**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

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| HEATHER LORRAINE BAYNAR, et al.,<br><br>Plaintiffs,<br><br>v.<br><br>BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al.,<br><br>Defendants. | Civil Action No. 2:10-cv-01736-DSC-RCM<br><br>ELECTRONICALLY FILED |

**REPLY BRIEF IN SUPPORT OF DEFENDANTS' MOTION FOR CASE MANAGEMENT ORDER**

**[ORAL ARGUMENT SCHEDULED]**

## I. INTRODUCTION

Plaintiffs oppose Defendants' Motion for Case Management Order ("CMO") without addressing any of the questions that the Court directed to them at the December 6, 2011 status hearing regarding their lack of Plaintiff-specific evidence as to exposure, dose, and causation. As the Court noted, the Third Circuit's decision in *In re TMI*, 67 F.3d 1103, 1118 (3d Cir. 1995), requires such evidence from *each plaintiff* claiming injury due to radiation exposure. Plaintiffs also ignore that Third Circuit law requires *epidemiological evidence* for Plaintiffs' theories, even though Plaintiffs' own expert acknowledges that such evidence is necessary. Although Defendants have cited several epidemiological studies that indicate Plaintiffs' claims are meritless, Plaintiffs ignore that evidence as well.

Instead of focusing on the Court's questions, Plaintiffs direct their arguments to the alleged unfairness of Defendants' proposed CMO. Plaintiffs claim this CMO is "draconian" (Opposition, at 3) even though, consistent with Federal Rule of Civil Procedure 16, it simply would require each Plaintiff to produce the basic information on exposure, dose, and causation – based on epidemiological evidence – that is required by Third Circuit law. Plaintiffs resist any effort to require such information, because they know the epidemiological evidence eviscerates their claims. Every peer-reviewed study in the scientific literature indicates that the Apollo and Parks facilities had *no impact* on cancer incidence or mortality in Plaintiffs' communities.

Plaintiffs' resistance to supporting each claim they have filed can only be explained by the fact that these claims were not vetted before they were filed. Instead, as Defendants have learned in discovery, nearly every Plaintiff was added to these actions because a community activist and paid agent for Plaintiffs' counsel directed them to mass meetings where they could join the lawsuit simply by filling out a card. The only criteria used for "screening" each Plaintiff were whether the individual had been diagnosed with cancer and had lived within several miles

of the Apollo and Parks facilities. Therefore, it is not surprising that no Plaintiff has come forward with a scintilla of evidence supporting a *prima facie* case of radiation injury.

Plaintiffs want to avoid the day of reckoning, when they must demonstrate that claims they have forced the Court and Defendants to contend with for more than two years can be supported with admissible evidence. Therefore, they propose that 14 Plaintiffs be hand-picked for further proceedings, before anything is known about the claims and supporting evidence for these arbitrarily chosen individuals, permitting Plaintiffs to avoid any work to support the vast majority of their claims. This proposal is a stalking horse for Plaintiffs' proposed bellwether trial plan, even though Plaintiffs acknowledge that the Court has indicated that bellwether trials will not be efficient or effective in resolving this litigation. Certainly the experience in *Hall* demonstrated that bellwethers do not promote quick or efficient resolution of toxic tort litigation.

There is nothing unfair or "draconian" about requiring individuals suing for alleged injury, seeking large recoveries and punitive damages, to support claims as to which they have the burden of proof on exposure, dose, and causation. Plaintiffs have had full access to the documents and testimony in the *Hall* litigation, and have retained experts who should be capable of providing *prima facie* evidence, if it exists, for each Plaintiff's claim. Defendants' proposed CMO will set the stage for Plaintiffs' claims to be resolved through summary judgment motions, allowing the Court to eliminate theories that have no basis in law or fact, and narrowing the scope of this litigation. Therefore, Defendants request that the Court adopt their proposed CMO.

