IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	)	Chapter 11
	)	
W.R. Grace & Co., *et al.*,	)	Case No. 01-1139 (JKF)
	)	
Debtors.	)	(Jointly Administered)

GRACE'S MEMORANDUM IN OPPOSITION TO CLAIMANTS' MOTIONS TO EXCLUDE EXPERT TESTIMONY

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INTRODUCTION

There has been much talk in this case about the asserted "novelty" of Grace's approach to estimation, as compared to the historical or "traditional" approach to which the claimants so fervently cleave.

It is true that there is novelty here, but it all emanates from a single fact, a fact that is both unfortunate and should underscore – rather than diminish – the importance and merit of Grace's estimation case. That single fact is that no prior asbestos debtor (and no prior asbestos bankruptcy court) has persevered against the implacable opposition of the asbestos bar and assembled block-by-block the full legal and scientific foundation for an estimate of contested current and future personal-injury liability. This fact is unfortunate in that it has both closed the door to meaningful Chapter 11 relief from meritless claims brought against prior debtors (that were ultimately financed by shareholders and other creditors) and in that it has retarded the development of a thoughtful and fully informed asbestos Chapter 11 jurisprudence. The same fact underscores rather than diminishes the importance of Grace's case. This Court has an unique opportunity to consider and decide the fundamental legal and scientific matters now before it unencumbered by undeveloped facts, distorting allegiances involving the debtor and the proponents of unfounded claims, and inapposite legal contexts, such as the confirmation of consensual plans or the litigation of fraudulent-conveyance claims.

While this case is thus novel in the history of asbestos Chapter 11 cases (and a completely grounded liability estimate is thus novel for the same reasons), the substance of Grace's estimate – the principles of law and science that provide the outcome-determinative structure of Grace's case – is anything but novel. To the contrary, the principles that drive Grace's case are traditional in the highest sense of that word. They are the state-law requirement of causation proven up scientifically under *Daubert*, *i.e.*, a classic toxic-tort law inquiry, and they

must govern this case. They call for the deployment of accepted scientific methods that have been the bedrock of toxic-tort science for years (industrial hygiene, risk assessment, and epidemiology) and the sole guide to disease forecasts for just as long (epidemiology).

Grace has answered this call. The work has been completed meticulously, from the industrial-hygiene analysis of exposure settings for Grace products, to the calculations of dose and risk, to the criteria for gathering medical evidence, and, finally, to the application of the resulting criteria to the claimants' own evidence of exposure and disease. No stone has been left unturned. No convenient convention or *ipse dixit* junk science has been allowed. It is risk assessment and disease projection the right, accepted, "old fashioned" way.

At its core, the claimants' attack on Grace's estimate is an attack on the very concept of rule-based liability. As shown in Section I of this brief, their arguments regarding "fit" reduce to the hide-bound, self-defeating contention that bankruptcy isn't really bankruptcy at all. When it comes to the core task of determining liability, they say, we all must close our eyes and imagine we are still outside of bankruptcy. Claimants simply refuse to yield to a federal court. Never have. Never will. They do not even yield to state law in their imaginary world. Rather, the only world in which they believe disputed liability can be resolved is the barter-and-trade souk of privatized state tort-system settlements, complete with inauthentic goods and veiled threats. We cannot and do not seek to solve the problems of that "system" here, but rug-trading is not endorsed by the rules of law applicable to this proceeding.

As shown in Section II, far from departing from scientific method, Grace has used the only appropriate scientific methods; indeed, Grace has done the only scientific estimation in this case. The law requires the projection of Grace-caused disease. Science responds that such a projection can only be done using the methods followed by Grace's experts. The law then

replies (per *Daubert*) that the projection must then be done that way if the evidence is to be admissible.

Finally, Section III turns to the litany of specific criticisms lodged by the claimants. In each case, the claimants are just plain wrong, even incredible. Their contentions reduce to propositions as extreme as that they have been prevented from mustering the exposure data that uniquely rests in their hands to begin with. And those as misleading as that Grace's analysis of settlement amounts is comprised solely of information from six claims. Grace's analysis gave due consideration to hundreds of claims. And those as mundanely wrong as that Dr. Anderson's analysis excluded consideration of exposures that were "substantial contributing factors." Dr. Anderson excluded no such evidence.

At the end of the day, Grace has done its job in bringing the estimation of asbestos liability back to the world of law and science. This must in the end be the basis of estimation, not the haggling of the bazaar or the *ipse dixit* pronouncements of the claimants all-purpose "estimation" experts.

ARGUMENT

I. GRACE'S EXPERTS HAVE ASKED THE RIGHT QUESTION: WHAT IS GRACE'S LEGAL LIABILITY FOR ASBESTOS PERSONAL-INJURY CLAIMS AND FUTURE DEMANDS?

Grace's experts' reports meet the *Daubert* "fit" test because the reports and the testimony to be provided at trial are designed to provide this Court with evidence of Grace's actual legal liability on account of asbestos personal-injury claims and future demands under applicable state law and the federal rules of procedure and evidence – ***precisely*** the issue to be determined in the estimation proceeding.

A. Bankruptcy Law And Precedent Mandate An Assessment Of The Merits Of The Claims At Issue.

As previously argued in Grace's Opening Brief (at 9-16), the benchmark in this estimation proceeding is Grace's liability as a debtor; namely, what claims are allowable under § 502 of the Bankruptcy Code. Indeed, "[c]laims that are unenforceable against the debtor or against property of the debtor under any agreement or by applicable law . . . are simply not allowable for purposes of a right to share in a distribution of the debtor's assets." 4 *Collier on Bankruptcy* ¶ 502.03[2][b][iii] at 502-25 (15th ed. rev. 1999). Furthermore, Grace can only be held liable under § 502(b) of the Bankruptcy Code for asbestos personal-injury claims that are enforceable against it under state substantive ***law***, applying also the Federal Rules of Civil Procedure and the Federal Rules of Evidence to the allowance of any contested asbestos personal-injury claims.

These rules do not change because this is an estimation. And the robust factual record provided by the personal-injury POCs and PIQs authorized by the Court now permits a merits-based estimate of Grace's personal-injury liability that is consistent with § 502(b) of the Bankruptcy Code.

The *Dow Corning* case was discussed in Grace's Opening Brief, but should be consulted in further detail here because it is particularly instructive in understanding the application of state law and the Federal Rules of Evidence and Civil Procedure in determining a debtor's actual legal liability. There the debtor contested tort liability for thousands of breast-implant claims. Following extensive briefing concerning the proper method for estimating a disputed liability, the bankruptcy court decided that an estimation proceeding was not going to save time; instead, the court concluded that the parties should proceed directly to a full-blown claims-allowance process. *In re Dow Corning Corp.*, 211 B.R. 545, 573-574 (Bankr. E.D. Mich. 1997). The court

then explained that there were three possible paths upon which the allowance and liquidation of the mass-tort claims could proceed: "(1) settlement between the [parties]; (2) individualized adjudication of [the] tort claims; or (3) some form of collectivized adjudication." *Id.* at 576. Because of the delays associated with individualized adjudication of the tort claims in bankruptcy and the unlikelihood that the parties were going to reach a consensual settlement, the court favored the collective-litigation approach. *Id.* at 579. As the court explained, "actual liquidation via consolidation and bifurcation would prove to be the preferred option in this case if the case is not resolved consensually." *Id.* at 589.

Most importantly, the court made it clear that, in any causation trial that would result from the process, evidence would need to be admissible under Federal Rule of Evidence 702 and *Daubert*. *Id.* Hence, barring settlement, however the parties and the court in *Dow Corning* decided to undertake the claims-allowance process (via individual or collective adjudication), that process would be a federal-court proceeding governed by state substantive law as applied via the Federal Rules of Civil Procedure and Evidence. In fact, following issuance of Judge Spector's estimation opinion, Dow Corning incorporated the results of a Rule 706 Panel Report into a Consolidated Motion for Summary Judgment based upon causation and *Daubert*. This motion was pending at the time settlement was achieved.

The same rules necessarily govern estimation here, as estimation is simply a device by which the Court estimates or previews the aggregate result of the same full-blown litigation that the Court recommended in *Dow Corning*.

A similar merits-based approach to determining the debtor's liability within the parameters of a bankruptcy proceeding was outlined in *In re USG Corp.*, Case No. 01-2094 (JKF) (Bankr. D. Del. 2001). The *USG* court ordered the use of a claimant questionnaire for a

sample of the pending personal-injury claims very similar to (although somewhat more limited than) the questionnaire ordered in this case. (*See* Oct. 17, 2005 Order Re: Personal Injury Claim Estimation, (*In re USC Corp.*)) The parties ultimately settled before conducting the estimation trial. Until then, however, the case was proceeding on course to assess the underlying merit of the claims: the debtors were gathering evidence bearing upon the extent of their legal liability for asbestos claims, and the court was expressly approving the necessary discovery.

As reviewed in Grace's Opening Brief (at 14), this is also the approach taken in *Robins* in connection with the estimation of Dalkon Shield claims. *In re A.H. Robins Co.,* 880 F.2d 694, 700 (4th Cir. 1989) (affirming a district court's merits-based estimation of thousands of tort claims within the bankruptcy case).

B. In This *Bankruptcy* Case, the Law Does Not Allow Us to Somehow Pretend The *Bankruptcy* Case Was Never Filed.

Fighting to the end any effort to squarely address the fundamental legal principles Grace has placed before the Court in this case, claimants predictably urge that Grace is required as a matter of law to measure its liability by calculating the costs Grace would have incurred in the state tort system if Grace had never filed for bankruptcy. (PI Mot. at 13; FCR Mot. at 6) As discussed in Grace's Opening Brief (*see* pages 16-18), claimants rely on *Owens Corning, Armstrong, and Federal-Mogul* to support this contention. These cases should not be followed because they substitute settlement practices in the tort system for actual liability, in violation of § 502(b) of the Bankruptcy Code. *In re Armstrong World Indus., Inc.,* 348 B.R. 111, 124 (D. Del. 2006) (both sides proposed methodology based on the debtor's historical settlements); *Owens-Corning v. Credit Suisse First Boston,* 322 B.R. 719, 722-23 (D. Del. 2005) (court relied on historical settlements taking into consideration certain adjustments for probable changes in

the tort system); *In re Federal-Mogul Global, Inc.*, 330 B.R. 133, 157-58 (D. Del. 2005) (experts for competing sides both relying on historical settlement values. Moreover:

- The ultimate merits of the debtors' liability in the claimants' cases was not contested, there was no data collected in these cases that allowed an assessment of the merit of the claims, the parties essentially agreed to the use of settlement history as a proxy for determining actual liability (differing only in how that history should be applied). *See, e.g., In re Eagle-Picher Indus., Inc.*, 189 B.R. 681, 684-86 (Bankr. S.D. Ohio 1995); *Federal-Mogul*, 330 B.R. at 145-47; *Armstrong*, 348 B.R. at 123-124.

- The debtors, in some instances, supported or did not oppose the claimants' estimates. *See, e.g., Federal-Mogul*, 330 B.R. at 135 n.2 (debtors did not appear at contested estimation proceeding between a PI committee and a PD committee); *Armstrong*, 348 B.R. at 123-24 (debtor adopting PI committee approach to estimation as a co-proponent to the plan); *Owens-Corning*, 322 B.R. at 721 (debtor did not argue for any particular estimate in contested estimation between PI committee and FCR on the one side, and banks and bondholders on the other).

- Relevant legal principles received only glancing consideration, or no consideration at all. *See, e.g., Owens Corning*, 322 B.R. at 721-22; *Federal-Mogul*, 330 B.R. at 136, 155; *Armstrong*, 348 B.R. at 123 (all failing to consider the application of the Federal Rules of Civil Procedure or Evidence or *Daubert*).

- Evidence was barred for procedural reasons. *See Owens Corning*, Case No. 00-3837 (Bankr. D. Del) (Memorandum and Order dated Nov. 22, 2004) (denying as untimely motion of Credit Suisse First Boston to obtain certain medical records and related discovery).

Focusing on the meager legal analysis in these cases, it is obvious that two legal propositions were misused to bypass a careful construction of the legal foundations of estimation and deployment of legal tests in conducting the estimation. First, the unremarkable concept that value should be determined "as of" the petition date was taken to require that the claims must be analyzed as if the bankruptcy had never been filed, thereby obliterating the code provisions governing contested proceedings such as estimation. In *Owens Corning*, for example, the court correctly observed that claims under § 502(b) of the Bankruptcy Code are to be valued on the petition date. *Owens Corning v. Credit Suisse First Boston*, 322 B.R. 719, 722 (D. Del. 2005).

"Value as of the petition date," however, does not mean that the court should ignore the bankruptcy. It simply means that the total liability for present and future claims should be reduced to present value as of the date of the bankruptcy petition. *See, e.g.*, *In re Loewen Group Int'l*, 274 B.R. 427, 434 (Bankr. D. Del. 2002) (§ 502(b) requires the amount of the claim to be determined as of the petition date and where a disputed claim has been asserted in respect to future payments due post-petition, the claim must be discounted to present value as of the petition date).

Second, the cases take the applicability of state substantive ***law*** to mean that the court should assume we are still in state ***court***, indeed, ***outside*** the state courthouse in a state-based ***settlement*** negotiation process. Thus ignoring the bankruptcy filing ***and*** state substantive law violates § 502(b) of the Bankruptcy Code, which requires: (1) ***federal court*** application of (2) state ***substantive law*** (3) using the Federal ***Rules of Civil Procedure*** and ***Evidence***. The court in *Owens Corning* thus simply got it wrong when it noted, in a cite relied on by the FCR (*see* FCR Mot. at 15), that "[a]ll cases which can survive summary disposition under state law have some potential value." *Owens Corning v. Credit Suisse First Boston*, No. 04-00905 (Bankr. No. 00-03837), 2005 U.S. Dist. LEXIS 10752, at *3 (D. Del. Apr. 13, 2005). Whether a claim can survive a state summary disposition is entirely irrelevant. The only relevant issue is whether there will be legal liability under state substantive law as applied via federal procedures and rules of evidence.

A simple hypothetical illustrates the absurdity of the claimants' position were it to be applied to this case. Imagine a situation where a claimant's sole evidence of causation is the opinion of an expert witness whose work does not meet the requirements of Rule 702. Assume further that this same expert's opinion would, nonetheless, be presented to the jury in a state-

court trial. Obviously, there is the potential for liability in state court, but, ***as a matter of law***, ***no*** possibility of liability in a ***federal*** proceeding. Under the claimants' interpretation of the law, this claim would presumably command value in bankruptcy despite the fact that if the bankruptcy court (or the district court) were to conduct an allowance proceeding, the claim would be found to have ***no value at all***. This amounts to nothing short of an outright rejection of § 502(b) of the Bankruptcy Code, and tramples on all manner of rights held by Grace and other constituents in the process.

And the claimants' position is more absurd still. It would assign value based not on the predicted outcome of state-court litigation, but on the predicted outcome of settlement discussions, which are – by definition – even further removed from a merits adjudication in federal court.

C. It Has Been Plain for Years that Grace Does Not Seek To Disallow Claims.

Claimants reprise an argument that was rendered moot years ago: that Grace improperly seeks to disallow claims. There is simply no truth to this assertion. It was at claimants' insistence that Grace long ago forewent any attempt to engage in a consolidated allowance process. Instead, the decision was made to embark on a course of estimation – the whole point of which was to ***avoid*** the very issue claimants now seek to raise.

What claimants are really unhappy about is that, in an aggregate estimation of Grace's liability, claims that are not supported by appropriate evidence of legal liability are given no value for estimation purposes. This, claimants argue, amounts to a claims-disallowance process. (PI Mot. at 13 n.3; FCR Mot. at 2, 10-11)

This is false on its face. Grace is not asking the Court to disallow any claims or otherwise engage in a liquidation of individual personal-injury tort claims. The purpose of the estimation is to determine Grace's aggregate liability for asbestos personal-injury claims and

future demands for purposes of plan feasibility and confirmability. No individual claims will be allowed or disallowed in this estimation proceeding.

Moreover, not only is there is no legal prohibition on estimating one or more claims at zero value, § 502(b) ***mandates*** a zero-value estimation if the claim is without merit. *Bittner v. Borne Chem. Co.*, 691 F.2d 134, 136-37 (3d Cir. 1982) (no abuse of discretion in temporarily allowing claims at $0 based on the court's view of the ultimate merits of the claim); *In re Corey*, 892 F.2d 829, 834 (9th Cir. 1989) (lower court estimate of certain property claim at $0 affirmed "[g]iven the highly speculative nature" of those claims); *In re MacDonald*, 128 B.R. 161, 167 (Bankr. W.D. Tex. 1991) (post-petition administrative claim for fraud valued at $0 for voting purposes where the claimant offered at estimation hearing "no competent 'summary trial' evidence"); *In re Baldwin-United Corp.*, 55 B.R. 885, 898 (Bankr. S.D. Ohio 1985) (court estimated certain claims at $0 for purposes of allowance under § 502(c)).

And the notion that estimation of non-meritorious claims at zero value is prohibited yields a pile of inconsistent absurdities if it is followed to its logical conclusion. If no claim can be estimated at zero, every claim must be credited with value and the aggregate estimate will, by definition, ***overstate*** actual liability. This problem cannot be avoided by arguing that some claims can be assigned low values. All value should be a function of the legal merits. Would claimants be satisfied if Florence had added $1 to his estimate for each of the claims he valued at zero? What about $100, or $1000? The test cannot be whether an estimate includes zero values. The test is whether the estimate tracks legal liability.

D. Grace's Approach Alone Follows "State Law" and the Bankruptcy Code.

Claimants contend that Grace's experts have rejected state-court settlement values as the measure of liability and substituted "unprecedented criteria" that "do not reflect the law of any state or the tort system generally." (PI Mot. at 5; *see also id.* at 5-6, 16-18; FCR Mot. at 13-14)

Nothing could be further from the truth. Far from overriding or supplanting the law, Grace's approach – in contrast to that of the claimants – follows and applies the law.

As discussed extensively in Section II, below, the key drivers of the estimation process ***in this case*** are, first, a basic element of tort law in every jurisdiction, proof of causation. The second driver is the federal evidentiary law that governs proof of toxic-tort causation in federal court litigation.

These were ***not*** the same criteria that drove settlements. (*See* Peterson Dep. at 171-72 (actual exposure data and actual medical condition and actual causation had little to do with settlements)) They may or may not be the criteria that would drive adjudication in state court were anyone to engage in that exercise. They ***are***, however, the drivers here, in federal bankruptcy court.

Claimants have not, and cannot, argue otherwise. They cite ***no*** case holding that state law does not include the requirements of causation. They cite ***no*** case that says a plaintiff's expert causation evidence in a toxic-tort case litigated in federal court is excused from satisfying the requirements of Rule 702 and *Daubert*. Indeed, it is no accident that asbestos plaintiffs have ***never engaged in significant federal court litigation.*** (Dunbar Rebuttal Rpt. to Biggs at 10-12; Dunbar Rebuttal Rpt. to Peterson at 4-6 ("History demonstrates" that the federal system handles claims differently, and since 1992 "all federal court asbestos cases have been subject to an order dismissing the claims of those who cannot produce evidence of impairment caused by asbestos.")) For claimants to do so would, given *Daubert*, have exposed critical weaknesses in their cases and led to unfavorable legal precedents. This estimation is forcing the day of reckoning. Application of the law, however, cannot be avoided by arguing the results would be different if we were ***not*** in a federal bankruptcy court.

Claimants have no more basis to argue against the application of federal standards for proof of their claims than a diversity plaintiff has the right to appeal an adverse summary judgment ruling or adverse verdict on the ground that things would have turned out better for him had he been able to press his case in state court under different procedural rules and evidentiary standards. *See, e.g.*, *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) ("[T]he admissibility of expert testimony in federal court sitting in the diversity jurisdiction is controlled by federal law. ***State law, whatever it may be, is irrelevant***.") (quoting *Cavallo v. Star Enter.*, 100 F.3d 1150, 1157 (4th Cir. 1996) (emphasis added); *Schrott v. Bristol-Myers Squibb Co.*, 403 F.3d 940, 943 (7th Cir. 2005) ("It is frivolous to assert that a federal court should not have applied the federal rules governing expert witnesses, just because the case happened to be a diversity case and thus one governed by state substantive law. Federal courts do, and must, apply both the Federal Rules of Evidence and other evidentiary rules derived from federal statutes, Supreme Court decisions, or other sources of federal law, in their proceedings"); *Grant Thornton, LLP v. FDIC*, 297 F. Supp. 2d 880, 882 (S.D. W. Va. 2004) ("The admissibility of expert testimony in federal court is controlled by federal law, namely the Federal Rules of Evidence").

II. GRACE'S EXPERTS USE ESTABLISHED SCIENTIFIC METHODS TO ASSESS THE MERITS OF THE CLAIMS AT ISSUE.

The substantive state law of causation and the federal rules under *Daubert* converge on two key questions: (1) whether a claimant can prove he or she has an asbestos-related disease; and (2) whether a claimant can prove that disease was caused by a Grace asbestos-containing product. These are the questions that Grace asks of the claims pending as of April 2001, in order to determine the extent to which those claims are legally valid. That determination, in turn,

allows a further finding as to the likely number of Grace-caused valid claims to come in the future.

As a matter of law ***and*** science, analysis of these issues ***requires*** the deployment of established scientific methodologies, and the application of those methods to the facts of the case. This is what Grace's experts have done.

A. State Substantive Law and *Daubert* Impose the Key Requirements for Proving Legal Liability.

Though claimants spill much ink criticizing Grace's experts for not following what they say the "law" requires, they studiously avoid careful explanation of the actual legal standards that govern the validity of the claims to be estimated. This is because their true position is that claim values should not be determined by actual legal liability. The necessary explanation that they omit follows here.

1. The law requires proof of exposure to a specific defendant's product.

Every state's law requires an asbestos plaintiff to prove exposure to the defendant's product. "A threshold requirement of the toxic tort actions for asbestos-related injury is the identification of the injury causing product and its manufacturer, coupled with proof of exposure, once a plaintiff establishes that the defendant's asbestos-containing product was used at the job site at the same time plaintiff was employed there." *Asbestos Injury Litigation*, 60 *Am. Jur. Trials* 73 § 42 (Feb. 2007). *In re TMI*, 67 F.3d 1103, 1118 (3d Cir. 1995) ("plaintiff must demonstrate exposure" to alleged cause); *In re Paoli Railroad Yard PCB Litigation***,** 916 F.2d 829, 860 (3d Cir.1990) (holding exposure to be an element of claim for injuries from hazardous substance).

Thus, as an initial matter, claimants must provide evidence that they were actually exposed to asbestos attributable to Grace. *See In re TMI*, 67 F.3d at 1118 (requiring proof of

"exposure to radiation released during the TMI accident"); *Harris v. Owens-Corning Fiberglas Corp.*, 102 F.3d 1429, 1432 (7th Cir. 1996) (holding that plaintiff does not meet burden of showing cause "simply by establishing that he inhaled asbestos dust; rather, he must produce evidence tending to show that he inhaled asbestos produced by the ***defendant's*** product") (emphasis in original); *Gorman-Rupp Co. v. Hall*, 908 So. 2d 749, 757 (Miss. 2005) (finding summary judgment appropriate where plaintiff failed to provide evidence that he was exposed to any asbestos-containing product attributable to defendant); *see also Schmidt v. A-Best Prods. Co.*, 2004 WL 2676319, at *5 (Ohio App. Nov. 22, 2004) (same).

2. The law requires proof of risk and causation.

Every jurisdiction also requires that there be actual causation. It is axiomatic that "[p]roof of causation is a necessary element in a products liability action. Absent a causal relationship between the defendant's product and the plaintiff's injury the defendant cannot be held liable on a theory of negligence, strict product liability, or misrepresentation." *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 524 (W.D. Pa. 2003). *See also In re TMI*, 67 F.3d at 1118 (**"**In toxic tort litigation, however, causation is not a simple matter for the jury. The plaintiff must establish by a preponderance of evidence the presence of the injury-causing substance, that he or she has been exposed to the substance, and ***that the exposure has resulted in certain injuries."***) (quoting *A Guide to Toxic Torts* (MB), § 10.01[2](a), at 10-5 (1995) (emphasis added)).

