

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)	
IN RE: NEW ENGLAND)	Master Docket No. 12-cv-12052-FDS
COMPOUNDING PHARMACY CASES)	
_____)	
This Document Relates To:)	
_____)	
CHAD GREEN,)	
_____)	
Plaintiff,)	
_____)	Civil Action No. 12-12121-FDS
v.)	
_____)	
NEW ENGLAND COMPOUNDING)	
PHARMACY, INC.)	
_____)	
Defendant.)	
_____)	

**ORDER ON PLAINTIFF’S MOTION TO ADOPT STATE COURT ORDERS
GRANTING MOTION TO PERMIT INSPECTION OF PREMISES OF DEFENDANT**

December 10, 2012

Boal, M.J.

Plaintiff Chad Green seeks an expedited opportunity to enter the facility of defendant New England Compounding Pharmacy, Inc. (“NECC”) at 697 Waverly Street, Framingham, Massachusetts (the “Facility”), and conduct various inspections and tests at that location. The District Court referred that motion to the undersigned on November 29, 2012. Docket No. 59.¹ For the following reasons, the Court grants the motion within the parameters set forth in this order.

¹ Unless otherwise specified, references to docket numbers refer to the Master Docket No. 12-12052-FDS.

I. Factual and Procedural Background

On November 29, 2012, the District Court consolidated, for pre-trial purposes only, various personal injury cases against defendants NECC, Ameridose LLC, Medical Sales Management, Inc., Barry Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, and Glenn A. Chin, or some subset or combination of those defendants. Docket No. 57. The cases arise out of an outbreak of fungal meningitis in at least 19 states, which has sickened approximately 419 people and caused approximately 30 deaths. See, e.g., Chad Green Complaint² at ¶ 1. The plaintiffs allege that the outbreak originated from medication compounded by NECC. Id. Plaintiffs allege that the United States Food and Drug Administration (“FDA”) and the Centers for Disease Control and Prevention (“CDC”) have “implicated” NECC as the cause of the injuries and deaths. Id. at ¶ 2. According to plaintiffs, NECC’s facilities were unsterile and replete with fungus that contaminated the vials holding the medications. Id.

The United States Attorney for the District of Massachusetts and its law enforcement partners are actively investigating allegations concerning NECC. Docket No. 84 at 1. Other federal, state and possibly local public health authorities may also be investigating NECC. Docket No. 59 at 2. In addition, NECC is engaged in a recall of its products. Id.

Plaintiff Chad Green filed his complaint in the Massachusetts Superior Court on November 6, 2012. Green Docket³ No. 14 at 50. The Defendants removed the case to this Court

² Chad Green v. New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center, No. 12-cv-12121-FDS (D. Mass.), Docket No. 1-1.

³ “Green Docket” refers to the docket of Chad Green v. New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center, No. 12-cv-12121-FDS (D. Mass.).

on November 14, 2012. Green Docket No. 1.

Prior to the removal of Green's complaint to this Court, the Massachusetts Superior Court granted his ex parte emergency motion for inspection of the premises. Green Docket No. 14 at 13, 50. The order contained no restrictions on any such inspection. The case was removed to this Court before Green carried out the inspection. On November 20, 2012, Green filed a motion asking this Court to adopt the order of the Massachusetts court allowing the inspection. Green Docket No. 7. On November 29, 2012, the District Court vacated the order entered by the Massachusetts Superior Court granting plaintiff's motion to inspect the premises and referred Green's motion to adopt that order to the undersigned. Docket No. 59.

This Court issued a scheduling order on November 30, 2012. Docket No. 60. Pursuant to that scheduling order, Green, NECC and the United States⁴ filed written submissions to the Court regarding Green's request for an expedited inspection. Docket Nos. 72, 84, 86. Both Green and NECC submitted expert affidavits to support their respective positions.⁵ Docket Nos. 72-1, 86-1. The Court heard oral argument on December 6, 2012.

