UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: GADOLINIUM-BASED CONTRAST AGENTS PRODUCTS LIABILITY LITIGATION	)	**Case No. 1:08 GD 50000**
	)	**MDL No. 1909**
	)	
	)	**Judge Dan Aaron Polster**
	)	
	)	**MEMORANDUM OF OPINION AND ORDER**
	)	

THIS DOCUMENT APPLIES TO ALL CASES

Currently pending in this multi-district litigation ("MDL") is GE Healthcare's Motion to Reconsider Aspects of the May 4, 2010 Order on Generic Daubert Motions or, in the Alternative, to Certify the Issues Presented for Appeal under 28 U.S.C. § 1292(b) ("Motion to Reconsider") (**Doc #: 796**). The Court has reviewed the Motion, the Plaintiffs' Steering Committee's Memorandum of Law in Opposition etc. (Doc #: 805), and the Reply in Support of GE Healthcare's ("GEHC") Motion to Reconsider etc. (Doc. #: 808), the attachments and the record. For the reasons to follow, the Court **GRANTS** the Motion to Reconsider (**Doc #: 796**).

Having engaged in extensive reconsideration of the challenged rulings in the May 4, 2010 Order (or "the underlying Order"), the Court declines to change its rulings with one exception. The Court will modify its ruling regarding Dr. Waymack to the extent explained herein.

Furthermore, because the briefs and the Court's review were comprehensive, the Court finds that there is no need for oral argument and hereby **DENIES** GE Healthcare's Motion for Oral Argument Regarding its Motion to Reconsider etc. (**Doc #: 797**).

I.

Motions for reconsideration are " 'extraordinary in nature and, because they run contrary to notions of finality and repose, should be discouraged.' " *Plaskon Elec. Materials, Inc. v. Allied-Signal, Inc.*, 904 F.Supp. 644, 669 (N.D. Ohio 1995) (quoting *In Re August, 1993 Regular Grand Jury*, 854 F.Supp. 1403, 1406 (S.D. Ind. 1994). "As such, motions for reconsideration are granted 'very sparingly.'" *Plaskon*, 904 F.Supp. at 669 (quoting *Bakari v. Beyer*, 870 F.Supp. 85, 88 (D. N.J. 1994)). Generally, the factors that justify reconsideration of a court's orders are: an intervening change in controlling law, the availability of new evidence, and the need to correct clear error or to prevent manifest injustice. *Plaskon*, 904 F.Supp. at 669 (quoting *Bermingham v. Sony Corp. of Am., Inc.*, 820 F.Supp. 834, 856 (D.N.J.1992), *aff'd*, 37 F.3d 1485 (3rd Cir. 1993). As District Judge Katz has stated:

> Motions for reconsideration are not substitutes for appeal nor are they vehicles whereby a party may present arguments inexplicably omitted in prior proceedings. *Karr v. Castle*, 768 F.Supp. 1087, 1093 (D. Del. 1991), *aff'd sub nom.* 22 F.3d 303 (3rd Cir. 1994), *cert. denied sub nom.*, 513 U.S. 1084 (1995). "A party seeking reconsideration must show more than a disagreement with the Court's decision, and 'recapitulation of the cases and arguments considered by the court before rendering its original decision fails to carry the moving party's burden.'" *Database America, Inc., v. Bellsouth Advertising & Pub. Corp.*, 825 F.Supp. 1216, 1220 (D.N.J. 1993), citing *G-69 v. Degnan*, 748 F.Supp. 274, 275 (D.N.J. 1990).

Plaskon, 904 F.Supp. at 669.

II.

A.

Although GEHC purports to ask the Court to reconsider aspects of its May 4 Order, it in fact challenges every ruling by this Court that resulted in the partial or wholesale exclusion of the testimony or opinions of GEHC's expert witnesses. Generally speaking, GEHC claims that

the Court treated similar experts on opposite sides differently and to GEHC's disadvantage, and that the Court essentially failed in carrying out its role as gatekeeper. In its reply brief, GEHC argues that the these alleged inconsistencies constitute clear error that will produce manifest injustice if not corrected prior to trial.

