cited additional studies in his discussion of several of the other diseases mentioned before. He did not offer a medical monitoring plan with this report. *Id.* at 5-15.[138]

6. The Plaintiffs' Experts Quantify The Increased Risk for Those Persons Exposed to 2, 3,7, 8-TCDD: William Sawyer, Ph. D.

On February 15, 2010, William Sawyer, Ph. D., filed a report entitled *"Nitro Population Dioxin Risk Estimates – Children and Adults: 1948 – Present."* (dkt. no. 2880).[139] Dr. Sawyer assessed the most recent CALUX dioxin TEQ analyses conducted on 99 household (living quarter) dust samples within the Nitro community as well as residential soils, specifically from the November 2009 report of G. C. Flowers, Ph. D. entitled *"Spatial Distribution of Dioxin Contaminates in the Vicinity of Nitro, West Virginia."* He also relied on the reports of W. M. Auberle, PE, and M. J. Wade, each dated February 15, 2010. Finally, he also reviewed the prior dioxin sample data collected by Kirk W. Brown, Ph. D. which was analyzed using GC/MS. Based on this data, Dr. Sawyer stated that recent sampling of household dust, attic dusts, and soil throughout the class area was in excess of the 95th percentile for rural soil and household (living quarter) dust.[140] He attributed this contamination to Monsanto's plant and waste operations. Specifically, Dr. Sawyer stated that from 1948 through a portion of 1969, Monsanto's Nitro production operations produced 2, 3, 7, 8-TCDD as a by-product of the manufacture of 2, 4, 5-T

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[138] The Court notes that apparently Dr. Carpenter's deposition(s) were not filed in the record.

[139] Dr. Sawyer holds a Ph.D., in Toxicology from the Indiana University of School of Medicine, a Master of Arts in Cellular and Molecular Biology and a B.S., in Biology from SUNY-Geneseo, and an A. S., from SUNY-Morrisville (Agricultural and Technical College).

[140] The 95th % upper confidence level is a means used to determine that a result is very likely accurate. Throughout this case, various experts on both sides have made references to data at the 95% upper confidence level.

and during the incineration of 2, 4, 5-T during Monsanto's on-and-off site burning of wastes containing 2, 4, 5-T.

The Nitro soil data was statistically and significantly elevated, exceeding the 95th percentile value and upper confidence level mean. This soil was measured using CALUX, and compared to the USEPA background for rural soils measured by the same methodology. The Nitro soil samples ranged from 0.05 picograms[141] (pg)/gram (g) to 137.25 pg/g with a mean value of 18.9 pg/g. The USEPA study on rural soils revealed an average value of 5.11 pg/g with a 95% percent of 15.73 pg/g and an upper confidence level mean of 8.44 pg/g, *supra.* Fifteen household dust samples were assessed using GC/MS, and the results for CALUX were 30.5% higher than GC/MS. Dr. Sawyer opined that the mean dioxin TEQ across the entire Plaintiff's class area exceeded the USEPA updated Regional Screening Table (USEPA RSL) value for soil of 4.5 pg/g. It also exceeded the West Virginia Department of Environmental Protection *de minimis* clean-up standard of 3.9 pg/g.[142] He concluded that Nitro residential soils are statistically and significantly contaminated with dioxins above the extreme 95th percentile of the rural background comparison group which is far in excess of governmental public health recommendations. *Id.* at 6.

He stated that actual testing of Nitro household and attic dust samples revealed dioxin contamination present within the household and attic dust environment. *Id.* He discussed attic dust and the pathways by which it could enter living quarters. Dr. Sawyer referenced the 2004 and 2005 tests of 58 attics in homes and the 2008 test of 14 living quarters in homes referred to

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[141] The terms pg/gram and ng/kg will be used throughout this Order. Pg/gram represents picograms per gram. Ng/kg represents nanograms per kilogram. These are used interchangeably for different standards of measurement. For example, 1 picogram =0.001 nanogram and one kilogram equals 1000 grams, thus 3.9 nanograms equals 3900 picograms. http: www.aqua-calc.com/what-is/weight/picogram. (last visited on Dec. 20, 2012).

[142] *See supra* note 73.

by Kirk W. Brown, Ph. D. The purpose of the limited sampling was to determine whether or not the homes were contaminated with dioxins as predicted by the isopleth model. The samples were not collected in sufficient quantity to calculate average levels of contaminant in each home. The living quarter dust was in great excess of the 95th percentile values reported in the literature. *Id.* at 10.

Dr. Sawyer determined that the 58 attic dust samples demonstrated a statistically significant and uniform decrease in average contaminant level with average distance from the primary emission source. *Id.* at 16. He also stated that the exposure data and location parameters relied on were referenced in the reports of Auberle and Flowers. *Id.* at 17.

Based on all of the above, Dr. Sawyer applied generally accepted risk assessment methodologies to the air inhalation isopleths with a minimal value of 0.000020 ug/m^3 dioxin TEQ as well as the household dust analysis of the 99 homes in the Nitro class region. The living quarters of these homes were severely impacted with dioxin TEQ as measured by GC/MS and CALUX analytical methods to a degree consistent with increased risk of adverse effects on human health. *Id.* at 17.

Based on these he broke down the increased risk categories as follows:

1. Childhood inhalation for at least 3 years (1948 – 1968) within the 0.000020 ug/m^3 TEQ isopleth for children between 1-7 years of age between 1948 – 1968. Using the CDC NHANES III[143] database, he used the mean default child body weight for a 1-7 year old child to calculate the additional risk of cancer over a 70 year life expectancy, and at the lowest level of exposure, calculated the cancer risk at 5.37 x 10^{-5}.
2. Combined Childhood/Adult Inhalation for at least 6 years (1948-1968) within the 0.000020 ug/m^3 isopleth between the ages of 1 to 31 years (aggregate residential age) with exposures between ages of 1-6 years and 7-31 years totaling at least 6 years between 1948 –

[143] *See* IV. C. for a discussion of NHANES.

1968. Using the NHANES III methodology he calculated the cancer risk at 5.24×10^{-5}.

3. Adult inhalation for 6 years (1948 – 1968) within the 0.000020 ug/m^3 isopleth for residents over 18 years of age and residing full time for at least six years between 1948 to 1968. Using the same NHANES III methodology, he calculated the cancer risk at 3.6×10^{-5}.
4. Children living outside Isopleths; attending Nitro Schools (1948 – 1968) within the 0.000020 ug/m^3 isopleth for 13 years between 1948 to 1968. Using the same NHANES III methodology, he calculated the cancer risk at 1.1×10^{-5}.
5. Workers who resided outside and worked inside the isopleths (1948 – 1968) with the 0.000020 ug/m^3 isopleth who were 18 years or older who worked for at least 6 years between 1948 to 1968. Using the same NHANES III methodology, he calculated the additional cancer risk at 2.93×10^{-5}.
6. Childhood household dust ingestion for 6 years (1969- Present) in the specific region identified by Dr. George Flowers with the Nitro isopleth in which the living quarter dust dioxin TEQs are greater than 90 pg/g. He calculated the additional cancer risk as 1.2×10^{-5}.
7. Childhood/Adult household dust ingestion for 30 years (1969 – Present) within the same ≥90 pg/g contamination region, he calculated the additional cancer risk at 1.16×10^{-5}.
8. Childhood Transitional Exposure (pre-1969 and later) residency for at least 6 months within the 0.000020 ug/m^3 inhalation isopleth and at least 3 years of childhood residency 1969 or later with the ≥90 pg/g contamination isopleth.
9. Adult Transitional Exposure (pre-1969 and later years); Pre-1969 adult residency for at least 1.5 years within the 0.000020 ug/m^3 inhalation isopleth and at least 10 years of adult residency 1969 or later with the ≥90 pg/g contamination region.

Id. at 18-21.