II. Analysis

Green seeks an expedited inspection of the Facility. Green listed the tests to be

⁴ Given the proposed inspection's potential effects on the ongoing investigations and/or the performance by public health authorities of their statutory and regulatory duties, the Court invited federal and state authorities to file submissions and/or to attend the December 6, 2012 hearing. Docket No. 60. The United States filed a statement on December 5, 2012 (Docket No. 84) and attended the hearing. A representative from the Framingham Board of Health appeared at the hearing and stated that it had no objection to an inspection. Otherwise, no state or local authorities filed any papers or appeared at the hearing.

⁵ Plaintiffs Lance Martin and Toby Martin concurred with Green's request. Docket No. 88.

performed, see Docket No. 72 at 11-12, and stated at oral argument that the tests could be completed in four days. As set forth by the District Court, the resolution of Green's request for an expedited inspection is complicated by a number of factors, including:

1. The NECC facility has apparently been the subject of extensive investigation, testing, and other actions by federal, state, and possibly local public health authorities. Those investigations appear to be ongoing. It is unclear whether the proposed inspection and testing might interfere with the performance by public health authorities of their statutory and regulatory duties. For obvious reasons, the discovery process in this case must yield, when necessary, to the protection of the public health.
2. The Court understands that NECC is engaged in a recall of its products. It is likewise unclear whether the proposed inspection and testing might interfere with or affect that process.
3. Green contends that the testing and sampling at issue is time-sensitive, in that he seeks to ascertain the current presence of bacteria, mold, particulate matter, and other contaminants. It is unclear whether such testing undertaken now would produce scientifically meaningful evidence as to conditions at the facility at the relevant time.

Docket No. 59 at 2. In addition, cases against NECC are now pending in various federal and state courts, with more likely to be filed. A motion for transfer and consolidation seeking to coordinate these actions for pretrial discovery and proceedings pursuant to 28 U.S.C. § 1407(a) is currently pending before the Judicial Panel on Multidistrict Litigation. See Docket No. 13 at 2; Docket No. 57 at 3.

At oral argument, NECC conceded that Green is entitled to an inspection. However, NECC opposes the inspection because it believes that the passage of time since the relevant events would render any testing scientifically invalid. Docket No. 86 at 5-9. Somewhat contradictorily, NECC also argues that an inspection is premature and unfair to the myriad other plaintiffs who may assert claims against NECC. Id. at 4-5. NECC further argues that an

inspection at this time would interfere with government investigations and its efforts to preserve evidence. Id. at 5.⁶

The United States does not oppose an inspection of the Facility but requests that any order authorizing entry and testing incorporate certain restrictions in order to avoid compromising the government's ongoing investigation. Docket No. 84. Green has agreed to the United States' proposed restrictions.

For the following reasons, the Court will allow Green to perform an inspection subject to the parameters set forth in this order.

A. Early Discovery

Green seeks early discovery. Rule 26(d) of the Federal Rules of Civil Procedure provides that: “[e]xcept . . . when authorized under these rules or by order or agreement of the parties, a party may not seek discovery from any source before the parties have conferred as required by Rule 26(f).” Fed.R.Civ.P. 26(d). In order for a party to obtain expedited discovery before the Rule 26(f) conference, it must show good cause. Fed.R.Civ.P. 26(b)(1). The First Circuit has not addressed the proper standard for determining whether good cause exists for expedited discovery.

The Court finds that Green has shown good cause for early discovery, namely an

⁶ During oral argument, NECC brought up for the first time that some of the proposed testing may affect property that is not owned or controlled by NECC or the other defendants. Nevertheless, NECC brought forward no specifics or evidence to back up its assertions. Indeed, it appears that the property where the Facility is located may be owned by entities related to the defendants in some of these actions. See, e.g., Erkan Complaint at ¶ 24 (the complex where the Facility is located is “owned by Gregory Conigliaro’s real estate companies, GDC Holdings Inc. and/or GDC Properties Management LLC.”). Accordingly, the Court does not find this argument persuasive.

inspection.⁷ Time is of the essence. Several months have passed since the relevant events and the passage of time will only make it more difficult for Green to obtain scientifically valid information.

