IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

LISA SYKES, et. al. Plaintiffs, v. BAYER CORPORATION Defendant.	Case No: 3:07-CV-660 (E.D. Virginia, Richmond Division)

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO QUASH THIRD PARTY SUBPOENA

Tobias Zimmerman (Mass. Bar 647668)
Terence J. Lynam
Christopher M. Egleson
AKIN GUMP STRAUSS HAUER & FELD LLP
1333 New Hampshire Avenue, N.W.
Washington, DC 20036
Telephone (202) 887-4000

Attorneys for Dr. McCormick

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Marie McCormick respectfully submits this memorandum in support of her Motion To Quash Third Party Subpoena. As explained below, the subpoena seeks to pry into the internal deliberations of the National Academy of Sciences, a nongovernmental scientific organization chartered by Congress and frequently charged with providing impartial scientific opinions to the Federal government. The Academy and its scientists are not parties to the action to which the subpoena pertains. Plaintiffs in personal injury actions routinely serve subpoenas on the Academy and its scientists attempting to force exactly the kind of disclosure at issue here, and federal and state courts just as routinely quash those subpoenas or otherwise forbid the inquiry. An unbroken wall of authority recognizes that the Academy could not perform its important function if it were forced to reveal its internal deliberations to private litigants, and every court ever to consider a motion to quash like this one has granted relief. Dr. McCormick respectfully requests that the Court quash the motion.

BACKGROUND

I. THE SUBPOENAS AND THE UNDERLYING LITIGATION

On the afternoon of March 26, 2008, Dr. McCormick was served with a subpoena *duces tecum* issued from this Court. *See* Ex. 1. Plaintiffs' counsel issued the subpoena in connection with a personal injury action pending in the United States District Court for the Eastern District of Virginia, *Sykes v. Bayer Corporation*, No. 3:07-CV-660 (E.D. Va.). The plaintiffs in the case are suing a vaccine manufacturer, alleging that their child developed autism as a result of being administered vaccines that contained thimerosal, a mercury-derived preservative.

Dr. Marie McCormick is a specialist in pediatrics and is the Sumner and Esther Feldberg Professor of Maternal and Child Health at the Harvard School of Public Health and a professor of pediatrics at Harvard Medical School. In 2000, Dr. McCormick was asked by the National Academy of Sciences to serve on its Immunization Safety Review Committee ("Safety

Committee"), which was to review and report on existing data about the safety of current vaccination practices. Dr. McCormick accepted the request and was appointed as the committee chair. She served on the Committee from 2001 to 2004. Like the rest of the of the Committee members, all of whom served the Academy as a public service, Dr. McCormick was not compensated for her work.

The Committee conducted a three-year analysis of safety issues raised by vaccines, and published eight reports on vaccine safety issues. The eight reports, along with extensive information about the Safety Committee's membership, its meetings, its work, and information it reviewed in developing its reports, are available on the Academy's web sites and in the Academy's Public Access file, both of which are publicly available.

The Safety Committee was constituted to review the state of the science on immunization questions, not to undertake its own laboratory investigations. In essence, the Committee was given a list of questions about the safety of using certain vaccines, and was charged with reviewing available public data, hearing dissenting views, and reaching a conclusion about the best answers to those questions then known to science. The Committee was asked in 2001 to evaluate the state of the science relating to thimerosal, a mercury-based preservative commonly used to thwart bacterial proliferation in vaccines. Specifically, the Committee was asked to report whether the literature in 2001 indicated that the use of thimerosal in vaccines tended to cause autism. After surveying the literature and listening in open session to the views of scientists and advocates on both sides of the question, the Committee issued a report indicating that its had seen no evidence linking thimerosal to autism.

The plaintiffs' success in the underlying case evidently depends on linking thimerosal to autism. The subpoena of course does not reveal the plaintiffs' litigation strategy, but presumably

the plaintiffs see the Safety Committee's report as an obstacle to recovery, and wish to call its conclusions into question. They apparently hope to do so by questioning the good faith of the volunteer scientists that constituted the Committee, and by casting doubt on the unanimity of the Committee's conclusion by ferreting out evidence of otherwise unexpressed dissenting views.

The subpoena includes two broad categories of document requests that suggest that this is the plan. The first category, which consists of Requests No. 4, 5, 7, 8, and 9(2) & (3), would require Dr. McCormick to produce documents relating to certain of the Committee's closed meetings and internal communications. The second category, which consists of Requests No. 1, 2, 3, 6, and 9(1), would require Dr. McCormick to produce every document she has that relates in any way to the constitution and operation of the committee, including in particular any financial dealings between members of the committee and any pharmaceutical companies.