Dr. Sawyer opined that the generally accepted *de minimis* benchmark level for cancer risk is 1×10^{-6} and that risk levels greater than the *de minimis* level are generally considered unsafe (citation omitted). Dr. Sawyer seems to conclude that using this lower number actually artificially deflated the risk. The source of his information was Part 201-*Generic Soil Direct Contact Criteria* from the Michigan Department of Environmental Quality dated August 31, 1998.

He further opined that the area meets the definition of a public health hazard. He concluded by stating that

> [M]embers of the region defined above are at a significantly increased risk for cancer compared to the general population. The measured cancer risk levels are beyond public health benchmarks with medical monitoring for dioxin-related disease clearly indicated. In addition, prospective property buyers should be provided with documentation of the increased cancer risks associated with highly contaminated living quarter dust and future potential of contaminated attic dust entering the living quarters even if the living quarters were cleaned.

Id. at 23.

Dr. Sawyer was deposed on July 19 and 20, 2010. (dkt. no. 1682). Dr. Sawyer was first contacted about this case in January of 2006. He understood that his role in the case was "to provide an objective eligibility criteria with respect to model data and objective analytical data, which validates and proves the class definition as certified by the judge in this matter." *Id.* at 10-11.

He reviewed his earlier report of August 24, 2007, and described those areas that had changed between then and 2010. To that end, he testified that he was no longer relying on the same ambient air concentrations as he did originally as they had been updated by Mr. Auberle. *Id.* at 18-20. He still intended to base his opinion on serum dioxin levels which were obtained from individual class members, with multiple warnings in terms of what could be ascertained from the data. *Id.* at 22. Dr. Sawyer also testified that he was no longer relying on any of the dust data referenced in his earlier reports of January 23 and August 24, 2007, for dose determination or risk assessment purposes, other than property remediation but was instead relying on the spatial distribution analysis performed by Dr. Flowers. This includes just the 99 household samples and not the earlier attic dust samples. *Id.* at 28.

He also believed that if an individual with a lower dioxin level in their blood had not been exposed since 1969, that they would have eliminated 96% of the dose. *Id.* at 38. However, they would still require monitoring. *Id.* at 47. This is because the genetic damage and promoter effects in the latency of the malignancies of making findings would not have resolved with the loss of dioxin from the body. He would defer to Dr. James Olson.[144] *Id.* at 47-48. He testified that the half-life of TCDD in soil could vary from one year to three years on surfaces but may be up to twelve years in interiors. *Id.* at 76-77.

Dr. Sawyer was questioned as to whether his risk assessment applied to non-cancerous diseases. He stated that he could not testify, from a dose perspective, as to certain diseases, specifically ischemic heart disease and gastric and duodenal ulcers. He testified that chronic obstructive pulmonary disease, elevated plasma, lipids, triglycerides and cholesterol, and endometriosis all occur at above background exposure similar to that to induce cancer. *Id.* at 115-116. He also stated that immunosuppression would be covered, but that he was not prepared to discuss liver disease and cirrhosis would not. *Id.* at 117.

He relied on Dr. Wade to distinguish the source of emissions from the power plant versus Monsanto dioxin. *Id.* at 127. He disagreed with Dr. Carl Werntz's testimony as to the importance of dioxin levels in the body. *Id.* at 137-138. He also believed that Dr. Werntz's medical monitoring program for 12 diseases should be expanded to cover breast cancer, brain cancer, elevated plasma, lipids, triglycerides and cholesterol, endometriosis, and soft tissue carcinoma. *Id.* at 139-140.[145] At this point, Class Counsel advised that Dr. Sawyer was not being offered on that issue. *Id.* at 141. Dr. Sawyer testified that no other facility in Nitro could have

[144] Dr. Olson's findings are discussed, *supra* IV.E.5.a.
[145] Dr. Werntz developed the final medical monitoring plan offered by the Plaintiffs, *infra* IV.E.7.

produced the massive amount of dioxin required to contaminate the homes except Monsanto. *Id.* at 142.

Dr. Sawyer confirmed the testimony given in his deposition of October 2, 2007 that the soil levels were, for the most part, inconsequential. He used dust ingestion to measure the risk, in that dust ingestion, due to the hours indoors, the time spent indoors and the higher bioavailability of fine particulate dust is a much more substantial contributing factor in the risk assessment methodology and calculation. Relative to that, the soil levels were, for the most part, inconsequential. In other words, they did not add much to the overall dose. *Id.* at 145-148. Dr. Sawyer stated that the ATSDR standard for residential soil to adequately protect human life at 1,000 parts per trillion has been replaced by a goal of 90 parts per trillion, and cited a Michigan Department of Environmental Quality Study from 2004 for that belief. *Id.* at 151-152. He defined the screening level as "a value that, once exceeded, toxicologists, public health professionals take note and may decide to perform additional studies and determine whether or not a significant risk is present." *Id.* at 155. He agreed that it was not the level at which there is a significant risk, but a level at which one looks to determine and do further investigation as to whether there is additional risk. *Id.*. He further agreed that his reference literature from the USEPA indicated that the preliminary remediation goal equaled the regional screening level which equaled the old-styled *de minimis*/screening levels. *Id.* at 156.

Dr. Sawyer next discussed why CALUX was a useful tool in this action. He testified that because Dr. Wade had already determined that Monsanto was the source of the dioxin in the area, he believed that CALUX was more accurate because it actually measured the TEQ of a biological system. It is cheaper, requires a slightly smaller sample quantity, and has faster turnaround. He also stated that GC/MS had the ability to quantitatively profile the 17 dioxin and

dibenzofuran congeners and was useful in fingerprinting the source of the dioxin. *Id.* at 159-160. He stated that CALUX was initially used extensively as a screening procedure, but in more recent times it has been used in Europe for risk assessment for foods. *Id.* at 160-161.

He acknowledged the existence of a study which indicated that on average, CALUX TEQ values were 9.4 fold higher than GC/MS TEQ values, but stated that would not apply here due to the existence of 2, 3, 7, 8-TCDD in the area. *Id.* at 170-172. He arrived at his determination that CALUX overstated the results obtained by GC/MS by looking at the 14 samples provided in the sample provided by Dr. Brown in his affidavit of August 19, 2008, *supra.* These sites were depicted in Dr. Brown's affidavit on Figure 6. He believed it represented a reasonable transection of the class area. *Id.* at 177-180. Dr. Sawyer believed that the most recent NHANES report, a University of Michigan study of four counties in Central Michigan, a study from Louisiana, and a study by Donald Patterson, Jr., are the most reliable sources for background levels for serum dioxin. *Id.* at 180-182.

Dr. Sawyer also testified that he was aware of studies which attempted to correlate dioxin blood levels with the concentrations of dioxin in soil or home dusts. He did not think this would provide a reasonable or accurate measurement of risk for people in a residential setting, though it would for people in an occupational setting. *Id.* at 182-184. He stated that interior residential living quarter dust is more accurate with respect to dioxin dose exposure as opposed to attic dust, although he also stated that attic dust would need to be remediated to avoid serious health consequences "down the road." *Id.* at 187.

The transcript of the first day of Dr. Sawyer's deposition referenced numerous exhibits, which were made part of the record; among them were a series of his earlier reports. On January 23, 2007, he issued a report based on his review of Mr. Auberle's original report. *Id.*at Ex. 4.