In the toxic tort context, as the *Restatement (Third) of Torts* explains, "[m]ost causation issues are resolved under the 'but-for' standard for factual cause. . . . The plaintiff must prove by a preponderance of the evidence that, but for defendant's tortious conduct with respect to the toxic substance, the plaintiff would not have suffered harm." *Restatement (Third) of Torts: Liab. Physical Harm* § 28, cmt. *c(1)*. In the asbestos context, "[t]he plaintiff must introduce direct

expert medical testimony that exposure to a defendant's asbestos-containing product was the cause of his or her asbestos-related disease. Stated somewhat differently, it is incumbent upon plaintiff to produce expert medical testimony showing that 'but for' exposure to defendant's asbestos-containing product, he or she would not have contracted an asbestos-related disease." *Asbestos Injury Litigation*, 60 *Am. Jur. Trials* 73 § 44 (Feb. 2007).

It should go without saying, but exposure is not the same thing legally as causation. *In re TMI*, 67 F.3d at 1119 (the law "breaks up the causation and injury requirements into three elements, adding an "exposure" prong into the causation and injury inquiry"); *id.* (summary judgment may be entered on exposure, injury, ***or*** causation)**.** In the asbestos context, "the mere 'showing that the asbestos manufacturer's product was present somewhere at his place of work' is insufficient." *Stark v. Armstrong World Indus., Inc.*, 21 Fed. Appx. 371, 376 (6th Cir. 2001) (quoting *Roberts v. Owens-Corning Fiberglas Corp.*, 726 F. Supp. 172, 174 (W.D. Mich. 1989)); *see also Lohrmann v. Pittsburgh Corning Corp.*, 782 F.2d 1156 (4th Cir. 1986) (under Maryland law, evidence of the use of three manufacturers' asbestos products in the plaintiff's workplace was insufficient to attribute liability for the plaintiff's injury); *Anchor Packing Co. v. Grimshaw*, 692 A.2d 5 (Md. Spec. App. 1997) (evidence that manufacturer's asbestos products were generally used in the plaintiff's workplace was insufficient alone to establish that the defendant's products caused the plaintiff's injury), *vacated on other grounds*, *Porter Hayden v. Bullinger*, 713 A.2d 962, 969 (1998)). *Cf. Wendt v. Asbestos Corp.*, 983 F.2d 1071, 1992 WL 379433, at *3 (6th Cir. 1992) ("Under Ohio law, Mrs. Wendt must prove not only that Mr. Wendt's lung cancer was caused by asbestos exposure but that it was caused specifically by exposure to asbestos fibers sold by ACL."); *Lee v. Pittsurgh Corning Corp.*, 616 A.2d 1045 (Pa. Super. 1992).

We then get to the next, related (but separate) issue: the rules governing the ***evidence*** of causation. Saying that a plaintiff must establish causation under state substantive law, however, is a distinct issue from saying ***how*** a plaintiff must prove toxic-tort causation in a federal-court proceeding. Put another way, state substantive law describes what a defendant can be held liable for (*e.g.*, causing injury via exposure to a product), but federal procedural rules – including *Daubert*'s requirement of legal relevance and scientific reliability – determine what evidence will suffice to establish that condition has been met (*e.g.*, did the defendant's product cause the injury).

Daubert, the Federal Rules of Evidence, and federal courts require in toxic-tort cases that a plaintiff prove by a preponderance of the evidence, that the substance at issue is both capable of causing the disease at issue, so-called general causation, and that the substance did in fact cause the plaintiff's disease, so-called specific causation. *Soldo*, 244 F. Supp. 2d at 524-25 ("to meet her causation burden, plaintiff must first establish that Parlodel ***is capable of causing*** ICH (general causation). She must then establish that, in her particular case, Parlodel ***did in fact cause*** her ICH (specific causation).").

General causation is, itself, an absolute prerequisite to showing causation. "If plaintiff has not demonstrated sufficiently reliable evidence of ***general*** causation, her claims fail and there is no need to consider ***specific*** causation." *See id.*; *see also Wade-Greaux v. Whitehall Labs, Inc.*, 874 F. Supp. 1441, 1485 (D.V.I. 1994), *aff'd without opinion*, 46 F.3d 1120 (3d Cir. 1994) ("To prove specific causation, plaintiff must ***first*** prove that the products at issue can cause [injury] and must ***then*** exclude other possible causes for the plaintiff's injury."). As one court has noted, "Far from constituting some type of dubious 'shield' . . . , the requirement of general

causation as an aspect of a scientifically-reliable causation opinion is the very essence of *Daubert*." *Soldo*, 244 F. Supp. 2d at 525.

Under *Daubert*, whether a plaintiff is able to provide evidence of causation depends upon whether he or she can produce scientifically-reliable evidence that exposure to the agent can demonstrably ***increase the risk*** of disease in a population (general causation). The plaintiff must also show that his or her ***increased risk*** is such that the toxic agent is the likely cause of his or her disease (specific causation). Such proofs are impossible without ***quantification of exposure and assessment of any resulting increase in risk*** as determined by the application of the scientific discipline of epidemiology. *See* Fed. Jud. Ctr., *Reference Manual on Sci. Evid.* 401 (2d ed. 2000) (citing National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (1983) ("The National Academy of Sciences defines four components of risk assessment: hazard identification, dose-response estimation, exposure assessment, and risk characterization.")); *see also In re W.R. Grace & Co.*, 355 B.R. 462, 486 (Bankr. D.Del. 2006) (same).

To pass *Daubert*'s reliability and relevance requirements, the result of any risk assessment (whether on a population basis for general causation or an individual basis for specific causation) must be a statistically significant increase in relative risk – generally at least by a factor of 2.0. This proposition is confirmed in innumerable authorities: "***The threshold for concluding that an agent was more likely than not the cause of an individual's disease is a relative risk of greater than 2.0***." Fed. Jud. Ctr., *Reference Manual on Scientific Evidence* 333, 383-84 (2d ed. 2000) (citing cases); *DeLuca v. Merrell Dow Pharms., Inc.*, 911 F.2d 941, 958-59 (3d Cir. 1990) (requiring Bendectin plaintiffs to establish relative risk of limb reduction defects arising from epidemiological data of at least 2.0, which equates to more than a doubling of the

risk); *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1320 (9th Cir.), *cert denied*, 516 U.S. 869 (1995) (requiring Bendectin plaintiffs to show that mothers' ingestion of the drug more than doubled the likelihood of birth defects); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1403 (D. Or. 1996) (requiring breast-implant plaintiffs to demonstrate that exposure to breast implants more than doubled the risk of their alleged injuries, which, in epidemiological terms, requires a relative risk of more than 2.0); *Manko v. United States*, 636 F. Supp. 1419, 1434 (W.D. Mo. 1986) (stating that a relative risk of 2.0 in an epidemiological study means that the disease more likely than not was caused by the event), *aff'd in relevant part*, 830 F.2d 831 (8th Cir. 1987); *Marder v. G.D. Searle & Co.*, 630 F. Supp. 1087, 1092 (D. Md. 1986) (stating that, in IUD litigation, a showing of causation by a preponderance of the evidence, in epidemiological terms, requires a relative risk of at least 2.0); *Cook v. United States*, 545 F. Supp. 306, 308 (N.D. Cal. 1982) (stating that in vaccine cases, when relative risk is greater than 2.0, there is a greater than 50% chance that the injury was caused by the vaccination).

Without evidence of a doubling of risk, there is no basis for scientifically reliable testimony that the toxic agent is capable of causing the disease at a general level, or, in the context of an individual risk assessment, caused the plaintiff's disease. *See, e.g., Ambrosini v. Upjohn Co.*, 1995 WL 637650 (D.D.C. 1995); *Sanderson v. Int'l Flavors & Fragrances, Inc.*, 950 F. Supp. 981 (C.D. Cal. 1996); *Hall*, 947 F. Supp. 1387; *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217 (D. Colo. 1998).

In some cases, the doubling-of-risk requirement has been relaxed in degree, but not in kind, and even then only where there is additional scientifically reliable evidence of causation that, when considered with the epidemiology, allows for a finding of causation. *See* Mem. Op. re Summary Judgment Mots re ZAI Property Claims, *In re W.R. Grace & Co.*, No. 01-01139 at 33-

34 (Bankr. D. Del. Dec. 14, 2006) [Dkt. No. 14014] ("some courts have allowed slightly lower rates (*e.g.*, 1.75 or 1.5) when other factors such a genetics combine to raise the risk to 2.0") ("*ZAI* Opinion") *see also* Fed. Jud. Ctr., *Reference Manual on Scientific Evidence* 333, 386 (2d ed. 2000); *In re Joint E. & S. Dist. Asbestos Litig.*, 827 F. Supp. 1014, 1030 (S.D.N.Y. 1993). Here, however, claimants have ***not*** provided any scientifically valid basis upon which to lower the 2.0 relative-risk threshold. The classic doubling-of-risk requirement therefore applies, and provides a working standard for relevant and admissible evidence of general causation in estimating the appropriate liability for existing and future asbestos personal-injury claims in this case. *See*, *e.g.*, *ZAI* Opinion at 34 ("We have no such evidence on this record and no reason to lower the rate below 2.0. Therefore, we accept Grace's position that Claimants must establish causation by a 2.0 relative risk rate.").

3. State law regarding "substantial contributing factor" does not change the analysis.

Claimants argue that the "substantial factor" test for causation reverses the requirements of *Daubert* and abrogates the basic principles of causation under state law. It does not. Moreover, no matter what the implications of the substantial-factor test are for what constitutes a legal cause under state law, it has no ultimate impact on ***how*** – with what ***evidence*** – a plaintiff must prove causation under the Federal Rules of Evidence. Regardless of what "type" of causation one must prove, the proof must be scientifically reliable under *Daubert.* In the toxic-tort context, that still means showing, via reliable epidemiological evidence, a doubling of risk as a result of exposure to a defendant's product.

As an initial matter, the "substantial factor" test does not properly expand the scope of legal causation under state law; if anything, properly applied, it limits it.

> [M]any courts have held that the "substantial factor" standard is a heightened one compared to the "but for" test. For example, in

> *Zuchowiz v. United States*, Judge Guido Calabresi outlined "the substantial factor" test for the Second Circuit as follows: "(a) that the defendant's negligent act or omission was a but for cause of the injury, (b) that the negligence was causally linked to the harm, and (c) that the defendant's negligent act or omission was proximate to the resulting injury." . . . Clearly, in [this] jurisdiction, the "substantial factor" test requires an additional showing beyond "but for."

J. Rue, *Returning to the Roots of the Bramble Bush: The 'But For' Test Regains Primacy in Causal Analysis in the American Law Institute's Proposed Restatement (Third) of Torts*, 71 Fordham L. Rev. 2679, 2713-14 (2003); *Cf. Menne v. Celotex Corp.*, 861 F.2d 1453, 1461 (10th Cir. 1989) ("under the Nebraska concurrent cause cases, neither group causation nor reliance on a solitary substantial factor test has replaced the need for ***each*** liable defendant to be a but-for ***and*** substantial contributor to the indivisible injury.") (emphasis in original).

Some state courts have held otherwise, and, according to the American Law Institute, "employed the substantial factor test in ways, and in the pursuit of ends, utterly foreign to the original purpose of the rule." *Id.* at 2682. Indeed, "[i]t is not at all clear that the ALI intended the 'substantial factor' doctrine to offer courts the option of a reduced standard of causation. In fact, in coining the phrase 'substantial factor,' the drafters of the original Restatement seem to have been primarily concerned with protecting defendants from unlimited liability from the 'but for' results of their tortious acts." *Id.* at 2690. *See also* D. Gifford, *The Challenge to the Individual Causation Requirement in Mass Products Torts*, 62 Wash. & Lee L. Rev. 873, 874-75 (2005) ("With or without a requirement that the plaintiff prove that the injurer acted with fault in order to recover, tort law traditionally accepted the notion that a particular plaintiff must prove that a particular defendant's acts caused the plaintiff's injuries. Yet during the past quarter-century, this requirement has been challenged, particularly in mass products torts and in environmental cases. As early as 1987, legal philosopher Judith Jarvis Thomas observed, 'Fault

went first . . . [n]ow cause is going.'") (quoting Judith Jarvis Thompson, *The Decline of Cause*, 76 Geo. L. J. 137, 137 (1987)).

Regardless of which side one takes in this particular debate, however, it is undisputed, and indisputable, that in ***every*** jurisdiction there must still be a showing of causation, whether by a single cause or multiple causes, one of which was a "substantial factor" in causing the injury. In other words, a toxic tort plaintiff must still prove a "causal relation between a chemical compound and a set of symptoms or disease," and to do so via expert testimony based on reliable epidemiologic principles and studies. *In re W. R. Grace & Co.*, 355 B.R. at 482 (citing *Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1356 (N.D. Ga. 2001)). Even under a substantial-factor regime, it remains "incumbent upon plaintiff to demonstrate by a preponderance of the evidence that exposure to each named defendant's asbestos-containing product was a substantial factor in causing or bringing about the alleged injury." *Asbestos Injury Litigation*, 60 *Am. Jur. Trials* 73 § 42 (Feb. 2007). Thus, a federal-court plaintiff must still prove causation, by providing scientifically reliable evidence of: exposure, increased risk sufficient to show that, more likely than not, the agent or agents at issue cause the injury, and that the defendant's contribution to the established increased risk was "substantial."

It is also true – and completely consonant with Grace's position – that courts assessing whether a defendant's contribution was "substantial" under state law typically employ the so-called "frequency, regularity, and proximity" test. One authority has categorized such showing as "proof of risk" including identification of defendant, defendant's asbestos-containing product, demonstrating exposure to the asbestos containing product, and establishing the duration of exposure. *Asbestos Injury Litigation*, 60 *Am. Jur. Trials* 73 § 41 (Feb. 2007). In fact, "[t]he vast majority of State and Federal courts considering asbestos cases have adopted the test as set forth

in *Lohrmann v. Pittsburgh Corning Corp.*, 782 F.2d 1156 (4th Cir. 1986), the so-called 'frequency, regularity, and proximity test." *Wehmeier v. UNR Indus., Inc.*, 572 N.E.2d 320, 335-36 (Ill. App. 1991) (citing cases).

> The *Lohrmann* court noted the test required a plaintiff to prove ***more than a casual or minimum contact*** with the product. In *Lohrmann*, the court directed a verdict for four asbestos defendants after finding there was insufficient evidence of causation presented. Plaintiffs' evidence established only that the defendants' product was at the workplace while plaintiff was employed there. The court noted that applicable State law (Maryland) required evidence from which a jury could reasonably find that conduct of the defendant was a substantial factor in bringing about the result.
>
> *Id.* at 336 (citing *Lohrmann*, 782 F.2d at 1162).

This test is entirely consistent with *Daubert*, the Federal Rules, and, ultimately, the doubling-of-risk requirement. As the Maryland Supreme Court explained:

> Whether the exposure of any given bystander to any particular supplier's product will be legally sufficient to permit a finding of substantial-factor causation is fact specific to each case. The finding involves the interrelationship between the use of a defendant's product at the workplace and the activities of the plaintiff at the workplace. This requires an understanding of the physical characteristics of the workplace and of the relationship between the activities of the direct users of the product and the bystander plaintiff. Within that context, the factors to be evaluated include the ***nature of the product***, the ***frequency of its use***, the ***proximity***, in distance and in time, of a plaintiff to use the product, and the ***regularity*** of the exposure of that plaintiff to the use of that product. In addition, trial courts must consider the evidence presented as to medical causation of the plaintiff's particular disease.

Eagle-Picher, 604 A.2d at 460 (emphasis added; citation omitted); *Johnson v. Owens-Corning Fiberglass Corp.*, 729 N.E.2d 883, 887 (Ill. App. 2000) (to meet the burden of proving causation in fact, "a plaintiff must show that the injured party was exposed to the defendant's asbestos through proof that he regularly worked in an area where the defendant's asbestos was frequently used and the injured party worked in sufficient proximity to this area so as to come into contact with the defendant's product. This test is often referred to as the 'frequency, regularity and proximity' or 'substantial factor' test.").

Critically, the legal formulation of substantial factor ***does not change the scientific mandate under federal law Daubert*** that a causal association can only be shown in a toxic-tort case via a quantification of exposure and an epidemiological assessment of the resulting increase in risk. *See e.g., Grant v. Bristol-Myers Squibb*, 97 F. Supp. 2d 986, 992 (D. Ariz. 2000) (applying 2.0 relative-risk threshold under federal law even though same standard would not be mandated under state law). *Compare also, DeLuca*, 911 F.2d at 958-59 (requiring in case arising under New Jersey law that if Bendectin plaintiffs are to establish causation of limb-reduction defects via epidemiological data, they must show an increased relative risk of at least 2.0, which equates to more than a doubling of the risk), *with Landrigan v. Celotex Corp.*, 605 A.2d 1079, 1087 (N.J. 1992) (rejecting a 2.0 relative-risk threshold for the admission of epidemiological evidence).

Put simply, frequency, regularity, and proximity sufficient to prove cause must be established ***scientifically*** using ***scientific evidence***. *See Jones v. John Crane, Inc.*, 143 Cal. App. 4th 990, 9998 (Cal. App. 2005) ("the critical question is whether a 'plaintiff's exposure to [a] defendant's asbestos-containing product in reasonable medical probability was a substantial factor in contributing to the aggregate ***dose*** of asbestos the plaintiff or decedent inhaled or ingested; and hence to the ***risk*** of developing asbestos-related cancer.'"). Thus, Grace claimants must still have reliable, quantified evidence of ***exposure*** to Grace asbestos-containing products that, under established epidemiological models shows sufficient ***increased risk*** to have caused their disease. Properly applied, the substantial factor test ***adds*** the requirement that Grace's contribution to any aggregate increase in risk they experienced was ***substantial***. Even if one assumes, however, that the substantial factor test somehow relaxes the ***legal*** requirement for showing causation, they have not and cannot point to any precedent that holds the substantial-

factor test lowers the ***scientific*** requirement of showing a doubling of risk to establish any form of causation – substantial or otherwise.

The ***same conclusion*** – that proof of causation requires classic toxic-tort risk assessment – also is compelled by ***consensus science***. This is described immediately below.

B. Established Law and Science Say that Epidemiology Is the Only Way to Go and Epidemiology Frames the Overall Task Here: Determining Past and Future Grace-Caused Disease.

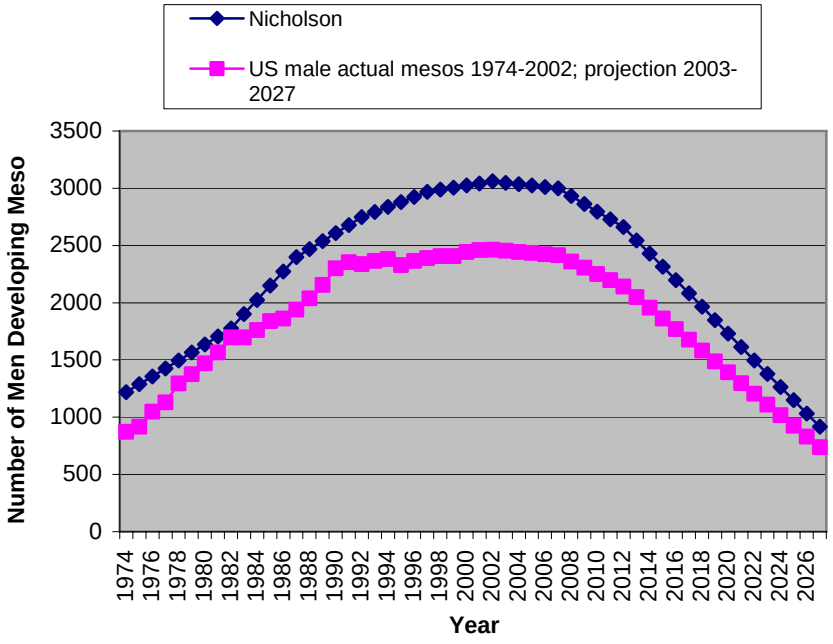
Grace's estimation is grounded on – indeed driven by – basic epidemiology. Epidemiology focuses on disease (a required element of legal liability) and causation (another required element). Epidemiology also uses the disease process to forecast the future (required here for Chapter 11 purposes). Thus, epidemiology and epidemiology alone, provides the overall scientific framework for estimation of legal liability. And legal liability reciprocally mandates epidemiology as a predicate for reliable evidence. Fortunately, the epidemiology of asbestos-related disease is mature science.

1. The Nicholson model.

Dr. Irving Selikoff is universally recognized as one of the original scientists credited with epidemiological research firmly establishing the scientific link between asbestos exposure and disease, including cancer. In this case, as in almost every asbestos case in the state-court system, the parties – including plaintiffs and their experts – discuss and rely upon Dr. Selikoff's scientific work, and that of his Mount Sinai colleagues. (*See, e.g.*, Peterson Rpt. at 62) Based upon their early epidemiological studies, Dr. Selikoff and his colleagues, including Dr. William Nicholson, helped OSHA and the EPA create the first dose-response models for asbestos exposure and disease. EPA, *Airborne Asbestos Health Assessment Update* (1986); *see also* 51 F.R. 22612 (June 20, 1986) (numerous references to Dr. Nicholson at 22633-40); William J. Nicholson, *Environmental Protection Agency Health Effects Update,* OSHA Docket H033C #84-224 (June

1983). Further, Dr. Nicholson is credited with publishing an epidemiologically based estimate of future cancers that has been hailed for predicting the number of mesotheliomas that would occur in the future due to past asbestos exposures. This work has generated disease "curves" that show the progression, over time, of various asbestos-related conditions, as exemplified in the following chart, which shows the projected and actual incidence of cases of mesothelioma in men from 1974-2027:

Nicholson's Estimate of Number of Men Developing Mesothelioma 1974-2027 (top curve)
Actual Number of Men Developing Mesothelioma 1974 - 2002 (bottom curve)
2003-2027 Projection (bottom curve) Applies Nicholson's Rate of Change to Actual Numbers



(Ory Rpt. at 32)

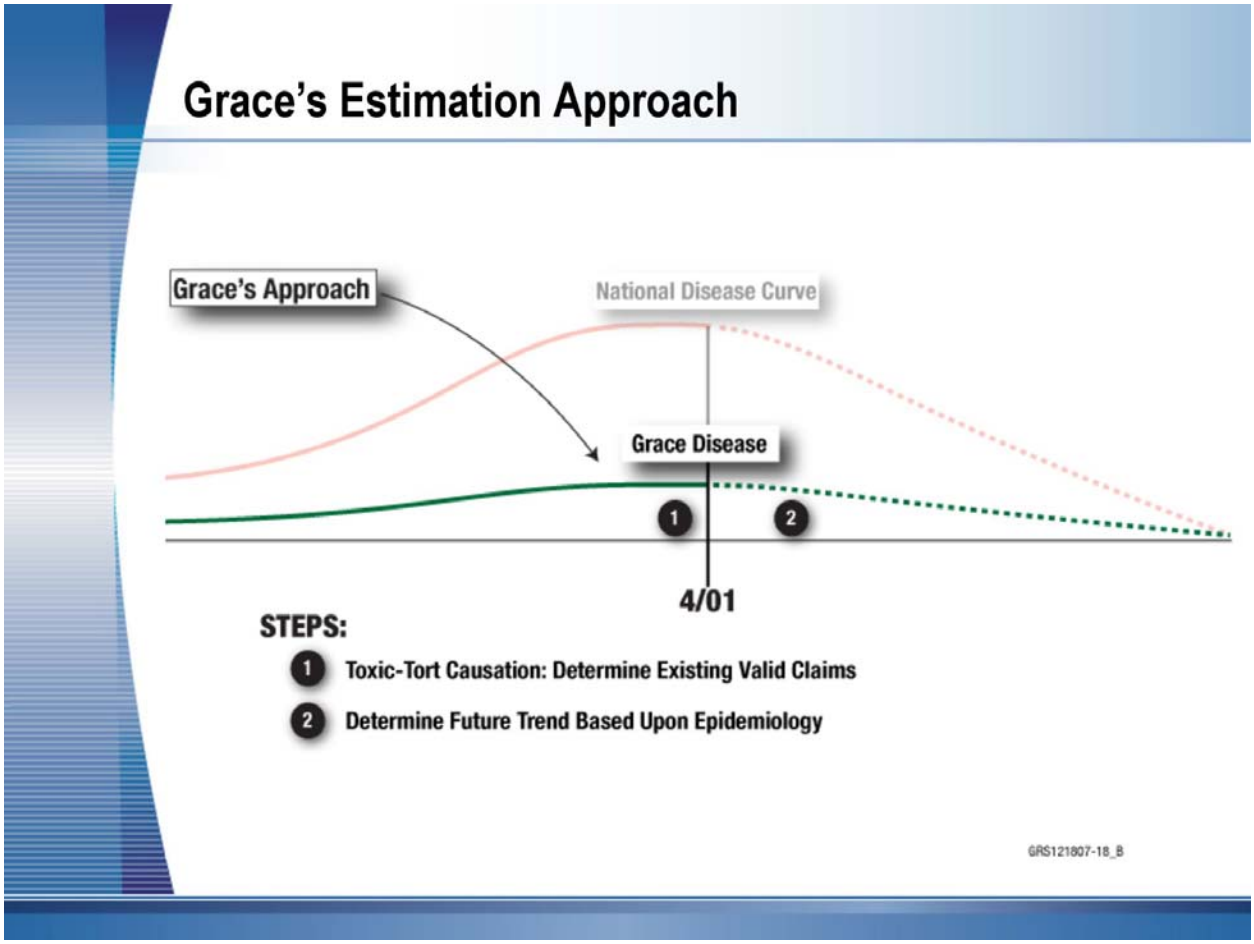
The efficacy of Nicholson's epidemiological approach to estimating the total mesothelioma cases that will result ***nationally*** from asbestos exposure ***nationally*** cannot seriously be disputed by the claimants or their experts in this case. Bankruptcy claimants' experts in past bankruptcies have testified that their models have ***as their foundation*** – the

epidemiological model established by Dr. Nicholson in 1982. *See, e.g.*, *M. Peterson Dep.*, *Official Comm. of Asbestos Personal Injury Claimants v. Fresnius Med. Care Hldgs.,* Adv. Nos. 02-2210 and 02-2211 ("Sealed Air"), at 37 (Bankr. D. Del. Sept. 9, 2002) ("I rely on the existing epidemiological work by Nicholson and his successors."); M. Peterson, *In re. Armstrong World Indus.,* No. 00-4471, at 35 (Bankr. D. Del. Mar. 29, 2006) ("In each future year the forecast number of mesothelioma claim filings is calculated by multiplying the Nicholson incidence for that year . . . times the propensity to sue for that year."); M. Peterson Rpt., *Official Comm. of Asbestos Claimants v. Asbestos Property Damage Comm.*, Adv. No. 05-59 ("*Federal-Mogul*"), at 31 (Bankr. D. Del. Nov. 9, 2004) ("The number of claims forecast for each type of cancer in each future year is derived by multiplying the number of deaths projected by Nicholson for that year by the likely propensity to sue for that cancer.").