In fact, the Court went to great lengths to assess the qualifications and methodology of each and every expert that was challenged regardless of which side retained that expert's services, as addressed in detail in the sixty-page May 4 Order. The Court spent ten pages explaining why it would allow Plaintiffs' experts to testify regarding the free (or dechelated) gadolinium theory, a theory that reasonably attempts to explain what happens to the not-insignificant amount of chelated gadolinium (here, Omniscan) that is injected into severely renally impaired persons, is never excreted, and is later found in one form or another in the biopsies of NSF patients. Since it is beyond dispute that gadolinium is not a trace element normally found in the body, and that gadolinium is highly toxic to humans, most researchers (including research scientists employed or retained by GEHC) believe that the gadolinium becomes unbound from its ligand during its prolonged retention time in renal patients where it, either alone or newly bound to other substances, may trigger the process leading to NSF.

GEHC did not dispute any of the factual assertions made by the Court in arriving at its decision to allow Plaintiffs' experts to testify about this theory which, as GEHC experts Drs. Newton and Waymack acknowledge, is the prevailing theory on NSF causation. Since it is also undisputed that the incidence of NSF rose and fell with the administration of GBCAs to renally compromised persons, the association between gadolinium-based contrast agents, severe renal impairment and NSF is virtually inescapable – although the precise mechanism of NSF is not yet

known. As such, it would have been a misapplication of this Court's gatekeeper duties to exclude the testimony of experts on a theory that has been the subject of research conducted for the past twenty years by independent scientists whose work has been peer-reviewed and by scientists employed or retained by GEHC.

The only other theory on this subject is offered by Dr. Newton, an employee of GEHC whom GEHC chose to designate as an expert on the subject of NSF causation. Plaintiffs asked the Court to exclude wholesale the testimony and opinions expressed by Dr. Newton on the basis that, prior to 2007, he admittedly had no knowledge, expertise or experience studying gadolinium-based contrast agents or NSF. It was not until after the first Omniscan product liability suits were filed that GEHC asked Dr. Newton to head up research on the mechanism of NSF.

The record shows that, at the time Dr. Newton was given the task of researching the mechanism of NSF, he already understood that more reported NSF cases were associated with Omniscan than other GBCAs. (See Doc #: 737-1, Newton Dep., at 82-85.) Armed with this understanding, Dr. Newton commenced reviewing the vast landscape of literature and GEHC's own studies which reflect, in significant part, the instability of certain GBCAs (including Omniscan or gadodiamide), and the prolonged residence time of GBCAs in the severely renally impaired. (Id. at 71-82.) Dr. Newton focused his research on whether GBCAs in general were really as inert as GEHC, and every other GBCA manufacturer, thought they were. (Id. at 81.) He furthered the research reflected in a handful of studies suggesting that chelated (rather than dechelated or free) gadolinium may trigger at a cellular level the fibrotic process leading to NSF. Although this opinion appears to be a distinction without a difference, it does critique the free

gadolinium theory and the allegation that Omniscan is more likely than other GBCAs to cause NSF because it is less stable and more prone to dechelation. According to Dr. Newton's deposition testimony, GEHC appears to fund most of the research currently conducted on this subject. (See Doc #: 737-1, Newton Dep., at 86-97.) Despite the red flags attending Dr. Newton's opinions on this theory, the Court overruled the PSC's objections and permitted GEHC to use Dr. Newton and this research to challenge the free gadolinium theory.

While the Court allowed Dr. Newton to opine on NSF causation generally, it precluded him from opining that dechelated gadolinium does not cause NSF on the basis that NSF has occurred in the absence of GBCA exposure. The Court precluded this opinion because it is based on the Collidge and Wahba studies, neither of which definitively confirmed the lack of exposure to GBCAs.

The purpose of the Collidge study was to compare the frequency and cumulative dose of GBCAs in dialysis-dependent patients who did, and did not, develop NSF. (*See generally* Collidge, et al., *Gadolinium-Enhanced MR Imaging and Nephrogenic Systemic Fibrosis: Retrospective Study of a Renal Replacement Therapy Cohort*, RADIOLOGY 245:1, October 2007.) The authors performed a retrospective study of adult patients undergoing dialysis in two teaching hospitals in west Scotland between January 1, 2000 and July 1, 2006. They reviewed electronic patient records in those hospitals and their satellite facilities for NSF diagnoses, MRI scans and GBCA dosage. They found fourteen patients who were diagnosed with NSF, thirteen of whom were exposed to multiple MRIs all of which were enhanced with Omniscan. The authors were unable to find GBCA exposure in the records of the fourteenth patient. Based on this retroactive study, the authors confirmed a positive association between Omniscan-enhanced

