UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PARENTERAL MEDICINES, INC., *et al.,* Plaintiffs, v. **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.,*** Defendants.	Civil Action No. 11-cv-0470 (RLW)

MEMORANDUM OPINION[1]

Plaintiffs Teva Peranteral Medicines, Inc. ("Teva") and McKesson Medical-Surgical Inc. ("McKesson") filed suit against Defendants U.S. Department of Health and Human Services ("HHS") and Kathleen Sebelius in her official capacity as Secretary of Health and Human Services. Plaintiffs are seeking declaratory and injunctive relief under the Administrative Procedure Act, 5 U.S.C. §§ 701(a) ("APA"), alleging that the Centers for Disease Control ("CDC"), a division within HHS, improperly denied Plaintiffs' request that certain CDC employees be permitted to give testimony in underlying lawsuits currently pending in Nevada state court.

[1] This unpublished memorandum opinion is intended solely to inform the parties and any reviewing court of the basis for the instant ruling, or alternatively, to assist in any potential future analysis of the *res judicata*, law of the case, or preclusive effect of the ruling. The Court has designated this opinion as "not intended for publication," but this Court cannot prevent or prohibit the publication of this opinion in the various and sundry electronic and legal databases (as it is a public document), and this Court cannot prevent or prohibit the citation of this opinion by counsel. *Cf*. Fed. R. App. P. 32.1. Nonetheless, as stated in the operational handbook adopted by our Court of Appeals, "counsel are reminded that the Court's decision to issue an unpublished disposition means that the Court sees no precedential value in that disposition." D.C. Circuit Handbook of Practice and Internal Procedures 43 (2011).

Before the Court are the parties' cross-motions for summary judgment. For the reasons set forth below, the Court concludes that the CDC was not arbitrary or capricious in its denial of Plaintiffs' request for testimony. Accordingly, the Court shall grant Defendants' motion for summary judgment and deny Plaintiffs' motion for summary judgment.

I. BACKGROUND

Teva and McKeeson are defendants in product liability tort actions filed by hundreds of litigants in Nevada state court related to a Hepatitis C outbreak that occurred in Clark County, Nevada between December 2007 and January 2008. In these state court actions, the plaintiffs claim that they have either contracted Hepatitis C, or have been unnecessarily exposed to the risk of contracting Hepatitis C, while being anesthetized during endoscopic procedures at clinics in Clark County, Nevada. Teva and McKesson are the manufacturer and distributor of Propofol, a short-acting hypnotic agent used in the induction and maintenance of anesthesia employed during these endoscopic procedures. The plaintiffs in the state court actions have sued Teva and McKesson under a theory of strict liability, claiming that they were exposed to Hepatitis C when they were anesthetized using contaminated Propofol vials, and that these vials were unsuitable for use at endoscopy clinics.

Both the Southern Nevada Health District ("SNHD") and the CDC investigated the Hepatitis C outbreak in December 2007 and January 2008. Among the CDC employees involved in the investigation were Scott Holmberg, Gayle Fischer Langley, Joseph Perz, and Melissa Scheafer. During these investigations, CDC employees conducted interviews with patients and medical personnel, collected specimens from patients, reviewed medical records, and observed medical personnel. In addition, "phylogenetic testing" was conducted in order to identify source patients.

On May 15, 2008, the CDC released its findings in the Epi-Aid Trip Report ("CDC Trip Report"). Dkt. No. 18, Ex. 3. The CDC Trip Report disclosed the investigation team's methodology, the information gathered, and suggested courses of action. *Id.* The CDC Trip Report concluded that some staff routinely reused syringes during individual procedures to withdraw anesthesia from single-use Propofol vials, and inappropriately used these vials to provide medication for multiple patients; "[t]his was considered the most likely mode of [Hepatitis C] transmission." *Id.* at 9. In December 2009, SNHD released a separate report ("SNHD Final Report") that contained the final results of the SNHD's two-year investigation. Dkt. No. 18, Ex. 4. The SNHD Final Report incorporated information from the CDC Trip Report and concluded that unsafe injection practices and reuse of contaminated Propofol vials were deemed to be the likely causes of the Hepatitis C infections. *Id.* at 50.