2. Applying the Nicholson model to Grace.

There obviously cannot be more valid claims against Grace than there are nationally cases of actual disease, nor could all cases of disease nationally be attributable to Grace asbestos-containing products. The Nicholson curve thus represents an out-of-reach upper-bound on valid claims.

The key question thus becomes how to determine the "Grace curve," *i.e.*, that portion of the area under the Nicholson curve of disease that represents disease ***caused by*** Grace. This necessitates an assessment of claims reflecting disease caused by Grace and lodged as of a certain date (here the filing of Grace's petition), an application of the Nicholson inputs to determine the future course of the Grace-caused disease curve, and, ultimately, a determination of the aggregate value of the current and future claims. This is illustrated in the following chart:



This analysis – the determination of how to take the established population-based disease curves and derive the Grace-specific curve – is driven by three key requirements that are imposed ***both*** by ***science*** and the ***law***:

KEY POINT #1: **If there is to be any hope of reliably establishing that the plaintiff's disease was caused by asbestos, it is *essential* that an asbestos plaintiff not simply show that he has been exposed to asbestos, but that the plaintiff identify the particular product to which he was exposed, and the conditions and manner in which that exposure took place.**

As far back as 1965, Dr. Selikoff recognized that causation of disease by asbestos was dependent upon certain factors and that some products and exposure circumstances would be capable of substantially contributing to risk of disease while others would not:

> It is inadequate to speak now of "asbestos workers." With the growth of asbestos utilization, including rapid multiplication of the number and variety of its applications, it would perhaps be more accurate to categorize workmen exposed to asbestos as "asbestos textile workers," "asbestos insulation workers," "asbestos miners," "asbestos mill workers," "asbestos-cement workers," etc. ***The different occupations vary widely in important respects; in intimacy, intensity and duration of exposure, in variety and grade of asbestos used, in working conditions, in concomitant exposure to other dusts or inhalants.*** The importance of this distinction and the parallel obligation to evaluate and study the experience of asbestos exposure in other trades, is emphasized by the fact that asbestos textile workers are now a minority of those exposed during the industrial use of asbestos.

I.J. Selikoff, J. Churg, & E.C. Hammond, *The Occurrence Of Asbestosis Among Insulation Workers in the United States,* 132 Ann. N.Y. Acad. Sci. 139 (1965) (emphasis added). The implication of these conclusions for asbestos plaintiffs (or claimants) is that it is not enough to simply say "I was exposed." More detail is required before there can be any ***scientifically*** reliable assessment of what the plaintiff/claimant's exposure was.

KEY POINT #2: **As a matter of both law and science, it is *essential* that an asbestos plaintiff not simply establish exposure, but that there be a reliable estimate of the dose he or she received as a result of this exposure to asbestos-containing products so that there can be a reliable assessment of the *risk* posed to the plaintiff by the exposure at issue and that that risk be sufficient to support the proposition that the exposure at issue caused the disease.**

Dr. Nicholson's model took into account: (1) exposure; (2) relative risk of disease; and (3) actual occurrence or incidence of disease. *See generally* William J. Nicholson, George Perkel & Irving J. Selikoff, *Occupational Exposure To Asbestos: Population At Risk And Projected Mortality - 1980-2030*, 3 Am. J. Indus. Med. 259, 285 (1982). Every scientific expert in this case has testified that it is well-settled that those factors are crucial to understanding the dose-response relationship of asbestos and disease and the capability of particular asbestos

exposures to be causally related to disease in individuals and populations. (*See, e.g.*, Welch Dep. at 56; Roggli Dep. at 102.) At the core of all of this work is the recognition that the development of asbestos-related disease is dependent upon the level of exposure to asbestos experienced by individuals in populations: "To calculate the asbestos-related cancer mortality in a given industry or operation, it is necessary to have an absolute or relative measure of exposure for the employee group." Nicholson, *et al.*, *Occupational Exposure to Asbestos* at 285. Put another way, exposure translates to dose, and dose translates to risk. This is the ***sole*** basis on which every scientific expert to study this issue has been able to determine causation. Insofar as a plaintiff or claimant must prove causation, he or she must provide reliable evidence of exposure, dose, and then risk in order to have a viable claim.

KEY POINT #3: **A plaintiff must have a reliable, verifiable diagnosis of a condition for which there is reliable epidemiological science providing adequate proof of *causation*.**

Finally, it should go without saying that in order for anyone to reliably conclude that a plaintiff's disease was caused by a given exposure to asbestos, the plaintiff must actually have the disease he claims was caused by his exposure to asbestos.

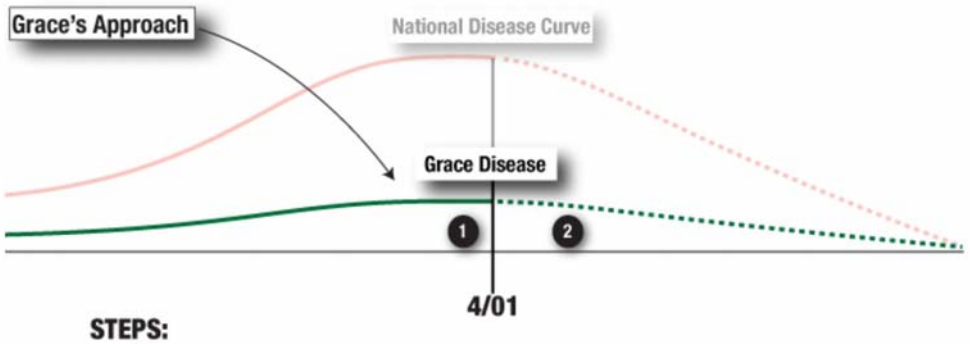
3. Plaintiffs' sleight-of-hand.

Claimants' experts also use Nicholson's model in connection with aggregate determination os national disease. However, their experts fail to apply these same methods to Grace-caused disease. Rather than considering the exposure and risk data relevant to Grace products, Dr. Peterson's approach instead performs a sleight-of-hand, using Nicholson's ***national*** epidemiologic projections to cover his failure to show Grace-caused disease. He does so by multiplying figures for the future ***national*** incidence of ***disease*** ("apples") by a "propensity to sue" Grace, which reflects only how often people make ***claims*** ("oranges") against Grace. Dr. Peterson thus vitiates any connection between his methodology and true science: unlike

Nicholson's conclusions, Dr. Peterson's conclusions are driven wholly by his "propensity to sue" rubric, and are therefore neither verifiable nor reproducible. As Peterson himself admitted, "Most of the variation that occurs in asbestos claiming settlements is because of behavioral effects, not biological effects." (Peterson Dep. at 76) More shockingly, Dr. Peterson dismisses actual exposure data, actual medical condition, and actual causation as "personal factors" that have little to do with the liabilities he estimates. (*Id.* at 171-72) Dr. Peterson ultimately must concede that his focus is on "claiming behavior" rather than epidemiology. (*Id.*)

The contrast between Grace's approach – driven by epidemiology – and Peterson's approach – driven by behavior, can be seen in the curves each analysis yields:

Grace's Estimation Approach

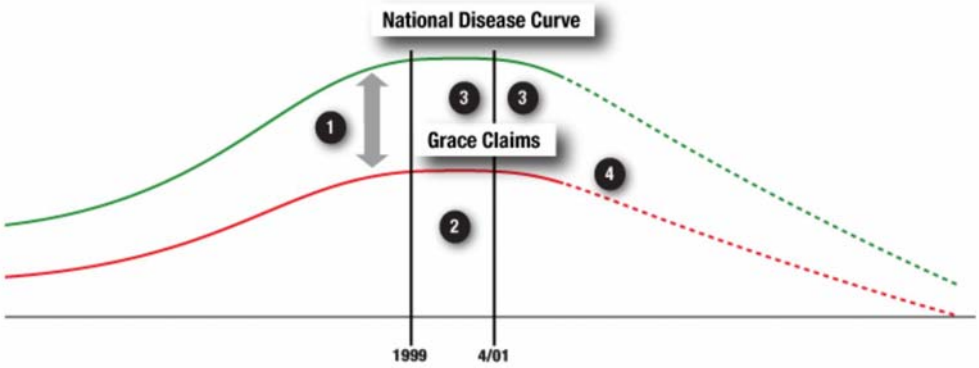


STEPS:

1. Toxic-Tort Causation: Determine Existing Valid Claims
2. Determine Future Trend Based Upon Epidemiology

GRS121807-18_B

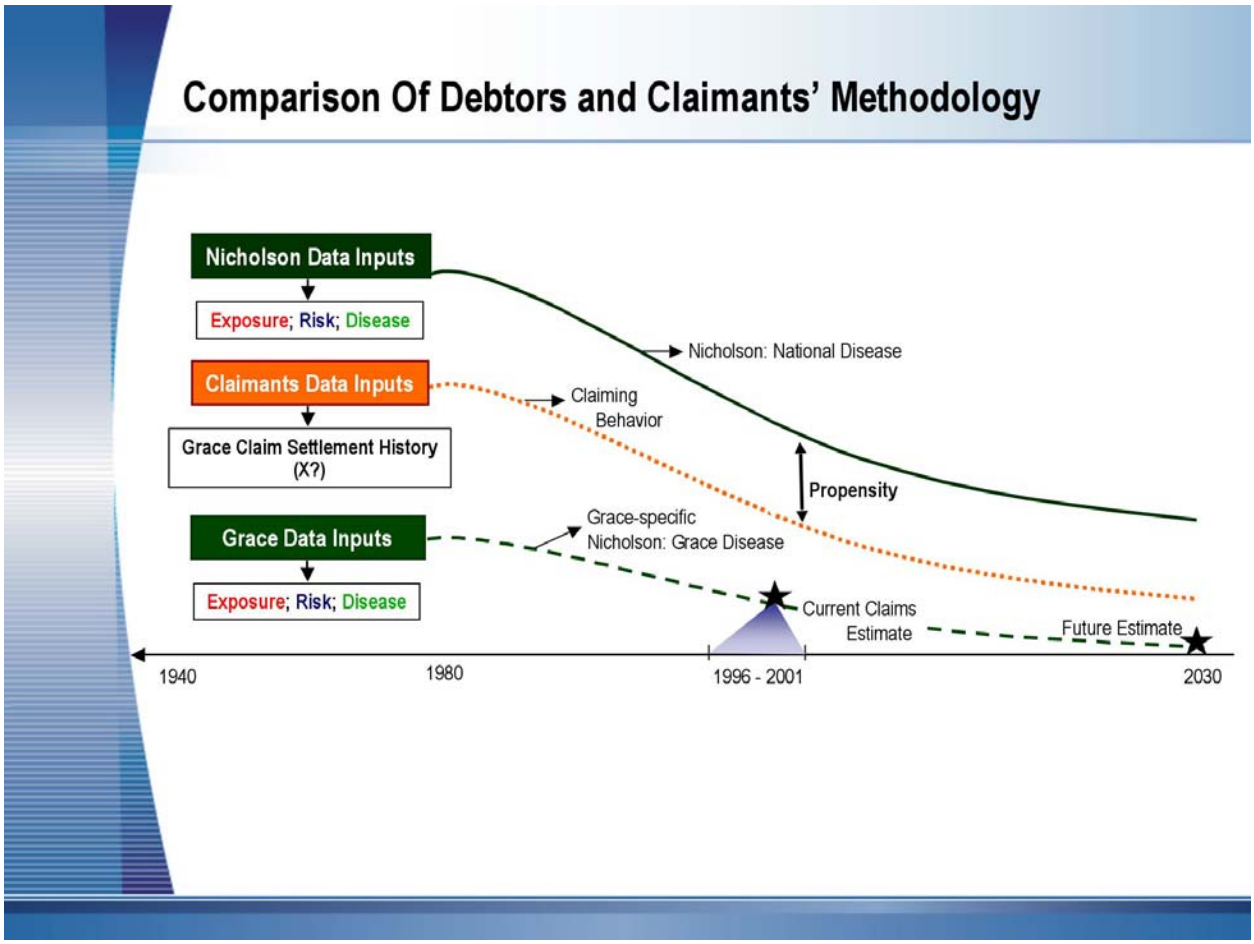
Peterson's Estimation Approach



Steps:

1. Ratio Equals "Propensity"
2. "Calibration Period" For Grace
3. Increases Propensity for '02 – '06
4. Assumes '99 – '01 Propensity Will Continue For All Time

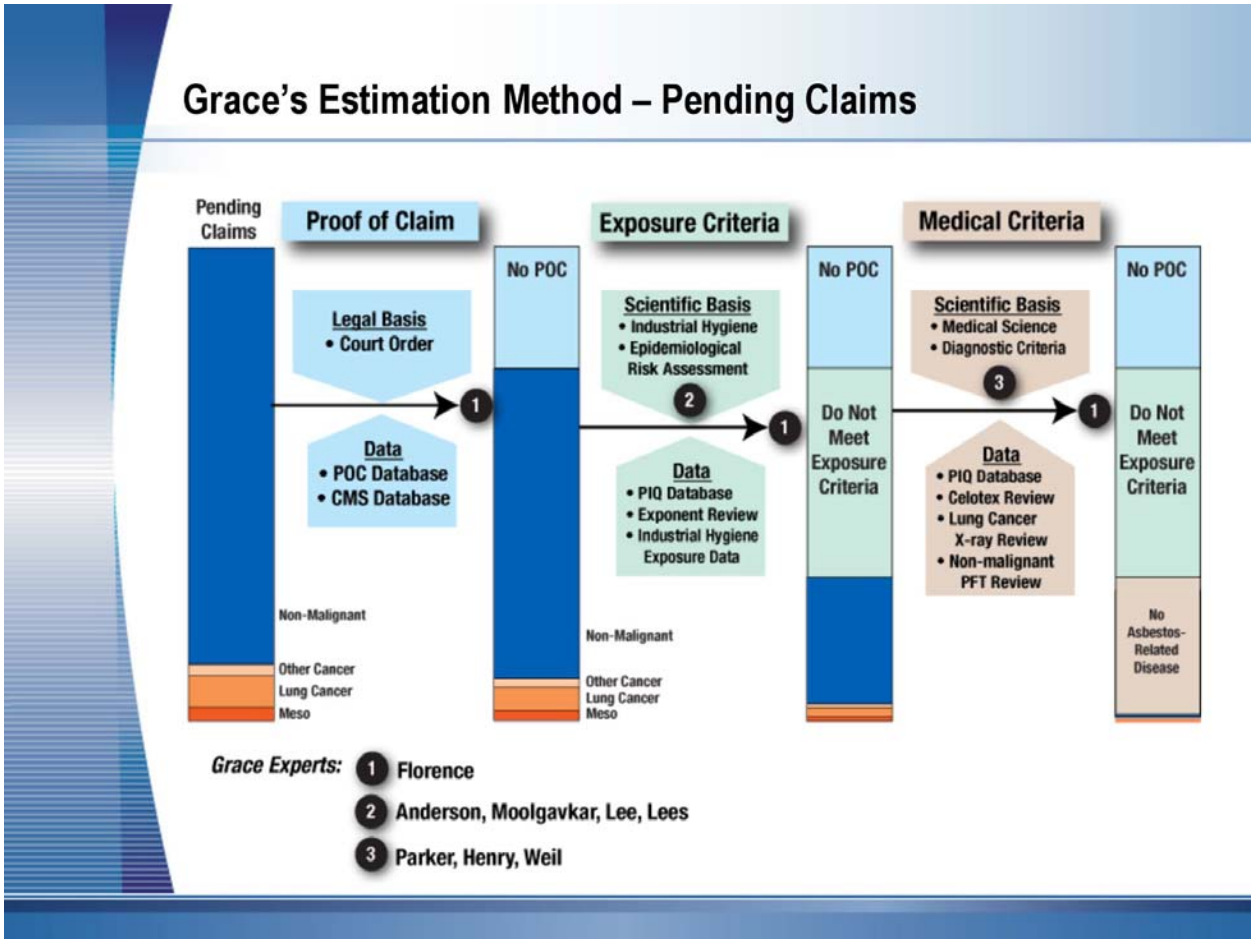
And it can also been seen in the following comparison of all ***three*** curves: Nicholson's ***national*** disease curve, Peterson's claims-driven curve, and the Grace-specific disease curve:



C. Grace's Estimation Constructs a Classic Toxic-Tort Causation Analysis and Epidemiological Forecast.

Deployment of an epidemiologically based estimate has several steps, each driven by distinct and established scientific disciplines. Put most simply, a classic toxic tort analysis (industrial hygiene, risk assessment, etc.) must be done to determine the Grace-caused disease reflected in current claims. Epidemiology then forecasts Grace-caused future disease. This chart should assist the Court in following the specific steps described below and in Section III.

Figure 1



1. <u>Step 1</u>: Determining who is a current claimant of those who had claims pending as of the filing of Grace's bankruptcy petition.

After determining the total number of existing claims against Grace for personal injuries allegedly caused by exposure to Grace asbestos-containing products (112,690), Grace expert Dr. Florence first undertook to determine the number of the total claims for which there had been filed a Proof of Claim. (*See* Fig. 1) To do this, Florence matched the POCs to Grace's historical claims database, and excluded from further analysis the historical claims for which there was no possible POC match, leaving 83,767 claims of a total of 112,690 historical claims. (Florence Rpt. at 8-9) This criterion was designed to determine the number of historical pending claims that would actually be pursued by claimants. (Florence Dep. at 291-92) A similar process was

used in *A.H. Robins Co. v. Piccinin*, 788 F.2d 994 (4th Cir. 1986). *See In re A.H. Robins Co.*, 880 F.2d 694, 694-99 (4th Cir. 1989)

This simple test – one would think an inarguably appropriate test – reduced the number of total claims by approximately 25% (to 83,767), with some slight variation depending on the type of claim asserted. (*See* Fig. 2) Claimants offer only the briefest of challenges to this aspect of Grace's experts' work – with the FCR devoting about a page of its brief (FCR Mot. 27-28) to the issue. This objection (and all other specific objections to this work) are discussed below in Section III.

2. Step 2: Requiring proof of exposure and causation.

The next step determines the extent to which the existing claims are supported by evidence of sufficient exposure to Grace asbestos-containing products to have caused an asbestos-related disease.

Grace expert Dr. Lees, an industrial hygienist, analyzed the composition and uses of Grace's asbestos (and vermiculite) containing products, as well as the types of exposures that individuals could have to such products. He further gathered and evaluated all available industrial hygiene data on Grace product exposure, then subjected it to standard data quality criteria. Using well-established techniques for exposure assessment, he created a job exposure matrix for which he calculated the eight-hour average exposure for individuals interacting with various Grace products. These exposures were broken down both by product type and by the ways in which the individuals interacted with the product (*i.e.*, mixer, sprayer, remover, bystander).

Grace expert Dr. Moolgavkar, an epidemiologist, analyzed published epidemiological articles and reports regarding the dose-response relationship for asbestosis, mesothelioma, and lung cancer. Dr. Moolgavkar's analysis determined what can be reliably asserted about

responses at various doses ("benchmarks"). These exposure benchmarks describe the dose-response relationship – using standard parameters of epidemiology – for specific application to the use of Grace products. These parameters address the following issues: (1) whether there is data to support an association between asbestos and a certain type of disease; (2) how strong the association is between asbestos and disease; and (3) at what levels of exposure that association exists.

Grace expert Dr. Anderson, a risk-assessment expert, then applied her experience to the types of exposures in this case. Dr. Anderson used conservative estimates of duration and frequency of exposure, as well as the data and job exposure matrix constructed by industrial hygienist Dr. Lees, in order to estimate the cumulative exposures associated with uses of Grace products. Dr. Anderson then used these cumulative exposures and the benchmarks inherent in the epidemiologic literature that Dr. Moolgavkar's analysis identified and concluded what can be reliably said about the risks pertaining to the various exposure levels.

Dr. Lees' exposure matrix, Dr. Moolgavkar's exposure benchmarks, and Dr. Anderson's risk assessments, allowed Grace expert Dr. Florence, a statistician, to take these analytical criteria and use them to sort the claims at issue in this case based on the information submitted by the claimants via the court-approved PIQ process.

The PIQs specifically asked each pending claimant to characterize the claimant's "Nature of Exposure" as: personally mixing Grace asbestos-containing products, personally installing Grace asbestos-containing products, or being in the proximity of Grace products. (Florence Rpt. at 9) Because many claimants did not provide exposure information on the PIQs themselves, an analysis was done of the back-up data provided as attachments to the PIQs. (*Id.*) By utilizing

these two sources of data, Florence took into account both the PIQs and their attachments concerning the existing claims.