II. THE ACADEMY AND ITS COMPELLING NEED TO PRESERVE THE CONFIDENTIALITY OF ITS SCIENTIFIC DELIBERATIONS

The Academy is a private, nongovernmental, non-profit membership corporation, which was chartered by Act of Congress in 1863. *See* 36 U.S.C. §§ 150301-150304. Dedicated to the furtherance of science and its use for the general welfare, the Academy has approximately 2,100 members who are leading scientists in virtually all significant scientific disciplines. *See* Ex. 2 (Declaration of Dr. E. William Colglazier) at ¶ 6. The Academy is frequently asked by various agencies of the United States Government to undertake scientific studies and investigations, which are typically conducted pursuant to government contracts. *Id.* at ¶ 9.

Every final report issued by the Academy is the product of a study committee and a review panel. *Id.* at ¶¶ 11-12. In performing its studies, the Academy generally appoints a volunteer study committee composed of prominent experts and scientists in the particular discipline under study; both Academy members and non-members may be included. *Id.* at ¶ 11.

The study-committee members volunteer their services to conduct the study and prepare a report. *Id.* The study committee reviews the relevant scientific literature and data and engages in an extended series of closed session deliberations. *Id.* Draft reports are prepared based upon the study-committee deliberations and revised until the committee reaches consensus. *Id.* The draft report then undergoes an internal review within the Academy, conducted by a panel composed of volunteer members who were not on the study committee. *Id.* at ¶ 12. The review panel considers (i) whether a report's conclusions derive from adequate data; (ii) whether uncertainties in the data are recognized; (iii) whether the report appears to be complete, fair and responsive to the charge given to the committee; and (iv) whether the presentation is clear and concise. *Id.*

The reviewers are cautioned not to discuss the drafts publicly. *Id.* at ¶ 13. Further, they are assured that the deliberations of the review panel are confidential. *Id.* Under Academy policy, review comments are not disclosed outside the Academy. *Id.* Academy policy also mandates that the names of individual reviewers are removed when their review comments are provided to the study committee in order to promote candor on the part of the reviewers. *Id.*

The review panel's comments are furnished to the study committee for consideration, further deliberation, and drafting and revision, as the circumstances require. *Id.* at ¶ 14. In the process, the study committee responds to the review panel's comments. *Id.* The final report is released only when the Chairman of the Academy's Report Review Committee, in consultation with the Report Review Monitor, determines that the Academy review has been satisfactorily completed and the report manuscript has been approved by the executive director of the study committee's parent unit within the Academy. *Id.* In the rare event that the study committee and review panel are unable to resolve differing views in a draft report, the Academy will not issue a report. *Id.* Academy final reports (other than reports which are classified for reasons of national

security) are generally made public, but drafts, internal reviews of reports, correspondence of reviewers, and other similar confidential materials are maintained as confidential. *Id.* at ¶ 16. It is the final report which alone carries the imprimatur of the Academy. *Id.* at ¶¶ 14, 19.

The confidentiality of its deliberative processes is crucial to the work of the Academy. *Id.* at ¶ 17. Disclosure would have a destructive effect on the important work of the Academy. *Id.* Participants in Academy studies would be inhibited in expressing their views concerning controversial topics under consideration and reviewers would be hesitant to express their candid opinions regarding draft reports if they knew their comments would subject them to a defense of those comments at a later date in an unrelated matter. *Id.* at ¶ 18. The threat of even limited disclosure of details of the deliberative process would disrupt the essential give-and-take between study-committee members, and moreover, disclosure of critical review comments would disrupt many working relationships. *Id.* Further, the Academy's ability to recruit volunteer scientists and experts to serve on its committees would undoubtedly be impaired, because individuals would be reluctant to serve if they knew their comments and deliberations were subject to disclosure. *Id.* Furthermore, disclosure of preliminary or incomplete drafts which have not undergone review, which may contain incorrect information, and which may undergo substantial revision before becoming final, could confuse and mislead the public. *Id.* at ¶ 19. Disclosure of this confidential information would adversely affect the Academy's ability to produce the best possible reports and would endanger the public interest. *Id.* at ¶ 18.