Because of the allegations lodged against them, Teva and McKesson have sought the deposition testimony of the CDC employees who investigated the Hepatitis C outbreak. In a letter dated August 20, 2010, Plaintiffs requested permission from the CDC to depose Scott Holmberg, Gayle Fischer Langley, Joseph Perz, and Melissa Schaefer in connection with the pending state court cases. On September 24, 2010, the CDC Director declined Plaintiffs' request and determined that the CDC employees would not be made available for deposition. Seeking review of the CDC's decision in this Court, Plaintiffs ask the Court to set aside the Defendants' decision and issue an injunction compelling the Defendants to permit the depositions sought by plaintiffs.

III. LEGAL STANDARD

Summary judgment is appropriate "if the movant shows [through facts supported in the record] that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477

U.S. 242, 248 (1986). "The rule governing cross-motions for summary judgment . . . is that neither party waives the right to a full trial on the merits by filing its own motion; each side concedes that no material facts are at issue only for the purposes of its own motion." *Sherwood v. Washington Post*, 871 F.2d 1144, 1148 n.4 (D.C. Cir. 1989) (*quoting McKenzie v. Sawyer*, 684 F.2d 62, 68 n.3 (D.C. Cir. 1982)).

II. REGULATORY FRAMEWORK

Under the federal "housekeeping statute," 5 U.S.C. § 301, a federal agency is authorized to promulgate regulations regarding the disclosure of agency information, including procedures for responding to requests for documents and testimony by agency employees. *See* 5 U.S.C. § 301; *see also Touhy v. Ragen*, 340 U.S. 462, 469-70 (1951). Regulations promulgated under Section 301 are commonly known as an agency's *Touhy* regulations. *Truex v. Allstate Ins. Co.*, 233 F.R.D. 188, 190 (D.D.C. 2006).

The HHS's pertinent *Touhy* regulations are found in 45 C.F.R. §§ 2.1-2.6. The conditions under which a party may request the testimony of a HHS employee are set forth in Section 2.4(a), which provides that:

> All requests for testimony by an employee or former employee of the DHHS in his or her official capacity and not subject to the exceptions set forth in § 2.1(d) of this part must be addressed to the Agency head in writing and must state the nature of the requested testimony, why the information sought is unavailable by any other means, and the reasons why the testimony would be in the interest of the DHHS or the federal government.

45 C.F.R. § 2.4(a). Therefore, a party requesting the testimony of an HHS employee must: (1) submit a request in writing which describes the nature of the testimony sought; (2) explain why the testimony is unavailable by other means; and (3) state why the testimony would be in the interest of DHHS or the federal government.

IV. ANALYSIS

When an agency denies an applicant's request for testimony pursuant to that agency's *Touhy* regulations, the applicant's "sole remedy . . . is to file a collateral action in federal court under the [Administrative Procedure Act ('APA')." *Cavanaugh v. Wainstein*, No. 05-123 (GK), 2007 WL 1601723, at *4 (D.D.C. June 4, 2007) (quoting *Houston Business Journal, Inc. v. Office of the Comptroller*, 86 F.3d 1208, 1212 (D.C. Cir. 1996). Under the APA, judicial review of the agency's decision is limited to determining whether the agency's decisions were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706; *see U.S. ex rel. Pogue v. DTCA*, - *F.R.D.* - , 2006 WL 1515914, * 7-8 (D.D.C. June 2, 2006). The party challenging the agency's action bears the burden of proof. *Schweiker v. McClure*, 456 U.S. 188, at 196 (1982). "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Arent v. Shalala*, 70 F.3d 610, 616 (D.C. Cir. 1995) (*citing Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 43 (1983)). Under this highly deferential standard, the court must determine "whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* Thus, no agency action should be set aside if the action is rational, based on relevant factors, and within the agency's statutory authority. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Additionally, the reviewing court is limited to the administrative record as it existed at the time of the agency's decision. *Eugene Burger Mgmt. Corp. v. U.S. Dept. of Hous. & Urban Dev.*, 192 F.R.D. 1, 4 (D.D.C. 1999).