It then remained for Florence to take the scientific exposure and causation measures developed by the experts in those fields and apply them to sort the universe of identified claims using his expertise as an analyzer of data. Based on the exposure criteria, Florence concluded a total of 10,956 claims met minimum-exposure requirements pursuant to method one, and 23,843 claims pursuant to method two. (Florence Supp. Rpt. at 10) Using the median of these two methods, of the 83,767 claims that had a POC, 17,400 met the established scientific criteria for establishing exposure sufficient to cause disease. The results of this work are shown in the transition from the second to the third column in Figure 1. Depending on the condition claimed, this left between 5 to 15 percent of the total claims as viable.

3. Step 3: Requiring Proof of Disease.

The next step is to determine those claimants who have scientifically viable proof of actually having the disease they allege was caused by Grace.

Grace expert Dr. Daniel Henry, a radiologist, conducted a study of the claimants x-rays, which the Court had ordered produced to Grace. (*See generally* Henry X-ray Rpt.; *see also* Henry Supp. X-ray Rpt. at 1-2) Dr. Henry looked at a proportional sample of x-rays related to 800 lung and other cancer claimants. The purpose of the study was twofold: (1) to see if claimants actually had evidence of significant asbestos exposure, and (2) to determine the reliability of the claimants' doctors' B-reads.

Dr. Henry conducted a classically designed double-blind study, comporting also with published ILO standards. First, Dr. Henry drew a proportional sample of 507 claimants from the 2,857 cancer claimants who produced original or certified x-rays. (*Id.* at 2-4) Dr. Henry then selected an overlapping sample of 471 claimants whose x-rays had accompanying ILO reads by

the claimants' doctors. (Henry X-ray Rpt. at 4-5) The x-rays were read by an independent panel of 3 blinded B-readers, consistent with the ILO standard, which requires replication. The B-readers were not told who was hiring them, who the claimants were, or what the study related to. (Henry X-ray Rpt. at 5) The panel also read 47 control films (22 positive, 25 negative). Analysis of those control films shows moderate to substantial agreement between the readers and the control films, demonstrating accuracy in the panel's reads. (*Id.* at 8) Moreover, the control film reads demonstrate that the panel was not biased to over-read or under-read the films. (*Id.*) The results of this x-ray study demonstrate that only 7% of the claimants were found to have profusion of 1/0 or greater by 2/3 or more of the panel. (*Id.* at 6) In contrast, claimants' doctors read 80% of the claimants' x-rays as 1/0 or greater. (*Id*)

Grace expert Dr. Weill, a pulmonologist, conducted a further study that analyzed a random sample of 150 pulmonary function tests of PFTs of nonmalignant claims, again in accordance with published PFT standards. (*Id.* at 34-35) In general, claimants are required to show impairment in order to recover for impaired asbestosis or severe asbestosis, and impairment is measured by lung function testing or PFT. The American Thoracic Society ("ATS") has issued authoritative standards governing such testing. (Weill at 31-34) Weill reviewed the PFT results to determine compliance with ATS standards. Dr. Weill found numerous errors in the testing and reporting of the testing data for the 150 claimants. In fact, none of the PFT tests reviewed complied with all ATS requirements for lung function testing and only 20 complied with the ATS standards for either FVC or TLC. (*Id.* at 38-40) Dr. Weill concluded: "[O]f the random sample of pulmonary function tests, evaluated for the 150 claimants and submitted by all 69 Law Firms, all 150 (100%) failed to comply with all ATS testing criteria." (*Id.* at 39) Accordingly, Dr. Weill concluded that these PFT results "[c]annot

be used in support of the submitted claim, since they represent inaccurate and incomplete tests[.]" (*Id.* at 40)

Finally, Grace experts Drs. Parker and Haber, pulmonologists, reviewed the practices of 24 doctors and at least 6 screening companies underlying non-malignant claims. In his June report, Dr. Haber identified and discussed accepted medical and scientific methodologies and standards that apply to all physicians. These standards, rules and guidelines govern the physician's practice and provide a paradigm to evaluate a doctor's methodology and behavior. Haber discussed individual doctors who provided supporting medical diagnoses for Grace claims and their practices in light of the standards. (*See generally* Haber Rpt.) In critiquing Claimants' expert Welch and endorsing Dr. Haber's report, Dr. Jack Parker opined that medical evidence generated for litigation and medical screening in a litigation context are neither reliable nor medically sound. (Parker Rpt. at 10-13) Both experts found these screening doctors' and screening companies' diagnostic practices to be unreliable.

As he did with the exposure data, Grace expert Florence took the input provided by those with expertise in the relevant disciplines and used their conclusions to review the data of record in this case. For the lung cancer claimants, Dr. Florence excluded claimants alleging asbestos-related lung cancer as evidenced by radiographic evidence who neither submitted a certified copy of an x-ray nor certified that the x-ray was held by a third party or destroyed. (Florence Supp. Rpt. 10) Dr. Florence then calculated the percentage of those claimants in Dr. Henry's sample who were found to have profusion of 1/0 or greater by 2/3 or more of the panel and applied that percentage to the remaining lung cancer population. (*Id*. at 10-11) Based on an expert exposure review of the claimants who met the 1/0 profusion criteria, Dr. Florence estimated the number of lung cancer claimants who could satisfy both exposure and medical

criteria for lung cancer. (*Id*. at 11) Dr. Florence estimated that, only 23 satisfied both exposure and causation requirements, and assuming the same proportion for those not providing data, 59 satisfied both. (*Id.*) Using the median of these methods, of the 5510 lung cancer claims that has a POC, only 41 met the medical causation and exposure criteria.

For "other cancer claims," (non-pulmonary cancers), Dr. Florence assigned value only to laryngeal cancer and excluded all claims alleging other types of non-pulmonary cancer. In 2006, the National Academy of Sciences, Institute of Medicine was "charged with evaluating the evidence relevant to the causation of cancers of the pharynx, larynx, esophagus, stomach, colon, and rectum by asbestos and with judging whether the evidence is sufficient to infer a causal association." *Asbestos: Selected Cancers* at 1 (2006). The Institute found that there was "not sufficient" evidence "to infer a causal relationship between asbestos exposure" and pharyngeal, stomach, and colorectal cancer. (*Id.* at 6, 9, 10) The Institute further found that "the evidence is inadequate to infer the presence or absence of a causal relationship between asbestos exposure and esophageal cancer." (*Id.* at 8) Only in the case of laryngeal cancer did the Institute find that the evidence was "sufficient to infer a causal relationship" between it and asbestos exposure. *Id.* at 7; *see* generally Weill Rpt. Accordingly, Dr. Florence assigned value only to "other cancer claimants" alleging laryngeal cancer.

Florence also excluded those "other cancer claimants" alleging laryngeal cancer who did not have sufficient exposure to asbestos to support their claim. To have sufficient exposure to Grace asbestos to cause disease, a claimant, in his or her questionnaire, had to indicate that he or she (1) personally mixed Grace asbestos-containing products, or (2) personally installed Grace asbestos-containing products. (Florence Rpt. at 9) Dr. Florence estimated that 33 claimants met the POC, medical (laryngeal cancer only), and exposure requirements necessary to support a

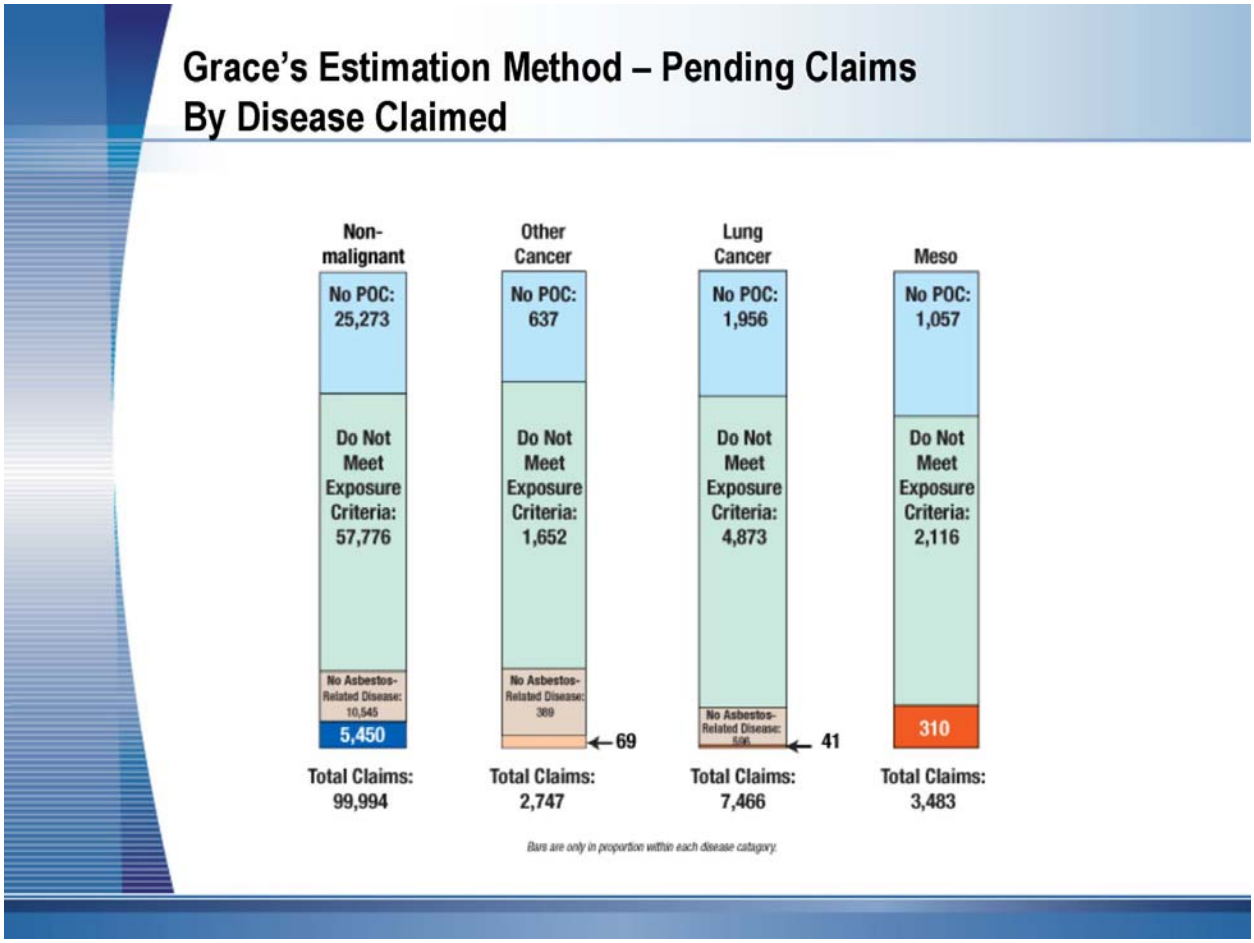
claim for "other cancer," specifically laryngeal cancer. (*Id.*) Dr. Florence also estimated that, assuming the same proportion s for those not providing data, there were 105 "other cancer claimants" who may have met both the medical and exposure data sufficient to support a claim against Grace. (*Id.*)

Using the median of these two methods, of the 2,110 other cancer claims that had a POC, only 69 met the medical and exposure criteria. Florence also categorized the nonmalignant claims into three categories (severe asbestosis, asbestosis, and unimpaired asbestosis). Dr. Florence estimated the number of non-malignant claims based on diagnoses not from underlying medical doctors found to be unreliable under Dr. Haber and Parkers' analysis and the claims that met the minimum profusion criteria of 1/0 for asbestosis. (Florence Supp. Rpt. at 12-13) Dr. Florence also used the analysis of Dr. Weill to calculate the percentage of non-malignant claimants who met the standard for severe asbestosis, asbestosis and unimpaired asbestosis based on PFT results that complied with ATS standards. (Florence Rpt. at 13-14) Dr. Florence then applied these percentages to the population of non-malignant claims. (*Id.*) After also applying the POC and exposure criteria, Dr. Florence estimated that only 7 should be classified as severe asbestosis, 160 as asbestosis, and 2,557 as unimpaired asbestosis. Assuming the same proportions for those not providing data, 22 were classified as severe asbestosis, 480 as asbestosis, and 7,672 as unimpaired asbestosis. (*Id.* at 14) Using the median of these two methods, of the 73,731 non-malignant claims that had a POC, only 5,450 met these criteria.

The final result of this step was that, using the overall median, out of the 17,400 claims that met the exposure criteria, only 5,869 met the relevant medical criteria as well. (*See* Fig. 1 (column three to column four)) This factor affects different types of claims differently (Florence excludes no mesothelioma claims on a medical basis, for example).

4. **<u>Step 4</u>: The final group of valid, Grace-caused disease claims as of April 2, 2001.**

Figure 2



After applying the criteria summarized above to the existing claims, Florence was left with 5,450 non-malignant claims, 69 other cancer claims, 41 lung cancer claims, and 310 mesothelioma claims. (Fig. 2) This group represented those cases of Grace-caused disease that satisfied a classic toxic-tort causation analysis. This aggregation of claims was then ready to serve as a basis for the final plotting of the Grace curve and provided a reliable basis for the next step in the analysis: projecting the number and nature of Grace-caused future cases of disease, according to the epidemiological principles established by Nicholson.

5. Step 5: Projecting the number and nature of future Grace-caused disease claims.

To estimate the amount of future mesothelioma and lung cancer cases that would arise, Dr. Florence relied on two epidemiological methods: Nicholson, Perkel, and Selikoff (1982) and Peto, Henderson, and Pike (1981) (Nicholson, *Occupation, Exposure to Asbestos*; *Julian Peto, Brian E. Henderson, and Malcolm C. Pike, Trends in Mesothelioma Incidence in the United States and the Forecast Epidemic Due to Asbestos Exposure During World War II* (1981)*;* Florence Supp. Rpt. at 18). To estimate the amount of Grace-caused other cancer and nonmalignancy claims, he used an "index series" to compare those disease trends to lung cancer and applied regression models. (Florence Supp. Rpt. at 19) He then calculated a median forecast based on 32 individual forecasts, incorporating two methods for calculating claims that would meet minimum criteria, two mesothelioma and lung cancer forecasting methods, four calibration periods, and two other cancer and nonmalignant forecasting methods. (*Id.*)

6. Step 6: Determining aggregate value.

Finally, Florence determined the potential aggregate value of the existing and future claims by ascertaining settlement averages for those past claims that met the scientific criteria discussed above and applied them to the projected cases of Grace-caused disease. (*See generally id.* at 15 *et seq.*) Combining pending and future claim estimates, Florence estimated Grace liability to range from $200 million to $989 million through 2049, with a median of $468 million. (*Id.* at 23)

III. CLAIMANTS HAVE NOT SHOWN (AND CANNOT SHOW) THAT GRACE'S ESTIMATION USES UNRELIABLE DATA OR UNRELIABLE METHODOLOGY.

Claimants' criticisms of particular aspects of Grace's experts' opinions can best be addressed by examining each under the foregoing legal and scientific framework. The

challenges therefore can be organized into the following categories: (1) issues relating to the underlying data used by Grace's experts; (2) issues related to the analysis of exposure to Grace products; (3) issues related to the analysis of causation; (4) issues related to proof of disease; (5) issues related to the application of these analyses to the Grace claims; (6) issues related to the projection of future claims; and (7) issues related to determining the aggregate value of the existing and future claims.

A. Grace's Experts Use Reliable Data.

The PI Committee attacks Dr. Florence's use of the POCs and PIQs, characterizing this as reliance on "incomplete and flawed information." (PI Mot. at 22-32) They also similarly critique Dr. Anderson's reliance on this data as well. (*Id.* at 47-50) None of these arguments are persuasive, for all turn a blind eye toward the unassailable pedigree of this information.

1. The POC and PIQ data clearly comport with Rule 702 requirements.

The information contained in the POCs and PIQs was, obviously, obtained from claimants themselves. It is odd, to say the least, that, having provided this information to the Court, claimants now argue it is unreliable for purposes of conducting an estimation. This argument mocks the months of effort that have gone into securing this information precisely for the purpose that claimants now argue it cannot fulfill.

The Court understood what the Debtors were doing in requesting the PIQ information, and made it precisely clear in this case on numerous occasions:

> The debtor wants to figure out what claims are legitimate claims - in quotes, "legitimate claims" in order to figure out what funding has to be committed through this plan to the personal injury claimants versus anybody else. That's the sole limited purpose for which this questionnaire was approached, brought into the Court, approved by me and sent out. ***And frankly it would seem to me to be in every claimant's best interest to do their darndest to try to answer it effectively and adequately*** because to the extent that there are really sick people out there, they should be getting paid and they should be getting paid sooner, and to the extent that there really aren't sick people out there, the debtor ought to know that

> it has to commit more of its resources to pay the really sick people. That's what it's all about. (Mar. 27, 2006 Hr'g Tr. at 42)
>
> [T]he reason we're going through the questionnaire process and looking for the x-rays and the B readers and the other evidence of what the current claims are is so that the Debtors' expert can take a look at the current claims that are before the Court and say, ***based on this evidence***, these claims are valued at 0. ***Not*** that the Debtor's ***settled claims in the past*** were valued at 0. (Oct. 23, 2006 Hr'g Tr. at 107)
>
> My understanding is we're going through this questionnaire process as to claims that have not yet been paid so that somebody can say the existing universe of claims are valued at these dollars for these reasons. And among them, for example, ***hypothetically, maybe this universe of claims is valued at 0 because there is no evidence of any impairment.*** You know, that might be something that they allege with the existing, unpaid, unsettled claims. (*Id.* at 114)
>
> Let's assume that there are 5,000 workers from a particular job site . . . [who] know that they were exposed at a particular time . . . in a particular place to a Manville product, but none of them know that they were exposed at a particular time . . . or a particular place to a Grace product . . . that may be relevant as to whether those future claims will, in fact, be allowed by a trust, ***which tells you then that there are numbers of claims that will come in that will be disallowed*** . . . That's the whole purpose. It's just to get to a bottom line. (July 19, 2005 Hr'g Tr. at 174-75)

Moreover, the only legally appropriate question here (in the context of a *Daubert* motion) is whether the material in the PIQ responses is the type of material that experts in the fields of industrial hygiene and risk assessment would normally rely upon.[1] Rule of Evidence 703 provides that an expert's opinion may be based on material "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject[.]" Fed. R. Evid. 703; *see also Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002) ("Under Rule 703 of the Federal Rules of Evidence, experts may rely on facts from firsthand knowledge or observation, information learned at the hearing or trial, and facts learned out of

[1] Also, it is plainly independently admissible under Federal Rules of Evidence. But that inquiry (if it is even necessary) is for another day.

court" if of the type reasonably relied upon by experts in the particular field); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir. 1994) ("[W]hen a trial judge analyzes whether an expert's data is of a type reasonably relied on by experts in the field, he or she should assess whether there are good grounds to rely on this data to draw the conclusion reached by the expert. Whether experts in the field rely on this type of data will simply continue to be a part of the judge's analysis."). Here, it is undisputed that the type of exposure history and product usage information provided by the individual claimants in their PIQ responses is the type of information that industrial hygienists and risk assessors typically rely upon when assessing historical asbestos exposures.

Grace's industrial hygiene expert, Dr. Peter Lees, explained that exposure assessment is one of the fundamental tools used by industrial hygienists. (Lees Rpt. at 2-3) Accurate assessment of individual exposures is a critical input to an epidemiological analysis looking at the nature of the dose-response relationship. (*Id.*) Assessing exposures requires an understanding of the products with which the individual worked, the type of job or activity the worker was engaged in, as well as the frequency and duration of all tasks that brought the worker into contact with the asbestos-containing material. (*Id.*) While some of this information may be available from the employer or published literature, information on frequency and duration "is dependent upon the quality of that worker's report." (*Id.* at 4) Dr. Lees further explained that "[i]n order to accurately assess the risk of disease for compounds such as asbestos, one must develop a lifetime asbestos exposure history." (*Id.* at 5) It is a routine practice in industrial hygiene to rely on reports, interviews and questionnaires sent to workers being studied in order to evaluate their asbestos exposure history. As Dr. Lees explained, the information provided in the PIQ responses is exactly the type of information relied upon by industrial hygienists to

develop such lifetime asbestos exposure histories. (*Id.* at 8) "The accuracy of the assessment of exposure (and thereby the validity of the risk and liability calculation) hinges on provision of complete, reliable and accurate data in the claimants' responses to the questionnaire." (*Id.* at 8-9)

Likewise, Grace's risk assessment expert, Dr. Elizabeth Anderson, explained that exposure assessment is one of the tools necessary to perform a risk assessment (*i.e.*, you need to know what the exposure is in order to determine the risk from the exposure). (Anderson Rpt. at 9-10) "Since claimants may have been exposed to asbestos from sources unrelated to W.R. Grace products, it is critical to characterize those exposures in an unbiased manner consistent with the assessment of exposure from W.R. Grace products." (*Id.* at 10) In assessing an individual's exposure, "[i]nformation about the claimant's exposure from sources such as his or her occupational history may be combined with literature data on asbestos exposures associated with that activity to estimate a lifetime exposure to asbestos associated with W.R. Grace products or operations." (*Id.* at 12) It is a routine practice for risk assessors to rely on occupational or exposure histories provided by individuals for whom risks are being assessed. As Dr. Anderson explained, "[c]laimants who can provide sufficient information can be evaluated according to the [risk assessment] framework I have outlined in this report. If this information is not provided, then it is not possible, within the bounds of scientific certainty, to determine that the alleged asbestos exposure from a W.R. Grace product is a substantial contributing factor to the asbestos-related disease." (*Id.*) Thus, not only is this type of information routinely relied upon, it is essential to conducting a risk assessment.

For these reasons, the PIQ responses can be relied upon by Grace's experts in their analyses for this estimation.

2. Claimants' stale mantra that they would have had more exposure information but for Grace is false and cynical.

Given the self-originated, court-directed pedigree of this data, claimants stoop to undermining their own submissions through unsupported and unsupportable assertions that there would have been more and better information to be had but their hands were tied – it was denied them. This argument is barred by the Court's orders and directions in this case, and it is nonsense.

(a) The claimants' arguments violate the Court's express bar against attacks on the completeness of the PIQ data.

As an initial matter, claimants' PIQ arguments must fail because the Court has prohibited them from raising these issues in connection with the estimation. Throughout the discovery period, the Court made clear to counsel that it expected – indeed ordered – that the PIQs would be filled out completely, accurately, and with the information the claimant intended to use to support his or her claim.

At the earliest stages of the process, the Court required claimants to provide evidence they intended to use in support of its claim, stating:

> ***It seems to me if the claimant is filing a claim*** against Grace in a State Court suit, which is what most of these things are, based on [certain medical evidence], ***they're going to have to produce it at some point. They can produce it now***. They won't have to produce it again for the Trust. They're going to have to produce it then anyway, and it will be their responsibility to produce it for the Trust not the Trust's. (July 19, 2005 Hr'g Tr. at 222; *see id.* at 232 ("But the standard is going to be whatever they need to get through the Trust process that they can put in this now they don't have to do again."))
>
> I do need to make sure . . . that counsel for all of the present claimants understands that this estimation process going forward, so if they want to submit that kind of questionnaire and have their own client's medical information included in it, they have the opportunity to do that, because ***they will be bound by the outcome of the estimation hearing.*** (Jan. 21, 2005 Hr'g Tr. at 140)

When faced with protests from the claimants' law firms that rather than provide answers to the PIQs, they intended to just point Grace to their allegations and to the discovery regarding the claims that had been taken in the tort system prior to Grace's filing for bankruptcy, the Court ruled that reference to such allegations and incomplete discovery was not sufficient, admonishing the claimants' lawyers:

> No, no, I'm not going there. . . . They're to fill out the questionnaire . . . . This is a bankruptcy case. I don't care what they said in the tort system. ***I want to know for proof of claim purposes, what they're alleging here,*** and that's what the questionnaire does. So that will not -- I will not go there. (July 24, 20056 Hr-g Tr. at 61)

The PIQs were approved as valid discovery for the Debtors in the estimation proceeding; they were not merely "surveys":

> I will approve a claim form . . . it may be useful to all parties in the estimation, and ***I will consider it appropriate discovery.*** Rather than taking depositions of 400,000 personal injury plaintiffs, ***we're going to do it through claim forms.*** (June 27, 2005 Hr'g Tr. at 80)

> So, folks, get it filled out and get it returned. It's now no longer just the debtor's mechanism for asking for something for estimation. ***It's now a formal discovery.*** (Aug. 21, 2006 Hr'g Tr. at 162)

As formal discovery, the PIQs are governed by Rule 26 of the Federal Rules of Civil Procedure made applicable in this contested matter by Bankruptcy Rule 7026. Pursuant to Rule 26, the claimants had a duty to answer these discovery requests fully and completely.