MRIs and the development of NSF in this patient population. They found that NSF patients were exposed to significantly higher doses of Omniscan than their non-NSF counterparts, and that NSF patients were exposed to more Omniscan-enhanced MRIs than non-NSF patients. The authors noted that the incidence of NSF rose with the use of MRIs in this patient population, that many centers worldwide had accepted the link between GBCAs and NSF and had reasonably changed their practice of administering GBCAs to this patient population prior to fulfillment of the Koch postulates of causation.

Dr. Newton amazingly relies on this study for the proposition that NSF occurs in the absence of GBCAs, based on the one patient for whom the authors were unable to find gadolinium exposure. The authors conducted a retroactive review of the medical history of this patient, but were unable to question her (presumably, about her care at other facilities or other possible scans) because she died three months after contracting NSF.

This MDL shows how difficult it is to track down gadolinium-enhanced scans even when the NSF patient is still able to be questioned. We have also learned that records at many facilities do not reveal whether a contrast agent was used or the type of contrast. Thus, plaintiffs' lawyers often must question not only their clients but their clients' families. They must also subpoena the records of, and depose, a multitude of treating physicians, radiologists, healthcare facilities, GBCA manufacturers and members of their sales force in order to discover gadolinium-enhanced scans and/or the identity of the GBCA manufacturer. Because these patients have a multitude of medical issues, it is common for a given patient to have many scans over many years at numerous facilities. Further, many of the records are archived at different locations, making their discovery that much more difficult and time-consuming. As such, some

scans are not discovered, nor the product identified, until well over a year after they are sought. In short, the process of locating gadolinium-enhanced scans is labor-intensive, even when conducted by plaintiffs' lawyers motivated by the possibility of significant financial reward.

In addition to the problems attending the retroactive, posthumous review of an NSF patient's medical records, the Collidge study notes that this allegedly gadolinium-naive patient's NSF was supported by a biopsy but neglects to say whether the biopsy contained gadolinium. The authors did not state whether they checked this patient's records for other types of scans where a GBCA may have been used. Under these circumstances, the Court reasonably precluded Dr. Newton from relying on the Collidge study to support the proposition that NSF occurs in the absence of exposure to GBCAs.

The purpose of the Wahba study was to show that exposure to GBCAs is not the only trigger for NSF. (*See generally* Wahba, et al., *Gadolinium is not the Only Trigger for Nephrogenic Systemic Fibrosis: Insights for Two Cases and a Review of the Recent Medical Literature.* AMERICAN JOURNAL OF TRANSPLANTATION 2007 Vol. 7:1-8.) The authors reported two case studies of organ transplant recipients who developed NSF and in whom extensive record review failed to document any prior gadolinium exposure. The authors stated that they had obtained records from all hospitals and outpatient facilities where the patients had received medical care and failed to find any test, scan, or procedure where the patients were exposed to gadolinium. The authors concluded that, while they still believed gadolinium is a risk factor for NSF development, it is not the only risk factor. They suggested that further studies are needed to confirm the association between gadolinium exposure and NSF, and that scientists should search for triggers of NSF beyond GBCAs.

This study, unlike the Collidge study, directly addresses the question of whether NSF occurs in the absence of GBCAs. The two patients in the study had lifelong histories of medical problems predating their transplants. Although the authors went to great lengths to find gadolinium exposure, they were unable to do so. However, as noted above, finding gadolinium-enhanced scans for patients with extensive medical records from a multitude of treating physicians and healthcare facilities is a daunting task.[1] It is noteworthy that the authors did not report whether the patients' NSF biopsies contained gadolinium. And, although the purpose of the study was to determine whether NSF occurs in the absence of GBCAs, the study, published one month after the FDA requested black box warnings be placed on all labels, necessarily fails to take into consideration the fact that no new cases of NSF have been reported since shortly after the warnings appeared on GBCA labels. As GEHC expert, Dr. Waikar, testified, population dechallenge (i.e., withdrawal of a drug from a patient population accompanied by the disappearance of adverse effects) is strong evidence of a link between that drug and the adverse event. (See Doc #: 737-4, Waikar Dep., at 440-41.) Under the circumstances, the Court properly precluded Dr. Newton from using this report to definitively show that NSF occurs in the absence of GBCA exposure.