III. THE ACADEMY'S SAFETY COMMITTEE AND THE AVAILABILITY OF INFORMATION RELATING TO THE COMMITTEE'S MEMBERSHIP AND WORK

The Academy created its Immunization Safety Review Committee at the request of two sponsoring agencies, the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH). *See* Ex. 3 (Immunization Safety Review Committee, Immunization

Safety Review: Vaccines and Autism, Executive Summary (2002)) at ix. The Safety Committee was established to evaluate *existing evidence* on possible causal associations between immunizations and certain adverse outcomes, and to present conclusions and recommendations based on its review of the evidence. *Id.* at 2 (emphasis supplied). The Committee was charged with examining up to three immunization safety hypotheses each year during the three-year study period. These hypotheses were selected by the Interagency Vaccine Group, whose members represent the Department of Defense, the Agency for International Development, and several units of the Department of Health and Human Services, including the CDC's National Vaccine Program Office, National Immunization Program, and National Center for Infectious Diseases; the NIH's National Institute of Allergy and Infectious Diseases; the Food and Drug Administration ("FDA"); the Health Resources and Services Administration's National Vaccine Injury Compensation Program; and the Centers for Medicare & Medicaid Services. *Id.* at 2.

To ensure that the Safety Committee brought the necessary expertise to bear, the Academy appointed as members of the Committee more than a dozen medical personnel and scientists, who had special expertise in pediatrics, neurology, immunology, internal medicine, infectious diseases, genetics, epidemiology, biostatistics, public health, nursing, risk perception and communication, decision analysis and ethics. The Committee then met three times a year from 2001 to 2004 and, at each meeting, it focused on a separate vaccine-safety question. For each vaccine-safety question, the Committee reviewed the relevant epidemiologic evidence, as well as case reports and clinical evidence. The Committee also heard presentations from the authors of key papers and from investigators in ongoing, unpublished research. As a result of this work, the Committee issued eight Immunization Safety Review reports on vaccine safety.

The Academy offers the public an enormous amount of information about the Safety Committee's work, including the Committee's published reports, transcripts of public meetings, materials provided to the Committee by persons who are not officers, employees or agents of the Academy, information about the Committee's members, and the identity of the principal reviewers from outside the Academy. Plaintiffs can obtain this information at www.iom.edu and in the Academy's Public Access Records Office.

IV. THE ACADEMY'S PROCEDURES FOR PREVENTING CONFLICTS OF INTEREST

Because of its important role in furthering science and the public welfare, the Academy employs stringent procedures to ensure that the scientists who serve on its study committees will thoroughly and objectively perform the study they have been assigned. In selecting members for a study committee, the Academy examines three aspects of each potential candidate's background: (1) expertise relevant to the committee's task, (2) possible conflicts of interest, and (3) potential sources of bias. *See* Ex. 4 (Declaration of Dr. Kathleen Stratton) ¶ 4. All three aspects are assessed against the particular task the committee is charged with performing. In evaluating these issues, the term "conflict of interest" encompasses any current financial or other interest that could impair an individual's objectivity. *Id.* The term "potential sources of bias" encompasses an individual's points of view or positions that are largely intellectually motivated, or that arise from a close identification with a point of view of a particular group. *Id.*

In determining whether any potential conflict of interest exists in a proposed candidate for a study committee, the Academy solicits information from the candidate. *Id.* at ¶ 5. The Academy also provides public notice of candidates being considered for committee service, and affords the public an opportunity to comment on the proposed candidates. *Id.* at ¶ 5. The Academy then considers all available information and, except when it determines that a conflict

is unavoidable, in which case it publicly discloses the conflict, bars any individual with a conflict from serving. The Academy finalizes the committee membership only after determining that the members possess the necessary expertise, that there are no unresolved potential conflict of interest issues, and that the scientific views of committee members are reasonably balanced.

In selecting members for the Safety Committee, the Academy precluded participation by anyone with a financial interest in a vaccine manufacturer; anyone receiving research funding from a vaccine manufacturer; anyone who had served on a major vaccine advisory committee; and anyone who had given testimony on or written about vaccine safety. *Id.* at ¶ 6. The Academy determined that none of the selected scientists had any conflict of interest. *Id.*

