IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge R. Brooke Jackson

Consolidated Civil Action No 13-cv-00573-RBJ-KMT

DORIS MORRIS; TONY ARMSTRONG; and MELVIN NUNES, as Personal Representative of the ESTATE OF STELLA NUNES, on behalf of all others similarly situated,

Plaintiffs,

v.

DAVITA HEALTHCARE PARTNERS, INC.,

Defendant.

ORDER

This order addresses the parties' respective "Daubert" motions. Defendant moves to exclude the testimony and opinions of plaintiffs' quality improvement and patient safety expert, Barbara J. Youngberg, R.N., and plaintiffs' nephrology expert, Steven Borkan, M.D. ECF No. 128. Plaintiffs move to strike portions of the testimony and opinions of defendant's nephrology expert, Stanley Goldfarb, M.D. ECF No. 130. Following full briefing the Court held an evidentiary hearing on April 29 and 30, 2015, during which all three experts testified. For the reasons discussed in this Order, defendant's motion is granted in part and denied in part. Plaintiffs' motion is denied.

BACKGROUND

The Court has discussed the factual background in this heavily litigated case in two orders addressing DaVita's motions to dismiss plaintiff's first and second amended complaints. *See* Orders issued April 9, 2014 [ECF No. 69] and March 23, 2015 [ECF No. 126]. For present purposes, suffice it to say that plaintiffs received hemodialysis at DaVita clinics. Plaintiffs claim

that an ingredient in the dialysate solution used in their treatments caused unsafe increases in their blood pH (alkalosis) that in turn resulted in serious injuries or death. This ingredient, called GranuFlo or NaturaLyte, was not manufactured by DaVita, and the Court has dismissed plaintiffs' products liability claims. The remaining claims against DaVita concern its monitoring of its patients. Plaintiffs claim that in the process of monitoring and collecting data DaVita either failed to observe changing blood pH levels and therefore acted negligently in administering care, or it observed the problems but kept the information secret, thereby perpetrating a fraud.

EXPERT TESTIMONY

Under Rule 702 of the Federal Rules of Evidence, a qualified expert may provide opinion testimony if the evidence is both relevant and reliable. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993). Expert opinions are **relevant** if they would "help the trier of fact to understand the evidence or to determine a fact in issue." Rule 702(a); *see Daubert*, 509 U.S. at 591. They are **reliable** if the expert is qualified by knowledge, education or experience, and his or her opinions are "scientifically valid" and based on "reasoning or methodology [that] properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 593. Reliability generally focuses on the methodology, not the ultimate conclusions of the expert. *Ho v. Michelin North America, Inc.*, 520 F. Appx. 658, 663 (10th Cir. 2013). Factors useful in this analysis include, but are not limited to, the following:

> (1) whether the opinion at issue is susceptible to testing and has been subject and has been subjected to such testing; (2) whether the opinion has been subjected to peer review; (3) whether there is a known or potential rate of error associated with the methodology used and whether there are standards controlling the technique's operation; and (4) whether the theory has been accepted in the scientific community.

Dodge v. Cotter Corp., 328 F.3d 1212, 1222 (10th Cir. 2003) (citing *Daubert*, 509 U.S. at 593–94).

The proponent of expert testimony has the burden to show that the testimony is admissible. *U.S. v. Nacchio*, 555 F. 3d 1234, 1241 (10th Cir. 2009). The trial court plays a "gatekeeping" role that involves an assessment of the "reasoning and methodology underlying the expert's opinion" and a determination of "whether it is scientifically valid and applicable to a particular set of facts." *Goebel v. Denver and Rio Grande Western R.R. Co.*, 215 F.3d 1083, 1087 (10th Cir. 2000). However, the trial court has discretion as to how to perform this gatekeeping function. *Id.* It is not a role that emphasizes exclusion of expert testimony. I have frequently cited Judge Kane's description of the purpose of Rule 702:

> A key but sometimes forgotten principle of Rule 702 and *Daubert* is that Rule 702, both before and after *Daubert*, was intended to relax traditional barriers to admission of expert opinion testimony. Accordingly, courts are in agreement that Rule 702 mandates a liberal standard for the admissibility of expert testimony. As the Advisory Committee to the 2000 amendments to Rule 702 noted with apparent approval, "[a] review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule."

Cook v. Rockwell Intern. Corp., 580 F. Supp. 2d 1071, 1082 (D. Colo. 2006) (citations omitted).

With those broad principles in mind, I turn to the task of assessing the relevance, reliability, and, ultimately, the admissibility of the challenged testimony.

BARBARA J. YOUNGBERG

A. Facts.

The Court has reviewed Ms. Youngberg's Declaration of September 2, 2014 [ECF No. 109-1], her Reply Declaration [ECF No. 118-3], and substantial portions of her deposition testimony. Based on those materials and testimony and exhibits admitted at the hearing, the Court makes the following findings:

1. Ms. Youngberg is a licensed attorney and a registered nurse. Although she worked as a critical care nurse before she graduated from law school, her career thereafter has focused on risk management, quality improvement and patient safety in medical care. For 20 years she worked for an alliance of academic medical centers during which she was often charged with designing systems for evaluating new products such as drugs and medical devices so that they could be safely used in patient care. She created a desk reference for risk managers and has written several texts and on-line sources concerning these issues. At the present time she teaches risk management to law students, physicians and health care administrators at the Beazley Institute for Health Law and Policy of the Loyola University College of Law in Chicago. She is a Fellow of the American Board of Health Care Risk Managers and a member of the American Hospital Association's Patient Safety Fellowship program.