He attributed the dioxin contamination from Monsanto to be from the production of 2, 4, 5-T and the burning of hazardous waste within the onsite coal-fired burners. *Id.* at 1. He referenced a 15 x 10 km region around the Monsanto facility as defined by an outer isopleth ring of 133 pg dioxins/m^3 of air. He believed that the danger for persons living in that area from 1948 through at least 1969 was from inhalation, and possibly thereafter as a result of improper site remediation activities. Additionally, persons continued to be exposed through household dusts. He set out 23 conditions which were related to dioxin exposure. *passim.*

His next report, dated August 24, 2007, was issued after his review of the Auberle report which was ultimately used to create the class area shown on Exhibit 1 of the Amended Class Certification Order. (dkt. no. 939). This modeled ambient air concentrations of 0.00016 and 0.000082. *Id.* at Ex. 5. He based his dose calculations upon these isopleths. He discussed the contamination of household dust. He further stated that "average ingestion rates specific to individual age groups and residency durations are continually used in dose calculations and provide a measure of historic and current dioxin intake with the contaminated Nitro community. Blood samples from community members have also been collected and compared to household dust measurements with striking congener patterns detected which match the Monsanto dioxin profile within the highly contaminated household dust." *Id.* at 1.

He established several specific inhalation dose groups based on (1) childhood inhalation for children aged 1-7 who lived within the 0.00016 ug/m^3 which elevated their 70 year cancer risk to 1 x 10^{-3}; (2) childhood inhalation for children 1-7 who lived within the 0.000082 ug/m^3 isopleth for 6 years between 1948 – 1970 which elevated their 70 year cancer risk to 5.1 x 10^{-4}; (3) childhood/adult inhalation for persons aged 1-31 who lived within both isopleths (0.000082ug/m^3 TEQ and 0.00016ug/m^3 TEQ) for 10 years between 1948 – 1970 which

elevated their 70 year cancer risk to 4.1 x 10^{-4} and 8.1 x 10^{-4} respectively; (4) adult inhalation for persons 18 years of age and over and who worked and resided within both isopleths (*see* 3) for 10 years between 1948–1970 which elevated their 70 year cancer risk to 4.6 x 10^{-4} and 9.0 x 10^{-4} respectively; (5) children who lived outside the isopleths but attended Nitro schools for at least 10 of 13 years within both isopleths (*see* 3) between 1948 – 1970, which elevated their 70 year cancer risk to 2 x 10^{-4} and 4 x 10^{-4} respectively; (6) workers who resided outside and worked inside both isopleths (see 3) who were 18 years of age or older for over 10 years (5 day work week) between 1948– 1970, which elevated their 70 year cancer risk to 2.25 x 10^{-4} and 4.5 x 10^{-4}, respectively; (7) childhood household dust ingestion for 6 years in the "extreme" contamination zone for children aged 1-6 from 1970 to 2007, which elevated their 70 year cancer risk to 1.24 x 10^{-4}; (8) childhood/adult household dust ingestion for 30 years in the "extreme" contamination zone for persons aged 1-31 between 1970 – 2007, which elevated their 70 year cancer risk to 1.21 x 10^{-4}; (9) adult dust ingestion for 35 years for adult residents 18 years of age within the "extreme" contamination zone from 1970 – 2007, which elevated their 70 year cancer risk to 1.6 x 10^{-4}.

The "extreme" contamination zone is depicted on maps included in the report and appears to have been concentrated in the immediate Nitro area. "Extreme" contamination is measured as over 390 pg/g, or 100 times the preliminary remediation goal of 3.9 pg/g. There were also charts indicating the elevated levels of residents' lipid-adjusted 2, 3, 7, 8-TCDD blood levels compared to published reference ranges for residents 45 – 59 and 60 and up. Another chart depicted a comparison of the residents 2, 3, 7,-8 TCDD 95th percentile TCDD values to the published 95th percentile reference ranges, demonstrating the extreme elevation of the Nitro resident's blood. Several of these charts cited Patterson's work as the source for age-method

reference ranges. (Ex. 7 to Deposition of October 17, 2007, attached as Ex. to Deposition of July 19, 2010).[146]

Dr. Sawyer crafted a medical monitoring plan dated August 20, 2008, which is attached to his deposition of July 19, 2010 as Exhibit 8. This was based upon his review of Dr. Kirk W. Brown's recent affidavit, *infra*. He opined that the original isopleths which provided modeling of historic 2, 3, 7, 8-TCDD air levels during the plant operation era now included soil concentrations from the accumulated deposition which resulted from plant operations through 1969 when production ceased. Dr. Brown broke the soil readings into Groups 1, 2, and 3, based on mean soil 2, 3, 7, 8-TCDD levels of 14.4 pg/g, 24.3 pg/g, and 250 pg/gram. Dr. Sawyer stated that, within Group 1, children/adults with 30 years of residency faced an increased 70 year lifetime cancer risks of 2.0×10^{-5}. He further opined that, within Group 2, children between ages 1-6 with 6 years of residency, and children/adults with 10 years of residency faced increased lifetime cancer risks of 3.47×10^{-5} and 1.06×10^{-5}, repeatedly. He finally concluded, as to Group 3, that children with 6 years of residency, and children and adults with 10 years of residency would face increased lifetime cancer risks of 2.1×10^{-4} and 1.1×10^{-4}, respectively.

Dr. Sawyer's deposition resumed on July 20, 2010. He testified that the EPA methodology of performing a risk assessment involves the identification of a potential exposure pathway, confirmation of the pathway, measurement of the dose through that pathway and application of the dose based upon factors of time, period of exposure, body weight, and other variables. *Id.* at 200. In this case, steps 1 and 2 were completed by Randy Horsak, P.E. Once Dr. Sawyer had data about the spatial distribution throughout the Class Area, he conducted the

[146] It appears that all of the blood charts referred to a study completed by "Patterson, et al." This is the same Donald Patterson, i.e. Donald Patterson, Jr., who is a defense expert, *infra*.

dose evaluations and applied that to the actual risk values. There were several reports issued as the data developed. *Id.* at 201-207. In this case, Dr. Sawyer prepared his risk assessment using the EPA methodology as summarized in a State of Florida document. *Id.* at 220-221.

Dr. Sawyer explained that the *de minimis* level of 1 times 10 to the negative six is a screening level; that is, risk levels in excess of that number are then further evaluated. *Id.* at 222. He cited a source that stated that if the risk was less than one in a million, it was negligible. *Id.* at 223. He agreed that the USEPA position was that risk of less than ten to the minus six does not need further investigation and that risk above ten to the minus four needed to be remediated. *Id.* at 224. He also agreed that the EPA says that if the risk is less than ten to the minus six, it does not need further investigation and that the period between ten to the minus six and ten to the minus four needs to be looked at and factors taken into consideration before a determination is made. *Id.* at 225. He also discussed the use of the 95th percent Upper Confidence Level as per the methodology of the EPA and West Virginia in his report. *Id.* at 225-227.

He acknowledged that the air inhalation isopleths had changed from 2007 (.000082) to 2010 (.000020). *Id.* at 228-229. He also stated that the maps attached to his August 2007 report involving soil TEQ were no longer relevant to his opinion, but that those maps involving house dust, showing the transected house data, were. *Id.* at 232.

Dr. Sawyer was then questioned about his reliance on Figures 5.1, 5.2, and 5.3 in Mr. Auberle's report of February, 2010. Dr. Sawyer referred to the isopleth in Figures 5.1 and 5.2 in all of the dose groups in his February 15, 2010 report except for Groups 6 and 7, *supra.* He deferred the explanation of the isopleth depicted in Auberle Exhibit 5.3 to Mr. Auberle. This Exhibit depicted dioxin deposition from 1948 to 1969 resulting in an isopleths of .000032 micrograms per square meter of surface, and he did not rely upon this isopleth in developing his

dose groups. He also stated that there is not an EPA method available to directly calculate deposition with human dose. He agreed that the isopleths in Exhibit 5.1 and 5.2 could be used to determine class membership and that if someone was in the Group depicted in Figure 5.2, they were automatically in the group covered by Exhibit 5.1, but not vice versa. *Id.* at 235-239.

He then referenced Figure 15 from Dr. Flowers' report (Exhibit 25 to Sawyer deposition) as depicting the isopleths that he used to create dose groups 6 and 7. *Id.* at 239. He could not correlate on a relative basis the exposures described in Flowers' Exhibit 15 to the Auberle isopleths because that could not be done following generally accepted methodology in that one measured air and the other dust, with separate and distinct methodologies for each. *Id.* at 244.