## II. PLAINTIFFS FAIL TO ADDRESS THE FACTS AND LAW SUPPORTING DEFENDANTS' PROPOSED CASE MANAGEMENT ORDER

### A. Third Circuit Law Requires Plaintiff-Specific Evidence on Exposure, Dose, and Causation Based on Epidemiological Studies

Plaintiffs' Opposition avoids discussion of the controlling legal standards that govern their claims. As the Court noted at the December 6, 2011 status hearing, Third Circuit law

requires *plaintiff-specific* evidence of exposure and causation in any Price-Anderson Public Liability Action such as this. *See In re TMI*, 67 F.3d 1103, 1118 (3d Cir. 1995) (stating burden of proof in Price-Anderson action). The Third Circuit in *In re TMI* held that "*each plaintiff* must demonstrate exposure to radiation released during [a nuclear incident]," and each plaintiff must also demonstrate individual causation. *Id.* (emphasis added). Plaintiffs also must establish their alleged dose, and "demonstrate they have been exposed 'to a greater extent than anyone else,' *i.e*., that their 'exposure level exceeds the normal background level.'" *Id.* at 1119; *see also Gates v. Rohm and Haas Co*., 655 F.3d 255, 266-67 (3d Cir. 2011) (requiring scrutiny of each individual's unique exposure history in toxic tort action).

Plaintiffs also ignore the Court's comment, based on Third Circuit law, that epidemiological evidence is necessary in order for Plaintiffs to prove causation. The Third Circuit in *TMI* held that in actions involving exposure to ionizing radiation, "causation can *only be established* (if at all) from *epidemiological studies* of populations exposed to ionizing radiation." *In re TMI*, 193 F.3d 613, 643 (3d Cir. 1999) (emphasis added). Plaintiffs ignore this law even though their own expert witness, Bernd Franke, acknowledged in a 2008 report in *Hall*, that in "determining causation…two elements need to be considered: the exposure to the agent and *the results of epidemiological studies* with respect to the exposure...." Declaration of John P. Phillips in Support of Defendants' Motion, Ex. A (Franke Report, ¶13) (emphasis added).

As demonstrated in Defendants' Motion, the epidemiological evidence is unequivocal: any releases from Apollo and Parks have had no impact on cancer incidence or mortality in Plaintiffs' communities. Phillips Decl., Exs. B-G. Epidemiological studies published in the peer-reviewed scientific literature conclude that there has been "*no increase* in the number of cancers among populations living near the former Apollo-Parks nuclear materials processing sites in Pennsylvania" (*id.*, Ex. D, at 689 (emphasis added)), and that the epidemiological data

provides "*no evidence that the two former nuclear materials processing facilities in Armstrong County posed a risk to neighboring populations*.") (*id.*, Ex. E, at 698) (emphasis added).

Plaintiffs' opposition brief does not challenge any of these conclusions from the epidemiological literature. There simply is no evidence that the Apollo and Parks facilities, which ceased operations decades ago, caused any adverse health effects in Plaintiffs' communities.[1] Plaintiffs also ignore the epidemiological literature cited in Defendants' Motion that shows that uranium "is not considered a human carcinogen," according to the United Nations Scientific Committee on the Effects of Atomic Radiation ("UNSCEAR").[2] Phillips Decl., Ex. I, at Annex A, ¶130. UNSCEAR concludes that "*there is little or no epidemiological evidence for an association between uranium and any cancer*." *Id.* (emphasis added).

Plaintiffs' inability to point to Plaintiff-specific admissible evidence on the issues defined by the controlling Third Circuit law is sufficient reason, by itself, for the Court to order the *prima facie* showing required under Defendants' proposed CMO.

### B. Plaintiffs Fail To Address the Federal Court Authority Supporting *Lone Pine* Procedures as to Each Plaintiff

Defendants' Motion cited nearly 20 cases in which courts have adopted *Lone Pine* procedures pursuant to Federal Rule of Civil Procedure 16. One such case is *Acuna v. Brown & Root, Inc.*, 200 F.3d 335, 340 (5th Cir. 2000), in which the court required *prima facie* evidence of exposure and causation for each plaintiff alleging injury from uranium contamination. Plaintiffs ignore this case law, citing instead only a handful of cases that do not support their arguments.

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[1] The Apollo facility ceased operations in 1983, and the site was decommissioned in 1995. The Parks facility ceased final operations in 1993 and was decommissioned in 2001. After environmental remediation was completed as part of decommissioning, both sites were "released for unrestricted use."

