UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE SUBPOENA TO NATIONAL ACADEMY OF SCIENCES - INSTITUTE OF MEDICINE	Case No. 12-mc-414 (EGS)
COLORADO CHRISTIAN UNIVERSITY, Plaintiff, v. UNITED STATES, Defendant.	Case No. 11-CV-3350 (CMA)(BNB) United States District Court for the District of Colorado

MEMORANDUM OPINION

The National Academy of Sciences (the "Academy"), for and on behalf of its constituent organization, the Institute of Medicine ("IOM"), has moved for the entry of a protective order regarding a nonparty subpoena served on IOM by Colorado Christian University, the plaintiff in the underlying litigation *Colorado Christian Univ. v. Sebelius*, 11-cv-3350 (CMA) (BNB) (D. Colo.). For the reasons explained below, the motion will be **GRANTED**.

I. BACKGROUND

The underlying civil action pending in the United States District Court for the District of Colorado involves a challenge by Colorado Christian University ("CCU") to certain regulations promulgated by the defendant the United States Department of

Health and Human Services ("HHS") under the Affordable Care Act of 2010 ("the Act"). CCU is a Christian liberal arts university located in Lakewood, Colorado. Amend. Compl. ("Compl.") ¶ 2, No. 11-3350 (CMA) (BNB) (D. Colo.). CCU states that its religious beliefs "forbid it from participating in, providing access to, paying for, training others to engage in, or otherwise supporting abortion." *Id.* ¶ 3 CCU contends that certain regulations promulgated by HHS require CCU to "provide health insurance coverage for abortifacient drugs and related education and counseling." *Id.* Specifically, CCU alleges that the drugs Plan B and Ella cause abortions and that it is a violation of CCU's religious beliefs to provide insurance coverage for such drugs. *See generally id.*

The Academy is a private, non-profit membership corporation established under a charter granted to it by Congress. Decl. of James F. Hinchman in Supp. of Mot. for Protective Order ("Hinchman Decl.") ¶ 2. The IOM was established by the Academy to "secure the services of eminent members of appropriate professions in examining policy matters pertaining to the health of the public." *Id.* ¶ 6. The IOM acts under the responsibility given to the Academy under its federal charter. *Id.* The Academy is not a federal agency; it has no regulatory authority and no power to implement its own regulations. *Id.* ¶ 8. The Academy prepares reports of a scientific and technical nature,

primarily for the federal government, pursuant to contracts, grants, and cooperative agreements with sponsoring federal agencies. *Id.* ¶ 9. All of the Academy's agreements with the federal government for the performance of studies or the preparation of reports are of a contractual nature. *Id.*

On July 17, 2012, CCU served a subpoena in this Court on IOM, seeking documents related to a report issued by IOM, entitled "Clinical Preventive Services for Women: Closing the Gaps" (the "Report"). The related study was undertaken pursuant to a contract between the HHS and the Academy, in which HHS asked the Academy to "suggest a list of recommended guidelines describing which drugs, procedures, and services should be covered by all health plans as preventative care for women." Compl. ¶ 74.

The Academy's Report was published in July 2011. Recommendation 5.5 of the Report, which is the focus of the subpoena, provides:

> The committee recommends for consideration as a preventative service for women: the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

Following receipt of the subpoena, the Academy produced over 3,500 pages of documents. In its motion, the Academy seeks protection as to a sub-category of documents that reveal

internal confidential deliberations, such as draft reports, internal Academy communications, and review comments. The Academy argues that its internal processes should be protected from disclosure. Specifically, the Academy argues that confidentiality is essential to the frank and candid exchange of ideas and also ensures that the Academy can continue to recruit the top scientists needed to perform its vital work.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 26(b) authorizes discovery "regarding any non-privileged matter that is relevant to any party's claim or defense." *See, e.g., Food Lion, Inc. v. United Food and Comm. Workers Int'l Union*, 103 F.3d 1007, 1012 (D.C. Cir. 1997). Rule 26(c) provides, however, that the Court "may, for good cause, issue an order to protect a party or person [from whom discovery is sought] from annoyance, embarrassment, oppression, or undue burden or expense, including . . . (D) forbidding inquiry into certain matters, or limiting the scope of disclosure or discovery into certain matters; . . . [and] (G) requiring that a trade secret or other confidential research, development, or commercial information may not be revealed or be revealed only in a specified way." Similarly, under Rule 45, a party served with a subpoena may move to quash or modify the subpoena under Rule 45(c)(3) if the subpoena requires disclosing a trade secret or other confidential research, development, or

