

VERMONT SUPERIOR
Washington Unit
65 State Street
Montpelier VT 05602
802-828-2091
www.vermontjudiciary.org



CIVIL DIVISION
Case No. 247-7-20 Wncv

Hayek Medical Devices (North America), LTD vs. State of Vermont

Opinion and Order on the State's Motion to Strike

Pursuant to Vt. R. Civ. P. 37, the State has filed a motion to strike Hayek's amended expert disclosures for failure to comply with the Court's October 25, 2022 Order on its motion to compel and Vt. R. Civ. P. 26(b)(5)(A)(i). The State argues that the Plaintiff's new disclosures remain too summary. It also asserts that Hayek has continued to not produce related documents. Hayek argues that its current disclosures are manifestly sufficient, and there remain no related documents to produce.

Rule 26(b)(5)(A)(i) provides:

- (i) A party may through interrogatories require any other party
 - (I) to identify each person whom the other party may use at trial to present expert testimony under Vermont Rules of Evidence 702, 703, or 705, whether or not the witness may also testify from personal knowledge as to any fact in issue in the case;
 - (II) to state the subject matter and the substance of the facts and opinions as to which the expert is expected to testify; and
 - (III) to provide a summary of the grounds for each opinion.

The purpose of the disclosure "is to allow defendants to garner enough information to make a choice about whether and how to take a deposition." *Stella ex rel. Est. of Stella v. Spaulding*, 2013 VT 8, 193 Vt. 226.

Hayek originally disclosed 8 experts. The disclosures were abbreviated and vague in the extreme. At the hearing on the State's motion to compel, the Court (Mello, J.) said:

So the Court understands Hayek's position that the State knew what it was buying, and it doesn't have the burden of proving these ventilators were suitable for COVID or anything else. So that's fine. And Hayek could take the position, we don't need any experts. But having disclosed the experts, Hayek needs to comply with the rule. It seems pretty clear that these disclosures do not begin to describe the basis for any of their opinions. Has the expert ever used the machine? What information about the machine is the expert relying on in concluding that it's suitable for treating COVID? What experience does the expert have treating COVID? What expert[ise] does the expert have treating COVID with this machine or machines like it?

I mean, none of those details are included all of which would be necessary to show the basis for their opinion. Just simply saying that they're relying on their experience, training, and education doesn't tell us anything. It doesn't tell us what facts relevant to this machine and this disease the person is basing their opinion on that is suitable to treat this disease.

So the Court agrees with the plaintiff that the disclosure—if you're going to disclose experts—if you feel that you don't need experts, then you don't need to make a disclosure. But if you're going to disclose experts, it needs to comply with the requirement—that requirement, and this doesn't do that.

In the subsequent written order (Oct. 25, 2022), Judge Mello said: "The State has objected to all of Hayek's expert disclosures as far too summary to comply with Rule 26(b)(5)(A)(i). As discussed at the hearing, the disclosures do not comply with the letter or spirit of the rule. They shall be supplemented to comply with the rule, or the proposed experts will be treated as withdrawn." The Court interprets the written order to incorporate Judge Mello's related comments at the hearing.

In response to the Order, Hayek redisclosed 2 (Mefford and Cronin) of the original 8 experts and disclosed for the first time a third expert (Charla). Under the terms of the October 25 Order, the other 6 experts originally disclosed have been withdrawn. The State argues that the new disclosures remain so vague that it cannot properly determine whether to conduct depositions and cannot properly prepare for any such depositions. Hayek argues that the State is improperly trying to force expert disclosures to do far more than is required by Rule 26.

The Court generally agrees with Hayek. The original disclosures revealed nearly nothing. By way of example, other than a brief description of his qualifications, the entire original disclosure as to Dr. Cronin was as follows:

In the event that expert testimony is required regarding the application of BCV [biphasic cuirass ventilation], Dr. Cronin is anticipated to testify regarding the appropriate clinical use of BCV as provided by the Hayek RTX Model 01 ventilator, including in the care of patients with COVID-19 in appropriate clinical settings. The grounds for these opinions include Dr. Cronin's training, education, and experience.