GEHC criticizes the Court for unfairly applying greater scrutiny to Dr. Newton's opinions and testimony than it did to Plaintiffs' regulatory experts, Drs. Parisian and Plunkett. GEHC claims that they are professional expert witnesses who never researched NSF until they were retained to be experts in this litigation.

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[1]At deposition, GE's expert, Dr. Waikar, agreed that in every case of NSF where there is no known exposure to a GBCA, the only thing you can say with certainty is that there's no known exposure to a GBCA. (Doc #: 737-4, Waikar Dep., at 406 (emphasis added).)

The Court reviewed individually the reports and depositions of every challenged expert, including Drs. Newton, Parisian and Plunkett, and determined whether they were qualified to opine on certain matters and whether the Court should limit their testimony based on their methodology. Unlike Dr. Newton, Dr. Parisian is a regulatory expert with a pathology background. Specifically, Dr. Parisian is a clinical and anatomical pathologist who has performed well over 200 risk assessments as an FDA medical officer and has, among many other things, authored a reference book on the history and regulations of the FDA. The Court allowed Dr. Parisian to testify about the regulatory approval process and post-marketing surveillance obligations, subjects on which she is qualified to testify. The Court precluded her from providing a narrative history of Omniscan which must be presented through direct evidence, or from testifying about GE's knowledge, motivations, intentions or purposes. The Court allowed her to testify about GE's compliance with regulations based on internal reports, studies and regulatory filings only to the extent they are relevant to compliance issues and specialized knowledge is required to assess them. If specialized knowledge is not required to assess them, there is no need for expert testimony. The Court has reviewed the cases cited by GEHC wherein courts criticized Dr. Parisian's testimony, and found that those courts failed to properly limit her trial testimony. *See, e.g., In re Prempro Prod. Liab. Liti.*, 554 F.Supp.2d 871 (E.D.Ark. 2008). This Court is satisfied that it can properly limit Dr. Parisian's trial testimony. GEHC is free to challenge her credibility on cross-examination on the basis that she is an alleged witness-for-hire.

Also unlike Dr. Newton, Dr. Plunkett is a board-certified pharmacologist and toxicologist and a regulatory consultant who the Court determined was qualified to testify regarding

pharmacology, toxicology and regulatory matters. In addition, Dr. Plunkett actually performed a risk assessment of GBCAs in the early 1990s. GEHC did not challenge her qualifications to interpret toxicology and pharmacology studies, and the Court properly excluded her from opining broadly that Omniscan should have been contraindicated in patients with significant renal impairment as early as 1996. The Court did, however, allow her to testify, based on evidence presented at trial, on the accuracy and adequacy of the toxicology, pharmacology and pharmacokinetics data appearing on the Omniscan label at the time it was administered to the plaintiffs. Again, the Court is satisfied that it can properly limit Dr. Plunkett's trial testimony if necessary, and GEHC may challenge her credibility on cross-examination on the basis that she is a "professional" witness.

The fact that Drs. Parisian and Plunkett were not hired until after this MDL commenced is of no moment since regulatory experts are not typically retained as expert witnesses until well into the discovery period in a civil or criminal case. In contrast, Dr. Newton had no background or expertise on GBCAs or NSF prior to commencement of this litigation and now claims to be an expert on NSF causation. At the time the Court issued the underlying Order, Dr. Newton had published only one article reflecting the research of other scientists on a subject that had been the topic of limited research, which research appears to be currently funded primarily by GE. Under the circumstances, it was perfectly appropriate for the Court to apply greater scrutiny to Dr. Newton's opinions generally.

Finally, the Court finds that it adequately explained its reasons in the underlying Order for precluding Dr. Newton from testifying that evidence of Omniscan instability *in vitro* does not indicate Omniscan's *in vivo* instability; that rat studies (such as the Hazelton studies) do not

provide a predictive model of NSF in humans; or to opine on the histology of lesions in rats versus humans. Upon reconsideration of Dr. Newton's expert report and particularly his deposition testimony, the Court declines to change these rulings.