commercial information, or subjects the recipient to an undue burden.

A party seeking a protective order or to modify a subpoena must establish "good cause" under Rule 26(c) by demonstrating specific evidence of the harm that would result if the protective order is not issued. *Doe v. Provident Life & Acc. Ins. Co.*, 247 F.R.D. 218, 221 (D.D.C. 2008). The movant "must make a specific demonstration of facts in support of the request, as opposed to conclusory or speculative statements about the need for a protective order and the harm which will be suffered without one." *Huthnance v. District of Columbia*, 255 F.R.D. 285, 296 (D.D.C. 2008) (citation omitted). The court must then weigh the burdensomeness to the moving party against the requestor's need for, and relevance of, the information sought. *Doe*, 247 F.R.D. at 221. The burden of persuasion on a motion for protective order is borne by the movant. *See Aristotle Int'l, Inc. v. NGP Software, Inc.*, 714 F. Supp. 2d 1, 16-17 (D.D.C. 2010).

III. DISCUSSION

The Academy sets forth in detail its argument that it has good cause for seeking a protective order in this case. The Academy states that, under its standard procedures, when it agrees to provide a sponsor with a report, the Academy will typically establish a study committee with expertise in the

subject area, and that committee will conduct a study and prepare a draft report. Hinchman Decl. ¶ 11. The members of the study committee serve without compensation for their time and, according to the Academy, are drawn from some of the nation's most competent scientists in the particular field of study. *Id.* The committee reviews the relevant literature, research, and data, and engages in a series of extended deliberations involving the candid exchange of views between members in closed sessions. *Id.* Once a final draft has been prepared, the Academy provides a detailed and rigorous internal review of the draft report by independent experts who serve as reviewers. *Id.* ¶ 12. The reviewers consider whether the report is based on adequate data, among other issues. *Id.*

The Academy considers the reviews of a report to be privileged communications, and reviewers are assured that their deliberations will remain confidential. *Id.* ¶ 13-14. The Academy states that it does this to encourage individual reviewers to express their views freely and to permit committee members to modify their positions when convincing arguments to the contrary are presented. *Id.* To protect the confidentiality of the deliberative process, reviewers, study committee members, and staff are asked to refrain from disclosing any contents of the draft report or review comments. *Id.* Drafts, internal reviews of reports, correspondence of reviewers, and any

material that reflects the study committee's deliberative process or the review process are not released to the public. *Id.* ¶ 16. The Academy states that it utilizes this confidential review process to ensure that its reports are of the highest quality. *Id.* ¶ 18. The Academy strongly believes that the assurance of confidentiality given to reviewers ensures that the Academy receives candid, honest comments when reviewing drafts. *Id.*

The Academy argues that the threat of even limited disclosure would "disrupt the essential give-and-take between study committee members, and disclosure of critical review comments would disrupt many working relationships." *Id.* The disclosure of internal communications would chill the review process and diminish the rigor of the final report. *Id.* Furthermore, it contends, disclosure would discourage participants from serving on Academy study committees or as reviewers if they believed their preliminary, untested views would be disclosed. *Id.* The Academy states that this, in turn, would affect the Academy's ability to attract the most qualified committee members and reviewers, which would ultimately affect the quality of the Academy's work. *Id.* The Academy represents that it followed these review procedures when drafting the Report at issue in this case, and only the final Report has been made public. *Id.* ¶ 21.