2. In the present case Ms. Youngberg was asked to provide opinions as to whether DaVita's quality improvement standards and patient safety and risk management programs, as they related to the deployment and use of GranuFlo and NaturaLyte, met the standard of care in the health care industry for such programs. *See* Hearing Transcript, Day One [ECF No. 151] at 141-42.

3. In her opinion, an effective quality improvement program that meets the applicable standard of care would include the following features: (1) systematic and continuous collection of health-related data relevant to the patient care being provided; (2) analysis and interpretation of that data; (3) modification of existing patient care processes if analysis of the data indicates a need to do so; (4) reassessment of the modifications to confirm that the problems have been remedied; and (5) supplementation of the quality improvement program by review of current

literature and best practices in similar institutions. Declaration at ¶¶24–26; Deposition [ECF No. 127-2] at 165–66.

4. Ms. Youngberg acknowledges that DaVita actively collects clinical data from patients, both during treatment and after they leave the treatment center. De-identified data sets generated by the DaVita Quality Index are referenced in many research studies that she has reviewed. This data has revealed an increased incidence of cardiac arrests and sudden cardiac deaths. She read one article that suggests that linkage between alkalosis and cardiac arrest might be related to an increased incidence of cardiac events. Declaration at ¶27.

5. However, Ms. Youngberg states that she found nothing in the documents that were provided to her that indicates that DaVita has systematically reviewed data across its treatment facilities to attempt to determine common causes or similarities of adverse events. She continues, "[i]f done, DaVita could have identified early on the role alkalosis played in patients receiving hemodialysis using GranuFlo and NaturaLyte." *Id.* at ¶28.

6. She believes that DaVita would, in turn, have recognized health risks to patients receiving GranuFlo and NaturaLyte:

a. "Had DaVita instituted quality improvement standards, patient safety and risk management programs that met the industry standard of care, DaVita would have recognized that patients receiving dialysates containing excess acetate experienced much greater adverse effects, including but not limited to heart attacks and strokes." *Id.* at ¶19.

b. "DaVita would have recognized [that] dialysates containing excess acetate cause elevated blood bicarbonate levels and lowered blood potassium levels." *Id.* at ¶20.[1]

[1] Bicarbonate is essentially a buffer that keeps the pH of blood from becoming too acidic or too basic. Serum bicarbonate, a term used frequently in this Order, refers to the level of bicarbonate in the liquid part of the blood. If failing kidneys no longer can eliminate acidity created by diet and physical activity,

c. "It is quite likely that had this active surveillance of cardiac deaths, strokes and myocardial infarctions across all DaVita sites had [sic] been better tracked and more fully investigated DaVita would have identified issues with GranuFlo and NaturaLyte well before the 2012 warning issued by Fresenius and the Class 1 FDA recall."[2] *Id.* at ¶29.

7. In her Reply Declaration, Ms. Youngberg states, based upon a Power Point slide provided to DaVita by Fresenius, "it now appears that DaVita actually knew that GranuFlo was increasing bicarbonate levels across the patient population and thereby dramatically increasing the percentage of patients identified as of 'Alkalosis Concern.'" ECF No. 118-3 at ¶3. When cross-examined about this statement during the hearing, she acknowledged that the Fresenius study referenced in the slide used a serum bicarbonate level above 30 mEq/L (milliequivalents per liter) as an indication of "Alkalosis Concern," and that only 28 of the 4,793 patients (0.6 %) in the Fresenius study rose above 30 mEq/L. Day One Tr. at 162–67. The mean bicarbonate level in the Fresenius patients rose from 22.9 to 23.7 mEq/L, both being within what the study considered to be the desired range. *Id.* at 167–68.

8. In the Reply Declaration Ms. Youngberg also expresses the opinions that, "given the dangers of alkalosis documented by Dr. Borkan and acknowledged by DaVita," under the standard of care DaVita should have taken additional steps "to examine whether the switch to

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dialysis can be used to increase the serum bicarbonate level in order to counter the acidity. There is a physical limit as to the amount of bicarbonate that can be mixed into the solution before it precipitates calcium carbonate. Acetate in the dialysate converts to bicarbonate, thus further increasing the serum bicarbonate level and essentially bypassing the limit of the bicarbonate mixed into the solution. Thus, the acetate is helpful in treating a severely acidotic patient. If the serum bicarbonate level is increased too far, however, the result can be metabolic alkalosis, which is a risk factor for adverse health consequences. One goal of the nephrologist is to prescribe the level of bicarbonate in the dialysate that helps to achieve the proper balance between acidity and alkalinity. *See generally* Day One Tr. at 230–38, 247–48 (testimony of Dr. Borkan).

[2] Fresenius Medical Care North America is the manufacturer of GranuFlo and NaturaLyte. It issued a recall notice in 2012, warning clinicians that high concentration of acetate (the salt of the acid) could lead to high serum bicarbonate levels.

GranuFlo caused an increase in adverse outcomes and/or patient morbidity" and "to reduce bicarbonate in patients with levels that Fresenius's own study identified as in the range of 'Alkalosis Concern.'" *Id.* at ¶¶4–5. However, she has seen no evidence that DaVita has done so.