B.

1.

In the Motion to Reconsider, GEHC argues that the Court inconsistently allows the Plaintiffs' experts to use AERs as proof that Omniscan carries a higher risk for NSF than other GBCAs on the market and that GEHC missed a signal for NSF before 2006, but precludes GEHC's experts from testifying that the symptoms described in these AERs did not constitute signs of NSF. The Court finds that GEHC has mischaracterized the Court's rulings and disagrees that there was any inconsistency.

The Court excluded the generic testimony of Dr. Gaspari, a board-certified dermatologist, on NSF diagnosis and his medical analysis of four adverse event reports ("AERs"). Specifically, the Court explained:

> Dr. Gaspari's generic expert report discusses the history of NSF, how it is diagnosed, the differential diagnosis, complicating factors in diagnosing NSF, and an analysis of four Adverse Event Reports received by GEHC. The testimony concerning NSF diagnosis shall not be permitted because it is irrelevant and does not assist the trier of fact. To the extent that GEHC disputes that any of the plaintiffs in the four bellwether trials has NSF, it will need to offer a case-specific expert, who has examined the plaintiff and reached a conclusion on that plaintiff's NSF diagnosis. If there is no challenge to a given plaintiff's NSF diagnosis, generic expert testimony about various NSF diagnostic issues is not relevant. A generic expert testifying at length about how NSF is diagnosed and how other conditions, such as diabetes, complicates NSF diagnosis is not relevant unless the particular plaintiff has diabetes and a case-specific expert testifies that the plaintiff does not have NSF. In that case, the generic expert's testimony would be superfluous.

> Moreover, Dr. Gaspari may not draw conclusions from the four Adverse Event Reports received by GEHC that GEHC was unaware of Omniscan's potential risks. In his generic expert report, Dr. Gaspari examines four Adverse Event Reports received by GEHC between April 2002 and July 2005 and concludes that the data did not support a diagnosis of NSF in any of these cases and therefore that they did not offer "a compelling, consistent clinical history to alert GE Healthcare to the presence of any association between Omniscan and NFD/NSF." (Doc #: 736-5, at 18.) As observed by Plaintiffs, Dr. Gaspari only examined four Adverse Event Reports and was not provided any preclinical or animal studies conducted by GEHC, any medical literature, or any other relevant data GEHC had at its disposal. Adverse Event Reports examined in a vacuum have significant limitations and are therefore only useful when assessed in the context of other available date. *See* Adverse Event Reports Discussion, Sec. III (B), *supra*. Accordingly, Dr. Gaspari's conclusions are based on incomplete information and therefore do not satisfy the Federal Rule of Civil Evidence 702 requirement that expert testimony be based on sufficient facts or data.

(Doc #: 788, at 53-54.) The Court pointed out that a case specific expert (such as Dr. Gaspari) who opines that a particular plaintiff does not have NSF could, of course, give the basis for his conclusion, which could include an explanation of the difficulty in diagnosing NSF and how other conditions that plaintiff suffers from has complicated the diagnosis. (Id. at 54 n. 2.)

The record shows that Dr. Gaspari submitted an expert report, the primary purpose of which was to review the four AERs and "determine whether there was any consistency in [these] reports to suggest that exposures to gadolinium based contrast agents (GBCA) resulted in NFD/NSF." (Doc #: 736-5, at 5.) The report included preliminary information about the history of NSF and the difficulties associated with diagnosing it. This information formed the basis for his conclusion that the AERs did not support a clinical diagnosis of NSF. At deposition, Dr. Gaspari made clear that the purpose for this conclusion was to show that the four AERs did not give rise to a "safety signal of NSF." (Id. at 134.) The Court properly excluded this testimony.

The question of whether these AERs constituted a safety signal requires someone with expertise in pharmacovigilance. The expert must determine whether, given all the information

available to GEHC at the time, the AERs gave rise to a safety signal alerting GEHC to the risks associated with administering Omniscan, particularly to the renally impaired.[2] Hence, whether the four AERs supported a clinical diagnosis of NSF is irrelevant to the question of whether the AERs constituted a safety signal.