B. Standard of Review

“Discovery procedures set forth in the Federal Rules of Civil Procedure seek to further the interests of justice by minimizing surprise at trial and ensuring wide-ranging discovery of information.” Cartel Asset Mgmt. v. Ocwen Fin. Corp., No. 01-cv-01644, 2010 WL 502721, *9 (D. Colo. Feb. 8, 2010) (citing United States ex rel. Schwartz v. TRW, Inc., 211 F.R.D. 388, 392 (C.D. Cal. 2002)). To that end, Rule 26(b) permits “discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense . . .” or discovery of any information that “appears reasonably calculated to lead to the discovery of admissible evidence.” Fed. R. Civ. P. 26(b). Rule 26(b)(1) generally permits liberal discovery of relevant information. Baker v. Liggett Group, Inc., 132 F.R.D. 123, 125 (D. Mass. 1990). As the Supreme Court has instructed, because “discovery itself is designed to help define and clarify the issues,” the limits set forth in Rule 26 must be “construed broadly to encompass any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case.” Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 351 (1978).

There are limits, however, on the scope of discovery. A court must limit discovery if it determines that the discovery sought is (1) unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive;

⁷ At oral argument, Green also sought permission to interview NECC employees. This order authorizes an inspection only. All other discovery must at this stage follow the ordinary civil discovery process.

(2) the party seeking discovery has had ample opportunity by discovery in the action to obtain the information sought; or (3) the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the projected discovery in resolving the issues. See Fed. R. Civ. P. 26(b)(2)(C).

Subject to the limits imposed by Rule 26, Rule 34 of the Federal Rules of Civil Procedure allows a party "entry onto designated land or other property possessed or controlled by the responding party, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it." Fed. R. Civ. P. 34(a)(2). Because entry upon a party's premises may engender greater burdens and risks than other forms of discovery, at least one Circuit has recognized the need for a more searching inquiry into the necessity for inspection. See Belcher v. Bassett Furniture Indus. Inc., 588 F.2d 904, 908 (4th Cir. 1978).

When an inspection will involve destructive testing,⁸ courts generally consider four factors in determining whether to allow the testing: (1) whether the proposed testing is reasonable, necessary, and relevant to proving the movant's case; (2) whether the non-movant's ability to present evidence at trial will be hindered, or whether the non-movant will be prejudiced in some other way; (3) whether there are any less prejudicial alternative methods of obtaining the evidence sought; and (4) whether there are adequate safeguards to minimize prejudice to the non-movant, particularly the non-movant's ability to present evidence at trial.

⁸ Destructive testing is testing that results in alteration or destruction. Bostic v. Ammar's, Inc., No. 03-146-ART, 2011 WL 251009, at *2 n. 4 (E.D. Ky. Jan. 26, 2011).

See Garcia v. Aartman Transport Corp., No. 4:08 cv 77, 2011 WL 665451, at *2 (N.D. Ind. Feb. 14, 2011) (citing Mirchandani v. Home Depot, USA, Inc., 235 F.R.D. 611, 614 (D. Md. 2006)); Bostic v. Ammar's, Inc., No. 03-146-ART, 2011 WL 251009, at * 3 (E.D. Ky. Jan. 26, 2011) (citing Mirchandani, 235 F.R.D. at 614).

C. The Inspection Is Reasonably Calculated To Lead To The Discovery Of Admissible Evidence

NECC argues that the inspection and tests proposed by Green constitute an exercise in futility and would not lead to the discovery of relevant or reliable evidence. Docket No. 86 at 6. According to NECC and its expert, none of the tests proposed by Green are capable of providing scientifically reliable data regarding the means by which the lots of medication at issue may have been contaminated or can reliably pinpoint the date of the alleged contamination. Id.