9. Ms. Youngberg had some experience helping nurses care for end-stage renal disease patients who were receiving peritoneal dialysis or hemodialysis for a few days when she was a student nurse in the mid-1970s. Deposition [ECF No. 127-2] at 35–37. Other than that, she cannot recall receiving any specialized training in nephrology or dialysis. *Id.* at 41.

10. During her deposition Ms. Youngberg appeared to acknowledge that she did not know (and considered it to beyond the scope of her engagement to know) what measures of clinical outcomes of dialysis patients should be tracked. *Id.* at 181–82. She either did not know or indicated that she was not asked to comment on such things as the primary cause of death of dialysis patients, risk factors inherent in dialysis treatment, or who writes dialysis prescriptions. Hearing Transcript, Day Two [ECF No. 153] at 153, 172, 238–39. When asked if she had any evidence that DaVita did not look at its own data, she responded, "Only that they continued to use the GranuFlo and NaturaLyte after Fresenius knew that there was a problem." *Id.* at 141.

11. The FDA recall issued March 29, 2012 did not prohibit the use of GranuFlo or NaturaLyte. As indicated *supra* n.2, the notice reported that the manufacturer was cautioning clinicians to be aware of the concentration of acetate or sodium di-acetate contained in the products, and that inappropriate prescription could lead to a high serum bicarbonate level and, in turn, to metabolic alkalosis, which is a significant risk factor for conditions that might culminate in cardiopulmonary arrest and even death. ECF No. 127-4.

12. In her Declaration Ms. Youngberg states that GranuFlo and NaturaLyte contain sodium acetate that a patient's liver metabolizes into bicarbonate in the hours after dialysis,

which causes blood bicarbonate levels to exceed prescribed levels. ECF No. 109-1 at ¶12. When asked whether her statement was a fact or an assumption, Ms. Youngberg responded that she wasn't asked to comment on the clinical aspect of the case, and that she did not know whether there were differing scientific opinions on that point. ECF No. 127-2 at 131.

13. In its motion DaVita lists a number of examples of what it considers to be Ms. Youngberg's failure to review pertinent records and her lack of knowledge of things that DaVita does to track patient date, improve quality and keep up with relevant literature. ECF No. 127 at 8–10. I have reviewed the cited portions of Ms. Youngberg's deposition. *See* ECF No. 127-2 at 21–24, 142, 178–230. *See also* Day One Tr. at 180–85. One can quibble about the defendant's characterization of some of the examples, but overall, I agree that the testimony demonstrates what appears to be little knowledge of many of the quality control and risk management procedures that DaVita has implemented. *Id.* at 8–10.

14. During her hearing testimony Ms. Youngberg acknowledged that DaVita has written policies and procedures that do address many, if not all, of the quality control, patient safety and risk management practices that she believes a medical institution should have. Her opinions appeared to shift from the absence of appropriate procedures to her opinion that DaVita does not consistently follow (or at least she has not seen evidence that it consistently follows) the written procedures in their manuals. This opinion was based heavily on her interpretation of the deposition testimony of Irina Goykhman, DaVita's Vice President of Clinical Improvement. *See*, *e.g.*, Day One Tr. at 151–52, 158, 185, 189–90, 197, 215, 220. The deposition was taken on November 12, 2014, more than two months after Ms. Youngberg completed her declaration. Ex. 33 at 1.

B. Conclusions.

Ms. Youngberg has substantial and impressive credentials in developing, teaching and implementing quality control and risk management procedures in hospitals. She is well-qualified to be able to evaluate quality control policies and procedures in DaVita's clinics and to express an opinion as to the currency and adequacy of those policies and procedures. Her list of the five features of an effective quality control program could be used to evaluate a particular institution's program. DaVita does not question the reliability of that methodology. It seems eminently reasonable on its face.

However, Ms. Youngberg apparently did not apply her five-point methodology to DaVita's program. She does not, other than in conclusory form, state that DaVita's program lacks those features. To any extent that she did apply her methodology to DaVita, she appears to have missed many policies and procedures documented in DaVita's records that comprise its program. Moreover, when pressed on cross-examination, she did not seem to fault the written policies and procedures. Rather, based on her interpretation of the deposition of DaVita's Vice President of Clinical Improvement, her opinion seems to be that DaVita did not always follow its own policies and procedures. That opinion possibly might have some relevance to the specific issues in this case, but even so, to the extent that failure to follow policies can be shown by the testimony of Ms. Goykhman, this can be put before the jury without the need of expert testimony.

The real substance and focus of Ms. Youngberg's opinions is not a general critique of DaVita's overall quality improvement program, and her discussion of the five-point methodology appears to be largely irrelevant. Rather, as her Declaration shows, to a significant

extent she is expressing opinions requiring special knowledge of nephrology and dialysis. "[A]s long as an expert stays with the reasonable confines of his subject area, . . . a lack of specialization does not affect he admissibility of [the expert] opinion, but only its weight." *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001). The problem here is that Ms. Youngberg's opinions vary widely from the reasonable confines of her expertise.