They were obligated also to supplement their answers if they learned that the responses were incomplete or incorrect or if additional or corrective information was discovered:

> It seems to me . . . that it would be fair to simply say that you and your counsel have . . . and make this a continuing duty. ***If something else comes up, then they have to produce it***. (July 19, 2005 Hr'g Tr. at 223)

In fact, the Court could not have been more explicit about the Claimants' duty to respond fully to the PIQs and search for the information necessary to do so:

> The debtor has the right to discovery to know what the current claims are, and ***that will be a much better basis for estimation of current claims and possible future claims [then] anything else.*** So, let's get it done. Let's find out what the claims are, what people say they have by way of claims. (June 27, 2005 Hr'g Tr. at 80)
>
> If the lawyer already has the information in [the] file then I agree . . . . If the lawyer doesn't have it ***then the lawyer's going to have to get in touch with the claimants and it will be a burden on the asbestos plaintiff*** but so would filing a proof of claim and attaching any documentation that would be necessary." (Tr. of Hr'g at 191 (July 19, 2005)"It seems to me . . . that it would be fair to simply say that you and your counsel have . . . and make this a ***continuing duty***. If something else comes up, then ***they have to produce it***. (July 19, 2005 Hr'g Tr. at 223)

The Court likewise made it clear that if information was in the hands of a doctor, the claimants had a duty to obtain that information in order to respond to the PIQ:

> Well, it seems to me that if it's in the doctor's office, the doctor is the agent of the patient in this instance just like the attorney is. That's clearly within the patient's custody or control if not custody. . . . I've never seen a doctor yet who upon reasonable request and the copying fee doesn't produce a copy of the medial documents. ***So the plaintiff can get it, period, end of story. It's the plaintiff's information that's significant.*** (July 19, 2005 Hr'g Tr. at 230-31, 234)

In the same respect, the Court was direct and unambiguous as to the claimants' duty to prove their medical condition:

> If a claimant is filing a claim against Grace…based on a pulmonary function test, they're going to have to produce it at some point. ***They can produce it now.*** (July 19, 2005 Hr'g Tr. at 222)
>
> [T]o the extent that they're alleging that Grace's asbestos caused the problem, they have to prove the claim in this case, so they're going to have to produce the x-rays in this case . . . it's for estimation purposes. ***They need to produce that proof.*** (Oct. 23, 2006 Hr'g Tr. at 122-23)

These various directions from the Court were backed up by ***orders***, many orders. Certain of these orders required the provision of data in response to the PIQs and set deadlines for the provision of that data (including the provision of original x-rays):

- 8/29/05 Case Management Order for the Estimation of Asbestos Personal Injury Liabilities (Docket No. 9301) (approving PIQ and ordering that

holders of "Asbestos PI Pre-Petition Litigation Claims . . . shall complete and serve the Questionnaire")

- 12/22/06 Order Regarding X-ray Evidence (Docket No. 14148) (ordering non-mesothelioma cancer claimants relying on radiographic evidence of disease to produce x-rays for review by Grace's and other parties' experts)'

- 4/2/07 Order Regarding Case Management Order For the Estimation of Asbestos Personal Injury Liabilities (Docket No. 15078) (setting deadlines for final submission of supplemental PIQ responses).

Others prescribed the form in which the PIQ data should be submitted.

- 10/12/06 Order Concerning Debtors' Motion to Compel Asbestos Personal Injury Claimants to Respond to the W.R. Grace Asbestos Personal Injury Questionnaire (Docket No. 13393) (prohibiting citation to unspecified attachments and requiring claimants to indicate which specific page of attached evidence answered specific PIQ question)

- 2/20/07 Supplemental Order Regarding Production of X-rays By Non-Mesothelioma Cancer Claimants (Docket No. 14608) (modifying certification requirements and revising deadlines for provision of x-ray evidence)

The Court also entertained and overruled countless objections raised by the claimants to provision of data in response to the PIQ:

- 12/22/06 Order Regarding Motions to Compel Claimants to Respond to the W.R. Grace & Co. Asbestos Personal Injury Questionnaire (Docket No. 14149) (overruling attorney-client privilege and burden objections)

- 12/22/06 Supplemental Order Regarding Motions to Compel Claimants to Respond to the W.R. Grace & Co. Asbestos Personal Injury Questionnaire (Docket No. 14150) ("Consulting Expert Order") (overruling consulting expert privilege objection to production of certain medical documents)

- 3/06/07 Order on Certain Asbestos Claimants' Firms' Motion to Alter Or Amend Supplemental Order Regarding Motions to Compel Claimants to Respond to the W.R. Grace & Co. Asbestos Personal Injury Questionnaire Pursuant to Fed. R. Bankr. P. 9023 And Alternative Request for Entry of a Protective Order (Docket No. 14763) (overruling motion to reconsider Consulting Expert Order and entering protective order governing production of materials subject to order)

- 5/9/07 Order Denying Baron & Budd, P.C., LeBlanc & Waddell, LLP and Silber Pearlman LLP Request to Stay Compliance with the Consulting Expert Order Pending Appeal (Docket No. 15627)

Finally, and most importantly, the Court issued orders that made clear the consequences for the failure to provide the requested data in response to the PIQs or the POCs:

- 8/24/06 Order As To All Pre-Petition Asbestos PI Litigation Claims, Including Settled Claims, (I) Establishing Bar Dates; (II) Approving Proof of Claim Form; And (III) Approving Notice of Pre-Petition Asbestos Personal-Injury Claims Bar Date (Docket No. 13061) (setting bar date for PI Pre-Petition Claims, providing that failure to submit POC by bar date would result in claim being "forever barred, estopped or enjoined . . . against the Debtors or the § 524(g) trust, and providing that failure to submit PIQ could result in a request to "bar and disallow your Non-Settled Pre-Petition Asbestos PI Claim")

- 6/6/07 Supplemental Order Regarding Production of X-Rays By Non-Mesothelioma Cancer Claimants (Docket No. 15968) (prohibiting reliance by parties to the estimation or their experts on x-rays that have not been produced subject to previous orders and setting deadline for final receipt of x-rays)

None of these orders was appealed.

In the end, when the PI Committee stated its intention to offer the testimony of three lawyer witnesses (Peter Kraus, Theodore Goldberg, and John Cooney) to testify, in part, as to what evidence they would have presented at trial and to what extent such evidence would differ from that provided in their responses to the PIQs, the Court ruled that such testimony would not be admitted, referencing these prior rulings, and stating:

> [The evidence is] either in writing in those questionnaires or it's not there. I think I made those rulings clear early on. What's in is available for the fact and expert witnesses, and otherwise, ***for purposes of this estimation hearing, it doesn't exist. And that's the end of it.*** We are not getting into those questionnaires again, period. ***End of story.*** (Oct. 25, 2007 Hr'g Tr. at 93)

Accordingly, the issue of whether there is other data beyond that submitted is closed.

(b) The claimants have had more than ample time and opportunity to gather exposure data. They just decided not to produce it.

The only real impediment to the provision of information in response to the PIQs was the claimants' lawyers themselves, a fact candidly admitted both by the PI Committee and the law firms themselves. The bottom line was that they fought against directions to provide information and then just sat down and refused to provide it. Why? Because they knew it would hurt them in the estimation.

Any lack of incentive to provide this information in no way justifies the claimants' refusal to provide it. *See Gerling Int'l Ins. Co. v. Comm'r of Internal Revenue*, 839 F.2d 131 (3d. Cir. 1988) (party responding to discovery must provide "information which is in its possession or which is available to it upon reasonable inquiry"); *Nobles v. Jacobs/IMC*, No. Civ. 2002/20, 2003 WL 23198817, at *1 (D.V.I. July 7, 2003) (finding that under Federal Rules of Civil Procedure, "[t]he answering party cannot limit his answers to matters within his own knowledge and ignore information immediately available to him or under his control" but also must provide information within the knowledge of the party's lawyers or agents).

As this Court has recognized, Grace has made tireless efforts over the years to obtain specific information regarding claimants' exposure to asbestos-containing products and, despite those efforts, "has not been successful." (*See* Aug. 29, 2007 Hr'g Tr. at 69) The failure to obtain the requested information has been neither the result of any lack of diligence on the part of Grace nor the efforts of the Court to facilitate Grace's receipt of this information. Rather, it has been the direct result of the conduct of the claimants' attorneys, whose efforts have been openly obstructionist. (*See* Aug. 31, 2007, Motley Rice LLC's Objections and Supplemental Resps. to Debtor's Third Set of Interrogs. to Certain Asbestos Personal Injury Pre-Petition Litigation Claimants' Law Firms, Resp. No. 14) It would be the height of inequity to allow their tactics to

bear fruit, by permitting them to use their own recalcitrance as a basis for their *Daubert* challenge to Grace's experts' opinions. *See, e.g., SEC v. Grossman*, 887 F. Supp. 649, 660 (S.D.N.Y. 1995) (party prohibited from relying on exculpatory evidence "on the very issues for which they have declined to provide discovery for several years" in opposition to summary judgment motion).

(c) Claimants were and are uniquely in possession of any exposure data.

The key questions for the purposes of Dr. Anderson's exposure analysis relate to what tasks the claimants performed that gave rise to their alleged exposures. What job functions were performed by a claimant while performing his or her job is information that is uniquely and singularly known to the claimant – and would not be known by Grace. (*See* Jacoby Dep. at 86-87; Myer Dep. at 194) As PI Committee expert Daniel Myer admitted at his deposition, work histories (*i.e.*, what a plaintiff did) are generally developed by plaintiffs' lawyers at the beginning of the case, and lawyers "would know up front what the occupational history was of given plaintiffs." (Myer Dep. at 194; *see also* Florence Dep. at 159-61 (the key data that are used for the exposure criteria are gathered at the beginning of the case))

(d) The automatic stay posed no barrier to claimants gathering additional exposure data.

Claimants' contention that the automatic stay prevented them from obtaining relevant exposure data in response to the PIQs is groundless. In support of the assertion, they cite to a single self-serving and unsupported assertion made by the Motley Rice firm in response to Grace's Third Set of Interrogatories, in which it recited a litany of evidence that it claims it would have developed had a given claimant's case been readied for trial, including, inter alia, additional interviews with both the plaintiff, co-workers that had already been interviewed, and "additional investigation for additional co-worker and exposure witnesses have been conducted."

(*See* PI Mot. at 24) Thus, not only are the claimants' attacks on the PIQ barred, they are unsupported.

Claimants provide no evidence as to what types of information would be yielded in additional interviews or investigations, whether that information would even relate to the tasks performed by a specific claimant, or how the bankruptcy stay impeded the development of that information. Nor could they, as both the PI Committee and the FCR's own experts concede that the bankruptcy stay did not prevent the claimants' lawyers from making such inquiries. (*See* Jacoby Dep. at 82-83; Myer Dep. at 194 ("The stay certainly would have – would not have changed the historical occupational history of any given plaintiff.")) Without such evidence, the assertion that but for the bankruptcy, the claimants' lawyers would have been able to develop and present further evidence of their job histories, is simply rank speculation.

Moreover, the Court made it perfectly clear that the claimants had a duty to answer the PIQs fully, and if that meant going out to find information, they were required to do so, including through discovery of Grace:

> You have discovery rights. If you want evidence from the defendants, take them. (July 19, 2005 Hr'g Tr. at 239)

And, the PI Committee and FCR did just that. They took extensive discovery of the Debtors. Indeed, claimants served over 150 requests for production including subparts, and over 45 interrogatories, including subparts. In response to these discovery requests, Grace made available to the claimants its Boston repository – where Grace maintains documents relating to its asbestos-containing products and their sales and use. The repository is the same repository that Grace made available to individual plaintiffs litigating individual cases. After searching the Boston repository, claimants copied over 140,000 pages of documents (which represents just one small subset of the documents produced in this case). Grace also produced additional

documents, including samples of Grace's discovery responses from prior personal injury cases, trial exhibit sets from prior personal injury cases, and Grace's product appendices. Claimants also deposed Grace employees concerning the sales and use of Grace products.

Discovery is now closed. All of the information the claimants wished to provide to the Debtors through the PIQs must have been submitted by now and claimants will not have the opportunity to argue either that additional information should be reviewed or supplementation should be permitted before the Debtors can rely on such PIQ responses:

> He's not going to be explaining. ***It's either in writing in those questionnaires or it's not there*** . . . What's in is available for the fact and expert witnesses, and otherwise, for purposes of this estimation hearing, it doesn't exist. And, that's the end of it. We are not getting into those questionnaires again period. End of story. (Oct. 25, 2007 Hr'g Tr. at 93)

(e) The fact is that claimants routinely gather little, if any, real exposure data.

The fact of the matter is – and this speaks volumes to the impropriety of substituting settlement data for the legal measures of Grace's liability – claimants and their counsel routinely gather minimal, if any, exposure data. They have simply never bothered to collect such information, and, having essentially refused to do so already in response to the Court's discovery orders, would not do so in any event if given a second bite at the apple. Asbestos lawyers did not work up their cases in anticipation of adjudications on the merits; they worked up settlements, which, as claimants' own experts readily admit, had little to do with pesky facts like exposure and reliability of diagnosis, but had everything to do with the bizarre dynamics of the marketplace for state-court tort settlements. (*See* Peterson Dep. at 172-72) Confirming this, far more data is absent from the ***closed*** claims than from the attachments to the ***PIQs***. (*See* Florence Supp. Rpt. at App. G)

(f) In any event, Dr. Florence has given claimants the benefit of the doubt.

Dr. Florence used two methods to calculate the percentage of claimants who met the exposure criteria. One of the methods ***assumed*** that claimants who did not provide data could still meet the exposure criteria. (Florence Supp. Rpt. at 10) That method calculated the number of historical pending claims that provided some exposure data and met the exposure criteria. The method then simply assumed that claimants who did not provide any exposure data meet the criteria in the same percentage as those who did provide data. Thus, Dr. Florence used a scientifically-reliable methodology to account for the possibility that claimants who did not provide exposure information in their PIQs could still meet the exposure criteria. Therefore, the claimants' charge that Dr. Florence failed to take such a possibility into account is unfounded. The PI Committee does not dispute that Dr. Florence's methodology was sound. (*See* PI Mot. at 26) It simply objects to Dr. Florence's conclusions on the grounds that the data contained in the PIQ was "incomplete" and, thus, insufficient. *Id.*

3. Dr. Anderson appropriately used information from the PIQs.

The PI Committee argues that Dr. Anderson's opinions are unreliable because she relies on the information provided in the PIQs and settled claims files, which, according to the PI Committee, is less complete than the information a claimant would present at the summary judgment or trial stages. (*See* PI Mot. at 47-50) This argument must fail for the same reasons outlined above in Section II.A.3, and other reasons as well.

Dr. Anderson's causation determinations were based on the ***nature*** of the claimant's exposure to Grace products – *i.e.*, what the ***claimant*** did while performing ***his*** job that would have led to exposure to asbestos. The key question is whether the ***claimant*** worked directly with asbestos-containing products in such a way that could give rise to an exposure sufficient to cause

disease (*i.e.*, whether they mixed, cut or installed asbestos-containing products) or whether they simply worked in an area where asbestos-containing products were present. As explained above, this information is clearly in the ***claimants'*** possession, and is some of the first evidence traditionally developed by claimants' lawyers. (Myer Dep. at 194-95) The only barrier to the provision of this information was the willingness of the claimants' lawyers to do so.[2]

4. Claimants' other data-related criticisms are misplaced.

(a) Grace did not withhold key documents.

The PI Committee inaccurately claims that Grace withheld from its experts "key documents" necessary for their review and analyses of the Closed Claim Files. (*See* PI Mot. at 30) They present a chart of "withheld items" to make it appear that Grace withheld, as privileged, medical and exposure data from its own experts – something Grace did not do. Not only are several of the examples cited simply inaccurate, they are presented in a misleading manner that fails to distinguish between properly withheld privileged documents and disclosed medical and exposure documentation.

To be clear, Grace withheld some memos and letters, such as those from Grace's outside counsel to Grace's in-house lawyers, because they are privileged. When those letters attached original plaintiff information, such as work histories, medical records and the like, the covering

[2] The FCR contends that a single, out-of-context statement by one of Grace's experts, Dr. Gordon Bragg – that he typically "would have more information than a modestly filled out PIQ would provide" – implies that the PIQ questions were not sufficient to obtain adequate information to form the basis for Dr. Anderson's causation analysis (and, in turn, Dr. Florence's application of Dr. Anderson's analysis to determine the number of future claims that would qualify for future compensation). However, examination of Dr. Bragg's expert report and testimony demonstrates that this implication could not be farther from the truth. Indeed, Dr. Bragg testified that in performing an exposure analysis he "need[s] the data that's in this table [*i.e.*, PIQ Part III relating to the claimant's exposure to Grace asbestos-containing products]." (*See* Bragg Dep. at 148-49 (describing PIQ parts he would consider in an exposure analysis); *see also* Bragg Rpt. at ¶ 41 ("In order to reliably determine exposure of an individual to asbestos emissions and to provide input for a claim assessment, information such as that provided by a full and comprehensive response to the W.R. Grace Asbestos Personal Injury Questionnaire is the minimum amount of information required."))

correspondence or memo was properly withheld, but the remaining documentation, which might actually be germane to the an expert's analysis, was identified and produced at the Bates Numbers that followed the privileged document sheet or elsewhere in the production set. This is readily apparent to any person who reviews the documents in Bates number order.

Although Grace will not burden the Court with a point-by-point analysis of all the documents identified in the chart on page 30 of the PI Committee's brief, a few stark examples shine a disinfecting light on the allegations:

- In the case of S.O., Grace properly withheld a ***fax cover sheet*** and letter from Grace's outside counsel to Grace, but ***provided all medical records and information attached*** to that letter, such as the ILO form, medical/expert reports and evaluations, and diagnostic reports. (*See, e.g.*, BCF 0053330-0053346) In fact, the fax line at the top of the produced documents make clear they were the attachments to that withheld letter.

- In another case, D.H., Grace properly withheld items such as outside counsel ***deposition summaries*** and ***status reports***, none of which would be relied upon by Grace's experts. When a privileged letter attached ***documents and information from plaintiffs' counsel on exposure***, they were included immediately after the privileged sheet. (*See, e.g.*, BCF 0050304-0050317) Furthermore, some classically privileged documents, such as ***settlement*** consideration and analyses that were originally withheld, were ***eventually provided*** per stipulation. (*Compare* Privilege Sheet for BCF 0050278-0050283 and 0050284-0050288 with BOCAS 0000852-0000857 and 0000 853-0000857)

- In the case of J.K., Grace ***properly withheld cover letters*** from outside counsel attaching medical/expert reports, a complaint and the personnel files, but it ***produced*** the actual medical/expert reports, complaints, and personnel files that were attached. (*See, e.g.*, BCF 0048992-0049012 and BCF 0049092-0049344)

- In another case, M.P., Grace ***provided the medical reports*** attached to the various privileged letters, including pathology reports, and personnel records. (*See, e.g*, BCF 041154-041155, BCF 0041186-0041237. BCF 0041255-0041269, BCF 0041281-0041373) It appears that ***one*** pathology report may have been inadvertently withheld, but that had ***no final bearing*** on Dr. Florence's analysis, as this individual was excluded based on his lack of exposure evidence, not medical evidence. Regarding exposure, Grace's experts reviewed the work history provided, as well as medical reports that discussed exposure. Obviously, they did not consider

> the highly subjective deposition summaries, which were properly withheld.

Finally, and most critically, these were all documents from ***Closed Claims Files*** – in other words, people who were not required to respond to Questionnaires and who will not be factored into any trust fund. Rather, Dr. Florence relied on the information provided in the PIQs – not the closed claims files – for purposes of his estimation (other than to analyze past claim values).

(b) Grace accurately coded the closed-claims data.

The PI Committee also attacks the coding of the ***closed claims*** files by Exponent and the Delaware Claims Facility ("DCF"). (PI Mot. at 31-32) As an initial matter, they do not criticize the coding of the ***PIQs*** that was done by Exponent and DCF, and it is the data from the ***PIQs*** which were used by Dr. Florence to estimate the number of pending and future claims. (*See* Florence Supp. Rpt. at Ex. G) The closed claims files contained far less information than the PIQs, and the closed claims files were not used for estimation purposes, other than to analyze past claim values. Noticeably, in their briefs, claimants do not contend that the Exponent review improperly excluded any claims.

Moreover, the differences between the coding done by Exponent and the DCF are a result of the ***differing*** and complementary coding criteria employed, not the reliability of the coding itself. When examining the nature of exposure, the DCF did not examine whether the product to which the claimant was exposed was actually a ***Grace*** product. Dr. Florence explained that "it was decided to have Celotex Trust reviewers code any type of information concerning the nature of the claimant's exposure instead of requiring Celotex Trust reviewers to discern whether or not each exposure was linked to a Grace asbestos containing product." (Florence Rpt. at 9 n.6.) ***Exponent, on the other hand, required that exposure be linked to a Grace product.*** This explains why DCF coded 21 claimants as meeting criteria that Exponent found were not. In

addition, Exponent was retained because of their expertise in reviewing this type of information. Their more detailed review was able to find reference to Grace-specific exposures in several additional claimants. Differences between the coding done by DCF and Exponent does not mean that the coding was unreliable and arbitrary, but that the coders used different sets of criteria, as explained in the expert reports of Dr. Florence and Dr. Anderson.

B. Grace Deployed Scientific Methods for Determining Exposure: Grace Experts Lees And Lee.

1. Dr. Peter S.J. Lees used classic industrial-hygiene methods and all available exposure data.

The Claimants assert that Dr. Lees' analysis of average exposures to Grace products is unreliable because he does not show that the "handful" of historical measurements he has are representative of the exposed population. (*See* PI Mot. at 58.) Not so.

First, the analysis culminating in Dr. Lees' June and July 2007 reports and the job exposure matrix therein involved review of thousands of samples from hundreds of studies including all available Grace product exposure data – far from a mere "handful" of Monokote III samples. Specifically, Dr. Lees' report and reliance materials demonstrates that Dr. Lees reviewed approximately 300 studies involving 3,400 samples. Of these, 1,800 samples were taken during the use or application of Grace's products. (Lees Dep. at 111; Lees 2nd Supp. Rpt. at Tbl. 2-3)

Second, Dr. Lees uses ***all*** of the available data that passed his data quality criteria; hence, he uses as much of the scientifically sound data and information as was possible to use. Claimants complain that Dr. Lees did not base his work on "an adequately representative sample" of exposure data. (PI Mot. at 59) In this critique, claimants cite to standards applicable to "sampling studies" which purport to take a statistically significant subset sample of the greater universe of available data. (*Id.* at 50-61) This critique is fundamentally flawed because that is

not what Dr. Lees purports to do – and should do – in his exposure assessment. Instead, Dr. Lees utilizes ***all*** available Grace product historic exposure data. (Lees First Supp. Rpt. at 6-8; *see also* Lees Dep. at 42 ("In exposure reconstruction, you look at any and all of the available data."); *Id.* at 94 ("I requested from Grace all of their reports that talked about anything about exposure anywhere at any product."))[3] He excludes only data that (a) fails to demonstrate that measurements were collected and analyzed following good industrial hygiene practices using accepted standard methods or (b) lacked clear documentation of various standard elements of the exposure measurement data collection process. (Lees First Supp. Rpt. at 7-8; *see also* Lees Dep. at 110) The EPA itself addresses the use of available data for exposure reconstruction in its guidelines. (EPA, *Guidelines for Exposure Assessment* at 64-65 (May 1992) ("If data are rejected for use in favor of better data, the rationale for rejection should be clearly stated and the basis for retaining the selected data should be documented.")) ***Applying these criteria***, Dr. Lees explained that "only the highest quality, methodologically reliable data were included in the exposure evaluation. The adequacy and completeness of documentation of the sampling report formed the heart of the evaluation criteria." (Lees First Supp. Rpt. at 7) "Regardless of the source of exposure information, these same evaluation criteria were applied to candidate studies. (*Id.* at 8) It was entirely appropriate for Dr. Lees to rely on all available reliable data.