In their August 20, 2010 letter, Plaintiffs requested that Dr. Thomas R. Frieden, Director of the CDC and Administrator for Agency for Toxic Substances and Disease Registry, permit

Scott Holmberg, Gayle Fischer, Joseph Perz, and Melissa Schaefer to testify in depositions in the underlying state court proceedings regarding their investigation of the Hepatitis C outbreak in Nevada. Dkt. No. 18, Ex. 1. On September 24, 2010, Dr. Frieden sent a letter denying Plaintiffs' request for testimony, noting that while the request satisfies the first criterion under the agency's *Touhy* regulations—that the applicant submit a written request stating the nature of the testimony sought—the Plaintiffs' request fails to satisfy the second and third criterion because, in the agency's view, the testimony sought is available by other means and the CDC's participation in the underlying state court litigation would not substantially promote the objectives of the HHS. Dkt. No. 18, Ex. 2.

Plaintiffs contend that the agency acted arbitrarily and capriciously when it denied their request. Plaintiffs claim that the CDC's denial was arbitrary and capricious because "the CDC incorrectly asserted in its denial letter that the testimony sought is available by other means." Pls.' Mot. at 15. In other words, Plaintiffs disagree with the CDC's determination that the testimony sought by Plaintiffs can be found in the May 15, 2008 CDC Trip Report. Plaintiffs argue that the purpose of the requested testimony is to elicit testimony regarding the investigation that led to the CDC Trip Report, including information about interviews with the clinic personnel and information about patient care at the clinics observed by the CDC investigators. Pls.'s Mot. at 16. Plaintiffs maintain that the CDC Trip Report "does not include all of this information . . . and even if it did, it would be no substitute for the ability to personally to question the CDC investigators in order to probe their observations and conclusions." Pls.' Mot. at 16. In their letter, Plaintiffs state that because clinics have been shut down, and some personnel from the clinics are either criminally indicted or invoking their Fifth Amendment rights against self-incrimination, "the CDC employees who investigated the Hepatitis C outbreak . . . are the only source of *certain*

information about the practices at the clinics that could have spread Hepatitis C." Dkt. No. 18, Ex. 1 at 2 (emphasis added). Plaintiffs further state in their letter that information regarding a certified registered nurse anesthesiologist's ("CRNA") injection practices can only be obtained from the CDC investigator that interviewed him because the CRNA has been criminally indicted and is no longer providing any information. *Id*. In addition, Plaintiffs claim in their letter that information about the phylogenetic testing is unavailable from any other source because the specimens were tested by CDC employees. *Id*. Therefore, the testimony sought by Plaintiffs relates to "certain information about the practices at the clinics," information regarding a CRNA's "injection practices," and information about the phylogenetic testing that was conducted by the CDC.

Faced with these requests, Dr. Frieden acted rationally in concluding that the testimony sought by Plaintiffs was available by other means. First, Dr. Frieden stated that the CDC employees would only be able to testify as to what is in the May 15, 2008 CDC Trip Report. Dkt. No. 18, Ex. 2 at 2. Noting that Plaintiffs had the CDC Trip Report, Dr. Frieden concluded that the Plaintiffs already had the same information in written format that the CDC employees would be able to provide in deposition. Dr. Frieden's conclusion was rational because there was nothing in Plaintiffs' request letter that indicated that the information sought by Plaintiffs could not be found in the CDC Trip Report. In addition to the CDC Trip Report, Dr. Frieden also noted that there were other, non-CDC employed, medical professionals from the local health department who were involved in the Hepatitis C investigation that could answer questions regarding the information in the CDC Trip Report. *Id*. Plaintiffs argue that there are certain questions that only the CDC investigators can answer. However, Plaintiffs' request letter fails to specifically state which questions they seek to have answered. Plaintiffs' letter requests information related to the