Ms. Youngberg is not qualified to opine that sodium acetate metabolizes into bicarbonate that causes blood bicarbonate levels to exceed prescribed levels (and as noted above, when asked whether that statement in her Declaration was a fact or an assumption, responded that she was not asked to comment on the clinical aspect of the case). She has not provided any basis for her opinion that if DaVita had better tracked and more fully investigated patient outcomes, it would have recognized that dialysates containing excess acetate cause elevated blood bicarbonate levels and lowered blood potassium levels. She is not qualified to opine, or at a minimum she has not demonstrated that it is within her knowledge of the facts to opine, that better tracking and investigation of strokes and myocardial infarctions across all DaVita sites would have identified issues with GranuFlo and NaturaLyte well before the recall.

In her deposition Ms. Youngberg testified, again and again, that questions that involve special knowledge of nephrology and dialysis were beyond her expertise and the scope of her engagement. It appears to this Court that someone persuaded her to sign a Declaration containing opinions outside her expertise, and if so, she would be well advised not to yield to that temptation in the future. To the extent that her opinions involve questions requiring the expertise of a nephrologist or a dialysis clinician, they plainly are not reliable.

Ms. Youngberg's Reply Declaration did not help. She was apparently given a Fresenius Power Point slide after she issued her original Declaration. Her opinion that the slide showed

"dramatic" increases in the serum bicarbonate levels seems exaggerated in the context of the study on which the slide was based. That, by itself, is a matter easily explored on cross-examination. It is not the Court's role to evaluate the merits of her opinions as such. More problematic, however, is her opinion that "the standard of care required DaVita to immediately take steps to reduce bicarbonate in patients with levels that Fresenius' own study identified as in the range of "Alkalosis Concern." ECF No. 118-3 at ¶5. If that is the standard of care, a nephrologist would have to establish it. A nephrologist or perhaps a dialysis clinician would have the expertise to testify about what steps the clinic could or should take. The statements in the Reply Declaration again appear to indicate that someone has been "putting words in her mouth."

In addition, to the extent Ms. Young is basing her opinions on her interpretation of Ms. Goykhman's testimony, I conclude that the testimony was not timely disclosed, nor would it be helpful to the jury to have her comment on the testimony of another witness.

This is not to say that Ms. Youngberg has nothing of potential relevance to say in this case. As noted later in this Order, Dr. Borkan has expressed the opinion that safe health practices include monthly monitoring of the average blood content of sodium, potassium, calcium and bicarbonate for the entire dialysis population in each center. Borkan Declaration [ECF No. 109-2] at ¶19. Ms. Youngberg appears to have training and experience sufficient to enable her to review DaVita's monitoring practices and procedures; to determine what blood measurements were collected on a monthly basis; to determine whether the data collected revealed any trend in any of the categories of data collected during a specified period of time; and to determine whether there is evidence in DaVita's records concerning actions taken, including reporting or modification of procedures, based upon the data. She also has sufficient

training and experience to determine, based on a review of DaVita's records, what monitoring DaVita did of adverse health events experience by dialysis patients, and whether there appears to be a correlation between blood measurements and an increase in reported adverse health events.

Notwithstanding what her expertise makes her capable of discussing, however, her opinions must also be properly disclosed in compliance with Rule 26 of the Federal Rules of Civil Procedure. Construing her disclosures liberally, and to avoid further wrangling about them, the Court concludes that she may testify (if she can testify) to the following:

1. Her education, training and experience.

2. The DaVita documents she reviewed before she prepared her initial Declaration and before she prepared her Reply Declaration.

3. Based upon review of those documents, the monitoring DaVita did, if any, of the blood bicarbonate and potassium levels of dialysis patients, and whether the monitoring made it possible to distinguish patients who received dialysis solutions containing GranuFlo or NaturaLyte. The relevant period of time is the period of time during which either GranuFlo or NaturaLyte was used in any DaVita clinic.

4. The data generated by such monitoring.

5. The monitoring DaVita did, if any, of serious adverse health events (cardiac arrest, heart attacks, ischemic strokes and death) experienced by dialysis patients during or within 48 hours after a dialysis treatment, and whether the monitoring made it possible to distinguish patients who received dialysis solutions containing GranuFlo or NaturaLyte. The relevant period of time is the period of time during which either GranuFlo or NaturaLyte was used in any DaVita clinic.

6. The data generated by such monitoring.

As I noted above in the Findings section, DaVita has raised a number of questions concerning whether Ms. Youngberg's review of the records was thorough, and whether she has a good understanding of what DaVita actually does to track patient data and to improve patient safety. Those questions can be explored on cross-examination, just as they were during her deposition. They go to the weight but not the admissibility of the testimony.

For the foregoing reasons, DaVita's motion to exclude Ms. Youngberg' opinions is granted in part and denied in part. If plaintiffs wish to use Ms. Youngberg as an expert witness, as limited by this Order, and if DaVita wishes to take another deposition of Ms. Youngberg in order further to explore and pin down her opinions, permission to do so is granted.

STEVEN C. BORKAN, M.D.

As to both Dr. Borkan and Dr. Goldfarb, the Court has reviewed their declarations, portions of their deposition testimony, and their testimony during the April 29-30, 2015 hearing.

Findings.

1. Plaintiffs' nephrology expert, Dr. Steven C. Borkan, is an Associate Professor of Medicine and Associate Director MD in the PhD Program at Boston University School of Medicine. He is a Principal Investigator at the National Institutes of Health, specializing in nephrology. In addition to those responsibilities, he has an active clinical practice. He has privileges and has practiced with approximately 11 or 12 outpatient dialysis units, including DaVita's outpatient clinic in Boston. DaVita does not question his qualifications.