Case law cited by the claimants does not purport to dictate difference science. In *United States v. Mikos*, No. 02 CR 137, 2003 WL 22922197 (N.D. Ill. Dec. 9, 2003), for instance, the

[3] To fill in some gaps in the available Grace product data, Dr. Lees drew comparisons between monitored products for which he had available data and non-monitored products for which there was no data, and clearly sets forth the basis for such comparisons. Claimants' proffered exposure expert, Steve Hays, agrees that the methods employed by Dr. Lees in his historic exposure reconstruction for extrapolation regarding products without available sampling data are appropriate. (Hays Dep. at 155-56 (you would look to "[s]imilar products, similar activities, similar site conditions, similar tasks, of course."))

court held inadmissible an expert opinion that relied on a government study of bullet-composition, where there was no indication that the samples in the government study were "gathered in any approved scientific manner so as to be considered as representative of the bullet population as a whole." *Id.* at *4. Unlike the government's study in *Mikos*, Dr. Lees does not rely on a ***sample*** of exposure data, but rather on ***all*** available and reliable data. Similarly, *Hodgdon Powder Co. v. Alliant Techsystems, Inc.*, 512 F. Supp. 2d 1178, 1182 (D. Kan. 2007) and *Meanasha Corp. v. News America Marketing In-Store*, 238 F. Supp. 2d 1024, 1030 (N.D. Ill. 2003) involve surveys not conducted according to generally accepted survey principles. These cases are inapplicable because Dr. Lees' report is not a survey. And, *Cuffari v. S-B Power Tool Co.*, 80 Fed. Appx. 749 (3d Cir. 2003) did not involve a "sampling study" at all, but rather concerned an expert's conclusion that a saw was defectively designed based solely on the expert's unreliable and anecdotal review of literature and conversations with those who had used the saws. *Id.* at 751. In short, the expert reports at issue in claimants' cases, which look at subsets of available data not determined to be representative of the whole, are not remotely comparable to the comprehensive analysis performed by Dr. Lees, which analyzed all available data.[4]

Third, Dr. Lees testified that the distribution between the samples he reviewed was tight enough for various groups of products to conclude they were representative as well. Contrary to claimants' charge that Dr. Lees' opinions lack any assurances about the representativeness of the data underlying his report, at deposition, Dr. Lees identifies two main reasons why he concludes

[4] For the same reason, claimants' criticism that Dr. Lees did not look at "sample size" is beside the point. (PI Mot. at 60) Dr. Lees did not need to look at "sample size" because his study is not based on a sample of a larger collection of Grace exposure data, but rather is based upon all available data.

— for example — that the Monokote III samples underlying his report are representative of the population of such exposures:

> First of all is the relative tightness of the data in terms of their . . . variability, it's what I would normally expect to see within a population. And the second thing is, with respect to possible bias in the data, I averaged up the exposure concentrations from the studies done by Grace. And I averaged up the concentrations done by the state health departments. And they are virtually identical.

(Lees Dep. at 128-29) Dr. Lees goes on to explain that there is "[no] reason to believe there is any particular bias in the sampling" because "its relative tightness or homogeneity" give "confidence that [the universe of sampling results he relies upon] is a good and representative sampling." (*Id*. at 129)

Likewise, Dr. Lees conducted additional analysis to detect outlier values in the data that could potentially skew the calculated means. Only one outlier point was detected in all of the exposure groupings. Although this value may have skewed the average upward in this category, the data point was not excluded from analyses. (Lees 2nd Supp. Rpt. at 3) Dr. Lees followed standard exposure assessment practices with respect to outliers. In the Guidelines for Exposure Assessment the EPA states that "Outliers should not be eliminated from data analysis procedures unless it can be shown that an error has occurred in the sample collection or analysis phases of the study." (EPA, *Guidelines for Exposure Assessment* at 64-65)

Dr. Lees appropriately used all available reliable exposure data in his analysis, and claimants' argument misses the mark.

2. Dr. Lees' use of averages was appropriate.

Claimants assert that Dr. Lees' analysis of exposures from Grace products is methodologically flawed because he presents only the eight-hour average exposure and not a range or variance of exposures. This argument fails for several reasons.

First, when exposure assessments are conducted for epidemiological studies, the metric used is the average exposure. (*See* Lees Dep. at 66, 133, 149, 213, 242) For instance, when the EPA published its seminal epidemiologic model for asbestos dose response in 1986, the exposure data EPA used was the average exposure reported in several epidemiologic studies.[5] Likewise, the EPA guidance documents specify the use of average exposure to represent a long-term exposure: "An estimate of the average concentration is used because… average concentration is most representative of the concentration that would be contacted at a site over time."[6] In neither instance did the EPA use a range of exposures or the variance in exposures in calculating risks from the exposures. Here, Dr. Lees knew that he was preparing an exposure assessment to be used for comparison to benchmarks from epidemiological studies, and therefore, reported the metric that is relevant to that analysis.[7] (*Id.* at 66, 133, 149, 213-14, 242)

The PI Committee responds by asserting that epidemiologists report the variance in the risks that they measure, implying that this indicts Dr. Lees' failure to report variance. But the PI Committee is mixing apples and oranges here. It is true that, once an epidemiologist takes exposure data and health outcomes, controls for confounding, and finds a dose-response relationship, the epidemiologist will report the confidence interval associated with his or her

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[5] EPA, Office of Health & Envt'l Assessment, *Airborne Asbestos Health Assessment Update*, at Table 3-30 (June 1986).

[6] EPA, Office of Solid Waste & Emergency Resp., *Supp. Guidance to RAGS: Calculating the Concentration Term*, Pub. 9285.7-D81 (May 1992).

[7] The PI Committee contends that Dr. Lees stated that it is standard to calculate the standard deviation in industrial hygiene studies. (PI Mot. at 64) This quote is taken out of context. When asked if it was standard practice to calculate the standard deviation, Dr. Lees testified that it depended on what the data was going to be used for. (Lees Dep. at 130-31) He then explained that if the exposures were to be used for epidemiological purposes, "that's just not a number that would be carried forward into subsequent analyses, so I did not explicitly do it in this case." (*Id.* at 130) The PI Committee misleadingly cuts off his answer without providing the next sentence where he explains "My point and the reason I did not do it in this case, was that, in the subsequent risk analyses done by others, those measures of variability were not incorporated in there and are not typically incorporated in their estimates of risk." (*Id.* at 132)

results. It is also true, however, that when taking the exposure data to feed into the epidemiological model, the epidemiologist uses the average exposure (sometimes daily, sometimes yearly or even cumulative lifetime exposure) without accounting for variability in the exposure data. (*Id.* at 66, 133, 149, 213-14, 242)

Claimants cite no authority for the proposition that what Dr. Lees did here – calculate workers' exposures to Grace asbestos-containing products based upon historical data – was inappropriate. None of the claimants' cases involved epidemiological studies at all, much less ones attempting to estimate an individual's exposure to a hazardous substance.[8] Indeed, the expert in one of the claimants' cases was excluded precisely because he made no effort to calculate dose (based on averages or otherwise) but instead baldly asserted that any exposures could cause cancer. *See Willis v. Amerada Hess Corp.*, 379 F.3d 32, 49 (2d Cir. 2004) (excluding expert testimony on "oncogene" theory of causation – that cancer can be caused by a single exposure to a toxic substance – as unreliable under all the *Daubert* factors).

Second, Dr. Lees knew that reporting the variability in the data was not necessary for the additional reason that Dr. Anderson was going to make conservative frequency and duration assumptions that would significantly diminish any effect of variability in the data. As explained previously, while there is variability in exposure during the course of an eight-hour day, if you assume that an individual engages in the same activity every day for forty-five years, the

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[8] *See Biondo v. City of Chicago*, No. 88C3773, 2002 WL 1160948 (N.D. Ill. May 31, 2002) ("lost-chance" theory in employment discrimination lawsuit); *Hutchinson v. Hamlet*, No. CO2-974, 2006 WL 1439784 (N.D. Cal. May 23, 2006) (excluding expert opinion that a person's height will vary while running that was based on only four samples); *Perez v. City of Batavia*, 2004 WL 2967153 (N.D. Ill. Nov. 23, 2004) (racial profiling); *Willis v. Amerada Hess Corp.*, 379 F.3d 32, 49 (2d Cir. 2004) (excluding expert testimony on "oncogene" theory of causation —that cancer can be caused by a single exposure to a toxic substance — as unreliable under all the *Daubert* factors); *McDowell v. Brown*, 392 F.3d 1283, 1299-1300 (11th Cir. 2004) (excluding expert theory that earlier treatment of patient would have prevented injuries that was not based on any data, study, or other analysis; "an expert opinion is inadmissible when the only connection between the conclusion and the existing data is the expert's own assertions, as we have here.").

variability is significantly diminished. (Lees Dep. at 152, 198-200) Over the course of performing the same activity 11,250 times, the person's average exposure becomes almost identical to the average of the distribution. For this additional reason, it was not necessary for Dr. Lees to report a range of variability associated with the exposure data. Nonetheless, when asked, Dr. Lees explained that "its relative tightness or homogeneity" give him "confidence that [data] is a good and representative sampling." (Lees Dep. at 129)[9]

The PI Committee also presents Figure 2 on page 63 of their brief in an attempt to illustrate why Dr. Lees should have presented the range of exposures rather than the just the mean. This figure is misleading because Dr. Lees presented daily averages for exposure which the PI Committee purports to compare to benchmarks based on ***lifetime cumulative exposure***. Dr. Lees' daily averages were not compared to any benchmarks or thresholds other than the OSHA PEL. Rather, Dr. Anderson made very conservative frequency and duration assumptions to determine maximum possible lifetime exposures which were then compared to the benchmarks. And because her assumptions involved over 11,000 daily exposures, variability was rendered insignificant. This figure is misleading, inaccurate and should be disregarded.

Dr. Lees' reporting of the average exposures is completely appropriate because of the purposes for which the data was being used.

[9] For this reason, claimants' citation to the Reference Manual is also inapt. There, the authors simply noted there are different ways to deal with variation, and that the appropriate one to use in any given case depends on the specific facts. (*See* Fed. Jud. Ctr., *Reference Manual on Scientific Evidence* (2d. ed. 2000) at 115 ("There are no hard and fast rules as to which statistic is best.") Here, Dr. Lees accounted for the possibility of variance but concluded that any variations in exposure for a given day would even out over a forty-five year-period.

3. Dr. Lees' method for determining fiber count has been subject to peer review.

One factor in the *Daubert* analysis is whether the ***methodology*** used by an expert has been subject to peer-reviewd – not, as Claimants imply (*see* PI Mot. at 65-66) – whether the specific study applying the method had been published in a peer-reviewed journal. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. at 579, 593 (1993) ("Another pertinent consideration is whether the ***theory*** **or** ***technique*** has been subjected to peer review and publication") (emphasis added); *United States v. Van Wyk*, 83 F Supp. 2d 515, 519 (D. N.J. 2000) (In evaluating the scientific validity of proffered expert testimony a court should consider "whether the ***method*** [employed by the expert] has been subject to peer review" and "whether the ***method*** is generally accepted.") (emphasis added). There is no requirement in either *Daubert* or the Federal Rules that the expert report itself be published. *See Banks v. United States*, 75 Fed. Cl. 294, 301 (2007) ("The court agrees with the defendant that the report itself does not need to be published in order to meet the second factor in the *Daubert* test. Dr. Nairn prepared this report for the sole purpose of the present litigation. Therefore, it has not been published, and the court would not expect it to be published"); *Schieber v. City of Phila.*, No. CIV.A. 99-5648 2000 WL 1843246, at * 011 (E.D. Pa. Dec. 13, 2000) ("Peer review is not applicable to an expert report prepared for the sole purpose of litigation").

Exposure assessment is a fundamental tool of industrial hygiene that is used routinely. In conducting his exposure assessment, Dr. Peter Lees uses a common method for conducting an exposure assessment – a job exposure matrix, or JEM. (Lees First Supp. Rpt. at 4 ("The use of a JEM in the assessment of exposures of this population is an accepted standard technique widely used in published historical exposure reconstruction because it provides structure and consistency of exposure estimates based on known information")) The creation of a JEM, even

for historic exposures, is a standard and well-accepted tool. *See* Nils Plato & Gunnar Steineck, *Methodology and Utility of a Job Exposure Matrix,* 23 Am. J. of Indus. Med., 491, 491-502 (1993); Benedicte Stengel, et al., *Retrospective Evaluation of Occupations Exposure to Organic Solvents: Questionnaire and Job Exposure Matrix,* 22 Int'l J. of Epidemiology at Supp. 72 (1993); Karl Seiber, et al., *Development, Use and Availability of a Job Exposure Matrix Based on National Occupational Hazard Survey Data,* 20 Am. J. of Indus. Med. 163, 163-174 (1991); *see also* Laurie Piacitelli, et al., *A Retrospective Job Exposure Matrix for Estimating Exposure to 2,3,7,8-Tetrachlorodibenzo-p-dioxin,* 23 Am. J. of Indus. Med. 28-39 (2000); Jonathan M. Samet, *Asbestos and Causation of Non-Respiratory Cancers: Evaluation by the Institute of Med.* 15 J. L. & Pol'y 1117, 1126 (2007) ("[T]he study protocols include taking a full occupational history, covering each job and industry of employment. This work history information is then matched against a job-exposure matrix that gives the likelihood of being exposed for a particular job.")) Dr. Lees himself has published on this method in peer-reviewed publications. (Patricia Ann Stewart, Peter S.J. Lees & Marie Francis, *Quantification of Historical Exposures in Occupational Cohort Studies,* 22 Scand. J. Work Envt'l. Health 405-14 (1996)).

As demonstrated above, JEM use for the purpose of historical exposure assessment has been subjected to peer review and is a standard, commonly accepted method for such a study. Even claimants' proffered exposure expert, Steve Hays, agrees that Dr. Lees employed a generally accepted methodology: "Peter Lees' methodology for creating cumulative exposure estimates for a cohort is standard." (Hays Dep. at 158; *see also id.* at 155-57 ("So the [Lees'] methodology, I think, is pretty standard. . .")) Thus, the criticism that Dr. Lees could not at deposition identify published, peer-reviewed Monokote III product-specific job exposure matrices is a straw man.

4. Dr. Richard Lee's conversion factors from TEM to PCME are based upon a reliable and accepted methodology.

The claimants argue that Dr. Lee's conversion factor from TEM to PCME should be excluded because there is no universal conversion factor for converting TEM into PCME. (PI Mot. at 68-69) This a classic straw man argument. Contrary to the claimants' assertions, Dr. Lee does not purport to provide "generally applicable conversion rates from PCM values into a TEM equivalent measurement." (*Id.* at 69) In fact, Dr. Lee agrees that there is no general conversion factor for PCM and TEM measurements. Thus, Dr. Lee determines different conversion factors depending upon the different types of products and how they were used. (*See* Lee Supp. Rpt. at 7-10) At bottom, the claimants have simply demonstrated what is not in dispute: that there is no ***general*** conversion factor applicable to all products and situations. The claimants have failed to demonstrate that the methodology used by Dr. Lee to determine conversion factors for ***specific*** circumstances is anything less than reliable.[10]

As techniques and methods for analyzing asbestos concentration advance, conversion factors have been used to relate data from one method or technique to another. (*See, e.g.*, W. H. Walton, *Airborne Dusts*, in Mineral Fibers and Health at 65-71 (D. Liddell & K. Miller eds., 1991) (discussing various conversion factors for asbestos counting, including impinger to PCM, konimeter to PCM, and thermal precipitators to PCM); National Research Council, *Asbestiform Fibers: Nonoccupational Health Risks* at 87-90 (1984) at 87-90 (providing a matrix comparison of Impinger to PCM to electron microscope to mass measurements); Victor Roggli, Tim Oury, & Thomas Sporn, *Pathology of Asbestos-Associated Diseases* at 26-28 (2004) (presenting

[10] By way of example, consider the fact that different currencies have different exchange rates. Although there is no general exchange rate among all currencies, specific currencies have specific accepted exchange rates. The claimants' argument is akin to saying that it is inappropriate to determine the specific exchange rate of a Euro to a U.S. Dollar because there is no universal exchange rate among all currencies.

conversion of mass to PCM concentrations and indicating that "[t]hese conversion factors have been adopted by the EPA and other scientific bodies"); M. Trudeau, *Methods for the Evaluation of Asbestos Dust Concentrations*, in Short Course in Mineralogical Techniques of Asbestos Determination at 221-46 (1979) (discussing conversion factor between the Fibrous aerosol monitor and PCM, the comparison of two mass concentration devises, a comparison of PCM and mass concentration, and a Tydallometer to mass concentration))

Currently, there are two generally accepted methods for measuring ambient asbestos concentration – Phased Contrast Microscopy ("PCM") and Transmission Electron Microscopy ("TEM"). As the Claimants' recognize, before electron microscopes were available, PCM was the only method used to measure ambient asbestos concentration. Because of the cost and availability, only PCM values are available for many early asbestos exposure studies.

It is well-established that PCM counts include other non-asbestos fibers. (*See* EPA, Integrated Risk Information Systems, *Asbestos (CASRN 132-21-4)*, § II.C.3 (1993) ("It should be understood that while TEM can be specific for asbestos, PCM is a nonspecific technique and will measure any fibrous material.")) OSHA recognized this fact and recommends the NIOSH 7402 analytical method which allows for a correction factor to be applied to PCM data to determine the true estimate of asbestos concentration (called PCME). *See In re W.R. Grace & Co.*, 355 B.R. 462, 488 n.105 ("Because PCM does not positively identify asbestos fibers, [29 C.F.R. § 1910.1001, Appendix A] suggests differential counting [] (the practice of excluding certain kinds of fibers from the fiber count because they do not appear to be asbestos) techniques using TEM to achieve a more accurate count."). This is precisely the methodology underlying Dr. Lee's conversion factors. Dr. Lee took available side-by-side TEM and PCM data for specific Grace products and uses where available, and determined specific conversion factors. These

conversion factors were then used by Dr. Lees for similar products and uses in his job exposure matrix.

Moreover, the EPA has developed its own situation-specific conversion factor for TEM to PCME. In assessing health risks associated with asbestos at the Staten Island Landfill from the World Trade Center disaster cleanup, the EPA stated the following:

> Assuming the crude TEM to PCM conversion factor of 1/60 used by ATSDR and the TEM surface area to volume conversion factor of $3X10^{-4}$ [f/cc]/[S/mm^2], then this converts to a PCM-equivalent concentration of 0.0005 f/cc. This is significantly lower than the OSHA PEL of 0.1 f/cc. It is reasonable to conclude that the exposure of workers to asbestos at the Staten Island Landfill was minimal and potential short and long-term health impacts were minimal during the unloading of debris at the site.

EPA, *Exposure and Human Health Evaluation of Airborne Pollution from the World Trade Center Disaster* 93 (2002)) Similarly, the Arizona Department of Health Services and the Agency for Toxic Substances and Disease Registry recognized the necessity and acceptability of converting TEM data to PCME data:

> Historically, the majority of epidemiological studies performed on asbestos exposure used phase contrast microscopy (PCM) to determine fiber levels in air (f/cc). Advances in technology (e.g., transmission electron microscopy, or TEM) allows measurement of fibers many times smaller than those that would have been detected by PCM and thus typically results in counts much higher than those generated using PCM. Therefore, for risk assessment purposes, TEM data needs to be converted to an equivalent PCM value, referred to as PCM equivalents (PCMe). Two ways to make this conversion are 1) count (or bin) fibers with sizes equal to those that would be counted with PCM (diameter >0.4 µm and length >5 µm) or, 2) make simultaneous measures of TEM counts and PCM counts and compute a conversion factor.

Arizona Dep't of Health Servs. & ATSDR, *Health Consultation, W.R. Grace Exfoliation Facility, Phoenix, Arizona* at 9 (undated).

Finally, the PI Committee's own expert, William Longo, admitted that he has used conversion factors and that the practice is entirely appropriate. For example, because OSHA PELs and excursion limits are based on direct preparation, Longo applied a 10-to-1 indirect to

direct preparation conversion factor to PCM data from his Monokote-III simulations.[11] Longo justified applying this conversion factor based on data from one simulation to data from another simulation because both simulations involved the same material – Monokote-III. (Longo Dep. at 130-37) Here, Dr. Lee developed several conversion factors to account for not only different products, but how the products were used.

The claimants' criticisms that the conversion factors in Dr. Lee's report have not been peer-reviewed is based on a misunderstanding of *Daubert*. As explained above, one factor in the *Daubert* analysis is whether the ***methodology*** used by an expert has been subject to peer-review, *not* whether the specific study applying the method had been published in a peer-reviewed journal. Here, the methodology employed by Dr. Lee to arrive at the conversion factors has been published and is accepted by the government. (NIOSH 7402; OSHA, 29 C.F.R. § 1910.1001, Appendix A; EPA, *Exposure and Human Health Evaluation of Airborne Pollution from the World Trade Center Disaster* (2002); Arizona Dep't of Health Services and ATSDR, *Health Consultation, W.R. Grace Exfoliation Facility, Phoenix, Arizona* (undated))

The PI Committee attempts to create the misleading impression that the conversion factors at issue were somehow excluded in the *ZAI* Opinion. (PI. Mot. at 70) This is simply not true. The *ZAI* Opinion did not address the conversion of TEM to PCME. Rather, it addressed the exclusion of cleavage fragments. *See In re W.R. Grace & Co.*, 355 B.R. at 488 ("Only the portions dealing with the adjustment of counting procedures based on cleavage fragments are

[11] (Longo Dep. at 134-35 ("Q: And those, all of those limits that you gave are based on direct preparation, correct? A: Correct. Q.: How does that number that you arrived at by using indirect preparation compare to the OSHA regulations, can you make a comparison? A: Based on all our data we can. If you take the pulverization data and the dust and debris data, we have both direct and indirect TEM levels in that data. And there's a factor of ten on the direct versus the indirect on increase."))

excluded."). Dr. Lee's conversion factors are entirely unrelated to the cleavage fragment issues. Dr. Lee did not exclude cleavage fragments from his analysis for the estimation.

For these reasons, Dr. Lee's product and use specific conversion factor are reliable, based on government accepted practices, and should not be excluded here.

C. Grace Applied Scientific Methods for Analyzing Risk and Causation: Grace Experts Anderson and Moolgavkar.

1. Dr. Anderson developed a by-the-book risk-assessment model.

Claimants argue that Dr. Anderson fails to answer the appropriate question for *Daubert*. They argue that Dr. Anderson addressed only whether exposure to Grace products ***alone*** caused asbestos-related disease, rather than analyzing whether exposure to Grace products could have been a ***substantial contributing factor*** in causing asbestos-related disease. As discussed above in Section II.A.3, this argument misconstrues the applicable law and the scientific requirements incorporated via *Daubert* and the federal rules. Dr. Anderson's opinions are entirely consistent with but-for causation, substantial factor causation (however construed), and alone complies with the requirements for proof of causation under *Daubert*. As discussed below, claimants' apparently just don't get what Dr. Anderson in fact did.

The PI Committee's suggestion that Dr. Anderson considered only whether exposure to Grace products alone was capable of causing disease flatly misreads Dr. Anderson's work. In her June 2007 Report, Dr. Anderson calculated exposure by category of exposure and product type. In making this calculation, Dr. Anderson assumed, in addition to counterfactually high levels of duration and frequency of exposure, that ***all*** asbestos-containing products were Grace asbestos-containing products. (Anderson Rpt. at 12-13 ("this assessment also assumes, conservatively that all fireproofing products were Grace products"; cumulative exposure values "do not incorporate any consideration of the degree to which individuals in any of the categories

would work on sites that did not involve Grace products")) As a result, while Dr. Anderson calculated "Grace" exposure, this is only because she assumed that ***all*** exposure was Grace exposure. In other words, the cumulative exposure values calculated by Dr. Anderson do not leave open the possibility, like the PI Committee contends, that there is "other" exposure out there that could be added to Dr. Anderson's values – Dr. Anderson's cumulative exposure levels incorporate lifetime exposure ***irrespective of source***.