[2] UNSCEAR's mandate is to assess and report levels and health effects of exposure to ionizing radiation (http://www.unscear.org/unscear/en/about_us.html). "Governments and organizations throughout the world rely on the Committee's estimates as the scientific basis for evaluating radiation risk and for establishing protective measures." *Id.*

In the one case discussed at length by Plaintiffs, *In re Digitek Prod. Liab. Litig.*, 264 F.R.D. 249, 256 (S.D. W. Va. 2010), the court's decision whether to enter a *Lone Pine* order hinged on five factors: "(1) the posture of the action, (2) the peculiar case management needs presented, (3) external agency decisions impacting the merits of the case, (4) the availability and use of other procedures explicitly sanctioned by federal rule or statute, and (5) the type of injury alleged by plaintiffs and its cause." These factors all support Defendants' proposed CMO.

Regarding the first of these factors, "the posture of the action," the *Digitek* court noted that *Lone Pine* orders may be more appropriate when litigation is at an "advanced stage." 264 F.R.D. at 256 (citing *In re Vioxx Prod. Liab. Litig. ("Vioxx")*, 557 F. Supp. 2d 741, 743 (E.D. La. 2008)). The court quoted the finding by the judge in *Vioxx* that although "a *Lone Pine* order may not have been appropriate at an earlier stage before any discovery had taken place," sufficient discovery had been conducted to require the plaintiffs to support their claims. *Id.* at 256-57 (quoting *Vioxx*, 557 F. Supp. 2d at 744). This factor clearly supports Defendants' CMO. As in *Vioxx*, "this case is no longer in its embryonic stage." 557 F. Supp. 2d at 744. Plaintiffs have had access to Defendants' documents and the *Hall* deposition and trial testimony for more than a year, and have had more than two years to develop evidence to support their allegations.[3]

The second factor, "the peculiar case management needs presented," also supports Defendants' CMO. In *Digitek*, only one substance, a drug "widely used to treat various heart conditions," was at issue, and use of the drug could be established through medical records and questionnaires. 264 F.R.D. at 251, 258. In contrast, Plaintiffs in these actions allege exposure to eleven different radionuclides through multiple exposure pathways during a fifty-year period of

[3] *See Digitek*, 264 F.R.D. at 257 (quoting *In re 1994 Exxon Chemical Plant Fire*, 2005 WL 6252312, at *2 (M.D. La. Apr. 7, 2005) ("Before these suits were filed, and at least after the many years since filing them, one would expect that the remaining plaintiffs would have some concrete, factual basis to support their claims.")); *c.f. Morgan v. Ford Motor Co.*, 2007 WL 1456154, at *8 (D.N.J. May 17, 2007) (declining to implement *Lone Pine* process when no discovery had yet been conducted).

operation and remediation of two facilities. Therefore, these actions are more akin to *Abbatiello v. Monsanto Co.*, 569 F. Supp. 2d 351, 354 (S.D.N.Y. 2008), in which the court adopted a *Lone Pine* order due to the long and complex factual histories implicated by the plaintiffs' allegations.

The third factor, "external agency decisions impacting the merits of the case," also supports Defendants' CMO. As discussed in Defendants' Motion, the Pennsylvania Department of Health studied the epidemiological data for the communities near Apollo and Parks and concluded that "there is no evidence that the levels [of off-site contamination] are large enough to affect the annual [cancer] risk in this population." *See*, *e.g.*, Phillips Decl., Ex. C, at 38. No external agency has made a finding supporting Plaintiffs' allegation that they were exposed to radiation from Apollo or Parks, or that such exposure caused their injuries.[4]

The fourth factor cited in *Digitek* considers "the availability and use of other procedures explicitly sanctioned by federal rule or statute." The *Digitek* court noted that its existing procedures required each plaintiff to submit questionnaire responses, and concluded that this procedure would weed out plaintiffs who could not establish exposure to the defendants' drug. 264 F.R.D. at 258-59. In these actions, however, the Court already has attempted to use numerous "other procedures explicitly sanctioned by federal rule or statute."

The Court first employed plaintiff questionnaires in order to streamline fact discovery. As Defendants demonstrated in their Motion, that effort did not work, because Plaintiffs answered "I don't know" to every question regarding their alleged exposures, refusing to identify the radionuclide(s), exposure pathway(s), or specific facilities that allegedly caused their injuries.