ARGUMENT

I. THE SUBPOENA AS A WHOLE IS UNDULY BURDENSOME AND MUST BE QUASHED

The subpoena directs Dr. McCormick to produce documents and prepare herself for deposition during a phase of the litigation in which even the parties to the case are highly unlikely to be engaged in any discovery. The defendants in the case recently succeeded in winning judgment on the pleadings as to the claims stated in the original complaint. *See Sykes v. Bayer Pharms. Corp*, Slip Op. at 7 (E.D. Va. Feb. 12, 2008) (Ex. 5). The case survived only because the court allowed the plaintiffs to add new causes of action. *See id.* at 7-12. The defendant has now answered the amended complaint, but its answer makes quite clear that the defendant believes that the new complaint similarly fails to state a cause of action upon which relief may be grounded. *See* Ex. 6 (*Sykes* Amended Answer) at 5-12. There is thus every reason to anticipate that the defendant will shortly file a new motion for judgment on the pleadings; it would impose an undue burden on Dr. McCormick were she required to produce documents and submit to a deposition before the viability of the complaint has been resolved.

This is particularly true because the amended complaint betrays a likely want of federal jurisdiction. The plaintiff in the case has asserted claims under Virginia law for breach of contract and for negligence. The complaint invokes the court's diversity jurisdiction under 28 U.S.C. § 1332. *See* Ex. 7 (*Sykes* Amended Complaint) at 1. That statute grants jurisdiction only where the amount in controversy exceeds $75,000. "The black letter rule 'has long been to decide what the amount in controversy is from the complaint itself.'" *Choice Hotels Intern., Inc. v. Shiv Hospitality, L.L.C.*, 491 F.3d 171, 176 (4th Cir. 2007) (quoting *Horton v. Liberty Mut. Ins. Co.*, 367 U.S. 348, 353 (1961)). And the underlying complaint here asserts damages in a minimum amount of only $10,000. *See id.* at Ex. 7 at ¶ 35. There is no indication on the docket that any party has yet brought the complaint's failure to plead the requisite amount to the court's attention. But the defect is plain, and it seems likely that the defendant will soon move to dismiss the complaint on those grounds. It would impose an undue burden on Dr. McCormick to require her to respond to a subpoena when the underlying complaint fails to properly invoke the jurisdiction of the federal court in the first place and when the court entertaining the underlying action has yet to determine whether the action will be allowed to continue.[1]

Second, the subpoena would subject Dr. McCormick to the burden of searching her files for responsive documents when plaintiffs can conduct their own searches of the Academy's repositories and retrieve publicly available information. While some of the information sought in the subpoena will not be available in these repositories, because, as discussed below, it is confidential, plaintiffs should not be allowed to ask Dr. McCormick to do their work for them with respect to the publicly available documents. There is no justification for imposing a burden

[1] This Court has authority to transfer this motion to the Eastern District of Virginia if it decides that the jurisdictional issue is best resolved there. *See, e.g.*, *In re Digital Equip. Corp.*, 949 F.2d 228, 231 (8th Cir. 1991); *see also* 9A Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 2463.1 (2008). Should the court decide to transfer, Dr. McCormick respectfully requests that the Court stay the enforcement of the subpoena pending resolution of the motion.

on Dr. McCormick unless the plaintiffs have already exhausted the means at their disposal for recovering the same documents from public sources.

II. REQUESTS NO. 4, 5, 7, 8 AND 9(2) & (3) SEEK INFORMATION ABOUT CONFIDENTIAL INTERNAL DELIBERATIONS THAT ARE PROTECTED FROM DISCLOSURE

In Requests No. 4, 5, 7, 8 and 9, plaintiffs seek information relating to the highly confidential internal deliberations that occurred during the Safety Committee's closed meetings. Specifically, Request No. 4 seeks documents related to "closed door transcript discussions" about the Thimerosal and Measles-Mumps-Rubella reports; Request No. 5 simply seeks any documents related to those reports (as well as documents related to "conflicts of interest, either apparent, potential or real"); Request No. 7 seeks documents related to a particular presentation made to the Committee; Request No. 8 seeks documents that relate to statements to the press; Request No. 9(2) seeks "a specific break down" of the Committee's internal votes; and Request No. 9(3) seeks internal transcripts from one of the Committee's closed-door meetings.

Plaintiffs are not entitled to these documents or to any testimony on the same topic. The District of Columbia Court of Appeals and several other federal and state tribunals have specifically recognized the Academy's compelling need to preserve the confidentiality of its internal deliberations, and have refused to require the production of materials relating to such deliberations in response to subpoenas issued in other product liability cases like this one, and even in felony criminal cases. Nothing about the instant proceeding warrants a departure from that unbroken line of judicial precedent, or justifies the forced production of confidential information about the Safety Committee's closed meetings.