Following the Court's Order, Hayek improved Dr. Cronin's disclosure substantially.

It now reads:

In the event that expert testimony is required regarding the application of BCV, Dr. Cronin is anticipated to testify regarding the appropriate clinical use of BCV as provided by the Hayek RTX Model 01 ventilator, including in the care of patients with COVID-19 in appropriate clinical settings.

Dr. Cronin consults with practitioners treating patients in various clinical settings, including hospitals. He has been a resource to clinicians who have used the RTX Model 01 to treat patients with COVID-19, including assisting clinicians with selecting settings that could be helpful to transition a patient off of invasive ventilation or to avoid invasive ventilation altogether. The appropriate settings for

each patient depend on the patient's individual symptoms. COVID-19 is no different in this respect from other conditions resulting in respiratory compromise where ventilator support is indicated.

Dr. Cronin is expected to explain that in the earliest stages of the pandemic, COVID-19 was novel in terms of what was causing inflammation and the rapidity of the onset of symptoms, but the end point is and was similar to other disease processes. Dr. Cronin is expected to opine that the RTX Model 01 maintains functional residual capacity better than positive pressure ventilators and eliminates the negative aspects of positive pressure ventilation while achieving equally positive patient outcomes. The RTX Model 01 can be used to replace positive pressure ventilation or in combination with positive pressure ventilation to reduce the amount of pressure used.

Dr. Cronin is also expected to testify about the different modes available on the RTX Model 01 and how each works, including continuous negative pressure mode, control mode, synchronous mode, oscillation mode, and cough assist mode. Briefly, continuous negative pressure mode puts constant negative pressure on the anterior of the chest and abdomen and increases volume but holds the lungs open rather than forcing a full and complete exhalation. In control mode, the machine takes more control of breathing. In synchronous mode, the machine senses respiration and each time the patient inhales or exhales makes it more deep and complete. Oscillation mode uses various frequencies to shake loose secretions and cough assist mode also works on assisting secretions by amplifying the effect of a natural cough.

Dr. Cronin is expected to opine that the RTX Model 01 is contraindicated if the patient lacks an intact upper airway, for example if there is a thorax obstruction, or if there is massive destruction to the chest wall, for example if there is a burn. Otherwise, Dr. Cronin is expected to explain that there is a general trend towards noninvasive ventilation and in almost every setting where a positive pressure ventilator could assist a patient, the RTX Model 01 could be used. Intubation causes airway inflammation and trauma, particularly in COVID-19 patients. Both volume distension and shearing forces caused by pressure associated with positive pressure ventilation are avoided when the RTX Model 01 is used.

The disclosures of the other two experts are similarly detailed.

The State maintains that is not enough. It argues that more granularity is required by Vt. R. Evid. 702 because it is incorporated into Rule 26. It asserts: “Taking each aspect of what is necessary under Rule 702 as set out in the Reporter’s Note shows that Plaintiff’s purported disclosures do not meet the required criteria under Rule 26.” The Court disagrees.

Rule 702 is not incorporated into Rule 26 as the State urges. The purpose of the reference to the evidence rules in Rule 26 is made plain by the relevant notes:

Rule 26(b)(5)(A)(i) is amended to adapt the language of F.R.C.P. 26(a)(2)(A) for the provision of the Vermont Rule identifying expert witnesses whose identity must be disclosed in response to an interrogatory. The amended rule applies to “each person” who may be used at trial to present expert testimony under Vermont Rules of Evidence 702, 703, and 705. To remove uncertainty regarding whether this requirement applies to witnesses whose testimony falls within those Evidence Rules but who were not specially retained to develop their opinions, the present amendment makes clear that Rule 26(b)(5) applies “whether or not the witness may also testify from personal knowledge as to any fact in issue in the case.”

Reporter’s Notes—2019 Amendment, Vt. R. Civ. P. 26. The Court concludes that the cross-references in Rule 26 have nothing to do with the breadth of the required disclosures under that Rule.

