." Disclosure of Research Information, supra n. 4, at 2. This danger is not merely

hypothetical: under the federal FOIA, over 67% of requests for grant applications come from competing researchers and commercial firms, who may have selfish, competitive and hardly "public interest" motives.⁷ As the District of Columbia Circuit observed, "an undertaking to be audited by responsible [agency] personnel is not the same as an agreement to accept rummaging by the world at large."⁸

If the research ideas of university scientists must be disclosed upon request -- to competitors, journalists or anyone else -- those universities will be severely hampered in attracting additional funding from industry, and research will be stifled. Also, if the ability to obtain patent protection has been compromised by premature disclosure, industry will have little interest in sponsoring research that might lead to

⁷ Disclosure of Research Information at 16. See also, Ethics Advisory Board, Department of Health and Human Services, The Request of the National Institutes of Health for a Limited Exemption from the Freedom of Information Act, App. I(3) at 4 (1980).

⁸ Forsham v. Califano, 587 F.2d 1128, 1137 (D.C. Cir. 1978), aff'd. sub nom. Forsham v. Harris, 445 U.S. 169 (1980).

commercial products.⁹ Thus, "[i]n jurisdictions where scientific research is freely accessible to the public, a state university cannot guarantee that it can protect the results of industrial sponsored research from pirating before proprietary rights can be secured."¹⁰

Moreover, it cannot always be known at the outset of research whether it will yield patentable inventions. See, e.g., Declaration of Charles L. Rice at 3 (CP 286). Thus, "at the time disclosure is requested, it is unrealistic to expect that researchers or their institutions could take steps independently under patent laws to protect their intellectual property rights by filing a patent application at an early stage of research." Disclosure of Research Information, supra n. 4, at 12. Indeed, the very purpose of conducting the research may be to demonstrate that

⁹ See, e.g., Declaration of John Harlan at 3 (CP 260); Declaration of Melvin V. Koch at 3 (CP 282); Declaration of Alvin Kwiram at 8 (CP 278); Declaration of R. Gary Schweikhardt at 4 (CP 430); Disclosure of Research Information, supra, at 17.

¹⁰ K. Weber, State Public Records Acts: the Need to Exempt Scientific Research Belonging to State Universities from Indiscriminate Public Disclosure, 10 J. C. & U. L. 129, 145 (1983-84).

the idea is novel and therefore patentable. Id.
at 11.

Finally, the ability to determine the timing and forum of first publication -- a right inherent in copyright protection -- is especially important to academic researchers. Their tenure and promotions depend on their publications in prestigious scientific journals. However, most peer-reviewed scientific journals will not publish information that has already appeared elsewhere. See, e.g., Declaration of Linda Cork at 7-8 (CP 254-55). Thus, premature disclosure of research information would damage the peer-reviewed publication system that is important to both the scientific and the academic communities. Accordingly, the Court should hold that unfunded grant applications are exempt from disclosure under both RCW 42.17.330 and RCW 42.17.310(1)(h).¹¹

¹¹ An alternative basis would be to hold that the specific protection afforded by RCW 42.17.310(1)(h) to "research data" -- unusual in state public records acts -- means that preliminary university research such as the grant application at issue in this case should not be disclosed. See K. Weber, supra, at 141-42.

C. Premature Disclosure Could Compromise Ongoing Research

In addition to abrogating valuable intellectual property rights of researchers, premature disclosure of research goals and methods could compromise research that depends on the "naiveté" of the subjects. For example, in "participant observer" studies, the researcher observes human behavior in its natural environment while secretly becoming a part of that environment, as when students admitted themselves to mental institutions to observe first-hand how patients were evaluated and treated.¹² Obviously, such studies would be difficult or impossible to conduct if their purpose and methods were publicly known before they can be conducted.¹³

¹² See D. Rosenhan, On Being Sane in Insane Places, 179 *Science* 250 (Jan. 19, 1973).

¹³ Because such research is an exception to the rule that a researcher obtain a subject's "informed consent," the APA has established an extensive set of ethical principles and guidelines to prevent potential abuses. See American Psychological Ass'n, Ethical Principles of Psychologists and Code of Conduct, 47 *Amer. Psychologist*, No. 12, §§ 6.08-6.15 (Dec. 1992). This includes a requirement that "deception" research not be used unless alternative procedures are not equally effective, that the subject be informed about all factors that would affect his or her willingness to participate, and that the subject be fully informed as soon as possible afterwards. Id. § 6.15.

Similarly, disclosure of questions and "scoring" keys for psychological and aptitude tests would invalidate those tests, resulting in substantial financial loss to the publisher and author(s). In addition, because the number of scientifically validated tests for specific applications (e.g., measuring I.Q.) are limited, the public would suffer if a test became unusable as a result of disclosure.

Moreover, clinical trials of important new treatments could be thwarted if the public had access to preliminary data. Early trends often prove unreliable;¹⁴ but subjects might withdraw prematurely from clinical trials and recruitment of new subjects would be hindered if "trend data" are released as part of requests for continued funding. Clinical studies are typically designed so that neither the subjects nor the researchers know who is receiving a new treatment, a conventional treatment, or a placebo. If subjects learn that one treatment seems better than the other, they may be unwilling to continue with

¹⁴ Numerous examples of such reversals have been documented. See Ethics Advisory Board, supra n. 7 at 6-9; Report of the President's Biomedical Research Panel at 20 (Apr. 30, 1976).

random assignment, and may withdraw. New subjects will be difficult to recruit, and the study may be terminated without a sufficient number of subjects to achieve statistically significant results. As the President's Panel concluded, "[t]he most likely result from premature disclosure of preliminary results will be the failure of the clinical trial to reach a valid conclusion." Report of the President's Biomedical Research Panel at 21 (Apr. 30, 1976). Without completed statistically-valid research, scientific progress on important health problems could be crippled.