As set forth in the affidavit of Dr. E. William Colglazier, Executive Officer of the Academy, confidentiality is absolutely critical to the important work of the Academy. Not only have several tribunals around the country ruled in favor of preserving the confidentiality of the

Academy's own internal deliberations, the importance of confidentiality in other scientific and academic settings has been repeatedly recognized by the courts. The Academy's compelling need to maintain the confidentiality of its internal deliberations far outweighs any purported interest the plaintiffs may have in these confidential Academy materials. Moreover, not only would the interests of the Academy be critically harmed by permitting discovery of its confidential documents, the public interest would be damaged as well.

A. The Academy Must Preserve the Confidentiality of Its Deliberations

1. The Academy's Need for Confidentiality Has Been Repeatedly Upheld

The Federal Rules give this Court the power to protect a person subject to a subpoena by quashing a subpoena that seeks production of "confidential research." FRCP 45(c)(3)(b)(i). The rules furthermore require the Court to quash a subpoena when production would "subject[] a person to undue burden." FRCP 45(c)(3)(A)(iv). If Dr. McCormick were required to produce documents and give deposition testimony responsive to Requests No. 4, 5, 7, 8 and 9(2) & (3), she would disclose "confidential research." Furthermore, subjecting a doctor who serves the Academy to such an obligation would impose an undue burden on the doctor herself and would furthermore unduly burden the Academy by making it more difficult for the Academy to carry out its mission. For these reasons, the Court may and must quash the subpoena.

Every federal and state court and administrative tribunal to have considered a third-party subpoena that would have forced the disclosure of information like that sought here has concluded that the Academy must preserve the confidentiality of its internal deliberations concerning its published reports, and has forbidden the inquiry. The District of Columbia Court of Appeals held in *Plough, Inc. v. National Academy of Sciences,* 530 A.2d 1152, 1160-61 (D.C. App. 1987), that the defendant in a products liability suit was not entitled to discovery of Academy documents that reflected the confidential internal deliberations of the Academy study

committee, preliminary drafts of study-committee reports, and review panel comments. Plough was sued by a plaintiff who alleged that aspirin made by Plough caused him to develop Reye Syndrome. The federal Public Health Service (PHS) had conducted a pilot study on the association between aspirin and Reye Syndrome. PHS contracted with the Academy to review and critique the pilot study, which found that a strong association exists between the use of aspirin and Reye Syndrome. The Academy issued a series of reports concluding that the pilot study was methodologically sound and that its findings were scientifically valid.

Plough issued a third-party subpoena seeking production of Academy documents relating to its review of the pilot study. The Academy sought and obtained a protective order precluding discovery as to: (i) documents reflecting the study committee's confidential deliberations in closed session; (ii) preliminary drafts of the study committee's reports; and (iii) documents reflecting the Academy's confidential internal review of the study committee's reports. *Id.* at 1154. The Court of Appeals affirmed the protective order, permitting the Academy to withhold those documents from discovery. The court emphasized that "[e]ven limited disclosure of the preliminary conclusions, hypotheses, thoughts and ideas ventured by Committee members prior to their being tested and criticized would not only embarrass those members, it would discourage members of [Academy] committees in the future from expressing themselves freely during their deliberations, and might cause some potential volunteers to refrain from participating in [Academy] studies altogether." *Id.* at 1157, 1158.

Similarly, the District of Columbia Superior Court denied a subpoena sought by two criminal defendants charged with felonies who were seeking confidential Academy documents. In *United States v. Roberts & Veney*, Criminal Nos. F-771-01 and F-2986-00 (D.C. Sup. Ct. Feb. 4, 2003) (Ex. 8), the defendants attempted to obtain discovery from the Academy related to a

report on the evaluation of forensic DNA evidence for use in a hearing on the admissibility of DNA evidence. In denying the subpoena, the court expressed "concern that exposing [the Academy's] deliberative process to discovery could hinder the exchange of ideas." The court noted that "[The Academy's] study committees and review panels subject scientific issues to a robust, searching inquiry," and that this inquiry is "furthered by open and frank communication between participants." *Id.* (quoted in *McMillan v. Togus Reg'l Office, Dep't of Veteran Affairs*, 294 F. Supp. 2d 305, 319 (E.D.N.Y. 2003), *aff'd* 120 Fed. App'x 849 (2d Cir. 2005)).