2. Dr. Borkan's opinions, as expressed in his Declaration of September 1, 2014 [ECF No. 109-2] focus on two main issues. The first issue is whether GranuFlo and NaturaLyte cause adverse health effects to dialysis patients, or in his words, "the predictable and avoidable consequences of exposure of hemodialysis patients to excess acetate in the solution employed by

Fresenius and DaVita Hemodialysis Centers." *Id.* at ¶3. The second issue concerns DaVita's monitoring and reporting obligations. His opinions in both areas were further explored during the hearing.

3. Dr. Borkan testified during the first day of the April 29-30, 2015 hearing that by raising the average serum bicarbonate level, GranuFlo is good for many dialysis patients. Day One Tr. at 250; Day Two Tr. at 270, 349-50. He cautioned, however, that while minimizing one risk, metabolic acidosis (low pH), there is a potential risk of metabolic alkalosis (high pH), so that it is important to find the right balance. Day Two Tr. at 270, 349–50. He estimates that one or two percent of the patients whose dialysis treatments included GranuFlo (or NaturaLyte) experienced "arrest in the chair" or heart attacks or ischemic strokes, "a little more" if you include post-dialysis problems. Day One Tr. at 260. He does not argue that GranuFlo or NaturaLyte should be taken off the market, but he suggests that more research is needed to identify the patients for whom those products would be more beneficial than toxic. Day Two Tr. at 351.

4. Dr. Borkan's concern about the risks of the products focuses on patients who present to the dialysis clinic with a higher than average bicarbonate level. For patients of that profile, exposure to the higher acetate levels in GranuFlo or NaturaLyte dialysates (approximately double the typical acetate level in other dialysate products) results in predictable changes in blood composition (metabolic alkalosis) that predisposes them to increased morbidity and mortality. *See* Declaration at ¶4. These products predictably increase the risk of myocardial infarction, ischemic stroke, and even death. *See, e.g., id.* at ¶5; Day One Tr. at 257–59, 261; Day Two Tr. at 271–76.

5. DaVita's motion to exclude Dr. Borkan's testimony is based on its contention that his opinions are "no more than a hypothesis based on attenuated connections of various theories having no specific relation to any data and analysis relevant to the scientific issues in this case, to the specific facts of this action or the medical records of the named Plaintiffs." Motion [ECF No. 127] at 11.

6. Dr. Borkan responds that what DaVita calls a "hypothesis" was based on his "reading of the literature about the potential relationship between sudden and severe metabolic alkalosis in GranuFlo-exposed patients and the increased risk of sudden death." Day Two Tr. at 329. He listed the literature he reviewed for his original and reply declarations. He subsequently reviewed additional medical literature, listed in plaintiffs' Exhibit 35. These materials did not change his opinions. Rather, he testified that the additional materials provided further support for the opinions expressed in his declarations. Day One Tr. at 224–25.

7. During cross-examination, the following exchange occurred:

> Q And your opinion regarding the specific sequence of events that you've discussed in your declarations and under examination by plaintiffs' counsel, that happens after a patient is treated with GranuFlo, starting with elevated serum bicarbonate levels and ending in an increased risk of death or sudden death, that theory is a hypothesis, correct?
>
> A That's correct, supported by substantial data.

Day Two Tr. at 340.

8. On redirect examination he agreed that he had "spent the last two days telling us what data you think supports your hypothesis." *Id.* at 346.

9. Although there was no evidence that Dr. Borkan's hypothesis had been subjected to testing or peer review as such, he testified that he had presented his hypothesis (that "acute, severe metabolic alkalosis can cause cardiopulmonary arrest through the same mechanics as he is expressing in the present case) at a nephrology convention in front of "a thousand of my

colleagues," and not a single person expressed any disagreement. *Id.* at 340. *Accord* Day Two Tr. at 329. He believes that his hypothesis is shared by many others. *Id.* at 348.

10. He explained where there might be controversy among nephrologists and why his hypothesis cannot be tested on dialysis patients:

> Q Is your hypothesis as to what happened to these three plaintiffs a matter of controversy among your professional colleagues?
>
> A I don't believe so, no. And the reason I say that is that even in Dr. Goldfarb's report, which is a—takes the opposite tack, it would be difficult to find a nephrologist who would disagree about the potential toxicities of metabolic alkalosis. Every textbook on metabolic alkalosis contains the same untoward effects on potassium, on calcium, the Bohr effect, on oxygenation, on contractility of the heart and arrhythmia production or susceptibility. These are universally accepted toxicities of metabolic alkalosis.
>
> Q Right. But is there controversy with respect to your theory as to how these people got to there. Let's say everybody realizes and agrees that if you have metabolic alkalosis, it's a bad thing and can be a risky business. But your theory as to how these people got there has to do with elevated bicarbonate levels contributed to by the double dose of acetate in this one particular dialysate which put them into the, ultimately the metabolic alkalosis and they ended up being, three of the minority of patients that have terrible outcomes, is that correct?
>
> A That's correct.
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> Q Is that controversial, in your opinion?
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> A The outcome is not controversial. What is controversial is which one or ones of the untoward effect [sic] was responsible for their death. So the outcome is not controversial.
>
> Q But how they got there might be?
>
> A But how they got there, and the reason there is no specific study is that it would be very difficult to get anyone to agree to allowing [them] to do the study. It would be not considered safe or practical or moral.