As *Daubert* requires, Dr. Anderson next compared these values to known epidemiologic studies to determine whether the cumulative exposure levels in each category are capable of causing harm in humans. *Heller*, 167 F.3d at 161. Because the cumulative exposure levels in categories B, D, and E are below levels associated with disease, again, no matter how the total exposure was "contributed to," Dr. Anderson correctly concludes that it is scientifically implausible that disease in these categories is attributable to Grace asbestos-containing products. (Anderson Rpt. at 15) *See In re W. R. Grace*, 355 B.R. at 482.

As a result, the claimants' objection is illusory. There can be no difference between exposure that is a "substantial contributing factor " and exposure that is a "sole cause" when all exposure is assumed to be from a single cause – Grace. Because Dr. Anderson's risk assessment levels assume that all exposure was due to Grace products, her conclusion that disease for people in categories B, D, and E is attributable to Grace products is reliable and relevant whether subjected to a "sole cause" or "substantial contributing factor" analysis. *See DeLuca,* 911 F.2d at 958-59 (requiring Bendectin plaintiffs to establish relative risk of limb reduction defects arising from epidemiological data of at least 2.0 RR, which equates to more than a doubling of the risk).

But Dr. Anderson goes even further and addresses the very question posed by the claimants – whether the Grace exposure she analyzed could substantially contribute to disease

causation. She concludes: "Furthermore, these exposures have not been demonstrated scientifically to contribute to the risk of disease, even when added to other significant exposures." (Anderson Rpt. at 16) Simply put, these exposures were so de minimus that they could not substantially contribute to disease, even if other exposures were present. As Dr. Moolgavkar analogized, it would be like the lifelong smoker who alleged that the whiff of passive smoke he received in a bar caused his lung cancer rather than the thousands of cigarettes he smoked. (Moolgavkar Rebuttal Rpt. at 7)

Nicholson himself recognized that low exposure categories must properly be excluded in order to get an accurate estimate of future incidence of disease. Indeed, as Nicholson discovered when he included had exposures of less than 2-3 f-y/ml, although 32% of the population he included had exposures at these levels, individuals with these levels of exposures accounted only for 2% of the total cancer incidence. (Nicholson, *Occupational Exposure to Asbestos* at 288-89 (1982)) As a result, when estimating the total number of people he considered "exposed" for his projection of disease, he excluded people that had some, but not a significant amount of exposure. (*Id*. at 282) That his overall estimate of disease has been shown to be correct by comparison with SEER data suggests that Nicholson's exclusion of lower dose exposures was appropriate.

No jurisdiction holds that a claimant can recover in the absence of showing that exposure to a defendant's asbestos product was a substantial contributing factor. No pass is given to allow asbestos plaintiffs to prove causation in federal court, even "substantial factor" causation, without reliable epidemiology showing the exposures of record were, in fact, capable of being a

cause of the disease. Accordingly, Dr. Anderson's opinions fulfill the *Daubert* "fit" and helpfulness standards.[12]

2. Dr. Anderson's use of eight-hour time-weighted average exposures is appropriate for calculating lifetime cumulative exposures for risk-assessment purposes.

Claimants contend that Dr. Anderson's calculation of maximum cumulative lifetime exposures for claimants exposed to Grace products is unreliable because it is based on eight-hour time-weighted-average exposures and because she did not look at exposures of the subset of the population who actually developed disease. These criticisms represent a fundamental misunderstanding of both what Dr. Anderson did as well as basic principles of epidemiology.

(a) Dr. Anderson calculated maximum cumulative lifetime exposures, not average exposures.

Although Dr. Anderson used eight-hour time-weighted-averages for exposures to Grace products as calculated by Dr. Lees as an input to her model, she calculated the ***maximum*** cumulative lifetime exposures that individuals could have from exposure to Grace products. The PI Committee's expert Stallard argues that Dr. Anderson's reliance on Dr. Lees' calculation of the average eight-hour exposure is improper because some people will be exposed at levels above the average. This attack is misplaced for two reasons.

First, while it may be true that, on any given day, some individuals are exposed at the average exposure — some above and some below — that is not true over the long term. Dr. Anderson used maximal frequency and duration assumptions for exposure to Grace products, in most cases assuming that people were exposed to such products every single work day of their

[12] As in many toxic tort cases where plaintiffs attempt to avoid their causation burden by arguing that substantial-factor causation lowers the bar, the argument is more smoke than fire. No claimant expert has identified a shred of evidence that there is reliable evidence of causation for any claimant excluded by Grace's experts by virtue of a substantial contribution by Grace to other exposures which, in the aggregate, suffice to meet the claimants' burden.

45 year working lifetime. (Anderson Supp. Rpt. at 4, 9) This assumption results in 11,250 individual days of exposure to a Grace product (45 years x 250 days/year). When you take a distribution of single-day exposures, such as those evaluated by Dr. Lees, and assume someone has those exposures 11,250 times, that person's average exposure will be essentially identical to the average of the distribution. This follows from the well-established principle in statistics that the means of samples drawn from a population approach the population mean as the sample size increases.

To take a more common sense example, when you flip a coin, you know that, on average, half the time it will be heads and half the time it will be tails. If you flip the coin ten times, you may end up with a broad distribution of results (7-3, 2-8, 6-4, etc). The results of any ten coin flips may or may not be close to the known mean. If, on the other hand, you flip the coin 11,250 times, you can be much more certain that the number of times it comes up heads will be very close to 50%. By the same token, if a person was only exposed to a Grace product for a handful of days, the exposures could be quite variable. But by assuming that the individuals were exposed for 11,250 days, Dr. Anderson can be quite confident that the average exposure is truly representative of that individual's actual exposure over the long term. (Anderson Dep. at 171, 245-46; Lees Dep. at 152, 198-200) Thus, Stallard's criticism that she failed to consider variability among the exposure data misses the mark.[13]

Moreover, the use of long-term average concentrations to estimate exposure over long durations is entirely consistent with EPA risk assessment guidance. EPA's Superfund guidance specifies the use of an average value to represent a long-term exposure, stating "[the] average

[13] Dr. Anderson will provide a more detailed affidavit responding to Stallard's declaration on January 3, 2008, per the parties' stipulation.

concentration is most representative of the concentration that would be contacted at a site over time."[14] Similarly, chronic risks assessed under the Clean Air Act's residual risk program are based long-term average air concentrations combined with maximal assumptions for exposure duration and frequency.[15] Under the residual risk program, the risk to the "maximum individual receptor" is calculated on the basis of a long-term ***average*** air concentration assuming a lifetime of exposure to this level: This approach is equivalent to Dr. Anderson's evaluation in which the long-term average exposure levels are combined with maximal assumptions for duration and frequency. For these reasons, Dr. Anderson's use of the eight-hour time-weighted-average exposure is both appropriate and reliable.[16] Stallard's calculations, using the highest possible theoretical exposure as well as the maximum frequency and duration assumptions, produce unreliable results that are wildly out of proportion to any exposures people actually could have had to Grace products. (*See* Stallard Decl. ¶¶ 16-18)

Second, it is simply not true that Dr. Anderson used "the Exponent-calculated average duration and frequency of such work." (PI Mot. at 44) To the contrary, Dr. Anderson used the ***maximum*** possible duration and frequency of exposure. (Anderson Supp. Rpt. at 4, 9; Anderson

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[14] EPA, Office of Solid Waste & Emergency Resp., *Supp. Guidance to RAGS: Calculating the Concentration Term*, Pub. 9285.7-D81 (May 1992).

[15] EPA, Office of Air & Radiation, Office of Air Quality Planning & Standards, *Residual Risk Report* (Mar. 1999)

[16] The PI Committee also argues that different working conditions could exist over time which could result in different long term exposures. (PI Mot. at 46) First, the PI Committee has presented no sampling data or testimony about the actual application of Grace products to support this assertion. Second, the "bad technique" possibility discussed by Dr. Lees and Mr. Hays may be relevant to mixers or sprayers, but it is not relevant to bystanders who would be bystanders to numerous different mixers and sprayers at numerous different sites during the course of their careers. Third, Dr. Anderson's maximal assumption that people worked every work day for forty-five years in proximity to the mixing or spraying of Grace products builds in a huge level of conservatism. For instance, even if someone had hypothetically been exposed to twice the level that Dr. Lees calculated from the Grace exposure data, that person would still have to be exposed to that concentration for every work day for over twenty years to reach the levels in Dr. Anderson's screening analysis.

Dep. at 249, 309) For people who mixed, installed, cut or removed Grace products, or were bystanders to any of these activities, Dr. Anderson assumed that the only asbestos-containing products that they were exposed to were the Grace products, and that they used Grace products and only Grace products every single day that they worked over a forty-five year working life. (Anderson Dep. at 309) This is unrealistic and counterfactual. No one used only Grace products and no other asbestos-containing products. No one used Grace products eight hours a day every single work day for forty-five years. Dr. Anderson's point was to be so overly conservative that she could be confident no one had exposures above her calculated lifetime maximum cumulative exposures from Grace products.

When you combine the fact that Dr. Anderson used maximal assumptions regarding duration and frequency of exposure with the fact that being exposed to a Grace product for over 11,000 days means an individual's lifetime exposure essentially equals the average exposure, it becomes apparent that Dr. Anderson's calculated lifetime cumulative exposures are, in fact, the ***maximal*** lifetime exposures in each of her categories. Indeed, that was the whole point. By showing that these maximum possible lifetime exposures for people in categories B, D and E fall below the benchmarks provided by Dr. Moolgavkar, she was able to conclude that there was no reliable scientific evidence that the Grace exposures could have caused those individuals' diseases. This screening-level analysis is a reliable, accepted and time-tested risk assessment technique — calculate the maximum possible exposure and see if it is below the amount that has been shown to cause disease. (*Id.* at 208-09) This *Daubert* challenge is meritless.

(b) Whether people who actually contracted disease had higher exposures is irrelevant.

Stallard also argues that Dr. Anderson's methods are flawed because she used average exposures to Grace products as opposed to average exposures of people who became ill. Again,

Stallard fails to understand what Dr. Anderson did. As explained above, she used conservative frequency and duration assumptions to ensure that her calculations represented the maximum possible lifetime cumulative exposure from various Grace products. (Anderson Dep. at 283-84) Thus, anyone exposed to Grace products, regardless of whether they contracted a disease or not, fell below the cumulative lifetime exposures she calculated. It was those maximum possible exposures for people in categories B, D and E which she compared to the benchmarks and found to be below the level science has found capable of causing disease. As a result, she was able to conclude that no one exposed to a Grace product (other than mixers and installers) could possibly have a Grace exposure above the level at which science has established a causal relationship.

Again, Stallard's calculations are fundamentally flawed because he calculates a theoretical maximum single day exposure, then assumes an individual was exposed at that level every day over a working lifetime, in order to gin up an exposure above the benchmarks applied by Dr. Anderson. (*See* Stallard Decl. ¶¶ 16-18) It defies logic and accepted risk-assessment practice to assume an individual was exposed to the single highest possible daily exposure every day over a working lifetime. As explained above, ***the standard practice*** in risk assessment, as ***employed by EPA***, is to use the average daily exposure combined with conservative frequency and duration assumptions. *See, e.g.,* EPA, *Guidelines for Exposure Assessment* (May 1992). It is understandable that Stallard, who is an actuary and not a risk assessor or epidemiologist, would not be familiar with reliable practices for calculating lifetime maximum risks from asbestos exposure. When Stallard conducted his own forecasts outside of the litigation context, however, he also used the average exposures of the cohort he was studying rather than the upper bound exposure:

> We approximated the relative risk for occupation groups 7 and 8 as 10% of the risk of insulation workers. This level roughly approximated the 1976 OSHA standard for ambient asbestos concentrations (Table 8.8, n.5).
>
> [This] . . . Estimate is based on ratio of the 1976 OSHA standard of 2 f/ml to our estimate of 20 f/ml for unit relative risk - ***the rough average*** of 20-40 f/ml in primary manufacturing and 15 f/ml in insulation work.

(Eric Stallard, Kenneth G. Manton & Joel E. Cohen, *Forecasting Product Liability Claims* 282-83 (Springer 2005) (internal citations omitted) (emphasis added))

Finally, the fact that people who are not mixers and sprayers of Grace products have asserted claims against Grace is irrelevant. Those individuals – to the extent they actually have a disease – could have been exposed to products made by other manufacturers, radiation, or could be idiopathic mesotheliomas. There is no methodological flaw in Dr. Anderson's analysis.

3. The disease thresholds used by Dr. Moolgavkar are not only permitted but required for admissibility under *Daubert.*

Claimants criticize Dr. Moolgavkar's use of benchmarks below which asbestos-related disease has not been observed. Claimants contend that state tort systems do not require a scientific inquiry into the actual exposure level that is required to cause disease; they argue that this Court therefore should ignore these scientifically ascertainable levels and therefore exclude Dr. Moolgavkar's analysis. These criticisms attempt to turn *Daubert* on its head by arguing both that Dr. Moolgavkar's scientific methods should be excluded under *Daubert* and, by contrast, that their own unscientific tort-system analyses should be permitted under *Daubert*. Precisely the opposite is required.

Epidemiological studies that show an association are required to show a "causal relationship between a chemical compound and a set of symptoms or disease." *In re W. R. Grace*, 355 B.R. at 482. The strength of an association, and thus the strength with which an expert may reliably opine as to causation, is measured in terms of relative risk ("RR"), which is

"defined as the incidence rate in the exposed divided by the incidence rate in the unexposed. Incidence rate is used to express the risk that, within a specified period of time, a member of the relevant population will develop the disease. A risk of 1.0 means that the risk of disease to individuals exposed to an agent is the same as that to unexposed individuals." *Id.* at 482-483 (internal citations omitted). A RR of 2.0 implies a "50 percent likelihood that an exposed individual's disease was caused by an agent. *Id.* at 483.

Because a RR of 2.0 indicates a 50% likelihood that an agent caused a disease, courts will equate a RR of greater than 2.0 with the plaintiff's burden of proving that the harm was more likely than not caused by the agent at issue. *See DeLuca*, 911 F.2d at 958-59 (requiring Bendectin plaintiffs to establish relative risk of limb reduction defects arising from epidemiological data of at least 2.0 RR, which equates to more than a doubling of the risk); *W. R. Grace*, 355 B.R. at 483. *See also Daubert*, 43 F.3d at 1320 ("plaintiffs must establish not just that their mothers' ingestion of Bendectin increased somewhat the likelihood of birth defects, but that it *more than doubled it*.") (emphasis added). As a result, in the absence of extenuating factors, "[c]laimants must establish causation by a 2.0 relative risk rate." *W.R. Grace*, 355 B.R. at 483. If they fail to establish causation by a 2.0 relative risk rate, they fail to meet their burden of proof. *Id.*

Because, as this Court has noted, "the dose makes the poison," a claimant's failure to identify an exposure level to a chemical agent that is hazardous to humans renders expert opinions on the causal connection between that chemical agent and the injury unreliable. *Heller*, 167 F.3d at 161; *see also W. R. Grace*, 355 B.R. at 476. For this reason, courts have held that an expert opinion that a chemical agent caused a disease based on less than a RR of 2.0 is not helpful to the trier of fact and must be excluded from evidence. *See, e.g., Ambrosini*, 1995 WL

637650; *Sanderson*, 950 F. Supp. 981; *Hall*, 947 F. Supp. 1387); *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217.

Consistent with *Daubert* requirements, Dr. Moolgavkar's opinions are based on observed data that show asbestos exposure levels at which the risk of disease has doubled. For example, Dr. Moolgavkar opines that based on case-control studies, the average cumulative exposure to asbestos at which there is any documented increased mesothelioma risk is 15 f/ml-y. (Moolgavkar Supp./Rebuttal Rpt. at 9) Further, applying the Peto formula, Dr. Moolgavkar calculated the doubling dose for mesothelioma from exposure to chrysotile fiber (79 fiber years) and Libby amphibole (8.9 fiber years). (Moolgavkar Supp. Rpt. at App. 2) This opinion is relevant because it establishes a basis for comparing possible asbestos exposure in order to determine whether there was a statistically significant increase of mesothelioma risk. In addition, Dr. Moolgavkar offers the opinion that a doubling of lung cancer risk due to asbestos exposure occurs at 100 f/ml-yr. (Moolgavkar Supp./Rebuttal Rpt. at 10) This opinion is relevant because it establishes a basis for comparing possible asbestos exposure products in order to determine whether there was a statistically significant increase of lung cancer risk. Furthermore, Dr. Moolgavkar addresses other possible causes for diseases, like lung cancer, that are associated with asbestos. (*Id.* at 11) Opinions of this type, based on scientific evidence and epidemiological data, are not only permitted under *Daubert*, but in fact ***required*** when an expert seeks to render a causation opinion. *DeLuca*, 911 F.2d at 958-59; *W. R. Grace*, 355 B.R. at 483. Because Dr. Moolgavkar's opinions reliably address the relevant question before the Court – that of causation – his opinions are permitted under *Daubert*.

4. Dr. Moolgavkar reliably applied epidemiological principles to derive dose levels at which risk of disease was doubled.

The PI Committee objects to Dr. Moolgavkar's calculation of levels at which asbestos is known to be associated with an increased risk of disease. These objections, however, are rooted in a failure to understand his methodology and a failure to grasp the importance of a scientific approach to estimating disease. First, the PI Committee repeatedly states that Dr. Moolgavkar derived "thresholds" of exposure, implying that these thresholds in some way excluded people from consideration of risk. This is flatly untrue. Rather, Dr. Moolgavkar presented estimates of asbestos exposure that would be required to double the risk of disease. (Moolgavkar Supp. Rpt. at App. 2) The PI Committee also implies that Dr. Moolgavkar opines that that women are not exposed to asbestos in the workplace. This is a misreading of Dr. Moolgavkar's report. As stated more fully below, Dr. Moolgavkar's basis for the background rate he chose is well-established by the scientific literature, notably a 2005 article by Price & Ware.

Second, the PI Committee suggests that Dr. Moolgavkar incorporate assumptions into his analysis that raises the estimated exposure required for doubling of the risk of disease. Quite to the contrary, Dr. Moolgavkar's assumptions, when necessary, are conservative: that is, they tend to ***underestimate*** the level of exposure required to double the risk of disease. For example, Dr. Moolgavkar estimates the background probability of developing mesothelioma without excluding individuals under 20-30-years old, although it is very unlikely that someone would develop mesothelioma due to asbestos exposure at those ages.

Third, in an obvious attempt to distract the Court from the merits of Dr. Moolgavkar's conclusions, claimants suggest that Dr. Moolgavkar's arithmetic has not been "peer reviewed." To the contrary, Dr. Moolgavkar used well recognized formulas that have been in scientific literature for years to calculate exposure levels necessary to double risk. For example, in

Appendix 2, Table 2 of his supplemental report, he uses the Peto formula, which has been in the literature for more than two decades and is used by the EPA both in its 1986 asbestos risk assessment model and the 2003 update to that model by Berman and Crump.[17] In Appendix 2 Table 3 of this report, he uses the formula published by Hodgson & Darnton to present estimates in Libby.[18]

In a similar attempt to distract the Court from the merits of his conclusions, the PI Committee suggests, almost incredibly, that Dr. Moolgavkar's credentials as an epidemiologist are not sufficient. Dr. Moolgavkar has been on the faculties of university departments of epidemiology for 30 years. He has published extensively in the epidemiology literature and published numerous studies in epidemiology. He has served on numerous epidemiology panels and has sat on the editorial board of Genetic Epidemiology. He is an elected member of the elite American Epidemiological Society. He has several publications on carcinogenesis induced by fibers. Finally, he was invited to serve on a recent expert panel convened by the International Agency for Research on Cancer to consider asbestos substitutes. (*See* Moolgavkar C.V., Ex. A to Moolgavkar Rpt.)

The FCR also argues that Dr. Moolgavkar improperly underestimates the mesothelioma background rate, thereby inflating his calculation of the dose required to double the mesothelioma risk. This attack, based entirely on criticism of a Price & Ware paper, misreads

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[17] EPA, Office of Health & Envt'l Assessment, *Airborne Asbestos Health Assessment Update*, (June 1986); D.W. Berman and K.S. Crump, *Final Draft, Technical Support Document for a Protocol to Assess Asbestos-Related Risk, Prepared for Office of Solid Waste and Emergency Response*, (Oct. 2003).

[18] J.T. Hodgson, Darnton A., *The Quantitative Risks of Mesothelioma and Lung Canceron Relation to Asbestos exposure*, 44 Ann. Occup. Hyg. 565, 565-601 (2000).

both Price & Ware's clear conclusions themselves as well as its own expert's characterization of that paper.

Price & Ware compare the mesothelioma incidence rates among men and women over the period surveyed by SEER.[19] The authors observed that while mesothelioma incidence in men increased, peaked, and then started to decline, reflecting the rise, peak, and decline in average U.S. asbestos consumption, by contrast, "all women were exposed to asbestos in the environment, an exposure that would have increased since the 1930s, especially the dramatic increase during the 40-year period from 1930-70 in the amount of asbestos used in US products. . . . Nevertheless, the mesothelioma risk for women has not increased." (Price & Ware, *Mesothelioma* at 111) They conclude, therefore, that the U.S. environmental exposure levels must, therefore, have been below the threshold level for an increased mesothelioma risk. (*Id.*) They continue that the presence of a mesothelioma threshold that is "higher than the typical environmental asbestos exposures" "implies the existence of background mesotheliomas" and opine that this background is nearly 4 per million. (*Id.*) In other words, the mesothelioma incidence rate among women has been flat although average exposure has risen, peaked, and begun to fall off, indicating that however much mesothelioma in women is attributable to asbestos exposure, it is less than the mesothelioma background rate. (*Id*. at 110-11)

The FCR does not – indeed it cannot – counter this clear conclusion with any scientific studies or data. Rather, it miscites its own expert, Dr. Roggli, for the proposition that "the rate of asbestos disease in women echoes the pattern in men." (FCR Mot. at 37) While Dr. Roggli commented that, without examining the underlying data, the rate in women appears to rise

[19] B. Price & A. Ware, *Mesothelioma: Risk Apportionment Among Asbestos Exposure Sources*, 25 Risk Analysis 937-43 (2005).

somewhat, he also testified that "I wouldn't be surprised if that curve is not statistically significant different from a flat curve." (Roggli Dep. at 136) While the FCR fails to mention Dr. Roggli's testimony, Roggli makes the crucial point: the mesothelioma incidence rate for women is not, in Dr. Roggli's own words, "statistically significant [sic] different from a flat curve." (*Id.*) As a result, the FCR's contention that Price & Ware cannot be relied on to demonstrate a mesothelioma background rate is wholly unpersuasive. Because Dr. Moolgavkar's use of Price & Ware is scientifically reliable and relevant to the determination of a background rate for mesothelioma, his opinions with respect to background rate are admissible under *Daubert.*

D. Grace Followed Consensus Scientific Standards and Methods Relating to Diagnosis and Disease: Grace Experts Henry and Weill.