Dr. Gaspari's deposition testimony makes clear that he is not an expert in pharmacovigilance. (See, e.g., Doc #: 737-12, Gaspari Dep., at 81-87.) He repeatedly testified that his sole assignment was to review, as a dermatologist, the four AERs and the followup information that was given to him by GE, and to determine whether there were any consistencies or inconsistencies between those AERs, and whether they supported a clinical diagnosis of NSF. (See, e.g., id. at 51, 52, 77, 80, 93, 94.)

Furthermore, his report and deposition answers showed that he arrived at his "safety signal" conclusion without reviewing all the information GEHC had available to it at the time, including epidemiological studies (id. at 51-52), relevant GEHC internal documents (id. at 79-80), GE's *in vivo*, *in vitro* and human studies reflecting GEHC's knowledge regarding gadolinium toxicity (id. at 130-132, 155-163), clinical and preclinical data (id. at 93-94, 145), and the Omniscan label for safety information (id. at 111-115). Rather, he looked only at the information in the AERs and limited followup information given to him by GEHC in opining whether the AERs constituted a safety signal.

Likewise, the Court properly precluded Dr. Waikar, a board-certified nephrologist, from testifying about the difficulty of diagnosing NSF in the four AERs and whether they constituted

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[2]Dr. Gaspari admitted that the patients in the four AERs all had advanced renal insufficiency. (See, e.g., Doc #: 737-12, Gaspari Dep., at 110.)

safety signals. The Court did so because Dr. Waikar admitted that he has no expertise in pharmacovigilance and is unaware of any further investigation responsibilities a drug manufacturer may have upon receiving AERs. (Doc #: 737-4, Waikar Dep., at 327-348.) His deposition testimony also made clear that he did not review any of the relevant internal or external information GEHC had available to it at the time the AERs were reported in determining whether they constituted a safety signal.

In contrast, a review of the reports of Plaintiffs' regulatory experts shows that they expressed opinions about whether the AERs constituted safety signals only after reviewing and discussing in detail the vast amount of internal and external information available to GEHC at the time of those reports, which background provided context for their opinions.

2.

GEHC also argues that the Court unfairly excluded the AER testimony of Drs. Gaspari and Waikar on NSF diagnoses while allowing Plaintiffs' experts to opine on comparable risk using AERs. This is a comparison of apples to oranges.

In the May 4 Order, the Court stated that it had reviewed the reports of Plaintiffs' challenged experts and their reasons for opining that Omniscan posed a higher risk of causing NSF than the other GBCAs. The Court found that AERs provided only one of numerous bases for their conclusions. The Order further observed that the Plaintiffs' experts used the same data and methodology utilized by the FDA's Office of Surveillance and Epidemiology when investigating the relative risk of GBCAs and concluding that the highest risk of NSF was associated with Omniscan, Magnevist, and Optimark – satisfying the *Daubert* reliability component. The Court ruled that it would not permit any expert to opine that Omniscan carries a

higher risk of causing NSF than other GBCAs based on AERs alone, and that GEHC was free to cross-examine Plaintiffs' experts on their use of AERs as one of several factors in determining comparative risk. The Court stands by this ruling.

3.

GEHC challenges the Court's ruling precluding Dr. Waikar from testifying that NSF has occurred in the absence of GBCA exposure. The Court properly excluded this testimony because it was based on the Wahba and Collidge studies – the same ones upon which Dr. Newton relied for the same proposition. The Court has again reviewed Dr. Waikar's expert report and finds that, in addition to the Wahba and Collidge studies, Dr. Waikar cites as an additional basis for this opinion the Deng study. (See Doc #: 677-9, at 37) (citing Deng, A., et al., *Nephrogenic Systemic Fibrosis with a Spectrum of Clinical and Histopathological Presentation: A Disorder of Aberrant Dermal Remodeling*, J CUTAN. PATHOL. Mar 31, 2009.)

This is the same 2009 Deng study the Court previously precluded Dr. Gaspari from relying on to support the identical proposition. (See Doc #: 642, at 2 (prohibiting Dr. Gaspari from opining that NSF occurs in the absence of GBCA exposure based on the Deng article because the authors, one of whom is Dr. Gaspari, stated that possible gadolinium exposure in other hospitals could not be ruled out).) For the same reasons the Court precluded Dr. Newton from relying on the Wahba and Collidge studies for the proposition that NSF occurs in the absence of GBCA exposure, the Court precludes Dr. Waikar from relying on the Deng study for the same proposition.