Id. at 346–48. Regarding testing, *see also id.* at 321.

11. Turning to monitoring and reporting, Dr. Borkan's Declaration states,

> 19. Safe health practices include monthly monitoring of the average blood content of sodium, potassium, calcium and bicarbonate for the entire dialysis population in each center to ensure rapid and timely detection of unexpected changes in the blood chemistry that increase morbidity and mortality in these susceptible patents. Regular monitoring of key laboratory values by the dialysis

> center using incorrectly manufactured Naturalyte or Granuflo solutions more likely than not would have detected a trend towards elevated blood bicarbonate levels (as well as lower potassium levels) in its patients exposed to a dialysate containing sodium di-acetate, the source of excess acetate.
>
> 20. Once the defect is identified and the clinic recognizes that patients have received more bicarbonate than prescribed, the standard of care and the clinic's obligations to its patients require that patients be informed that NaturaLyte or GranuFlo produced non-prescribed and unanticipated elevated bicarbonate levels that potentially increased their health risks. Doing so permits patients exposed to Naturalyte or Granuflo to consult with their physicians regarding possible negative consequences of prior high bicarbonate levels.
>
> 21. In some cases, this knowledge might significantly affect the course of future treatment including, but not limited to, improved physician and patient recognition of anticipated side effects, enhanced compliance with current medications and therapies, and immediate adjustment in the dialysate chemical composition such that less metabolic alkalosis occurs. Finally, it would permit the patients' physicians to evaluate the patients' adverse health events using all available information and facts, and to properly evaluate, diagnose, and educate their patients regarding events that occurred while excess bicarbonate was being delivered during hemodialysis.

Declaration [ECF No. 109-2] at ¶¶ 19–21.

12. During the hearing Dr. Borkan reiterated that if DaVita had monitored bicarbonate levels across its entire dialysis population, it would have detected the trend of elevated bicarbonate levels following exposure to GranuFlo. Day Two Tr. at 279.

13. He also reiterated that DaVita should have educated nephrologists and patients about the potential risks of GranuFlo and NaturaLyte. Day One Tr. at 264; Day Two Tr. at 276–79.

14. In his Reply Declaration [ECF No. 118-2], Dr. Borkan re-summarizes his opinions, i.e., that (a) substitution of GranuFlo for a dialysate that contains 4 mEq/L acetate will result in the patient's receiving significantly more bicarbonate than prescribed and experiencing higher bicarbonate levels than would have been achieved with standard dialysates; (b) this in turn exposes patients to an increased risk of acute, severe metabolic alkalosis and known, associated medical risks; and (c) it is the responsibility of the dialysis unit, not the prescribing nephrologist,

to insure that the dialysate delivers the prescribed bicarbonate content. *Id.* at 2. Regarding the latter opinion, Dr. Borkan explained that although the physician prescribes the bicarbonate, he is not aware of the acetate content in the dialysate. Day Two Tr. at 312–13.

15. The Reply Declaration also contains Dr. Borkan's comments on several of Dr. Goldfarb's opinions, most of which plaintiffs do not challenge under Rule 702. He does express the opinion that Dr. Goldfarb's analysis of individual patient lab values is unsound, because Dr. Goldfarb did not (and could not) compare bicarbonate levels before and after GranuFlo exposure. *Id.* at ¶19. However, Dr. Borkan has not examined the medical records of the three named plaintiffs, and he has not developed opinions regarding their specific cases. Day Two Tr. at 352.

B. Conclusions.

Dr. Borkan's testimony is plainly relevant. The jury needs experts in the field of nephrology and dialysis to explain the medicine and whether and how the challenged products might cause serious adverse health effects in certain dialysis patients.

Dr. Borkan's testimony also meets the reliability requirement of Rule 702. There is no question about his credentials and qualifications as a clinician, a professor, and an investigator for the National Institutes of Health. His theory of causation can be labeled an hypothesis. However, the reason it cannot be tested as such has been explained. A physician cannot easily test a theory as to how a dialysate can cause serious adverse health effects on actual patients. However, Dr. Borkan testified that there is support for the theory in data and in medical literature. He denies that his theory is controversial among his professional colleagues, perhaps evidenced to some extent by the absence of any expression of disagreement when he presented it at a convention of nephrologists. This is not junk science. Rather, it is an opinion that should be

heard, subject of course to cross-examination and to the opinions of DaVita's equally well qualified nephrologist, Dr. Goldfarb.

STANLEY GOLDFARB, M.D.

A. Findings.

1. DaVita's nephrology expert, Dr. Stanley Goldfarb, is a Professor of Medicine and Associate Dean at the Perelman School of Medicine at the University of Pennsylvania. His CV lists numerous academic appointments and memberships in national committees in the field of nephrology. Like Dr. Borkan, Dr. Goldfarb also has significant clinical experience. He has done a great deal of research and has written and lectured extensively in his field. Plaintiffs do not question his qualifications.

2. Dr. Goldfarb's opinions, as summarized in his Declaration of October 28, 2014 [ECF No. 112-8], can be broken down into three topics: (1) the medical standards of care in providing hemodialysis treatment to patients; (2) the medical condition of the named plaintiffs; and (3) his analysis of Dr. Borkan's opinions.