D. Premature Disclosure Would Damage the Integrity of the Peer Review System

The very essence of peer review is its objective evaluation of the scientific merit of proposed research. Indeed, "peer review is one of the most valuable management tools for ensuring that public funds are spent on technically sound projects with high probability of yielding significant data." Disclosure of Research Information, supra n. 4, at 18.

However, if (as explained above) researchers' intellectual property rights may be jeopardized by premature disclosure, they will be reluctant to provide the complete information

necessary for accurate peer review. Id. at 20. Moreover, because unsuccessful applicants often revise and resubmit their proposals, it is vital that their preliminary ideas remain confidential throughout the review process. Under federal law, peer review comments and deliberations are not disclosable even after a project has been funded. See Washington Research Project, 504 F.2d at 250.

Disclosure of the preliminary ideas contained in unfunded grant applications could also politicize the peer review process. Projects with scientific merit could be rejected due to political pressure if they involve sensitive issues, such as discrimination based on race or sexual preferences, substance abuse, child abuse, or sexual practices of teenagers that increase their risk of HIV infection. Scientific merit, not politics or protests, should determine which research receives funding.

Given limited resources and the daunting public health issues that remain unresolved, public funds should not be wasted or poorly-targeted due to distortion of the peer review process.¹⁵

¹⁵ See Disclosure of Research Information, supra, at 21-22; NIH Grants Peer Review Study

The APA does not advocate shielding general information about publicly-funded research from public scrutiny; rather, it urges this Court to recognize the dangers of premature disclosure of preliminary research ideas. Before public funds have been committed to a proposal, the public policy considerations clearly weigh in favor of maintaining confidentiality.¹⁶ "Congress struck a balance in fashioning the FOIA, which precludes the boundless pursuit of one policy goal, even a dominant policy, to the exclusion of all countervailing considerations." Forsham v. Califano, 587 F.2d 1128, 1137 (1978), aff'd sub nom. Forsham v. Harris, 445 U.S. 169 (1980).

Finally, it should be stressed that both animal and human subjects of research are protected by federal law and professional codes of ethics. Research facilities using experimental animals must establish committees to review and

Team, Grants Peer Review: Report to the Director, NIH at 116 (Dec. 1976).

¹⁶ Although not directly at issue in this case, the APA also believes that for certain projects, such as those involving particularly sensitive intellectual property rights or where research data would be compromised by disclosure, confidentiality should be maintained even after funding. See Ethics Advisory Board, supra n. 7 at 33-40 and App. II.

monitor the care and use of those animals. See 9 C.F.R. § 2.31 and Part 3 (1993). Similarly, all federally-supported research involving human participants must be reviewed and monitored by Institutional Review Boards to assure compliance with federal standards and ethical guidelines.¹⁷ In addition, the APA (like other professional and scientific societies) has established and enforces ethical principles governing research conducted by its members.¹⁸

Information about research projects actually funded by state and federal agencies or conducted at state universities is already available to the general public. This strikes the correct balance of competing interests at stake. As the President's Panel observed:

¹⁷ See 45 C.F.R. Part 46 (1992). Virtually identical regulations have been adopted by all federal agencies conducting or supporting research with human subjects. See 56 Fed. Reg. 28002 (June 18, 1991).

¹⁸ See, e.g., American Psychological Ass'n, Ethical Principles of Psychologists and Code of Conduct, 47 Amer. Psychologist, No. 12, §§ 6.08-6.15, (Dec. 1992). The APA's ethical standards were first promulgated in 1953, and were revised most recently in 1992. See also, American Psychological Ass'n, Ethical Principles in the Conduct of Research with Human Participants (1973) (revised 1982).

Researchers have no interest in concealing their ideas indefinitely from the scientific community or from the public. . . .The point of disagreement is really over when such information should be released and who will control the release.

Disclosure of Research Information, supra, at 22.

II. THE CONFIDENTIALITY OF PRELIMINARY RESEARCH APPLICATIONS CANNOT BE DETERMINED ON A CASE-BY-CASE BASIS

The court below held that each grant application that is the object of a public disclosure request must be subjected to individual in camera court review to determine whether it must be released in whole or in part. Such a case-by-case approach is overly cumbersome, inherently unworkable, and would still violate the rights of the researcher. In addition, state universities will be forced to litigate in court each request for unfunded grant applications. This would divert significant resources from the universities' teaching and research missions.

Moreover, it is often impossible to determine at the outset whether proposed research will yield commercially valuable information. Courts would be required to read highly technical grant applications and identify the nuggets of valuable information that advance beyond the conventional. A judge - unaided by extensive

expert testimony - simply will not be able to do this in the myriad technical scientific areas.

Therefore, this Court should establish a presumption that information in unfunded grant applications is non-disclosable -- absent a clear and convincing showing of an overwhelming public need.


CONCLUSION

For the foregoing reasons, this Court should reverse the decision of the trial court and declare that unfunded grant proposals are protected from release.

Respectfully submitted,

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