UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

CURT & NANCY COOLEY,	:	**Case No. 1:05-CV-17734**
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Plaintiffs,	:	
	:	
v.	:	
	:	
LINCOLN ELECTRIC CO., et al.,	:	
	:	**Judge Kathleen M. O'Malley**
Defendants	:	
	:	
	:	**MEMORANDUM & ORDER**
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For the reasons and to the extent stated below, plaintiffs' motion to limit the testimony of Dr. Atlas (docket no. 98) is **granted in part and denied in part**.

I. Dr. Atlas's Opinions.

Defendants in this case have designated Dr. Scott Atlas to testify regarding the science of using magnetic resonance imaging ("MRI") of the brain to diagnose movement disorders, and regarding plaintiff Cooley's neuro-radiological test results. Among other opinions, Dr. Atlas asserts that: (1) a "normal brain MRI excludes the diagnosis of manganism in patients who are still exposed to their source of excess manganese or who have been withdrawn from the source of manganese exposure within months and possibly years prior to the normal brain MRI;" and (2) "Mr. Cooley's brain MRI dated 1/23/03 excludes

the diagnosis of manganism, given the facts that [a] the brain MRI shows no evidence of manganese accumulation and that [b] this MRI was performed within only two weeks following his cessation of exposure to manganese in welding fumes."[1] At a pretrial *Daubert* hearing, Dr. Atlas explained these opinions as follows: "in a patient who has . . . clinical symptoms that suggest or may suggest manganism, and who has had exposure [to manganese] . . . within the several months [prior to] . . . [his] MRI, you can say if the MRI is normal, [then the diagnosis of manganism] is excluded."[2] As a codicil, Dr. Atlas also opines that "less manganese is needed to be in the brain to cause the MRI abnormality than [to] cause[] the amount of [brain] damage needed to have symptoms" – or, put differently, "MRI is more sensitive to the presence of excess manganese in the brain than the sensitivity of the clinical exam to detect manganese-related damage in the brain."[3]

The syllogism that Dr. Atlas uses to reach his conclusions goes as follows. First, Dr. Atlas has seen, in the medical literature and, on limited occasions, in his practice, examples of patients who have: (1) MRIs showing manganese accumulation in their brain, but (2) no symptoms of any movement disorder. As an example, Dr. Atlas has personally reviewed MRIs of patients who, after undergoing total parenteral nutrition ("TPN"), suffered manganese accumulation in the brain, but did not suffer any clinical symptoms

[1] Report at 3.

[2] Pretrial tr. at 164 (Sept. 2, 2009).

[3] *Id.* at 212, 176; declaration at ¶13.

of brain damage (such as tremor).[4] This is part of the basis for Dr. Atlas's opinion that it takes more manganese accumulation in the brain to produce clinical symptoms of neurological damage than it takes to cause an MRI to appear abnormal.

Second, Dr. Atlas is familiar with case reports in the medical literature of patients who: (1) had an MRI showing manganese accumulation in the brain; and (2) then had follow-up MRIs, which showed these manganese accumulations persisting for months and even years after the patient's manganese exposure had ceased. That is, Dr. Atlas relies upon medical articles which report that consecutive MRIs of patients, where the first MRI showed manganese accumulation in the brain, continue to show the accumulation for some period of time; the shortest *reported* period of such a patient's abnormal MRI "clearing up" and returning to normal is three months. This is part of the basis for Dr. Atlas's opinion that Cooley's normal MRI within two weeks of his last welding fume exposure "definitely" rules out a diagnosis of manganism.

Based on these premises, Dr. Atlas concludes that an MRI will *always* show manganese accumulation in a patient's brain before that patient shows any clinical symptoms of brain damage caused by manganese. Conversely, Dr. Atlas also concludes that a patient with clinical symptoms caused by manganese exposure will *always* have an abnormal MRI, so long as the patient's manganese exposure did not cease more than three months before the MRI. Ultimately, then, Dr. Atlas concludes that Mr. Cooley's normal MRI, which was taken within two weeks of the date he stopped welding, excludes a diagnosis of

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[4] TPN involves feeding a person intravenously, when the person cannot engage in the normal processes of eating, digestion, and excretion. TPN bypasses the liver, which normally removes and excretes manganese from the body; thus, patients undergoing TPN suffer build-up of manganese levels in the body, and this manganese can accumulate in the patient's globus pallidus, a part of the brain. Similar circumstances occur with patients who have liver damage. MRIs can reveal this manganese accumulation.

manganism.

II. *Daubert.*

Plaintiffs invoke Fed. R. Evid. 702 and *Daubert*[5] and seek to preclude Dr. Atlas from testifying that Mr. Cooley's negative MRI conclusively rules out a diagnosis of manganism.[6] Plaintiffs' challenge goes only to the methodology Dr. Atlas employs; plaintiffs do not challenge Dr. Atlas's qualifications to offer expert neuro-radiological opinions.[7]

Rule 702 states: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."