3. Plaintiffs here challenge only that part of Dr. Goldfarb's opinions addressing specific causation for each named plaintiff. They argue that he used unreliable methods to advance opinions favorable to his client. Motion to Exclude [ECF No. 129] at 2.

4. This case is the consolidation of six original cases. Initially there were more than a dozen named plaintiffs. Determining whether each individual was treated with a dialysate containing GranuFlo or NaturaLyte took some time, and ultimately it was determined that the majority of the named plaintiffs were not treated with either product. When Dr. Goldfarb's Declaration was prepared the list was down to five individuals. Since then the list of named

plaintiffs has been further reduced. The individuals who have been determined to have been treated with GranuFlo or NaturaLyte are Doris Morris, Tony Armstrong, and Stella Nunes.

5. Based upon his review of medical records, Dr. Goldfarb has the following opinions regarding the three named plaintiffs:

a. Doris Morris (dob August 27, 1952) began chronic dialysis treatment in February 2010. She experienced chest pain on April 8, 2012, approximately 48 hours after receiving dialysis treatment. The next day she was diagnosed in the ER with acute systolic heart failure, pulmonary edema secondary to [a] combination of hypertensive and ischemic heart disease, and acute coronary syndrome/non-ST segment elevation myocardial infarction. Dr. Goldberg lists multiple risk factors for coronary artery disease, including hypertension, diabetes, and the fact that she smoked five packs of cigarettes daily for 20-40 years. ECF No. 112-8 at ¶¶32–33.

Between July 8, 2009 and May 30, 2014 Ms. Morris's serum bicarbonate level was measured on 77 different occasions, fluctuating between 19 mEq/L and 35 mEq/L. When she was admitted to the hospital on April 9, 2012 her serum bicarbonate level was 33 mEq/L. ECF No. 112-8 at 9–10. Dr. Goldfarb states, "In my medical opinion, Ms. Morris's lab values do not reflect a consistent trend towards elevated bicarbonate levels nor do they demonstrate a patterned decrease in total blood calcium or blood potassium levels." *Id.* at ¶34.

However, Dr. Goldfarb acknowledges that Ms. Morris' bicarbonate levels were higher when she came in with her episode of chest pain that they had been before. Day Two Tr. at 395. He attributes this to the report that she had vomited on the way to the hospital and had been vomiting for the past week or so. *Id.* at 395–96.

b. Tony Armstrong (dob January 3, 1963) began chronic dialysis treatment in May 2009. In his Declaration Dr. Goldfarb states that Mr. Armstrong is alleged to have experienced an

adverse cardiac event on August 15, 2011. *Id.* at ¶45. He states that there are no medical records documenting this. There are records indicating that Mr. Armstrong was admitted to the hospital on at least eight occasions between June 2011 and February 2014 complaining of shortness of breath and chest pain. No specific cardiac event was documented in his records, but he had a history including myocardial infarctions, chest pain, coronary artery calcifications and smoking, among other things. *Id.* at ¶44–45.

The relevance of that part of his Declaration was called into question by defense counsel's suggestion at the hearing, to which Dr. Goldfarb agreed, that the date was September 11, 2010. Day Two Tr. at 391. Apparently he needs to re-examine the medical records and verify the relevant dates.

Dr. Goldfarb relates that the medical records indicate that Mr. Armstrong's symptoms "were most often attributed to fluid overload, non-compliance with dialysis treatment, and drug use." ECF No. 112-8 at ¶45. His records between April 22, 2009 and May 20, 2014 include 115 separate lab values measuring his serum bicarbonate levels. The levels fluctuated between 16.8 mEq/L and 38 mEq/L, and during August 2011 fluctuated between 23 and 25 mEq/L. *Id.* at ¶46.[3] Dr. Goldberg states, "In my medical opinion, Mr. Armstrong's lab values do not reflect a consistent trend towards elevated bicarbonate levels nor do they demonstrate a patterned decrease in total blood calcium or blood potassium levels. Mr. Armstrong's potassium levels were repeatedly noted to be abnormally high." *Id.* at ¶46–47.

c. Estella (Stella) Nunes (dob May 23, 1936) began chronic dialysis treatment in September 2007. On December 26, 2011 she became hypotensive and non-responsive during dialysis, which was stopped after five minutes of treatment. She was transported to an

[3] During the hearing Dr. Goldfarb recalled that Mr. Armstrong's predialysis serum bicarbonate level on the date of his cardiac event was 27, perhaps again reflecting confusion about the date.

emergency room where she was diagnosed with bradycardia and acute inferior wall myocardial infarction. Her potassium level was elevated. She underwent cardiac catheterization and placement of a pacemaker. However, the next day she experienced ventricular fibrillation and died. *Id.* at ¶¶40–41.

Records between August 31, 2007 and December 27, 2011 include 63 separate lab values measuring Ms. Nunes serum bicarbonate levels. Her levels fluctuated between 13 mEq/L and 38 mEq/L. Upon her hospital admission on December 26, 2011 her serum bicarbonate level was 27 mEq/L. Dr. Goldfarb states, "In my medical opinion, Ms. Nunes' lab values do not reflect a consistent trend towards elevated bicarbonate levels nor do they demonstrate a patterned decrease in total blood calcium or blood potassium levels." *Id.* at ¶43.