Dr. Sawyer was asked about how the various inhalation isopleths were chosen and by whom. He testified that rather than him choosing the isopleths to indicate risk, the original model produced a number of 0.000082 micrograms per cubic meter for an outer isopleth, which he characterized as producing very high, significant and substantial levels of risk to residents during the 1948 to 1969 time period. He testified that he did not provide a risk number, but rather ran Mr. Auberle's number through his (Sawyer's) risk assessor model and determined that it was substantial. He stated that the early models were really a worst-case calculation. He knew that the inputs were being revised based on a reduced emission factor. Based on the new data, the old isopleths have no relevance *Id.* at 245-251. He agreed that those who are or who are not at risk would not be based on the original class map (with an isopleth of .000082) or the other exhibits (21, 22 & 23 referenced, *supra*). *Id.* at 253.

He believed that Mr. Auberle and he somehow arrived at the 0.000020 number. He "may have given him some information as to what concentration in the air is of interest to me as a risk assessor. And I don't remember exactly what values, but I – I do believe they were somewhere

in the 20 to 25 picogram-per-cubic-meter range. And Bill ran the model. I don't know exactly how he arrived at exactly 20 picogram per cubic meter, but we did, and that was the end result." *Id.* at 255. He testified, by way of example, that the 20 picograms per cubic meter value, using the 6-year old child as well as adult transitional and child transitional exposure, resulted in excessive risk levels in excess of 1 times 10 to the minus 5. Based on that, he gave Mr. Auberle that range of risk values between 20 and 25 picograms per cubic meter, which Mr. Auberle then modeled to create the isopleth using values in that range. *Id.* at 256-257.

Dr. Sawyer testified that he based the opinion in his February 15, 2010 report on the CALUX docs and TEQ analysis that were conducted by Dr. Flowers, the prior docs and sampling by Brown, the statistical analysis conducted by Wade, the spatial distribution and sampling statistical analysis by Flowers, including the CALUX sampling data, and Mr. Auberle's report. He agreed that if those reports were in error he would have to revise at least parts of his risk assessment. *Id.* at 258-260. He independently looked at the sampling data and decided it was reliable. *Id.* at 261.

He agreed that the regional screening levels are intended to help determine if potentially sufficient levels of contamination are present to warrant further investigation, and not necessarily to indicate that anything above that number is dangerous. *Id.* at 265. He also believed that there were confirmed pathways to human exposure in the area. *Id.* at 266. He also agreed that if the *de minimis* levels are below the natural background level, then the natural background level would be used as a *de minimis* standard. *Id.* at 270.

Dr. Sawyer testified that while he relied on the household sampling done by Dr. Flowers to calculate risk, he also relied on attic dust sampling with request to remedial issues and as confirmation and validation that the contaminated dioxin dust was from Monsanto. *Id.* at 281.

He recognized that the final modeling reduced the isopleth size. The original isopleth figure of 0.000082 was not used at Dr. Sawyer's direction. He directed Mr. Auberle to use a number in the 20 to 25 picogram per cubic meter range as consistent with significant health risks. The number of "82" was used at the beginning as a worst case scenario. *Id.* at 313-315. Dr. Sawyer testified that the final value isopleth used an approximate risk level of 1 x 10^{-5}, which resulted in the 20 picogram/cubic meter isopleth boundary. *Id.* at 332.

Dr. Sawyer confirmed that all of his final risk groups, with the exception of Group 6 and 7, used inhalation as the exposure. These groups would have received incident dust in some amount through their respiratory tract. Groups 8 and 9 were combined inhalation and ingestion pathways. *Id.* at 339-341. He clarified that all of his calculations result in risk levels of greater than 1 times 10 to the minus 5, although that was not stated in his report. *Id.* at 343. All of his ingestion and inhalation rates were based on EPA Exposure Factors Handbooks as set forth in a Florida DEP document. *Id.* at 343. He used a dust level of 90 picograms per gram, which represented the Michigan health-based direct contact criteria for dioxins, produces a substantial level of risk, and is recognized by government agencies. He used this level in lieu of the actual readings, which were higher, but based on CALUX. *Id.* at 344-346. He first stated that he had understated the risks to each group and that the true risk was between the minimum floor of 1.2 times 10 to the minus 5 in the upper level to 4.8 times 10 to the minus 2. *Id.* at 348. However, upon further questioning, he stated that all of the risks were in the minus five range, in paragraphs 1 through 9, because that is based on either the shorter term exposure to air or the 90-picogram level from dust exposure. *Id.* at 349.

Finally, he confirmed that he provided the air modeling experts with a toxicologically significant air concentration, and asked them to show it on a map which he incorporated in his report. *Id.* at 375.

7. The Plaintiffs Present Their Final Medical Monitoring Plan: Charles L. Werntz, D.O.

Although several other individuals offered proposed medical monitoring plans,[147] class counsel chose Charles L. Werntz, D.O., to create the final product.[148] This plan was contained in his report of February 15, 2010, entitled *Health Effects of Exposure to Dioxin and Dioxin-Like Compounds in the Nitro Area of West Virginia.* (dkt. no. 2280). Dr. Werntz reviewed the Veterans Administration's Agent Orange Program, which he categorized as the most comprehensive review, to determine those conditions which are associated with dioxin. He also reviewed other governmental reports to gather additional information on the potential effects of dioxin. He also reviewed Dr. Carpenter's report. He stated that:

> On the basis of the specific nature of the exposure in this community, it is my opinion that members of the community are at increased risk for developing diseases, including:
>
> Non-Cancers
> - AL Amyloidosis
> - Diabetes (Type 2)
> - Ischemic Heart Disease
> - Parkinson's Disease

Cancers with increased frequency include:
- B Cell Leukemias
- Chronic Lymphocytic Leukemia

[147] Both Drs. Carpenter and Sawyer developed medical monitoring plans which are in the record, but were not offered by Class Counsel.

[148] Dr. Werntz obtained a degree as a Doctor of Osteopathic Medicine from the Kirksville College of Osteopathic Medicine. He also holds a Masters in Public Health with a concentration in Occupational and Environmental Health from West Virginia University, and a Bachelor of Science from Drexel University. He was Board-Certified in Internal Medicine and Occupational Medicine.

- Hodgkin's Disease
- Multiple Myeloma
- Non-Hodgkin's Lymphoma
- Prostate Cancer
- Respiratory Cancer (lung, larynx, trachea and bronchus)
- Soft Tissue Sarcoma (other than Osteosarcoma, Chondrosarcoma, Kaposi's sarcoma, or Mesothelioma)

Id. at 1-2.

He referenced Dr. Sawyer's model examining the various contaminant levels, routes and duration of exposure, and the risk of developing disease for each. He believed that these exposures placed the exposed person at increased risk of developing cancer and non-cancer diseases, and opined that tests were available which could provide earlier diagnosis, while not being onerous or significantly invasive. This would lead to earlier treatment, which can decrease the impact of these diseases and improve the chance for cure in affected individuals.

Dr. Werntz recommended that a medical monitoring program be established for all persons in the class area who have an exposure profile that gives them an additional risk of developing disease due to the dioxin exposure greater than 1:100,000. *Id.* at 3.

The program called for initial and recurrent screenings for the Class Members with an exposure profile resulting in an increased risk of disease due to the dioxin exposure greater than 1:100,000 (1×10^{-5}). *Id.* at 3. He adopted Dr. Sawyer's criteria which would "be used to specifically qualify individuals for entry into the medical monitoring program. This methodology is based upon the location, timing, and duration of exposure. These are listed in his report under 'class criteria'." *Id.* at 3.