The *Daubert* court held that federal trial judges must serve a "gatekeeping role" when it comes to application of Rule 702: "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable."[8] The Supreme Court also suggested a non-exclusive list of

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[5] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

[6] Plaintiffs' motion does not seek to exclude other of Dr. Atlas's opinions. *See* motion at 6 (dkt. no. 98) (seeking a "limited remedy" of certain limits on Dr. Atlas's testimony); reply at 9 (dkt. no. 167) (defining objectionable opinions).

[7] There is no question but that Dr. Atlas is eminently qualified to offer expert opinions related to neuro-radiology. For example, he is Chief of Neuroradiology and Professor of Radiology at Stanford University Medical Center, serves as Editor in Chief of *Topics in MRI*, and has written chapters for the principal textbook in the field, *Magnetic Resonance Imaging of the Brain and Spine*.

[8] *Daubert*, 509 U.S. at 589.

factors for trial courts to consider when deciding whether proposed scientific[9] expert testimony is sufficiently "reliable," as required by the second and third conditions in Rule 702. The specific factors listed by the *Daubert* Court are: "(1) whether the expert's technique or theory can be or has been tested – that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the technique or theory has been subject to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) whether the technique or theory has been generally accepted in the scientific community."[10]

III. Analysis.

As an initial matter, it is important that Dr. Atlas has never earlier expressed his opinions regarding an MRI's capacity for definitively ruling out manganism outside of this litigation. Indeed, at the *Daubert* hearing in this case, Dr. Atlas conceded he is not sure whether he, himself, ever had a patient with

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[9] In *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999), the Supreme Court added that the "basic gatekeeping obligation" discussed in *Daubert* applies not just to "scientific" testimony, but to "all expert testimony," including technical or other specialized expert testimony.

[10] Fed. R. Evid. 702 (advisory committee notes, 2000 amendments) ("*Advisory Committee Notes*"); *Daubert*, 509 U.S. at 593-594.

This Court has undertaken a number of *Daubert* hearings and issued several *Daubert* opinions during the course of this MDL litigation, both within the context of specific bellwether trials and also regarding the admissibility of evidence relevant to the entire MDL. *See, e.g, Byers v. Lincoln Elec. Co.*, 2008 WL 4849339 at *2-3 (N.D. Ohio Nov. 6, 2008) (*Byers* docket no. 313) (addressing the admissibility of testimony from defense expert neuro-radiologist Dr. Gordon Sze in a bellwether trial); *In re Welding Fume Prods. Liab. Litig.*, 2005 WL 1868046 (N.D. Ohio Aug. 8, 2005) (master docket no. 1353) (addressing the admissibility of testimony from numerous core experts, and assessing whether any defense expert could offer certain global opinions). In the latter opinion, the Court set out in greater detail the applicable *Daubert* standards. *See* 2005 WL 1868046 at *2-6. Rather than repeat the discussion here, the Court incorporates that opinion by reference.

manganism – Dr. Atlas suggested he "probably has," because he has viewed hundreds of thousands of MRIs, and many of those MRIs showed manganese accumulation, but he cannot be sure any of those patients had manganism.[11] Further, when asked if he ever "ruled out manganese toxicity in [his] practice," he stated again only that he was sure must have, but could not remember any specific cases.[12] More specifically, Dr. Atlas could not point to a single instance in which he employed the three-month window (or any other window, for that matter), which he proposes to describe to the jury, to tell a doctor or clinician that an MRI result ruled out a diagnosis of manganese neurotoxicity.[13] Moreover, there is no evidence that Dr. Atlas ever published or otherwise documented the specific opinions listed above before he was retained by defendants in this litigation.

A trial judge should consider whether experts propose "to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying."[14] In this case, although Dr. Atlas is very widely published in connection with the science and medicine of MRI testing, he does not point to any previous statement in any of his publications asserting that a "normal brain MRI excludes the diagnosis of manganism in patients who are still exposed to their source of excess manganese or who have been withdrawn from the source of manganese exposure within months and possibly years prior to the normal

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[11] Pretrial tr. at 157-58 (Sept. 2, 2009).

[12] *Id.* at 157-58 & 197-98. Although the point was not elicited explicitly during examination of Dr. Atlas, his testimony suggested a disconnect between his review of a patient's MRI results and any examination of the patient, himself. It is not clear the extent to which Dr. Atlas actually engages in hands-on examination of patients, assessment of their clinical symptoms, and correlation of those symptoms with MRI results.

[13] *Id.*

[14] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995).

brain MRI."[15] "If the proffered expert testimony is not based on independent research, the party proffering it must come forward with other objective, verifiable evidence that the testimony is based on 'scientifically valid principles.'"[16] For the reasons below, the Court concludes defendants do not meet this test.