Green, on the other hand, argues that his expert is able to identify the age of mold through scientifically valid analysis supported in well-respected literature. Docket No. 72 at 15. He also argues that collection of samples would allow his experts to create and evaluate a data set of samples to determine whether an area has had a consistent presence of fungal spores or not. Id. Finally, an inspection will allow Green to determine whether the Facility complies with standards for pharmaceutical compounding. Id. at 15-16.

The Court finds that the inspection is reasonably calculated to lead to the discovery of admissible evidence. Whether or not the inspection and testing will lead to reliable evidence is best left for a Daubert challenge or a challenge to the weight of the evidence at trial. Indeed, NECC concedes that the proposed testing may determine the existence and concentration of mold at the facility at present. Docket No. 86 at 6. If, for example, Green's experts are able to locate the fungus that was in the recalled vials of NECC's product in one or more locations at the

Facility, that evidence would certainly be relevant even if it is not dispositive of the issue.

Accordingly, the Court finds that Green is entitled to an inspection at this time.

D. Destructive Testing

Green proposes to conduct some “minimally invasive” testing, such as “sampling of wall, roof, ceiling and foundational assemblies and cavities, interior mechanical systems, including, but not limited to HVAC systems and its ductwork and plumbing systems,” sampling of edging of carpeting and testing of the clean room. Docket No. 72 at 12. After consideration of the parties’ submissions and arguments, the Court finds that such testing appears to be reasonable, necessary and relevant; that there are no adequate alternative methods to obtain the information; that the defendants will not be prejudiced; and there are adequate safeguards to minimize the prejudice to the defendants, such as allowing the defendants and their expert to attend the inspection, to allow them to perform similar tests or take their own samples if they so desire, and to provide them with the results of any tests performed.

Nevertheless, the Court is cognizant that destructive testing may affect the ongoing government investigation. Accordingly, Green must confer with the United States regarding protocols for any destructive testing.

E. Parameters Of The Inspection

Having found that an inspection is appropriate in this case,⁹ the Court orders Green to confer with other plaintiffs, the defendants, and the United States in an attempt to agree on a

⁹ At oral argument, NECC’s counsel argued that under certain circumstances, this Court’s order could restrict the rights of any potential defendants in a criminal case. To be clear, this order applies only to the civil cases before this Court and is not intended to have any effect to restrict the rights of any potential criminal defendants.

protocol for the inspection. If the parties are unable to agree on a protocol, each of them shall file its own proposed order and protocol for inspection. Any such protocol(s) shall be filed with the Court no later than the close of business on Friday, December 14, 2012.

To aid the parties in the development of an inspection protocol, the Court sets the following parameters:

1. Any inspection and testing pursuant to this Order must be completed in four business days or less and no further entry into the Facility for purposes of testing will be allowed after the four-day period absent good cause shown. The parties shall confer and attempt to agree on the dates of the inspection and testing.
2. Green, his attorneys and/or his expert(s) may enter the Facility only with prior notice to the United States and in the company of one or more representatives of the Office of the United States Attorney and/or federal law enforcement. All testing, examination and inspection shall occur under the supervision of such representatives.
3. Any party's inspection and testing shall under no circumstances extend to drugs or packages of drugs that are presently located at the NECC Facility following return by customers and/or pickup and processing by federal agencies, and under no circumstances shall the parties remove any drugs from the Facility for testing or otherwise.
4. Any party's inspection or testing shall not extend to the interior of any locked drug vault at the NECC Facility.
5. The defendants and/or their expert(s) may be present during the inspection and

may also take samples for their own testing.

6. Green shall share the results of testing with the other plaintiffs, the defendants, and any federal or state authorities that request results.
7. Green shall share the results of testing with any future plaintiffs. Future plaintiffs shall not be entitled to perform their own inspection absent good cause.
8. Green shall advise the United States with specificity of the nature and subject of any destructive testing, including cleaning the Facility, and shall attempt to reach an agreement with the United States regarding any such testing.

/s/ Jennifer C. Boal
JENNIFER C. BOAL
United States Magistrate Judge