His program included an initial screening for all concerned persons, which consisted of the completion of a health questionnaire; blood work, specifically – plasma dioxin levels

(sensitive testing – most likely CALUX testing), fasting glucose and hemoglobin A1C, fasting lipid profile, erythrocyte sedimentation rate, and CBC; and a physician examination and explanation of test results, to include examination for Parkinson's – like changes, including cogwheeling. *Id.* at 4.

It also included an educational component, delivered as early in the program as practical, to all present residents of the class area and to all participants in the medical monitoring program, which would include (1) the nature of the historic and current exposure ; (2) the risk of disease from these exposures (cancer and non-cancer); (3) activities that may increase the risk, and how to avoid those additional risks; and (4) signs and symptoms that may suggest the onset of one of the targeted diseases, encouraging that they seek medical evaluation. *Id.* at 4.

Lastly, it including recurrent monitoring every five years, for 30 years past remediation, which included a repeat of the above-mentioned protocol without plasma-dioxin testing. It also included general recommendations of liberality of entry and exit into the program, the choice by the participant of which parts to participate in, a limited number of physicians being involved to develop expertise, follow-up of positive tests, liberality in favor of the participant, periodic review, repeat tests as necessary, physician follow-up in person, and if the participant does not show up, follow-up by mail, and provision for persons out of the area, along with other recommendations. *Id.* at 5.

Dr. Werntz explained the reasons why each test was chosen, and provided for the option to have additional testing if a dioxin-associated disease was suspected. Testing would be paid for by the program until either a dioxin-related disease was diagnosed, or it became clear to the evaluating physician that the condition was not dioxin related. *Id.* at at 6-9.

Dr. Werntz also prepared a document entitled *Medical Monitoring Usage Estimates in Support of the Program Proposed due to the Risks from Exposure to Dioxin and Dioxin-Like Compounds in the Nitro Area of West Virginia* dated February 22, 2010. (dkt. no. 2346). He commented that there was little information in published literature upon which to base estimates of participation or utilization rates. Instead, he based his estimates on incidence data from external sources and his own medical and clinical experience. He postulated that 70% of the eligible class members would participate in the initial screening, and that there would be 5% attrition from participation, expressed as a percentage of the remaining participants, at each subsequent screening.

He planned for every household in the class area (whether eligible or not for medical monitoring) to get the educational material. He also provided estimates as to the likely participation of class members at each component of the medical monitoring program, and estimates of what percentage of persons undergoing each test would require treatment or be negative as to each of the twelve diseases. *Id.* at 2-9.

Dr. Werntz was deposed on May 26, 2010. (dkt. no. 2346). He was retained in the Summer of 2008. *Id.* at 9. His role was to craft a medical monitoring program for dioxin exposure in Nitro. *Id.* at 11. He testified that all fees paid for his work go to the Institute of Occupational and Environmental Health at WVU. *Id.* at 16. He was questioned about his background and work on medical monitoring matters. *Id.* at 17-63. He testified about the sources be relied on to better understand diseases that are associated with dioxin exposure. *Id.* at 64-70. He included the diseases where there was a clear causal relationship in the medical monitoring program. As to those where there was a less clear causal relationship, after

discussion with the other class experts, some were included and some were not. *Id.* at 70-71. He stated that this is the first case where he has ever really reviewed materials on dioxin. *Id.* at 74.

He reviewed the Nitro Schools and Community Study done by ATSDR and disagreed with its conclusions. *Id.* at 75-79. He also reviewed the EPA Review of State Soil Cleanup Levels for Dioxins for 2009 and noted that there does not appear to be a clear West Virginia cleanup level. *Id.* at 82. He briefly discussed his review of other expert's reports and what role, if any, they played in his opinion. He reviewed Dr. Carpenter's report of January 2007. Dr. Carpenter's report was helpful to continue his understanding of the issue, but Dr. Werntz stated that his (Werntz's) approach was more pragmatic or focused. *Id.* at 85-86. He relied upon Dr. Flowers' report to help him understand the actual exposure and levels of exposure in the community. *Id.* at 86. He saw the Class Area Remediation Map and it helped him to understand that there may be different entry criteria for different people in different parts of the exposed, contaminated area because of different risks. *Id.* at 88.

Although Dr. Werntz was contacted by class counsel in July 2008, he did not begin his work until December 2009, when he was asked to start work on the medical monitoring recommendation, beginning with Dr. Carpenter's report. *Id.* at 99. He did his research regarding the nature of the exposure and the risk. He participated in a series of conference calls with Drs. Flowers, Sawyer, and counsel in which it was decided to set the entry criteria to enter the medical monitoring program at a cancer risk of about 1 in 100,000 (1×10^{-5}), and then develop the criteria to reflect that. He wanted the entry criteria to be expressed in a way that would allow a clerk or a secretary to figure out if a person was eligible for medical monitoring. *Id.* at 101-104.

He explained that he prepared two reports so that one would contain his medical opinions, rooted in the scientific literature and evidence reflected by other bodies relating to the exposure. The second report was prepared to determine participation rates and likely outcomes, so that a cost estimate could be calculated for the program. *Id.* at 105-107.

On January 29, 2010, Dr. Werntz participated in a phone conference with Drs. Flowers, Carpenter, Mr. Carr, and class counsel, which had a goal to come up with a way to mix both the geographic information with the required time of exposure to craft the entry criteria for the medical monitoring program. The 1 in 100,000 number was chosen after discussions regarding risk. Understanding that 1 in 100,000 is only for cancer risks, they wanted to set a number that was not too high or too low to cover the non-cancer risk. 1 in 100,000 was chosen for the non-cancer risk as well. *Id.* at 107-109.

Additional phone conferences were held which now included Dr. Sawyer and Mr. Auberle as well as Calwell, Flowers, Carr, and on one occasion, Carpenter. During these conferences, the air isopleths and soil and dust maps were reviewed. The figures of 41 parts per billion for soil and 90 parts per billion for dust seemed to be where the level was falling, for a 1 in 100,000 risk. *Id.* at 110. There was also agreement on what diseases would be included. *Id.* at 111. It was decided that Dr. Sawyer's report would include the final entry criteria. *Id.* at 114. Lastly, Dr. Werntz conferred with Drs. Brookshire and Sciarra so that they could prepare a cost estimate for the program. *Id.* at 109-119. Dr. Werntz was then asked about what he believed was the purpose of medical monitoring and what criteria should be used to assess the appropriateness of a medical monitoring program. *Id.* at 130-142.

Dr. Werntz was questioned about his report of February 15, 2010. He described his understanding of the exposure routes and times of potentially affected persons. He also

explained how he determined that these persons faced a significantly increased risk of each disease.[149] Based on his calculations, he only included the conditions where there was an increased risk. *Id.* at 142-157.

In his report, he recommended that plasma-dioxin levels be measured to quantify body burden to assess a person's risk. He saw risk in two ways – the first is the risk assessment done based on calculated exposure to the community. That is done to establish entry into the program. The second assessment is for the individual to determine their specific level of risk. Therefore, body burden is not an entry criteria, but a means of providing information to the exposed persons. His plan required everyone to be given a plasma dioxin test on the first examination. Those with higher exposure would be monitored more closely than those with lower exposure. *Id.* at 160-165.

He explained how he came up with the twelve diseases that required medical monitoring. He believed that in a dioxin-exposed population there would be an increased frequency of these diseases. Even though Dr. Sawyers' model only evaluated the risk for developing cancer, Dr. Werntz believed that Dr. Sawyer's selection criteria were also appropriate to cover non-cancers. He stated that his report was the final medical monitoring program. *Id.* at 169-172. Dr. Werntz also stated that:

> I know Dr. Carpenter is more inclusive and includes other testing that is related to, that shows testing abnormality. He wants to test for all the testing abnormalities that have been associated with dioxin but that is not associated with an end disease. And I don't know what to do with those results. So I recommend not including them.