In examining whether Dr. Atlas's opinions meet the standards set out in *Daubert*, the Court has carefully weighed those things that Dr. Atlas conceded (during questioning in his deposition and at the pretrial *Daubert* hearing) that he did not consider. Dr. Atlas stated he did not know – and did not need to know, before reaching his opinions – the following information: (1) when Mr. Cooley's clinical symptoms began to manifest; (2) the span of time during which Mr. Cooley suffered manganese exposures; (3) the details or extent of Mr. Cooley's daily and weekly manganese exposures, such as whether his exposures ever exceeded the TLV (which, as defendants admit, carries risk of neuro-injury)[17]; (4) how Mr. Cooley's exposures during the six-month period before his MRI compared with his exposures during the rest of his career; (5) the amount of manganese exposure necessary to result in an abnormal MRI; (6) the amount of manganese exposure necessary to cause clinical symptoms; (7) the rate at which manganese clears from the brain; and (8) whether manganese clears from the brain even if exposure to manganese continues.

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[15] Report at 3.

[16] *Daubert*, 43 F.3d at 1317-18.

[17] Threshold Limit Values ("TLVs") for manganese are established by the American Conference of Governmental Industrial Hygienists ("ACGIH"). The ACGIH describes a TLV as follows: "[TLVs] refer to airborne concentrations of chemical substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed, day after day, over a working lifetime, without adverse health effects. TLVs are developed to protect workers who are normal, healthy adults." *See* www.acgih.org/Products/tlv_bei_intro.htm. *See also In re Welding Fume Prods. Liab. Litig.*, 526 F.Supp.2d 775, 784 n.33 & 789-90 n.65 (N.D. Ohio 2007) (discussing the history and meaning of the TLVs and PELs for manganese).

The current TLV for manganese is 0.2 mg/m^3. Defendant ESAB's warning labels currently state: "Overexposure to manganese and manganese compounds above safe exposure limits can cause irreversible damage to the central nervous system, including the brain."

In addition, Dr. Atlas was wholly unfamiliar with relevant opinions offered by other defense expert witnesses. For example, Dr. Daniel Perl is defendants' expert neuropathologist. Dr. Perl has testified that clinical symptoms of manganism probably will not appear until about 50% of the brain cells in the globus pallidus have been damaged by manganese. Dr. Atlas conceded he did not know this fact, and more importantly did not know: (1) over what period of time this damage might occur; (2) how much manganese accumulation was required to cause this amount of damage; or (3) whether that amount of manganese would show up on an MRI. Thus, Dr. Atlas did not know whether an MRI would be abnormal even if 50% of the brain had been damaged by manganese accumulation. Similarly, he did not know that defense toxicology expert Dr. Jeffrey Brent has testified that manganese is constantly being cleared from the brain, so that the amount of manganese in the brain at any given time has accumulated within the last six to twelve months.

Ultimately, Dr. Atlas asserted he did not need to know any of the information recited above: to reach his opinions, all he needs to know is the date of the patient's MRI, and the date of that patient's last exposure to manganese. Dr. Atlas holds that, if the two dates are less than three months apart and the MRI is normal (as is the case with Mr. Cooley), then the patient simply cannot have manganism.[18] Dr. Atlas asserts this is true regardless of the patient's historical, occupational manganese exposures over his working career; regardless of when the patient's clinical symptoms began; and regardless of the absolute or relative or comparative amounts of manganese exposure it takes to: (a) cause brain damage and (b) make an MRI appear abnormal.

This opinion satisfies none of the *Daubert* criteria. The first test is "whether the expert's technique

[18] *See* Atlas depo. at 222 (agreeing that his opinion, essentially, is that, "[if] the last date of exposure is inside two months, a normal MRI rules out the diagnosis [of manganism]").

or theory can be or has been tested – that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability." There is no objective test against which to measure Dr. Atlas's opinion that, if less than three months separate the dates of a patient's normal MRI and his last exposure to manganese, the patient cannot have manganese-induced brain damage. At best, the only metric available to validate this opinion is Dr. Atlas's review of the literature and his findings that: (1) no cases are reported where manganese accumulation in a patient's brain, as shown by MRI, "cleared up" in less than three months; and (2) some patients with manganese accumulation in the brain, as shown by MRI, have no clinical symptoms.[19] Certainly, Dr. Atlas can testify as to what the literature shows, and he can even assert that he infers from this information that it is unlikely that Mr. Cooley has manganism. But Dr. Atlas cannot offer the opinion that a normal MRI "rules out" or excludes the diagnosis of manganism.[20]