The State also relies on *Stella ex rel. Est. of Stella v. Spaulding*, 2013 VT 8, 193 Vt. 226. *Stella* was a medical malpractice case. The decedent died of an infection following surgery. Between surgery and death, she had been treated by numerous physicians. The surgeon was sued. The trial court ultimately described the deficient expert disclosure as follows: “Plaintiff has not provided the specifics of Plaintiff’s expert’s opinions as to specific acts of negligence and the standard of care

and failure to meet the standard of care requested in those two interrogatories.” *Stella*, 2013 VT 8, ¶ 10, 193 Vt. at 232. The “disclosure” provided no useful information as to what the defendant was alleged to have done wrong. The trial court found that insufficient and sanctioned the plaintiff. The Supreme Court affirmed, concluding that “[i]t was wholly within the court’s discretion to require more specific answers.” *Id.*, 2013 VT 8, ¶ 18, 193 Vt. at 234.

While the dissenting opinion in *Stella* would have approved of the scant disclosure in that case, *id.*, 2013 VT 8, ¶¶ 35–36, 193 Vt. at 242–43 (Robinson, J., dissenting), the majority and dissenting opinions do not disagree significantly as to the general approach to expert disclosures under Rule 26. Both embrace the thrust of federal case law prior to the 1993 amendment to the federal rule. Despite rejecting the disclosure, the majority made clear that the “dissent’s recitation of the law is largely correct. We agree that ‘a party cannot require, by interrogatory, disclosures that are more extensive than provided for in Rule 26(b)(4).’ Certainly, Rule 26(b)(4) places an obligation of disclosure on plaintiff, but also limits the bounds of that disclosure to a specific list of items. In this way, a party may not through interrogatory obtain ‘all of the details a requesting party might ultimately want to know.’” 2013 VT 8, ¶ 19, 193 Vt. at 235 (internal citations omitted). The *Stella* majority and dissent took different views as to how the Rule applied in the specific circumstances at issue, but *Stella* did not usher in an era of greatly more expansive disclosure requirements than existed in prior Vermont practice.

Hayek's current disclosures are nowhere near the opaqueness and brevity of the one at issue in *Stella*. They reasonably describe the subject matter and provide a summary and description of the nature of each expert's opinion. The Court understands on a broad level that the State's position is that the ventilators were not appropriate for use with patients with Covid and that it hopes to probe Hayek's experts' positions to the contrary. No doubt, more specific information would be beneficial to such pursuits. Rule 26(b)(5)(A)(i), however, requires only summary information about an expert's opinion to facilitate the decision on whether to depose the expert and to assist in general preparation for such discovery. It does not demand that the disclosure contain all the information that will likely be explored in the deposition. The Court is not persuaded that the current disclosures by Hayek are deficient under Rule 26, the Court's October 25, 2022 Order, or the principles of *Stella*. To the extent the State wishes to obtain more detailed information as to the bases and scope of the opinions, it may be obtained through deposition practice.

The State also argues that Hayek has continued to fail to produce documents related to its expert disclosures. At the hearing prior to the October 25 Order, Hayek represented that it had produced all related documents but that it would revisit the matter in anticipation that the Court would be granting the motion to compel. It is not fully clear what documentation may have been produced thereafter; but Hayek now maintains, again, that it has no related documents to produce. Those representations are made under the umbrella of Vt. R Civ. P. 11. The Court cannot order Hayek to produce something that it does not have. If Hayek

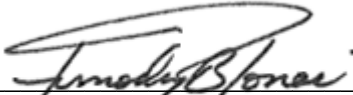
attempts in the future to rely on a document that should have been produced but was not or belatedly produces a responsive document that is supportive of the State's position, the State may seek appropriate relief at that time.

Finally, Hayek produced a document that is a list of articles assembled by Mr. Mefford. The State objects to the document, but the nature of the objection is unclear to the Court. Hayek appears to be willing to attempt to voluntarily resolve the objection. The Court requests that the parties confer and make all reasonable efforts at resolving this issue without further involvement of the Court.

Conclusion

For the foregoing reasons, the State's motion to strike is denied.

Electronically signed on Monday, March 25, 2024, per V.R.E.F. 9(d).


Timothy B. Tomasi
Superior Court Judge