During the hearing he added, or clarified, that her bicarbonate level was irrelevant, because "[n]o one would propose that over five minutes, there's a substantial change of her bicarbonate level from baseline." Day Two Tr. at 382. While commenting on Ms. Nunes' case, Dr. Goldfarb explained (possibly in response to Dr. Borkan's argument that Dr. Goldfarb could not compare bicarbonate levels before and after GranuFlo exposure) how bicarbonate levels can be back-calculated to the time of her arrest. *Id.* at 383–84. His back-calculation supported his conclusion that nothing in the dialysis other than the fact that dialysis is stressful to the patient contributed to her episode. *Id.*

6. During the hearing Dr. Goldfarb summarized, "you cannot attribute the problems that these three patients faced to metabolic alkalosis or to really anything associated with acute dialysis treatment because their difficulties arose distant from that event or in the absence of metabolic alkalosis attributing to dialysis." Day Two Tr. at 397.

7. In their motion to exclude this patient-specific testimony, plaintiffs note that as to each of the three patients, Dr. Goldfarb's opinions are similar—after noting the cardiac event and reciting the patient's medical history, Dr. Goldfarb expresses the opinions that the patient's including serum bicarbonate measurements do not reflect a trend towards elevated bicarbonate levels or a patterned decrease in total blood calcium or blood potassium levels. ECF No. 129 at 2–3.

8. Plaintiffs argue that these opinions are inadmissible for three reasons:

a. They are irrelevant, because plaintiffs do not contend that GranuFlo causes patients' bicarbonate levels continuously to trend upwards or potassium and calcium levels continuously to trend downwards. Moreover, in his deposition Dr. Goldfarb admitted that the fact that one patient's personal bicarbonate levels did not trend over time did not tell him anything about the effect of GranuFlo on bicarbonate levels.

b. Dr. Goldfarb does not know when or how often each of these patients was dialyzed with GranuFlo and therefore cannot know the effects of GranuFlo on the patient.

c. Dr. Goldfarb cannot testify about whether GranuFlo (by extension alkalosis) could cause these patients' cardiac events because, as he has admitted, serum bicarbonate values taken after the patient's cardiac event are not indicative of serum bicarbonate values before the cardiac event. Because Dr. Goldfarb has admitted that he cannot determine whether a patient was alkalotic before the cardiac event, any conclusions he draws from the post-event bicarbonate levels are unreliable. *Id.* at 3–6.

9. In response DaVita states:

a. Dr. Goldfarb noted the absence of trends in the three named plaintiffs' serum bicarbonate levels in response to plaintiffs' argument that DaVita knew or should have known

that its patients' aggregate serum bicarbonate levels were elevated or gradually increasing. *See* ECF No. 143 at 3–6.

b. Dr. Goldfarb's observations about these three patients support his opinions that the effect of GranuFlo on patients' serum bicarbonate levels is not what plaintiffs and their expert claim it to be. Under plaintiffs' theory, there should have been a correlation between severely elevated bicarbonate levels as a surrogate for pH and the cardiac event, but there was not in these three cases. Absent evidence of a correlation, Dr. Goldfarb reasonably concluded that the use of GranuFlo as a dialysate in the treatment of these three patients did not contribute to their cardiac events. *See Id.* at 7–8.

c. The alleged shortcomings in Dr. Goldfarb's knowledge (did not know when or how often the patients were treated with GranuFlo; the lab values did not include the patients' serum bicarbonate levels immediately prior to the cardiac event) can be explored on cross-examination. *Id.* at 8–9.

B. <u>Conclusions</u>.

Dr. Goldfarb's analysis of the three named plaintiffs' medical records and his opinion as to whether their cardiac events resulted from other risk factors and not the dialysate used in their treatment is relevant, as this is a threshold issue that the jury will have to consider before they can determine whether DaVita's failure to monitor the patients properly was a cause of their cardiac events. Dr. Goldfarb is a highly trained and experienced specialist in nephrology, and his credentials have not been questioned. He is qualified to review the named plaintiffs' medical records and to express opinions as to the probable cause or causes of their cardiac events, including whether the dialysate is or is not a likely contributing cause.

The plaintiffs' nephrology expert, Dr. Borkan, has not yet examined the medical records of the three named plaintiffs, putting the plaintiffs in a weaker position to challenge the analysis of those records by Dr. Goldfarb. The fact that Dr. Goldfarb did not know when or how often these patients were treated with GranuFlo or what their serum bicarbonate levels were immediately prior to the cardiac events goes the weight of the testimony, not whether the testimony is admissible under Rule 702. *Id.* at 8–9.

The Court concludes that Dr. Goldfarb's opinions based upon the medical records of the three named plaintiffs are admissible. There is no basis under Rule 702 or *Daubert* to exclude them.

ORDER

1. Defendant's motion to exclude testimony and opinions [ECF No. 128] is GRANTED IN PART AND DENIED IN PART. It is granted as to Ms. Youngberg's purported opinions that concern matters of nephrology and dialysis, as indicated in this Order. It is denied as to Ms. Youngberg's opinions on the narrow subjects identified in this Order as to which she is qualified to express her opinion. It is denied as it applies to Dr. Borkan.

2. Plaintiffs' motion to strike portions of Dr. Goldberg's declaration and testimony [ECF No. 130] is DENIED.

DATED this 28th day of May, 2015.

BY THE COURT:

R. Brooke Jackson
United States District Judge