[4] The only "agency decision" Plaintiffs cite regarding this factor is the policy decision by Congress to compensate *former radiation workers* through the Energy Employees Occupational Illness Compensation Act ("EEOICPA"). Opposition, at 7. This program has no bearing on Plaintiffs' claims. Because of EEOICPA's pro-claimant assumptions, the Department of Health and Human Services states that EEOICPA findings should not be cited in litigation or other proceedings outside the EEOICPA claims process. 67 Fed. Reg. 22,296, 22,300 (May 2, 2002); *see also Gates*, 655 F.3d at 268 ("Particularly problematic are generalizations made in personal injury litigation from regulatory positions…").

Plaintiffs also refused to provide such information in their "Preliminary Expert Reports" and in their depositions. Therefore, although the Court attempted to use "other procedures" to weed out meritless claims and theories, Plaintiffs' vague and non-responsive answers have frustrated these efforts. No Plaintiff has come forward with evidence supporting a *prima facie* claim.[5]

Plaintiffs ignore altogether the fifth factor in *Digitek*, which considers "the type of injury alleged by plaintiffs" and its cause. Plaintiffs in these actions allege that radiation caused them (or their decedents) to develop cancer. As the Third Circuit noted in *TMI*, ionizing radiation "is not currently known to leave a tell-tale marker in those cells which subsequently become malignant." 193 F.3d at 643. Therefore, the Third Court noted:

> [M]edical evaluation, by itself, can neither prove nor disprove that a specific malignancy was caused by a specific radiation exposure. Therefore, the primary basis to link specific cancers with specific radiation exposures is data that has been collected regarding the increased frequency of malignancies following exposure to ionizing radiation. In other words, *causation can only be established (if at all) from epidemiological studies of populations exposed to ionizing radiation.* [*Id*. (emphasis added) (citations omitted)].[6]

As discussed above and in Defendants' Motion, the epidemiological literature does not support Plaintiffs' allegations that releases from Apollo and Parks caused their injuries. Therefore, this fifth factor in *Digitek* supports Defendants' CMO, because Plaintiffs' allegations lack scientific support. *See* 264 F.R.D. at 256 (quoting 2 Lawrence G. Cetrulo, *Toxic Torts Litigation Guide* §13:49) ("'*Lone Pine* orders are most appropriate in those cases where there is a

[5] Plaintiffs have attempted to preserve indefinitely every possible theory regarding exposure, dose, and causation, claiming without supporting evidence that their injuries might have resulted from: (1) airborne releases; (2) discharges into the Kiskiminetas River; (3) groundwater contamination; (4) "take-home" transport of radionuclides by workers at Apollo and Parks; and (5) alleged releases during decommissioning activities at Apollo and Parks. Defendants' proposed CMO will require Plaintiffs to eliminate all exposure pathways that they cannot support, resulting in significant efficiencies during every future phase of this litigation.

[6] Because "medical evaluation" cannot prove or disprove whether radiation caused a particular Plaintiff's cancer, there is no scientific basis for a medical doctor to use "differential diagnosis" to determine the cause of any Plaintiff's cancer.

serious issue over what medical condition or disease, if any, can be causally related to the toxic agent exposure alleged by each plaintiff."); Ex. I to Phillips Decl., at Annex A, ¶130 ("[T]here is little or no epidemiological evidence for an association between uranium and any cancer.").

The five-factor test in *Digitek* demonstrates the appropriateness of Defendants' proposed CMO. Plaintiffs fail to cite to any authority suggesting that adoption of the CMO would be an improper exercise of the Court's discretion. Therefore, Defendants' Motion should be granted.

## III. PLAINTIFFS' ARGUMENTS DEMONSTRATE WHY JUDICIAL MANAGEMENT OF EACH OF THEIR CLAIMS IS NECESSARY

Rather than address the factual record and case law cited in Defendants' Motion, Plaintiffs devote most of their brief to the argument that it would be "draconian" to subject each of their claims to scrutiny under to Rule 16.[7] Opposition, at 3-8. Other courts have rejected this argument, noting that *Lone Pine* orders only require "that information which plaintiffs should have had before filing their claims pursuant to Fed. R. Civ. P. 11(b)(3)." *Acuna*, 200 F.3d at 340; *see also In re Vioxx*, 557 F. Supp. 2d at 744 ("Surely if Plaintiffs' counsel believe that such claims have merit, they must have some basis for that belief; after all this time it is reasonable to require Plaintiffs to come forward and show the basis for their beliefs….").