The other *Daubert* factors yield similar results. Dr. Atlas cannot assert that his opinion has been subjected to peer review and publication; it does not appear in any published work. Further, there is no known or potential rate of error of his theory as applied to welders, or any other persons exposed to manganese. And there is no evidence suggesting that his theory has been generally accepted in the scientific community. Indeed, with the possible exception of defendants' other neuro-radiology expert, Dr. Sze, defendants point to no other person or text to support the assertion that, if less than three months

[19] Even the metric of Dr. Atlas's literature review provides only a weak ruler, because the rule Dr. Atlas uses is, to a degree, self-fulfilling. If Dr. Atlas and all of the neuro-radiologists he teaches use his rule consistently, then the literature will never report a contrary case. Perhaps, after welders' deaths, neuropathological assessments of whether they had manganese-induced parkinsonism ("MIP") could be used to verify Dr. Atlas's contention that their normal MRIs ruled out MIP. But the lack of reports of such cases in the literature may be due partly to the very rule that he applies.

[20] It is true that the absence of reports in scientific literature may be used to support an expert opinion. *See, e.g., Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 246 (5th Cir. 2002). But the absences relied upon by Dr. Atlas in this case cannot bear the weight of his ultimate opinions.

separate the dates of a patient's normal MRI and his last exposure to manganese, the patient cannot have neurological damage caused by manganese.

Dr. Atlas's own experience and literature review shows that some patients with enough manganese accumulation to yield an abnormal MRI have no clinical symptoms. He may testify to this fact. His literature review also indicates that patients who have abnormal MRIs due to manganese accumulation seem to maintain these abnormal MRIs for at least three months. Again, he may testify to what the literature reports. And, he may testify that, because he has never seen a report in the literature of a faster clearance rate than three months, he infers that faster clearance rates are unlikely. He may also say he infers from these facts that it takes less manganese accumulation in the brain to cause an abnormal MRI than to cause sufficient brain damage to result in clinical symptoms.

But these facts and his literature review simply do not *mandate* or even support the conclusion, as Dr. Atlas seeks to opine, that a patient with a normal MRI has never had enough manganese exposure over his working career to suffer brain damage yielding clinical manifestations – regardless of when the patient's manganese exposure ceased.

The defendants "need not prove to the [Court] that [Dr. Atlas's] testimony is correct, but [they] must prove by a preponderance of the evidence that the testimony is reliable."[21] This is particularly true when the proffered expert seeks to provide testimony that is so far outside a layman's normal level of understanding that the opinions expressed are likely to be given substantial weight by a jury. *Daubert* calls upon the Court to guard against an expert's presentation to the jury of a false litmus test, and that is what Dr. Atlas proposes to do.

This Court exercises its discretion to conclude there are simply too many analytical gaps between

[21] *Moore v. Ashland Chemical Inc.*, 151 F.3d 269, 277 (5th Cir. 1998).

the opinions Dr. Atlas offers and the data upon which he relies (or does not rely) to derive them.[22] In sum, Dr. Atlas's central opinions have never been rendered outside the litigation context; the test he proposes has never been used (by him or others) in a clinical setting; his standard has never been tested; his conclusions have not been subjected to peer review; there is no evidence that his proposed diagnostic criteria have been widely accepted in the scientific community;[23] and his opinions are not premised upon a thorough and reliable scientific methodology. Thus, these opinions are not admissible.

While Dr. Atlas is surely a preeminent expert in his field and highly qualified to render a panoply of opinions relating to neuroradiology, the law does not authorize him to express the ultimate opinions defendants seek to elicit in this case. Accordingly, to the extent set forth above, plaintiffs' motion to limit Dr. Atlas's expert opinions is granted in part.

IT IS SO ORDERED.

/s/ Kathleen M. O'Malley
KATHLEEN McDONALD O'MALLEY
UNITED STATES DISTRICT JUDGE

DATED: September 15, 2009

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[22] An analogy: the Court would not allow an economist to offer expert opinions regarding lost profits if the economist did not include in his analysis important factors, such as his only competitor's actual sales figures. *See Zenith Electronics Corp. v. WH-TV Broadcasting Corp.*, 395 F.3d 416 (7th Cir. 2005). Similarly, the derivation of Dr. Atlas's ultimate opinion simply ignores too many pieces of important data.

[23] Indeed, it is telling that two of Mr. Cooley's treating neurologists (Drs. Worrell and Sharma), who reached their diagnoses of manganese neurotoxicity before Mr. Cooley filed this case, reached their diagnoses in spite of having seen Mr. Cooley's normal MRI, and continue to maintain those diagnoses are correct. Similarly, in the bellwether case of *Jowers*, the treating neurologist (Dr. Millette) diagnosed MIP despite his patient's normal MRI. And even defense expert neurologists Dr. Lang and Dr. Olanow allow only that MRIs are important diagnostic tools – not that a normal MRI obtained within some time of last welding fume exposure can, without more, definitively rule out MIP. These circumstances do not indicate wide acceptance of Dr. Atlas's opinions by the medico-scientific community.