phylogenetic testing because, as they assert, "information about the phylogenetic testing is unavailable from any other source because the specimens were tested at the CDC by CDC employees." Dkt. No. 18, Ex. 1 at 1. However, Plaintiffs fail to specify what information they are seeking regarding the phylogenetic testing and why that information is not contained in the CDC Trip Report or otherwise unavailable. Ultimately, Dr. Frieden acted rationally and considered the reasons the Plaintiffs presented in their letter as to why they thought the testimony they were seeking was not otherwise available. There is nothing arbitrary or capricious about Dr. Frieden's conclusion that the information sought by Plaintiffs could be found in the CDC Trip Report or obtained from the other medical professionals who are not employed by the CDC. Plaintiffs have pointed to nothing in the administrative record to indicate otherwise.

Plaintiffs also argue that the CDC's decision should be set aside because the CDC did not provide a reasoned explanation for its determination that the CDC's participation in the underlying state court cases would not substantially promote the objectives of the HHS. The Court disagrees. Plaintiffs have cited to no regulatory provision or other authority that requires the CDC to provide a comprehensive and exhaustive analysis of why it reached each conclusion. In fact, it is the requesting party's burden to demonstrate that allowing the testimony is in the CDC's interest. 45 C.F.R. § 2.4(a). Plaintiffs have clearly not done so in this case. Plaintiffs' letter merely states in conclusory fashion that "neither the CDC nor the federal government has an interest in withholding the information obtained through the CDC investigation" and that "the CDC and the federal government have an interest in preventing the spread of infectious disease and ensuring that practices by healthcare providers that spread infectious disease are precisely identified." Dkt. No. 18, Ex. 1 at 2-3. In similar conclusory fashion, Plaintiffs also state that "[t]hose interests will be advanced by permitting the CDC employees to provide deposition

testimony about their investigation of the clinics and the Hepatitis C outbreak." *Id.* at 3. As Defendants rightly point out, if the CDC were to determine that the interests advocated by plaintiffs here—preventing the spread of disease and identifying unsafe healthcare practices—satisfy the *Touhy* requirements, then any litigation even tangentially related to the spread of infectious disease would also be in the interest of the CDC. Plaintiffs have not established how permitting the CDC employees to testify serves anyone's interests other than the Plaintiffs' interest in bolstering their case in the pending state court proceedings.

Moreover, contrary to Plaintiffs' assertion, the CDC's explanation for why it determined that involvement in the underlying state court cases was not in the CDC's interest was far from a "barebones regurgitation" of the agency's relevant provisions. Dr. Frieden's letter provided a detailed and reasoned explanation for the CDC's determination. Dr. Frieden duly consulted with the Office of General Counsel as he is required to do pursuant to 45 C.F.R. § 2.3. In addition, while acknowledging Plaintiffs contention that the CDC has "an interest in preventing the spread of infectious disease and ensuring that practices by health care providers that spread infectious disease are precisely identified," Dr. Frieden informed Plaintiffs that "this goal can be met in other manners that would not require Scott Holmberg, Gayle Fischer, Joseph Perz, or Melissa Schaefer's testimony. Dkt. No. 18, Ex. 2 at 2. Dr. Frieden further states that "a primary concern in this case is minimizing the disruption of employees' official duties." *Id.* The denial letter indicates that the CDC believed that its mission of promoting health and quality of life by preventing and controlling disease, injury, and disability "must take precedence over the interests of the litigation in which [the Plaintiffs] are involved." *Id*. The denial letter also indicates that the agency did not feel it could view Plaintiffs' request in isolation, but rather was compelled to consider the cumulative impact of allowing such a request, especially in light of the

numerous requests that the CDC receives for testimony in litigation, administrative proceedings, and public hearings related to work conducted by the agency.