Id. at 173.

[149] In making his calculations he used the upper confidence limit.

He explained the difference between association and causation, and stated that, apart from "a dermatitis", there was no disease that was caused only by dioxin exposure. But he explained that this involved an excess risk. The problem would be to determine, out of a group of exposed persons who developed an associated disease, whose was caused by the exposure and whose occurred naturally. *Id.* at 176-177.

Dr. Werntz then reviewed each of the twelve diseases that were to be monitored for in his program, and how each would be detected by it. *Id.* at 182-227. He stated that he kept the testing to "just the essential testing for the disease of concern." *Id.* at 228. He discussed a testing regimen for non-resident class members. *Id.* at 234-235.

He also discussed the educational component of his program as set out in the report. He wanted it developed and delivered in a way that did not require significant literary skills. *Id.* at 237. He chose a 30 year period, beyond remediation, based upon the half-life of the exposure. *Id.* at 237-238.

In answering questions about how he determined the participation rate, he noted that there have only been a few studies done about them in these types of programs. He noted one study where participation was in the high 90 percent range. *Id.* at 238. Dr. Werntz believed that the program should take the participant to the point of diagnosis. *Id.* at 239-240. He described CALUX as a test that has been designed for screening that gives a summary number for the amount of all dioxins that are present. He did not believe that it was currently approved by the FDA. While it does not provide information on the source of the exposure, it does get a TEQ which is of more interest in discussing human health risk. *Id.* at 240-243. He believed that physician interpretation of the results was essential. *Id.* at 245-246. The purpose of finding plasma dioxin levels in the tests is to stratify the risk of the subject. It would not exclude

participation. It is appropriate for use in surveillance of long term exposures, such as these would be. *Id.* at 248-249. He also testified that persons with significantly elevated dioxin levels would have to be evaluated more frequently. *Id.* at 250.[150]

8. The Plaintiffs Determine How Many Persons May Potentially Qualify For Medical Monitoring: Randall W. Jackson, Ph. D.

Simultaneously, Class Counsel sought an estimate of the number of persons who could potentially be eligible for medical monitoring from Randall W. Jackson, Ph. D.[151] Although a large area was shown in Exhibit 1 to the Class Certification order, it had become obvious that it was inaccurate and too large, based on the evidence developed during discovery. At one time,

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[150] On June 14, 2012, Dr. Werntz gave an Affidavit which is filed with "*Class Counsel's Supplemental Answer to Limited Discovery as to the Fairness, Adequacy and Reasonableness of the Proposed Settlement*," filed at dkt. no. 3165. Dr. Werntz opined that,

> The medical monitoring program provided for in the Settlement is substantially the same as the monitoring program that I previously recommended in this case, based on my education and experience. I understand that the Program Administrator intends to include a meaningful educational component for participants as part of the administration of the program.

Id. ¶ 6.

Dr. Werntz further agreed with his previous testimony that persons with substantially elevated serum dioxin levels should be examined more frequently than those who do not have such high levels. He believed that the use of a "trigger" was consistent with his opinion, and that the upper confidence level of the 95th percentile represents a value that is clearly elevated above the general population, and is consistent with general medical practice. He noted that the trigger was based on dioxin TEQ, not just 2, 3, 7, 8-TCDD. This gives medical monitoring participants the benefit of a measurement of their serum dioxin based on all dioxins, not just TCDD. He concluded by stating that:

> In my opinion, the best way to determine whether participants have been excessively exposed to dioxin is to determine whether participant's serum dioxin levels exceed the 95th percentile of serum dioxin levels in the general population. The 'trigger' will accomplish this by comparing participant's serum levels to the upper band of the 95th percentile of the NHANES population described in *Patterson, et al.*, Chemosphere, 73 (2008), S261-5277 (Table 8). I note that the 'trigger' will be met if an excess of only 25% of the participants have serum dioxin levels that exceed this level.

Id.¶ 12. *See also*, IV. C., *supra.*

[151] Dr. Jackson's curriculum vitae does not appear to be in the record.

Class Counsel estimated that the Class could include approximately 80,000 people.[152] *Id.* at 154. On June 27, 2010, Dr. Jackson filed his *"Population Estimate for Selected Medical Monitoring Categories, Nitro, WV Region"* (dkt no. 1793). He estimated that there were 5,019 surviving persons that met the exposure categories identified and defined in the expert report of Dr. Sawyer. He stated that "these opinions are founded on standard demographic theory and practice, and are accurate to a reasonable degree of technical certainty." *Id.* at 2.

9. The Plaintiffs Develop Evidence Concerning The Defendants' Tortious Conduct : Steven Amter, M.S.

The Plaintiffs offered Steven Amter, M.S., as an expert witness on several issues relating to Monsanto's liability in this action[153] Mr. Amter's opinions and the methodology for them are contained in his report titled *"Expert Report of Steven Amter"* dated February 15, 2010. (dkt no. 2880). Mr. Amter stated that he had "been retained to provide opinions relating to Monsanto Company's 2, 4, 5-trichlorophenoxyacetic acid (2, 4, 5-T) pesticide manufacturing operations in Nitro, West Virginia." *Id.* at 3. His opinions concerned the company's waste disposal practices and relevant past knowledge and standards, particularly with respect to the waste generated by the Company's manufacture of 2, 4, 5-T and the dioxin impurities it contained.

In that report, Mr. Amter concluded that:

1. From the mid-1950's through the 1960's, it was known that toxic and chlorinated organic wastes, including many pesticides (which

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[152] *See Declaration of Shannon R. Whitman, Ph. D., on adequacy of Amended Class Certification Notices and Notice Plan* 3, which states "Plaintiff's demographer, Randall W. Jackson, Ph. D., has advised me that the Class is estimated to include 88,164 people." (dkt no.1793). *See also*, Complaint ¶103, where Class Counsel claimed that approximately 25,000 people were affected.

[153] Mr. Amter had previously provided expert testimony in the *Perrine* case. Mr. Amter holds a Master of Science degree from the University of Arizona in Hydrology and Water Resources, and a Bachelor of Science degree from the State University of New York.

in his report, included herbicides), required special methods of disposal because of their environmental persistance (sic) and resistance to conventional treatment.

2. In the 1950's and the 1960's it was widely accepted, and specified in chemical industry guidance, that each chemical manufacturer had a responsibility to determine a safe method of disposal for such wastes, based on a careful consideration of specific chemistry and environmental setting.

3. In the 1950's, it was widely known that open burning of industrial wastes in general, and chlorinated pesticides in particular, was an inadequate method of disposal that could lead to dangerous air pollution in surrounding communities.

4. In the 1950's and 1960's, guidance from the chemical industry specified that engineered systems, including carefully controlled high-temperature incineration, was necessary to safely destroy chlorinated organic wastes, including many pesticides.

5. Since 1950, Monsanto knew that 2, 4, 5-T herbicide manufacturing at its Nitro plant produced organic wastes that were chlorinated and extremely toxic.

6. Monsanto's open burning of its 2, 4, 5-T wastes from the Nitro plant was inadequate and contrary to widely accepted requirements for safe disposal.

7. Given Monsanto's extensive experience with air pollution issues and engineered incineration systems, Monsanto's wholly deficient disposal of its 2, 4, 5-T waste was irresponsible.

Id. at 4.

Mr. Amter's report includes his review of Monsanto's production at the Nitro site. It discusses Monsanto's membership in various trade organizations which looked at issues of pollution and waste disposal. *Id.* at 5. Mr. Amter reviewed Monsanto's particular experience with 2, 4, 5-T and TCDD toxicity, focusing on the 1949 autoclave reaction and subsequent research performed by the Kettering Laboratory. He opined that Monsanto's interest was based more on liability concerns than worker safety. *Id.* at 6-8.