The most basic flaw in Plaintiffs' proposed approach is their assumption that the parties can select "representative" Plaintiffs as to which discovery may be permitted to proceed. Opposition, at 8. No Plaintiff in this action is "representative" of any other Plaintiff, because Plaintiffs are suing regarding 40 different types of cancer and each Plaintiff presents unique

[7] Plaintiffs mistakenly claim that the Court at the December 6, 2011 hearing endorsed their bellwether plan and "observed that it would not be fair to require Plaintiffs to undergo the burden of working up all 95 or so cases at once." Opposition, at 2-3. The Court, however, made no such observation or ruling. Instead, the Court decided to consider briefing on the parties' motions and conduct a hearing on January 24, 2012 to determine how it will proceed. Plaintiffs also misstate that Defendants have agreed that "trial groups" need to be established to resolve these claims. Opposition, at 4. Defendants have not agreed to this claim, nor have they endorsed any of the other supposed "areas of agreement" identified by Plaintiffs.

potential exposure histories, risk factors based on their lifestyle choices, and other confounding factors that will require individual inquiries into their unique situations.[8] *See In re Chevron U.S.A., Inc.* 109 F.3d 1016 (5th Cir. 1997) (individual variation among purported "bellwether" plaintiffs meant they would not be representative of other claimants). The only common factor among Plaintiffs is that nearly all of them were enlisted to join this litigation by an alleged agent of Plaintiffs' law firms, Patty Ameno, a community activist and former plaintiff in the *Hall* case. Plaintiffs' counsel are refusing to produce Ms. Ameno's communications with Plaintiffs, or provide a privilege log for documents they are withholding.

There is no legal precedent for adopting a bellwether case management plan where plaintiffs allege dozens of different types of diseases due to alleged exposures to multiple substances, through several different pathways, during decades of operations at two facilities, with no scientific basis for selecting "representative" plaintiffs. Because each Plaintiff's claim is unique, Plaintiffs' approach will accomplish none of the efficiencies they vaguely promise. As one example, even though more than 90% of the Plaintiffs allege they were exposed to radiation from Parks, Plaintiffs propose to litigate only the claims of a select number of "Apollo only" Plaintiffs. Opposition, at 8. Their plan would require Defendants to "select" bellwethers without knowing anything about each Plaintiff's alleged exposures from either Apollo or Parks, including information regarding exposure pathway(s) and dose, if any. Presumably if these Plaintiffs lost an Apollo trial, they would next attempt to try their claims regarding Parks. As in *Hall*, there are no efficiencies to be gained from a bellwether trial of Apollo-only Plaintiffs.

Plaintiffs' plan is designed not to promote efficiency, but instead to permit Plaintiffs to maintain as many unsupported claims, theories and allegations for as long as possible, regardless

[8] Even Plaintiffs acknowledge this fact is true, arguing that Defendants' CMO would require their experts to undertake a unique and separate analysis of each individual Plaintiff's circumstances. Opposition, at 3.

of the burdens on the Court and Defendants. Defendants' CMO, in contrast, proposes a timely and practical plan that will permit the parties and the Court to obtain the information necessary to make intelligent and informed decisions for dispositive motions and case management. *See Abbatiello*, 569 F. Supp. 2d 352 at 354 ("The purpose of *Lone Pine* style CMOs, requiring early individual causation expert evidence, is to protect defendants and the Court from the burdens associated with potentially non-meritorious mass tort claims.").

## IV. CONCLUSION

Plaintiffs oppose any effort to peel back the veneer on their complaints and allow evaluation of each Plaintiff's claim. Plaintiffs' interest in maintaining meritless claims for as long as possible, however, should not determine how these cases will be managed. Defendants' proposed CMO will permit effective and efficient judicial of this litigation, and therefore, Defendants request that the Court grant their Motion.

DATED: January 19, 2011

By: */s/* John P. Phillips

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