In opposition, CCU argues that the discovery it seeks is indeed relevant and necessary. CCU alleges that HHS intentionally discriminated against it and other religious groups by enacting regulations that mandate coverage of emergency contraceptives. Specifically, CCU alleges that HHS violated CCU's First Amendment rights by adopting regulations that initially contained no exceptions for religious institutions. Although the regulations were revised by HHS a year later to include a limited exception for certain types of religious organizations, CCU contends that this selective imposition of burdens on certain religious organizations also violates CCU's First Amendment rights. Though the regulations were implemented by HHS, and not the Academy, which is a private organization, CCU argues that discovery regarding the Academy's internal communications is relevant because the communications are an extension of the legislative history of the enactment of the regulations CCU seeks to challenge. CCU seeks to determine whether the IOM's recommendation is "tainted with bias against religious organizations." CCU's Response to the Academy's Motion for Protective Order ("Pl.'s Br.") at 7. Although CCU does not specifically contend that the Academy has failed to establish good cause for seeking a protective order, CCU does argue that the Academy's request for protection is overly broad.

The Court finds that the Academy has established good cause for seeking a protective order because it has set forth specific evidence of the harm that would result if the protective order is not issued. *See Doe*, 247 F.R.D. at 221. Specifically, the Court finds that confidentiality is essential to the Academy's work, a finding which is supported by the long line of cases cited by the Academy. For example, in *Plough v. Nat'l Academy of Science*, the District of Columbia Court of Appeals held that the defendant in a products liability suit was not entitled to discovery of documents that reflected the confidential internal deliberations of the Academy study committee, preliminary drafts of study committee reports, and review comments. 530 A.2d 1152, 1160-61 (D.C. 1987). In that case, the Academy was a non-party and had been issued a third-party subpoena seeking production of documents relating to the Academy's review of a pilot study on the association between aspirin and Reye syndrome. In the trial court, the Academy obtained a protective order precluding discovery as to (1) documents reflecting the committee's confidential deliberations; (2) drafts of the committee's reports; and (3) documents reflecting the Academy's internal review of the committee reports. *Id.* at 1154. The court affirmed, finding that the protective order was warranted and the Academy was entitled to withhold those documents from discovery. The court found that confidentiality was of utmost

importance to the Academy's work and that "[c]riticism would be less than frank if subject to disclosure outside the institution, even limited disclosure under a protective order." *Id.* at 1158. Although the court found that Plough had shown relevance, its claim of necessity was weak because its own experts could testify as to their evaluation of the study. Furthermore, the court found that the non-party status of the Academy further tipped the "balance of need against burden" in favor of non-disclosure. *Id.* at 1160.

The Academy cites several other cases in which courts have recognized or upheld the Academy's need for confidentiality as to its internal deliberations. *See, e.g., Monroe v. United Air Lines, Inc.*, No. 79-C-360 (N.D. Ill. Nov. 26, 1980) (denying discovery as to the internal processes of the Academy); *In re Fosomax Prods. Liab. Litig.*, MDL No. 1789, 1:06-MD-1789, 2009 U.S. Dist. LEXIS 70246 (S.D.N.Y. Aug. 4, 2009) (quashing deposition subpoena of third-party Academy researcher where plaintiff had not demonstrated substantial need that could overcome the risk of chilling participation in beneficial public research). The recurring theme through those cases is that courts have consistently protected the Academy from disclosure of its internal review processes.

The arguments made by CCU are insufficient to overcome the Academy's showing of good cause. Many of CCU's claims of

relevance are attenuated, as they are ultimately seeking information about the implementation of regulations by HHS. HHS is a defendant in the Colorado litigation and is the entity responsible for the promulgation of the regulations CCU challenges. The Academy, on the other hand, is not a party to the underlying litigation. The Academy is a private organization that was asked to provide *suggestions* to HHS and has no regulatory authority. Furthermore, HHS was not privy to the confidential material that CCU now seeks from the Academy, a fact that CCU does not appear to dispute. Not only does this fact underscore the Academy's commitment to confidentiality, but it also undermines CCU's arguments that the Academy's confidential deliberations are relevant to HHS's promulgation of regulations.