Mr. Amter reviewed the interaction between Monsanto personnel internally, and with other manufacturers, including BASF, DOW, and others, concerning the toxicity of TCDD. He believed that throughout this time, Monsanto learned of the toxic impurity in 2, 4, 5-T and embarked on a long-term program to reduce the degree of worker exposure and to purify the product. *Id.* at 9-12. He also described Monsanto's waste disposal practice from 1948 to 1969, relying on the evidence presented by former employees and other individuals who were present during waste generation, collection, transport, and burning. *Id.* at 13.

He also discussed early warnings about 2, 4, 5-T emissions from burning, and about the atmospheric mobility of 2, 4, 5-T dust. He particularly focused on the *Conner & Amos* trial, claiming that Monsanto concealed documents during that trial that it would subsequently attempt to use as part of its defense in later lawsuits involving worker exposure to TCDD. *Id.* at 15, n. 36. It also provided evidence of how Monsanto reacted to these types of claims, and on the fact that it knew of these complaints. *Id.* at 5-16.

Mr. Amter also reviewed the chemical industry's concern over air pollution control as a part of its general responsibility to manage waste so as to protect the health of its neighbors and the general environment. He described the efforts of the Manufacturing Chemical Association (MCA) in forming an Air Pollution Abatement Committee. Monsanto was involved in that process. During the 1950's this activity developed. It was stated that pollution control must be considered at every step in industrial development by investigation of local conditions, requests, and trends regarding waste disposal. Monsanto personnel agreed that "more attention to pollution control could add several million dollars to the cost of a plant but that's the way we should go," further stating "that any appropriations request going to the board would have to

carry a statement indicating that the medical department had analyzed the proposal and had approved the measures for controlling pollution and toxicological effects." *Id.* at 17-18.

The MCA also published guidance in 1961 on the disposal of hazardous wastes, recommending that each plant study its operations and establish a "hazard index" and a "disposal index" for each waste. It warned about the hazards of "open burning", contrasting that with higher temperature incineration which would cause decomposition of irritant and toxic compounds without creating a neighborhood danger. *Id.* at 19. Mr. Amter concluded this section with a discussion of Monsanto's knowledge of the benefits of high temperature incineration of chlorinated pesticide waste. *Id.* at 19-22.

Lastly, in a section entitled "Pattern of Behavior" Mr. Amter offered his findings on Monsanto's alleged failure to build adequate waste disposal facilities at Nitro, stating that was not unique in its history. He compared Monsanto's activities at its Anniston, Alabama PCB plant with those at Nitro during the same time period. *Id.* at 22-25.[154]

10. The Plaintiffs Develop Their Property Damage and Remediation Case: Robert J. Carr, LRS

The Plaintiffs presented Robert J. Carr, LRS, as an expert on the property damage and remediation case.[155] Mr. Carr provided his opinions in a series of reports dated February 11, 2010, April 16, 2010, May 26, 2010, and March 30, 2011. (dkt no. 2980). His initial report of February 11, 2010 was titled *Engineering Opinion of Cost for the Remediation of Dioxin Contamination in the Vicinity of Nitro, West Virginia.* Mr. Carr stated that his report was

[154] The Court can only find small excerpts of Mr. Amter's deposition testimony in the record.

[155] Mr. Carr holds a Bachelor of Science degree in environmental engineering from the University of Hartford, and is a licensed professional engineer in Connecticut, New York, and Rhode Island. (*See* Deposition of March 31, 2010, *infra*).

commissioned to provide probable opinions-of-costs for remediating dioxin-contaminated homes and soil in the vicinity of the former Monsanto plant in Nitro. To do this:

1. Remediation or cleanup zones were established indicating areas where either soil exceeded State dioxin cleanup standards or household dust exceeded established health standards;

2. Remediation methodologies consistent with regulatory agency policies were proposed as presumptive remedies, and;

3. Probable costs to apply each selected methodology to the Class Area were calculated.

Id. at 1.

Mr. Carr reviewed the reports of Dr. Flowers (2009) and 3TM International (Horsak – 2005), to complete his work. He assumed a cleanup goal of reducing cancer risk to 10^{-5}, or 1 in 100,000. He used a risk-based equation used by the West Virginia DEP to calculate a residential cleanup level of 41 ng/kg. He used the State of Michigan Direct Contact Level of 90 ng/kg as the cleanup goal for household dust. He then broke the household dust into areas of "elevated concentration," "chronic concentration," and "subchronic Hazard concentrations." He divided residential soil into "elevated concentrations", "High concentrations", and "Extreme Concentrations." He then used the "Inverse Distance Weighted" method interpretation to classify sample results for soil and dust processes. These processes produced the remediation zones. *Id.* at 1-2.

Mr. Carr examined the methodology used to clean up Superfund sites in Minnesota and Florida as guidance for the soil and dust cleanup in Nitro. He also looked to the guidelines developed by the U. S. Department of Housing and Urban Development (HUD) to clean up lead-contaminated dust as a model for the cleanup of the dioxin-contaminated dust in this case.

Based on these reviews, as to household dust, Mr. Carr proposed a two part plan:

1. Comprehensive cleaning of living spaces, using the HUD lead-based paint guidelines, for buildings with chronic levels. (≥90 ng/kg and ≤900 ng/kg)

2. Permanent relocation of residents and the demolition and proper disposal of those buildings with subchronic hazard levels of dioxin. (≥900 ng/kg)

Id.

He proposed two types of cleanup for soil:

1. For those "extreme dioxin levels," (≥410 ng/kg) excavation of six inches of topsoil and replacement with six inches of new topsoil and grass seeding. The excavated soil would then be thermally treated and disposed of at a nearby landfill.

2. For "high dioxin levels", (≥41 ng/kg and ≤410 ng/kg) placement of four inches of topsoil over current yard surfaces and grass seeding.[156]

Id. at 3-4.

Mr. Carr stated that because there were relatively few soil and living-space dust samples results within the class area, and the proposed remediation was in the concept stage, he had developed an "order of magnitude", or Class IV cost estimate. He defined this as an estimate based on limited design information which is typically accurate within +100%/-50%. *Id.* at 4.

He obtained property data such as parcel and building sizes and assessed values from the Kanawha and Putnam County Assessor's Offices. He also obtained data from Applied Geographic, Inc., including computer assisted mass appraisal (CAMA) data for Putnam County. This data was not available for Kanawha County. He only included parcels zoned as residence or school in his cost estimates. He concluded that it would cost $47,000,000 to provide one cleaning for those houses and schools within the dust cleanup area, using HUD recommended

[156] Mr. Carr did not recommend treatment for "elevated dioxin levels" i.e., soil areas with dioxin concentrations ≤ 41 ng/kg.

techniques. He stated that it would cost $64,000,000 to purchase 1000 buildings at 120% of assessed value, relocate the residents, and properly dispose of the debris. Mr. Carr stated that it would cost $195,000,000 to place four (4) inches of topsoil on the area requiring that step, and $2,200,000 to remove and replace six (6) inches of topsoil, and reseed on the area where that action was needed. Finally, he opined that it would cost $6,800,000 to thermally treat and dispose of the dioxin-contaminated soil. The total cost estimate was $315,000,000. *Id.* at 5-6.[157]

Mr. Carr attached a series of maps depicting the various soil and dust test sites, and the proposed dust and soil remediation zones. Exhibit 5 to his report presents a consolidated map of both the dust and soil cleanup area.[158] He also noted, in Table 2 of his report, that there were 14,515 homes that needed to be cleaned, containing 24,842,105 square feet of space, costing $1.90 per square foot to clean, (as per Service Master), to clean homes to HUD Lead-Based Paint Cleaning Guidelines. (See Table 2).