In reviewing Dr. Gaspari's generic expert report a second time, the Court observed that Dr. Gaspari states, for the first time in his summary,

> Even in 2009, there is only an association of GBCA exposure, and the development of NFD/NSF in patients with chronic renal failure. There is no clear cause and effect. It is noteworthy that there are a number of cases of NSD/NSF occurring in patients with renal failure in the absence of GBCA exposure, including the case that my group has published in the clinical dermatology literature (1, 2, 18, 25-35).

(Doc #: 736-5, at 18 (emphasis added.) The Court notes that, in his deposition testimony, Dr. Gaspari made clear that he was not going to opine on the mechanistic cause of NSF or whether it has been demonstrated that gadolinium causes NSF (Gaspari Dep., Doc #: 737-12, at 55).[3] Yet, he reports that NSF occurs in the absence of GBCA exposure, based now upon fourteen different studies.

Interestingly, the first study upon which Dr. Gaspari relies for this opinion is the 2009 Deng study which he co-authored and which the Court earlier precluded him from relying on to support that particular proposition. The second study upon which Dr. Gaspari relies is another article he co-authored that reviews the case of a single NSF patient for whom he was unable to find GBCA exposure – while simultaneously noting that the patient was "lost to clinical followup." (Deng, A., et al., *Localized Nephrogenic fibrosing dermopathy: Aberrant dermal repairing?* JAAD 2008; 58: 336-9). At deposition, Dr. Gaspari testified that the tissue for this particular patient still exists and has not been tested for the presence of gadolinium. The Court has also reviewed the remaining twelve articles upon which Dr. Gaspari relies for the proposition

[3]Dr. Gaspari also testified that he was not going to be addressing the history or evolution of NSF. (Id. at 57.)

that NSF occurs in the absence of GBCA exposure and finds that these articles have the same deficiencies as the Collidge, Wahba and Deng studies.

C.

GEHC challenges the Court's exclusion of parts of Dr. Watson's testimony. In the May 4 Order, the Court with respect to Dr. Watson:

> The Court will not permit defense expert Dr. Alan Watson to testify on matters outside the field of bioinorganic chemistry. Dr. Watson holds a B.Sc. degree in Chemistry, a Ph.D. in Coordination and Bioinorganic Chemistry and an M.B.A. Since receiving his M.B.A. in 1988, his responsibilities appear to have been more on the business side than on the science side.
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> Dr. Watson's expert report contains the following substantive subject headings: (1) The Need for GBCAs; (2) GBCA Design and Stability; (3) Thermodynamic and Kinetic Stability Factors; (4) Macrocyclic Chelate Complexes as GBCAs; (5) Toxicity Studies of GBCAs; (6) The Issue of Gadolinium Retention; (7) Skin Lesions During Preclinical Testing; (8) The Early History of Salutar; (9) Salutar and Nycomed Publications; (10) Nycomed's Own Internal Documents; (11) Foreseeability; and (12) Commonality of All the Current Commercially Available GBCAs.
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> Given that Dr. Watson's responsibilities have been primarily on the business side at least since 1999 and perhaps since 1988, he is not qualified to provide expert testimony on most of the subjects discussed in his expert report. Because of his background, Dr. Watson is qualified to speak generally about bioinorganic chemistry, the study of how inorganic elements function in living organisms. The topics which may correspond to his knowledge of bioinorganic chemistry are: The Need for GBCAs, GBCA Design and Stability, Thermodynamic and Kinetic Stability Factors, Macrocyclic Chelate Complexes as GBCAs and The Issue of Gadolinium Retention. Dr. Watson does not have the requisite expertise to opine on the other issues within his report. In particular, Dr. Watson may not provide an opinion on the FDA's review of Omniscan, his assessment of Omniscan or GBCA toxicology or toxicology studies, any preclinical or clinical studies of Omniscan (including those done by Salutar and Nycomed), analysis of relevant publications on GBCAs, or foreseeability of gadolinium poisoning.