Similarly, the Superior Court of California and the New York State Supreme Court likewise issued orders protecting the Academy's internal deliberative processes in the face of subpoenas that plaintiffs in a silicone breast implant case had served upon volunteer members of an Academy committee that produced a report on the safety of such implants. *See Clegg v. Bristol-Myers Squibb Co. & Med. Eng'ring Corp.*, No. BS 085263 (Cal. Sup. Ct. Oct. 21, 2003) & *Clegg v. Bristol-Myers Squibb Co. & Med. Eng'ring Corp.*, No. 115708/03 (N.Y. Sup. Ct. Oct. 20, 2003) (Exs. 9 & 10). In both cases, the courts found that the documents and testimony concerning the confidential deliberations of the Academy were protected from disclosure.

The court in *Monroe v. United Air Lines*, No 79-C-360 (N.D. Ill. Nov. 26, 1980) (Ex. 11) also ordered protection of the Academy's internal deliberations and review process. The underlying litigation was an age discrimination action challenging an airline's mandatory retirement age for pilots, and the Academy had undertaken a study of that issue. The district court denied discovery of internal correspondence, notes, workpapers, drafts, memoranda, minutes; views or opinions of individual Committee or staff members expressed in private, including in closed sessions; communications from the Committee or its staff personnel to Committee members that are not disclosed to non-Committee members; unpublished documents

submitted to the Committee under assurances of confidentiality; and the potential source of conflicts statements submitted in conjunction with the Committee appointments process. *Id.* at 2.

An Administrative Law Judge similarly limited a third-party subpoena served upon the Academy in conjunction with a Federal Trade Commission proceeding. *See* Order in *In re General Nutrition, Inc.*, FTC Docket No. 9175 (March 19, 1985) (Ex. 12). The Academy had prepared a study of the scientific literature dealing with diet, nutrition and cancer. The complaint alleged that General Nutrition had falsely represented that the Academy report suggested that one of the company's products helped prevent cancer. General Nutrition's third-party subpoena sought drafts of the report at issue; all memoranda, notes, meeting minutes, correspondence, and other documents by, between and among the study committee, its members, and reviewers; and all studies, tests, reports and correspondence submitted to or considered by the study committee, its members, and reviewers. *Id.* at 1-2. The ALJ ruled that the discovery interests of the respondent in this material were required to "yield to the demonstrated needs of the Academy in maintaining its 'confidentiality' policy." *Id.* at 6.

Judge Weinstein, of the United States District Court for the Eastern District of New York, recently reviewed the cases noted above, and emphasized the importance of protecting the Academy from the intrusion of litigation. *See McMillan,* 294 F. Supp. 2d 305. As Judge Weinstein explained, the "[c]ourts have consistently and repeatedly ruled in favor of protecting the Academy against the chilling effects of unnecessary litigation." *Id.* at 317-18.

In all of the cases described above, the tribunals have recognized the Academy's compelling need to preserve the confidentiality of its internal deliberations and issued orders prohibiting the discovery of precisely the same type of materials the plaintiffs' subpoenas are seeking. That same result should apply here.

2. The Need for Preserving the Confidentiality of Deliberative Processes Has Been Generally Recognized in Other Contexts as Well

In addition to the tribunals that have specifically recognized the Academy's compelling need for confidentiality, many other courts have recognized that confidentiality is essential if deliberations, particularly scientific deliberations, are to proceed unfettered, without being chilled into silence. Confidentiality is vital in scientific and academic settings. "Scholarship cannot flourish in an atmosphere of suspicion and distrust." *Sweezy v. New Hampshire*, 354 U.S. 234, 250 (1957).

As the Seventh Circuit pointed out in *Dow Chemical Co. v. Allen*, 672 F.2d 1262, 1275 (7th Cir. 1982), the protection for academic freedom "extends as readily to the scholar in the laboratory as to the teacher in the classroom." The Court of Appeals affirmed the trial court's refusal to enforce third-party subpoenas seeking the disclosure of university research information. The court explained that "enforcement of the subpoenas would leave the researchers with the knowledge throughout continuation of their studies that the fruits of their labors had been appropriated by and were being scrutinized by a not-unbiased third party whose interests were arguably antithetical to theirs." The court concluded that this "realization might well be both unnerving and discouraging," and would "'inevitably tend [] to check the ardor and fearlessness of scholars, qualities at once so fragile and so indispensable for fruitful academic labor.'" *Id.* at 1276 (quoting *Sweezy,* 354 U.S. at 262 (Frankfurter, J. concurring in result)). It therefore believed that "enforcement of the subpoenas carrie[d] the potential for chilling the exercise of First Amendment rights." *Id.*