CCU's reliance on *University of Pennsylvania v. EEOC* is misplaced. In that case, the EEOC issued a subpoena for university tenure review records in an action brought by a faculty member who claimed that she had been discriminated against on the basis of race and sex. 493 U.S. 182, 185 (1990). The University challenged the subpoena, arguing that the tenure review records should be protected by a qualified privilege to protect the integrity of the peer-review process. *Id.* at 189. The Supreme Court declined to extend a privilege for "academic freedom" to peer review records. *Id.* The Court noted that

Congress had declined to do so in extending Title VII to educational institutions, and the effect was to expose tenure determinations to the same enforcement procedures as other employment determinations. *Id.* at 190. The Court also found that the alleged injury to academic freedom was speculative because confidentiality was not the norm in all peer review systems. *Id.* at 200.

In contrast to *University of Pennsylvania*, the Academy is not asking this Court to create a new privilege. Rather, the Academy argues that the burden that would be imposed on it by disclosing its confidential review materials would have far-reaching and devastating implications to the work of the Academy. The Academy relies on volunteer contributions from members of the scientific community, who are assured that their preliminary contributions and deliberations will remain confidential. As discussed above, several other courts have agreed with the Academy on that point, and many of those cases were decided after the *University of Pennsylvania* ruling. The Court agrees with those decisions and finds that the Academy has a compelling interest in keeping its deliberations confidential. This is particularly true where, as here, the Academy's scientific work has a significant social value. *See Solarex Corp. v. Arco Solar, Inc.*, 121 F.R.D. 163, 169 (E.D.N.Y. 1988), *aff'd and opinion adopted*, 870 F.2d 642 (Fed. Cir. 1989) ("In

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 distinctly social value than to purely private interests." (internal citations omitted)).

The Court is also mindful of the Academy's status as a non-party in this case, and the Court finds that this also weighs against disclosure. *See Watts v. S.E.C.*, 482 F.3d 501, 509 (D.C. Cir. 2007); *Katz v. Batavia Marine & Sporting Supplies, Inc.*, 984 F.2d 422, 424 (Fed. Cir. 1993); *Plough*, 530 A.2d at 1160. Not only does a non-party have a stronger claim of a burden, but in this case, the Academy's status as a non-party also supports its argument that CCU's claims are attenuated and misdirected. CCU's allegations in the complaint are largely directed to regulations implemented by HHS. Although CCU argues that the Academy's internal deliberations may have been "tainted with bias against religious institutions," *see* Pl.'s Br. at 7, these claims are speculative at best and do not outweigh the Academy's compelling reasons for keeping its internal review materials confidential.

CCU argues that even if the Court does not accept its arguments for full disclosure, that a confidentiality order granting "attorneys' eyes only" protection to the documents would be sufficient to protect the Academy's interests. The

Court disagrees. In this respect, the Court finds the words of the District of Columbia Court of Appeals to be persuasive:

> A protective order limiting discovery to litigation purposes would reduce the chilling effects of disclosure, but not eliminate them. In a case in which a higher level of need were shown, disclosure under such an order might be appropriate. Here, however, blanket protection is an appropriate remedy considering the balance of factors.

Plough, 530 A.2d at 1160; *see Solarex*, 121 F.R.D. at 180 (finding that the requested disclosure, if made only to those involved in the pending litigation, would reduce, but not eliminate "the risk, or at least the perception on the part of potential reviewers that a risk exists. There would thus be a 'chilling effect' on candid peer evaluations in the future."). The Court finds that a confidentiality order would be insufficient to protect the Academy's interests in this case.

IV. CONCLUSION

For the reasons explained herein, the Academy's motion is **GRANTED**. An appropriate Order accompanies this Memorandum Opinion.

Signed: Emmet G. Sullivan
United States District Judge
November 16, 2012