The FCR improperly criticizes Grace for not valuing claims of lung cancer claimants who failed to produce original or certified copies of x-rays as well as his "lung cancer causation criteria," specifically requiring a B-read of 1/0 or greater to attribute a malignancy to asbestos exposure. (FCR Mot. at 28-29)

For purposes of the estimation trial, lung cancer claimants who did not produce x-rays pursuant to the Court's order do not have radiographic evidence to support their assertion that their cancer is attributable to asbestos. This Court required all cancer claimants who intend to rely upon radiographic of evidence to attribute their malignancy to Grace asbestos to produce their x-rays or certified copies of their x-rays. (Dec. 22, 2006 X-ray Order at 1 [Dkt. 14,148]) Dr. Daniel Henry conducted an x-ray study to examine the prevalence of disease in a proportional sample of the x-rays produced by the claimants and found that only 7% had a profusion score of 1/0 or greater. (*See* Grace Opening Br. at 49, 73) With respect to those claimants who failed to produce original or certified copies of x-rays (or certify that the x-rays

were in the possession of a third party), this Court determined that these cancer claimants "are precluded from introducing any x-ray evidence, including but not limited to x-rays, b-reads, or other interpretations or reviews of x-rays ("X-ray Evidence"), in support of their claims at the estimation trial beyond what was timely provided to the Debtor by March 15, 2007." (June 6, 2007 Supp. X-ray Order at 2 [Dkt. 15,968]) That a claimant who failed to produce his x-ray pursuant to this Court order may have an x-ray "at the time of trial in the tort system" (FCR Mot. at 28) is a red herring given this Court's orders specifically limiting the evidence that can be considered for estimation to those x-rays that were produced pursuant to Court order. Accordingly, for those 2,421 individuals (51% of lung cancer claimants) who did not produce x-rays or certify that they were in the possession of a third party, their claims were properly estimated as if there were no x-ray evidence to support their allegation that their cancer was attributable to asbestos.

It is the claimants themselves who rely upon radiographic evidence of asbestos exposure in order to attribute their lung cancers to asbestos exposure. They have submitted their x-rays as their sole evidence of asbestos exposure, and therefore, their claims are dependent on whether the x-rays show evidence of asbestosis in order to attribute their lung cancer to asbestos exposure. Reliance upon a radiographic reading of 1/0 to attribute a malignancy to asbestos exposure is reliable and supported by epidemiological literature. (Weill 10/06 Rpt. at 19-24) Given that only 7% of the claimant sample in the Henry Study had a 1/0 or greater, only 7% of the claimants have radiographic evidence sufficient to attribute their malignancies to asbestos exposure. Moreover, the FCR's expert, Dr. Roggli, contends that a "dose" of 25 f/ml-yrs of exposure to asbestos is the level of asbestos exposure necessary to double the risk of contracting an asbestos-related cancer and acknowledges that 25 f/ml-yrs is also the threshold for asbestosis.

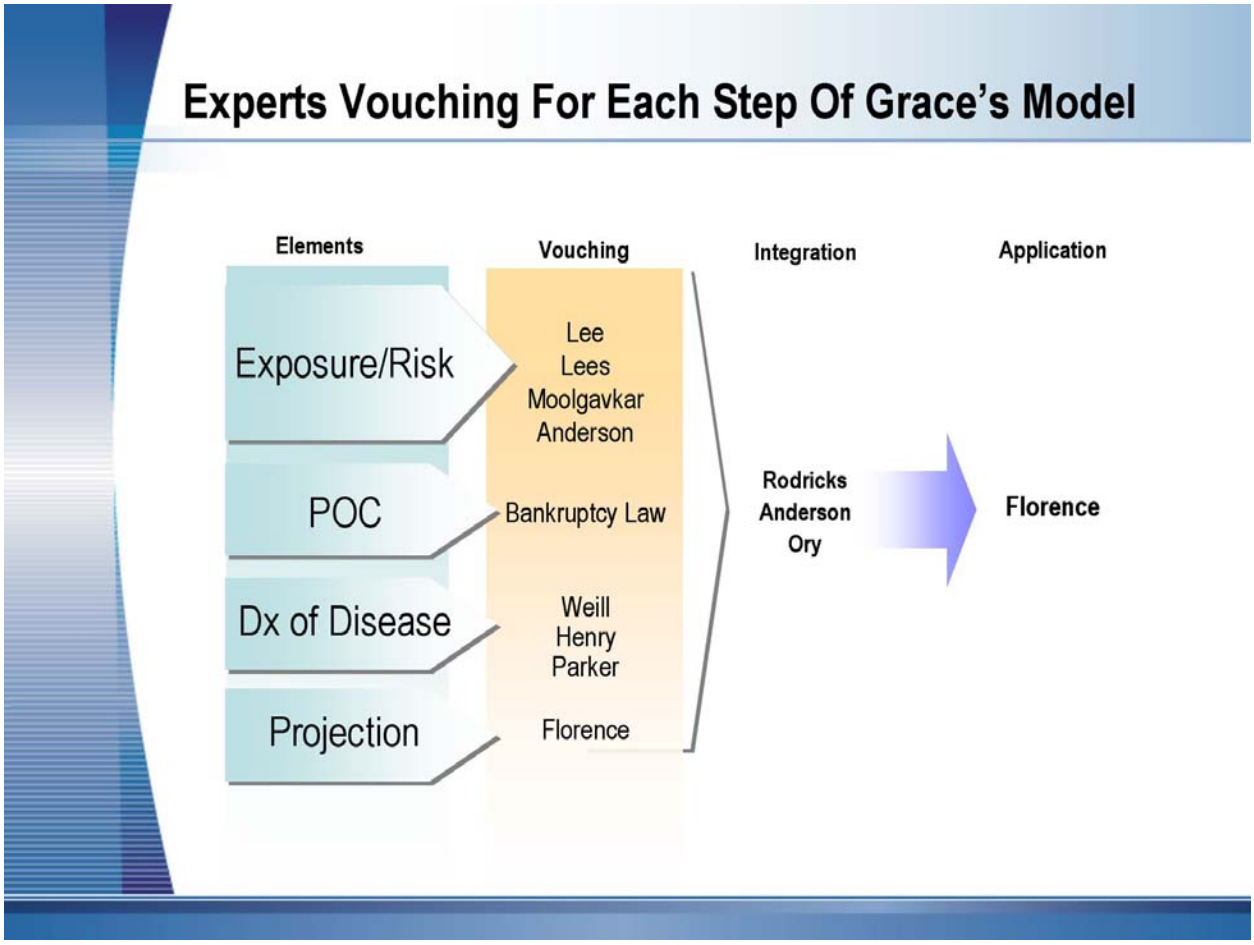
(Roggli 07/07 Supp. Rpt. at 3) Given that only 7% of the claimant population had radiographic evidence of asbestosis, it is unlikely that, even under Roggli's "dose" theory of causation, that more than 7% of these claimants had sufficient exposure to asbestos (25 f/ml-yrs) to double the risk of contracting lung cancer.

E. Grace Reliably Applied the Output of Its Scientific Experts to the Relevant Claims Data: Grace Expert Florence.

1. Florence did not improperly rely upon the work of other experts.

The PI Committee argues that Dr. Florence has improperly relied upon other experts in forming his opinions without vouching for the assumptions made by the other experts. (PI Mot. at 19-22) In support of this argument, the PI Committee cites *In re TMI Litig.*, 193 F.3d 613 (3d Cir. 1999), in which the court excluded expert testimony that one expert had "daisy-chained" together "to create a combined methodology that no single expert vouches for." (PI Mot. at 19) The PI Committee's argument misconstrues both the work of Dr. Florence and the *TMI* decision.

As described in detail above in Section II, Dr. Florence's role in this case was to take the scientific criteria derived by experts in the fields of industrial hygiene, epidemiology, risk assessment, and diagnostic medicine, and apply ***their*** conclusions to the claimant-specific data of record in this case. Each and every aspect of this combined effort was vouched for by an expert with appropriate credentials, experience, and methods.



No experts work was taken and processed in a manner inconsistent with their intent. No assumptions were glossed over; nothing fell between the cracks. Dr. Florence's role was the processing of data and ultimately it was also his task to present an aggregate value estimate, but to characterize his opinion as passing off the work of others without scrutiny is a patently false accusation.

Thus, Dr Florence's work is nothing like the expert work that was held improper in *TMI*. In *TMI*, Dr. Crawford-Brown opined as to the radiation dose to which the surrounding community was exposed based entirely upon the observations of other experts who had studied various "effect" in the area. *See In re TMI Litig. Cases Consol. II*, 911 F. Supp. 775, 824 (M.D. Pa. 1996) ("*TMI II*") (noting alleged effects including "chromosome dicentrics, tree damage,

[and] human and animal health effects"). Crawford-Brown's opinion was essentially that ***if*** the "effects noted" by the other experts were actually due to radiation, then the exposure was equivalent to a dose of 100 rem. *TMI*, 193 F.3d at 714. Crawford-Brown himself did not opine that radiation had in fact caused the "effects noted" by the other experts, nor had those experts rendered such opinions. Crawford-Brown also admitted he did not examine the methods used by the other experts to reach their conclusions, and he testified that normally, when doing an exposure assessment, he would assign varying levels of confidence to the different sources of evidence, and then gives a "cumulative confidence distribution," which he did not do in this case. *TMI*, 193 F.3d at 715. In sum, the problem with Crawford-Brown's work is that it reached a conclusion based on the assumption that radiation had caused certain observed effects when in fact no expert had opined as much.

The *TMI* court upheld the exclusion of Crawford-Brown's work, not because he relied on the work of other experts, but because neither he nor anyone else had not conducted the analysis necessary to use the information provided to him. The district court specifically noted that Crawford-Brown could have relied on other experts if he had taken the extra step of assigning confidence levels to each source of evidence; that is, if he had evaluated the probity of the evidence to speak to the presence of radiation. *See TMI II*, 911 F. Supp. at 825. Neither the district court nor the appellate court ever suggested that, had that missing link been supplied, his opinion would still be inadmissible. The Third Circuit did not announce or endorse a broad prohibition on experts relying on other experts. It simply confirmed that one expert cannot take another's work and ***use it for more than it rightfully supports*** without doing whatever assessment of it is necessary to allow such a use.

The PI Committee's claim that "[t]he Third Circuit concluded that this uncritical combining of opinions without an expert who endorses the entire methodology does not satisfy Daubert" (PI Mot. at 20) is thus unfounded. The Third Circuit imposed no requirement of an "uber expert" whose expertise must encompass all aspects of a party's approach to an issue. Such a requirement would immediately disqualify claimants' experts Peterson and Biggs, neither of whom are qualified to opine on all the factors and inputs that ultimately influence their estimation models.

Unlike the experts in *TMI* who had sought to shield themselves from scrutiny by playing shell game with the responsibility for the key link in their opinions on the issue of causation, Florence's use of data provided by other experts ***does*** make the reliability of his particular conclusions subject to the reliability of the inputs provided by others. *See, e.g.*, *In re Sulfuric Acid Antitrust Litig.*, 446 F. Supp.2d 910, 924 (N.D. Ill. 2006) (underlying data must be reliable). It ***does not*** render his methodology flawed or unreliable. "An expert can rely on . . . another expert's report, in arriving at an opinion." *In re Lake State Commodities, Inc.*, 272 B.R. 233, 242 (Bankr. N.D. Ill. 2002); *see also, e.g.*, *Janopoulos v. Harvey L. Walner & Associates, Ltd.*, 866 F. Supp. 1086 (N.D.Ill. 1994) ("an expert may rely in part on information supplied by another expert"); *McReynolds v. Sodexho Marriott Servs., Inc.*, 349 F. Supp.2d 30, 36 (D.D.C. 2004) ("[A]n expert may rely on . . . one's assistants to carry out analyses that the expert designed."); *Astra Aktiebolag v. Andrx Pharmaceuticals, Inc.*, 222 F. Supp. 2d 423, 491 (S.D.N.Y. 2002) ("There is no requirement that an expert must run his own tests."). Indeed, this reliance on other experts is routine – probably even necessary – in an asbestos estimation. Contrary to the allegations made by the FCR, Dr. Florence, like all experts who offer estimation opinions,

routinely bases his estimation opinions on assumptions provided by others. (*See* Florence Dep. at 30, 230)

Dr. Florence is allowed to rely on the opinions and reports of other experts to provide the inputs to his estimation model, so long as those other reports are reliable. Even if the opinions so utilized turned out not to be reliable, the result would be an exclusion or limitation on Florence's conclusions to the extent they were driven by unreliable data, not the exclusion of Florence's or Grace's estimation method in general.

2. Florence properly excluded 5,063 claims with post-petition diagnoses or filing dates.

The claim that Dr. Florence "excluded" 5,063 claimants because they filed their claim or were diagnosed after the petition date (FCR Mot. at 26-27) is wrong. Dr. Florence (as well as Dr. Peterson and Ms. Biggs) estimated the pending claims as of the petition date and estimated the post-petition claims as "future" claims. (*See, e.g.*, Florence Supp. Rpt. at 2, 17) Claims that were filed after the petition date or diagnosed after the petition date were not considered pending claims but could be future claims. Put simply, post-petition claims were not "excluded" but simply were not pending claims.

3. Florence properly excluded 28,923 claims from the CMS database.

The FCR's claim that Dr. Florence's exclusion of 28,923 claimants who did not file a POC from the pending claims somehow makes the estimate unreliable (FCR Mot. at 27-28) is without merit. The Court ordered each of the claimants whose claims were pending as of the petition date to file a "Proof of Claim" by November 15, 2006. (Aug. 24, 2006 Order as to All Pre-Petition Asbestos PI Litig. Claims at 2 ([Dkt. # 12,061]) It is black letter law that failure to file a Proof of Claim before a bar date bars a claimant from pursuing that claim. (*See id.* ("ORDERED that any holder of a Pre-Petition Litigation Claim who fails to file an Asbestos PI

Proof of Claim on or before the applicable Bar Dates shall be ***forever barred, estopped*** and enjoined from asserting such claim against any of the Debtors on the § 524(g) Trust . . . .") Thus, Dr. Florence's exclusion of the claims who did not file a proof of claim was appropriate. Indeed, Dr. Peterson's and Ms. Biggs' failure to exclude these claims renders their estimates unreliable.

F. Grace Followed Established Epidemiology in the Projection of Potential Grace-Caused Disease: Grace Expert Florence.

1. Exposure criteria used for forecast of incidence of mesothelioma and lung cancer were appropriate.

The FCR's complaint that the Nicholson/KPMG and Peto/ARPC models that form the basis of Dr. Florence's forecast "were based on different exposure criteria then Dr. Florence used" (FCR Mot. at 29-30) mixes apples and oranges. The Nicholson/KPMG model forecasts nationwide – not Grace – incidence of disease. The Peto/ARPC model estimates the population exposed to asbestos – not the diseased individuals. Thus, the Nicholson/KPMG model and the Peto/ARPC models do not forecast the incidence of disease caused by exposure to Grace product. It would not be appropriate to apply the exposure criteria to their models.

Dr. Florence calculated the incidence of disease caused by exposure to Grace product. To calculate the incidence of disease caused by exposure to Grace product, he used the exposure criteria. Thus, to determine the number of individuals whose disease was caused by exposure to Grace product, it was necessary for Dr. Florence to use exposure criteria.

2. "Calibration periods" used to estimate the number of future claims were appropriate.

The FCR's assertion that Dr. Florence's use of different calibration periods with time periods between two and five years makes his forecast unreliable (FCR Mot. at 30) is puzzling. Forecasting with multiple calibration periods and then using the median of these forecasts

increases the reliability of a forecast because "the influences of any single anomalous year would be mitigated." (Florence Rpt. 18) Thus, Dr. Florence's use of different time periods and then calculating the median is the appropriate method for forecasting future claims. By contrast, Dr. Peterson's method, which uses only a two and a quarter year calibration period, and Ms. Biggs, method, which uses only a four and a quarter year calibration period, are unreliable, especially given that they both include the entire period during which the spike in claims against Grace occurred.

G. Grace Applied Proper Statistical Methods in Determining Aggregate Value Estimates: Grace Expert Florence.

Claimants take issue with the use of six mesothelioma claims that meet Exponent's exposure review to value the claims. (*See* FCR Mot. at 20-22; PI Mot. at 27)[20] The FCR claims that Dr. Florence "fails to account for potentially huge error rates." (FCR Brf. at 20) These arguments totally misunderstand Dr. Florence's analysis.

As an initial matter, the reason that Dr. Florence used only six mesothelioma claims is because, based on a review of the exposure data, only six mesothelioma claims met the exposure criteria. Experts reviewed 350 historical settled mesothelioma claims. Of these, 318 (over 90%) did not have sufficient exposure information to even determine the claimants' nature of exposure to Grace products. Of the remaining claims, only six claims (less than 2%) had sufficient information to demonstrate that the claims met the criteria. For that reason, Dr. Florence used the values of only six mesothelioma claims.

[20] Noticeably, claimants do not contend that the Exponent review improperly excluded any claims. Indeed, of the two claims that Dr. Peterson asserted in his report that DCF improperly excluded (Peterson Rebuttal Rpt. at 20-23), one of them was included by Exponent (W.M.) and the other did not provide evidence that he actually mixed or applied any Grace asbestos-containing product (D.E.).

The fact that so few settled claims had sufficient exposure information, much less claims that met the criteria, demonstrates that exposure criteria is not a driver of values. Dr. Florence performed statistical analyses that confirm that meeting the exposure criteria is ***not*** a driver of settlement values. As Dr. Florence explained in his report and at his deposition, the average mesothelioma value for claims that ***meet*** the criteria are ***not statistically significantly different*** from the average value for the claims that do ***not*** meet the criteria. (Florence Supp. Rpt. at 15; Florence Dep. at 115, 297-301) Thus, the values of mesothelioma claims were not statistically significantly higher for claims meeting the criteria. Accordingly, Dr. Florence concluded that the exposure "criteria didn't seem to be what was driving the value." (Florence Dep. at 115) Claimants offer no evidence that meeting the exposure criteria increases the values of claims. Indeed, Dr. Peterson concedes just the opposite: that such factors do not affect settlement values. (Peterson Dep. 171-72)

The FCR's suggestion that the values would have been different for the mesothelioma claims that met the criteria had they been settled under a regime that had in place those criteria (which were not in place in the tort system) (FCR Mot. 19-20) is without basis. Given that exposure criteria are not a driver of values, there is no reason to believe, nor is there any evidence, that the values would be different had they settled under a regime imposing those criteria.

Dr. Florence also testified that the historical settlements would not have been any different even if they were made under a regime in which the criteria were in place. As Dr. Florence testified, "what I am really saying is that, had Grace settled those cases with the requisite criteria, there is probably no reason to assume that the average of those cases, whether they be 6 or 100, would differ from the overall average of $96,000." (Florence Dep. at 301)

Accordingly, the FCR mischaracterizes Dr. Florence's testimony when the FCR quotes only that Dr. Florence "has no way of knowing" if the historical mesothelioma claims that met the criteria "would have been different" if they "were settled under the specified assumption as criteria for settlement." (FCR Mot. at 15) After the FCR's ellipses, Dr. Florence testified that "it didn't make any difference whether -- statistically, whether the criteria were met or not met with regard to settlement value. So it probably wouldn't have made a difference." (Florence Dep. at 300)

In fact, the notion that the values of the claims that meet the criteria would be higher in a regime in which the criteria were in place would be counter to a plaintiffs' attorneys' duties. If claims that meet the criteria are higher value claims, then plaintiffs' attorneys would be obligated to obtain those values on behalf of their clients regardless of whether the criteria were in place. The fact that the values of claims that meet the criteria were not statistically significantly different than the claims that did not meet the criteria in the tort system means that these claims that meet the criteria are not higher values claims.

Mr. Stallard, the FCR's expert, confirms Dr. Florence's analysis. Mr. Stallard calculated a statistical range around the values of the six mesothelioma claims that met the criteria. Mr. Stallard calculated that "[t]he 95% confidence interval for the mean ranges from $25,173 to $285,306." (Stallard Decl. ¶ 24). The fact that the low end of the range of the value of the claims meeting the criteria is only $25,173, which is substantially lower than the overall average ($96,531) and even lower than claims with insufficient exposure information ($92,649) or claims that did not meet the criteria ($127,450) (Florence Supp. Rpt. at 15), means that the values of claims meeting the criteria are not statistically significantly different from all other claims.

In light of the lack of statistical significance, it would have been appropriate to use the overall mesothelioma average regardless of whether the claims met the criteria. The overall

average for mesothelioma claims is $96,531. As Dr. Florence testified, "one approach would have been to assign the overall average of $96,000 which probably . . . would have been a reasonable approach." (Florence Dep. at 298)

Nevertheless, although not statistically significant, Dr. Florence used higher values for purposes of his estimation because he found a trend in values based on level of exposure information and mesothelioma claims that met the criteria received higher values – albeit not statistically significant high values – of $155,000 per claim on average. Accordingly, even though not statistically significant, Dr. Florence used the ***$155,000 average*** of the historical mesothelioma claims that met the criteria as a conservative measure of values. As Dr. Florence explained in his report and deposition, the reason he used those values was because "the ***average increased steadily*** from those claims having ***insufficient*** exposure information to those ***having exposure information*** but not meeting the criteria to the highest average for those that ***met the criteria***. . . . Although it is not statistically apparent that claims were historically paid a higher amount on average based on the validity of Grace's exposure, ARPC use the higher average for these claims that met the exposure criteria to value the pending and future claims." (Florence Supp. Rpt. at 15; *see also* Florence Dep. at 289 ("It seems . . . there is a kind of natural progression depending on whether you have not had enough information or you . . . did not meet the criteria, whether you met the criteria.")) But as Dr. Florence made clear, "statistically, there is really no difference in the values." (Florence Dep. at 299; *see also* Florence Supp. Rept. at 15) ("However, the difference in the average for these that met the criteria and that that did not are not statistically significant."))

Thus, Dr. Florence's use of the higher mesothelioma average for claims that met the criteria ($155,000) was a reasonable, indeed, ***conservative*** assumption because the differences were not statistically significant.

Likewise the FCR's criticism that Dr. Florence's values for the claims that meet the exposure criteria are not "adjust[ed] for the fact that Grace's share of total liability would have been higher in such cases" based on what the FCR calls "simple logic" (FCR Mot. at 29) is meritless. As explained, Dr. Florence's analysis demonstrates that the values of the claims that meet the criteria are ***not*** statistically significantly higher than the values of claims that do not meet the criteria. (Florence Supp. Rpt. at 15) Accordingly, the data ***refutes*** the "simple logic" that claims meeting the criteria receive higher values. Moreover, notwithstanding the lack of statistical evidence that claims meeting the criteria would receive higher values, nevertheless to be conservative, Dr. Florence uses the higher (albeit not statistically significant higher) averages for the historical claims meeting the criteria. (Florence Supp. Rpt. at 15) Thus, Dr. Florence does "adjust" and increase his values for the claims that meet the criteria.

For the same reason, the FCR's assertion that Dr. Florence "provides no indication of the potential rate of error associated" with Dr. Florence's mesothelioma settlement averages (FCR Mot. at 20) is mistaken. Dr. Florence calculated an error rate and determined that the difference in values between the claims meeting the criteria and those claims not meeting the criteria were not statistically significant. As Dr. Florence testified; "I think we said – here, we actually tested to see if there was any statistical significance in the difference between the values." (Florence Dep. at 298) Dr. Florence concluded "there was little to suggest historically that those criteria made much difference in the value in the claim." (Florence Dep. at 299) Moreover, Stallard's analysis demonstrates the effect of such an error rate. Stallard calculates that the upper bound

average for mesothelioma claims meeting the criteria is $285,306. (Stallard Decl. ¶ 24) Even using this upper-bound value, which Stallard concedes is less than double the value used by Dr. Florence (*id.*), Dr. Florence's median estimate would still be less than a billion dollars.

In short, Dr. Florence determined that the exposure criteria do not drive the values of claims because there is no statistically significant difference in the values for claims meeting the criteria and those not meeting the criteria. Accordingly, it would have been reasonable to use the overall mesothelioma historical average settlement value. Nevertheless, because mesothelioma claims were being settled for higher values (although not statistically significantly higher), to be conservative, Dr. Florence used those higher values for purposes of his estimate.

CONCLUSION

The motions filed by the PI Committee (Dkt. # 17581) and the FCR (Dkt. # 17584) to exclude the testimony of Grace's experts should be denied.[21]

December 21, 2007

Respectfully submitted,

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[21] Grace acknowledges its Memorandum exceeds 75 pages, but is utilizing pages not used by the Equity Committee from their 40-page allotment to respond to all the issues raised in claimants' 72- and 38-page briefs.

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