Ultimately, Dr. Frieden was acting within his discretion to determine that Plaintiffs' arguments in favor of disclosure did not overcome the agency's presumption against providing employee testimony in private litigation. Dr. Frieden acted rationally in determining that the CDC's interests were furthered more by allowing its employees to continue with their work than by disrupting their official duties providing testimony which, in the agency's view, could be obtained in publically available reports and from non-CDC employees. *See Moore v. Armour Pharmaceuticals Co.*, 129 F.R.D. 551, 555 (N.D. Ga. 1990), *aff'd*, 927 F.2d 1194 (11th Cir. 1991) ("[Plaintiff's] interest in getting the deposition simply cannot compare to the government's interest in maximizing the use of its limited resources in dealing with a national health crisis."). Moreover, Dr. Frieden's consideration of the agency's interest in protecting itself against the *cumulative* disruption to its employee's duties as a result of routinely granting similar requests is also rational, especially considering the numerous state court cases related to the Hepatitis C outbreak. *See Moore*, 927 F.2d at 1198; *see also Liberty Nat'l Life Ins. Co. v. Social Security Admin.*, 216 F.R.D. 681, 688 (S.D. Ala. 2003) (finding that in light of all the similar cases before the agency where such a request may be useful to a private litigant, "this Court simply cannot find that the agency's belief that allowing Nelson's testimony (for even just one hour) would unduly burden it is arbitrary and capricious"). In addition, the CDC's decision to allow its employees to provide testimony before a grand jury in the criminal prosecution of clinic employees is consistent with the agency's decision to decline Plaintiffs' request for testimony here. Under, Section 2.3, Dr. Frieden has a broad mandate to promote the objectives of the agency, which, as a general matter, does not allow its employees to give depositions or trial testimony in private litigation.

Moreover, as set forth in Section 2.1(b), any decision to make an agency employee available for testimony is governed by the CDC's policy to "maintain strict impartiality with respect to private litigants and to minimize the disruption of official duties." 45 C.F.R. 2.1(b). Thus, the CDC's approval of grand jury testimony by its employees is consistent with the CDC's objectives because such testimony does not violate the agency's policy against becoming involved in private litigation nor does it implicate the agency's policy to maintain strict impartiality with respect to private litigants. In the end, the CDC's decision to not allow its employees to provide testimony amounts to "essentially a policy decision about the best use of the agency's resources." *COMSAT Corp. v. Natl. Science Foundation*, 190 F.3d 269, 278; *see also Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 866 (1984).

Therefore, based upon the information requested in Plaintiffs' *Touhy* request, the Court finds that the CDC's denial of permission to depose the CDC employees was not arbitrary or capricious. The CDC adequately considered the relevant factors and its decision contains no clear error of judgment. As the Court must afford substantial deference to the agency's decision where it is not arbitrary and capricious, and where it is supported by the administrative record, the Court will, therefore, decline Plaintiffs' request to set aside the agency's decision. Additionally, the Court will deny Plaintiffs' request to compel the production of documents pursuant to their Freedom of Information Act ("FOIA") request submitted to the CDC on August 3, 2010. Pls. Mot. At pp. 25-28. Plaintiffs' complaint consists of a single claim seeking review of Defendants' denial of Plaintiffs' request for deposition testimony under the APA. (Compl. ¶¶ 67-71). In addition, Plaintiffs' complaint asserts that jurisdiction is proper in this court because the claims arise under the APA. *Id*. at ¶ 1. Thus, Plaintiffs' complaint does not assert a FOIA claim, and the

Plaintiffs may not raise such a claim at the summary judgment stage because the claim was not properly raised in the complaint.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' motion for summary judgment is denied, and Defendants' motion for summary judgment is granted. A separate order accompanies this Memorandum Opinion.

SO ORDERED.

October 9, 2012

Digitally signed by Judge Robert L. Wilkins
DN: cn=Judge Robert L. Wilkins, o=U.S. District Court, ou=Chambers of Honorable Robert L. Wilkins, email=RW@dc.uscourt.gov, c=US
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Robert L. Wilkins
United States District Judge