Similarly, the court in *Richards of Rockford, Inc. v. Pacific Gas & Electric Co.* recognized that "society has a profound interest in the research of its scholars, work which has the unique potential to facilitate change through knowledge," and worried that "[c]ompelled

disclosure of confidential information would without question severely stifle research into questions of public policy, the very subjects in which the public interest is greatest." 71 F.R.D. 388, 390 (N.D. Cal. 1976); *see also Solarex Corp. v. Arco Solar, Inc.*, 121 F.R.D. 163, 179 (E.D.N.Y. 1988) (scientific society, recipient of third-party subpoena, had "demonstrated a strong interest in preserving the confidentiality of its reviewer's identity, and the values it seeks to foster in resisting this disclosure have traditionally been accorded substantial weight in assessing the competing needs and hardships involved in pre-trial discovery.")

These cases evince a clear recognition of the critical need to preserve the confidentiality of internal deliberations in the scientific and scholarly settings, and thus strongly support prohibiting discovery of the confidential Academy documents that the plaintiffs seek.

3. Confidentiality of Scientific Deliberations Is Essential to the Continued Work of the Academy and its Contributions to the Public Interest

It is vital to the work of the Academy, and, in turn, to the public interest, that there be vigorous debate within study committees and robust criticism by the reviewers. Disclosure of candid committee deliberations during their closed meetings could seriously inhibit the process of give-and-take between and among volunteer scientists that is so crucial to producing the best possible Academy reports. Disclosure of committee deliberations would seriously impair the Academy's ability to recruit volunteer scientists to serve on the study committees and as reviewers. Those who might still serve would be inhibited from giving their candid views in order to avoid the possibility of embarrassment or of jeopardizing working relationships for fear of subsequent disclosure. Deliberations of the volunteer scientists would be chilled if litigants could have easy access to their frank preliminary and internal comments and deliberations. The Academy's procedures have long operated effectively because committee members and reviewers give candid evaluations, knowing that their deliberations will stay confidential.

The public interest is another important factor supporting preclusion of discovery of the Academy's confidential documents. As the court in *Solarex* explained, "[i]n balancing conflicting interests, courts are admonished not only to consider the nature and magnitude of the competing hardships, but also to 'give more weight to interests that have a distinctively social value than to purely private interests.'" 121 F.R.D. at 169 (quoting *Marrese v. Am. Acad. of Orthopedic Surgeons*, 726 F.2d 1150, 1159 (7th Cir. 1984) (*en banc*), *rev'd on other grounds*, 470 U.S. 373 (1985)). Indeed, the decision in *Richards of Rockford*, discussed above, speaks of the public interest and how that interest is served by maintaining the confidentiality of researchers, scholars, and scientists. The Academy is one of the world's most important scientific organizations; its work is vital to the public and the advancement of science. The public interest is best served by enabling the Academy to recruit the best scientific minds possible to serve on its committees and as reviewers, in order to produce the most rigorous reports on important scientific issues. The public interest is also well-served by preventing the confusion about scientific issues that would result from the release of confidential deliberations containing preliminary, incorrect, or incomplete analysis.

III. REQUESTS NO. 1, 2, 3, 6 AND 9(1) SHOULD BE DISALLOWED

A. The Subpoena Relates to the Membership and Management of the Committee And Should Not Have Been Directed to Dr. McCormick

The remaining five requests seek documents that Dr. McCormick does not have, and, what is more, documents that she simply could not be expected to have. Request No. 1 asks for documents relating to "the setup" and "financing" of the committee. Request No. 2 asks for documents relating to "any association" between committee and staff members and the requesting agencies, i.e., the CDC and NIH. Request No. 3 asks for documents relating to "any association" between committee and staff members and "the pharmaceutical industry" and "any

other private persons or companies with financial interest in any topics" that the Committee reviewed. Request No. 6 asks for the rules, regulations and laws that governed the committee's operation, and Request No. 9(1) seeks any instructions that the CDC gave to the Committee.

These five requests relate to the constitution and management of the committee. Dr. McCormick did not establish the committee or handle its administrative affairs. She does not possess any documents in any of these categories, and plaintiffs can have no reason for thinking that she would have such documents. Such documents would be possessed and owned not by any individual member of the Committee but by the institution to which it belongs. Rule 45(c)(1) of the Federal Rules of Civil Procedure (FRCP) imposes on parties and their counsel the duty to "take reasonable steps to avoid imposing an undue burden or expense on a person subject to the subpoena." There is no indication that counsel investigated whether Dr. McCormick was the right party on which to serve these five requests. These requests should be quashed for failure to comply with the rule.