(Doc #: 788, at 52-53.) GEHC objects to the fact that the Court allowed Drs. Parisian and Fine to interpret outside publications and testify regarding the significance of clinical trials, while precluding Dr. Watson from analyzing similar, or in some cases identical, publications and

clinical trials. However, Dr. Watson's expertise is significantly different than Plaintiffs' two experts. As explained *supra*, Dr. Watson is a biochemist, not a medical doctor, and he has not worked directly on the scientific side of the pharmaceutical industry for at least twenty years. He has little to no experience analyzing clinical data, and little experience in any other field outside of biochemistry. Dr. Parisian, on the other hand, is a board-certified anatomic and clinical pathologist with a Masters Degree in Biology. She has particular experience reviewing and evaluating clinical trials through her work at the FDA. Dr. Fine is a board-certified nephrologist and an Associate Professor of Medicine. He has particular and extensive experience diagnosing, researching and treating NSF, and has published numerous articles on this topic since 2003. The Court allowed Drs. Parisian and Fine to analyze clinical trials and relevant publications because they have the experience necessary to understand and opine on them. However, Dr. Watson lacks the requisite expertise to provide a legitimate analysis of documents outside the field of biochemistry. Because Dr. Watson's background and experience are significantly different than the that of Drs. Fine and Parisian, they cannot properly be compared. As such, the Court properly precluded Dr. Watson from testifying about matters outside his field of bioinorganic chemistry.

D.

GEHC argues that the Court's ruling excluding all of Dr. Waymack's testimony is erroneous because the Court overread and misapplied the Supreme Court decision in *Wyeth v. Levine*, 129 S.Ct. 1187 (2009) to exclude his testimony. GEHC also argues that the ruling is unjust because the relief granted exceeds the partial exclusion that Plaintiffs actually requested.

In the underlying *Daubert* motion, Plaintiffs asked the Court to exclude Dr. Waymack's opinions about the roles of the FDA and the manufacturer in updating drug labels with safety information, as contrary to the principles set forth by the Supreme Court in *Wyeth v. Levine*, 129 S.Ct. 1187 (2009). There, the Supreme Court explained:

> [T]hrough many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. *See, e.g.*, 21 CFR § 201.80(e) (requiring a manufacturer to revise its label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug"); § 314.80(b) (placing responsibility for postmarketing surveillance on the manufacturer); 73 Fed.Reg. 49605 ("Manufacturers continue to have a responsibility under Federal law . . . to maintain their labeling and update the labeling with new safety information").

129 S.Ct. 1187 *Id*. at 1197-1198.

Dr. Waymack is GEHC's regulatory expert who submitted a report opining that GEHC conducted all appropriate and required preclinical and clinical tests during the development of Omniscan, provided all appropriate and required information to FDA when seeking approval, provided the FDA with all appropriate and required data following approval of Omniscan, and engaged in appropriate pharmacovigilance of Omniscan post-FDA approval. Dr. Waymack also opines that the FDA is the ultimate authority on information in the label, the FDA possesses a significant advantage over the manufacturer in evaluating safety information about the manufacturer's drug, the FDA can require the manufacturer to change its label to reflect updated safety information, and the manufacturer must follow the dictates of the FDA regarding the content of labeling. In other words, it was the FDA's responsibility, not GEHC's responsibility, to update Omniscan's label with safety information.

Because Dr. Waymack's opinions regarding labeling obligations plainly contradicts the Supreme Court's pronouncement on this subject, the Court properly excluded this particular testimony. However, because Dr. Waymack is GEHC's only regulatory expert and because Plaintiffs did not seek the wholesale exclusion of his testimony, the Court will modify its ruling and permit him to testify on the rest of the regulatory process except for labeling obligations.

III.

In conclusion, the Court **GRANTS** GEHC's Motion to Reconsider (**Doc #: 796**). Having reconsidered the issues raised in the Motion, along with another review of the underlying briefs, the expert reports, the deposition testimony and the record, the Court declines to change its rulings in the May 4, 2010 Order with one exception. The Court hereby **MODIFIES** its ruling regarding Dr. Waymack to the extent explained above.

Because the briefs and the Court's review were comprehensive, the Court finds that there is no need for oral argument and hereby **DENIES** GE Healthcare's Motion for Oral Argument Regarding its Motion to Reconsider etc. (**Doc #: 797**).

IT IS SO ORDERED.

/s/Dan A. Polster June 18, 2010
Dan Aaron Polster
United States District Judge