B. The Requests Seek Confidential Information About Individuals Finances and Interests

These requests should also be disallowed because they seek to inquire into the "financial interests," "relationships," "conflicts of interest" and "potential conflicts of interest" of twenty-three individuals. As previously noted, the Academy conducted evaluations of "potential conflicts" as part of the normal process of appointing members to its Safety Committee. In the course of those evaluations, the Academy determined that none of the individuals appointed to serve on the Committee then held any stock or other financial interest in a vaccine manufacturer or a vaccine manufacturer's parent companies, was receiving research funding from a vaccine manufacturer or a vaccine manufacturer's parent companies, had previously served on a major

vaccine advisory committee, or had previously given any testimony or authored any publications on vaccine safety. *See* Ex. 4 at ¶ 6.

In soliciting "conflicts" information from candidates for membership on its committees, the Academy notifies the candidates that the information they provide will be kept confidential. *See id.* at ¶ 5. The Academy has a compelling need to provide that assurance to candidates, since confidentiality is necessary to ensure candid and fully responsive information is provided during "conflicts" evaluations. The Academy also has a compelling need to protect the confidentiality of the information it receives during its "conflicts" evaluations, since the disclosure of such information would breach the privacy rights of the nation's scientists, could cause some of them personal embarrassment, and would ultimately discourage our nation's scientists from volunteering their time for the Academy's important work. *See, e.g., Plough*, 530 A.2d at 1157-58; *McMillan*, 294 F. Supp. 2d at 318-19 (citing *Plough*). That chilling effect on the Academy's scientific work would ultimately harm not only the Academy, but the interests of the public. For those reasons, the Northern District of Illinois prohibited discovery into the source of "conflicts" information the Academy has used in conducting "conflicts" evaluations during its committee appointment process. *See Monroe,* No 79-C-360, Order, at 2.

This need for protecting the confidentiality of an individual's financial information has also been recognized in cases that do not involve the Academy. As stated by this court, "[t]he right of privacy and the right to keep confidential one's financial affairs is well-recognized." *Hecht v. Pro-Football Inc.*, 46 F.R.D. 605, 607 (D.D.C. 1969). This is especially the case when the information sought involves non-parties, and when the information is collateral and not direct proof of the plaintiffs' claims. *See United States v. Federation of Physicians & Dentists, Inc.*, 63 F. Supp.2d 475, 479 (D. Del. 1999) (prohibiting disclosure of personal financial information of

non-party surgeons and practices because such information is "private and confidential and discovery would entail the disclosure of sensitive, private information"). Likewise, the financial information of Academy members is extremely private and sensitive information, especially considering the fact such information was submitted by members with the understanding that it would be kept confidential.

Moreover, to the extent that plaintiffs seek information about any purported "financial interests" that the specified individuals might have in the vaccine manufacturers which are defendant in the underlying litigation, or about any purported conflicts of interest arising from such interests, they should be required to obtain that information from the defendant, and not from Dr. McCormick. The defendant is an active litigant in the underlying case and, to the extent that anyone should be subjected to the burden of searching for and producing information about possible financial or other dealings between the defendant and the individuals identified in plaintiffs' subpoena, the burden should be borne by the defendant, not by a non-party individual. This approach is particularly appropriate here since, as noted, the Academy rigorously screened out potential conflicts of interest when appointing individuals to serve on the Committee.

For all of these reasons, this Court should prohibit disclosure of the information sought in Requests No. 1, 2, 3, 6 and 9(1). To require disclosure of this information would inevitably invade the privacy rights of our nation's scientists and impair the Academy's ability to recruit volunteers to serve on its committees. That, in turn, would harm the public interest.

CONCLUSION

Dr. McCormick respectfully requests that the Court quash the subpoena issued by plaintiffs' counsel.

Respectfully submitted,

AKIN GUMP STRAUSS HAUER & FELD LLP

By:

Tobias Zimmerman (Mass. Bar 647668)
Terence J. Lynam
Christopher M. Egleson
AKIN GUMP STRAUSS HAUER & FELD LLP
1333 New Hampshire Avenue, N.W.
Washington, DC 20036
Telephone (202) 887-4000

Attorneys for Dr. McCormick

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