On April 16, 2010, Mr. Carr provided Addendum No. 1 to his original opinion. (dkt no. 2980). This added an estimate to clean attics in residences. In searching the USEPA website, he came across an exemplar case which involved the remediation of attic dust. This was a Superfund site in Georgia, specifically the Woolfolk Chemical Works site. He described the cleaning methodology and opined that those residences and schools within the chronic and subchronic hazard area in his first report would require attic cleaning. This changed the total engineering opinion-of-cost for home and school cleanings to $80,000,000.[159]

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[157] Using the +100%/-50% model, the total range for cleaning/remediation expense would be $157,500,000 to $630,000,000.

[158] A copy of this map is attached to this Order as Ex. 13.

[159] He increased the number of homes to be cleaned. Also, the attic cleaning component represented an additional $29,750,000.

Thereafter, on May 26, 2010, Mr. Carr submitted Addendum No. 2 to his report at the request of Class Counsel (dkt no. 2980). This provided estimates for remediation of soil and dust levels to the "State *De Minimis* Standard", which establishes contaminant levels that do not present a significant risk to human health. These are based on levels which represent an excess upper-bound lifetime cancer risk of one in one million for residential land uses, and is set at 3.9 ng/kg. Mr. Carr applied the same factors as before to the much greater area represented by this lower cleanup level. These areas are depicted on the maps attached to this report. He again prepared his report to the Class IV standard. The living space dust cleanup cost was now $63,000,000 and the relocation, demolition and disposition of sub-chronic dust space homes was $64,000,000.[160] As for the cleanup of the soil, the placement of four inches of topsoil and grass seed was estimated at $1,533,000,000, the removal and replacement of six inches of topsoil and seeding was estimated at $116,350,000, and the cost to thermally treat and dispose of contaminated soil was $132, 290,000. The total cost to remediate the Class Area was estimated at $1,909,000,000.[161]

Finally, on March 30, 2011, at the request of Class Counsel, Mr. Carr provided an estimate as to the dust and soil remediation cost for commercial and industrial properties with the Class Area to the "West Virginia *De Minimis* Standard" for TCDD/dioxin in industrial soil of 270 ng/kg. (dkt no. 2980). This represents an excess upper-bound lifetime cancer risk of one in one million. He did not believe that soil excavation and treatment, nor home purchase/demolition options were necessary. *Id.* at 2. He opined that there would need to be

[160] On this occasion, he did not provide an estimate for cleaning attics. (*See* Table 1: Home Cleaning Calculations).
[161] At a +100%/-50% the total range for cleanup/remediation cost was $954,500,000 to $3,818,000,000.

building dust cleaning and the placement of four inches of topsoil and grass seed, (costing $16,500,000 and $5,500,000 respectively), for a total cost of $22,000,000. *Id.* at 3-4.

Mr. Carr was deposed on March 30, April 20, and July 7, 2010. (dkt. no. 2980). Mr. Carr testified that he

> [W]as asked to take a look at the release that had happened in what's defined as the Class Area, to review the materials associated and provided by experts, toxicology experts and others, to come up with a remediation plan, scenario, and provide a cost estimate for that scenario . . . that work did include evaluating the concentrations of the analytical results of soil and household dust that I was given, and compared to in this case state standards, and also on recommendation of the toxicologists on what those standards would be.

Id. at 33.

He made a site visit and did some investigative work on how to remediate dioxin. He addressed the house cleanup by recommending the adoption of the lead-based paint remediation techniques to remediate the dioxin-contaminated dust in the residences. He testified that in the lead-contamination dust cleanup protocol, after the cleaning, there was a test to determine how effective the cleaning was, with repeat cleaning until a safe level was reached. *Id.* at 40-52.

Mr. Carr testified that he was asked to perform a "Level Four" Order of Magnitude opinion of cost. This is also known as a conceptual cost estimate. *Id.* at 57-58. He testified that the decision as to where to establish the levels of remediation was made by him in conjunction with the toxicologists. *Id.* at 71. He understood that the contamination in this case was airborne. *Id.* at 75. He was not aware of any dioxin remediation projects where screening levels were used to define the area to be cleaned. *Id.* at 85.

He stated that his review of the real estate market was limited to a review of the Assessor's records. *Id.* at 89. In making his determination he used Dr. Flowers' report and the

2005 report from 3TM International. *Id.* at 91. His initial remediation zones were based on cleanup to a risk factor of one in one million, but after consultation with Drs. Sawyers and Flowers, he adopted 1 in 100,000 as the appropriate level, based on a child's risk. *Id.* at 95-98.

Mr. Carr stated that not all of the homes and soil in the class area were contaminated. He also said that he did not include commercial properties in his original estimate because he was asked to focus on residences and schools, the places with the highest risk. According to Mr. Carr, both the state and EPA believe there is more risk associated with residences and schools than with industrial/commercial property. He stated that all the homes that were sampled exceeded 4.5 ng/kg, but the figure to produce a 1 in 100,000 risk was 90 ng/kg. Not all of the soil exceeded the remediation standard. *Id.* at 101-104. He stated that when he received the tax information from Putnam County, if it met the tax assessor code for residences, it was included. *Id.* at 108.

He described a screening level as a concentration that in the EPA or state view would need further action. He also understood that the background level is a concentration that already exists either naturally or by human action.[162] *Id.* at 117. He also explained that the cleanup level is based on acceptable human health risk. *Id.* at 119. In this case he set the cleanup level for soil at a 1 in 100,000 increased risk of cancer, which produced the 41 ng/kg figure for soil. *Id.* at 123-124. The soil remediation was based on the EPA guidelines. To remediate dust, he used the Michigan direct contact level for dust of 90 ng/kg. *Id.* at 126. He also explained the proposed

[162] "Background" levels refer to (a) naturally-occurring levels: ambient concentrations of substances or agents present in the environment, without human influence; (b) anthropogenic levels: concentrations of substances or agents present in the environment due to human influence non-site(e.g., automobiles, industrial). USEPA Integrated Risk Information System (IRIS) Glossary.

dust cleanup protocol, which did not include attics. It also involved clearance by having post cleanup dust levels analyzed by CALUX. *Id.* at 130-135.

Mr. Carr based his opinions on dust and soil readings only, and not on blood sample results. *Id.* at 149-151. He was also questioned at length about the use of CALUX testing to determine exposure levels since it does not break down the level of 2, 3, 7, 8-TCDD. *Id.* at 166. He has performed tests for dioxins in his work but did not use CALUX. *Id.* at 171.

He was questioned about the use of the ArcView program to establish the various remediation zones. He was specifically asked about how big an area would be depicted as needing remediation based on a single sample. He stated that this would depend on how close it was to another sample, what the level was, and if there were lower samples around it. *Id.* at 178. Although Mr. Carr used the program, he made the decision as to the boundaries. *Id.* at 186. He stated that, based on one sample, he would remediate a half a mile to the north and other parameters because this is a very preliminary model of the remediation. *Id.* at 191. He had never used this program to determine remediation zones of other sites in his work, nor for determining contamination from an aerial dispersion source. He did not recall ever recommending remediation of as much as a square mile based on one point in his other work. *Id.* at 194-195. He could not account for the fact that there were low readings near the plant, with higher readings further away. *Id.* at 201.

Mr. Carr was also asked if his opinion would be affected if he knew that most of the 2005 samples were taken from attics as opposed to the living areas of the sampled houses. He stated that living space measurements would carry greater weight. If an attic reading was over the cleanup level, that would be determined on a case-by-case basis. *Id.* at 201-204.

When asked if he would demolish houses in his "demolition" area that were specifically found to be below the danger level, he stated that demolition would be the most viable alternative, but that this was a preliminary view without getting into individual properties. *Id.* at 208. He acknowledged that as additional information came to light, the decisions would be refined, but at this stage, no matter the likelihood, he assumed that every house in the demolition area would be demolished to provide a conceptual opinion of cost. *Id.* at 212-213.

Mr. Carr's deposition resumed on April 20. He testified that if he learned that a lot did not have a house on it, this would not change his opinion about the need for remediation because this is a Level 4 opinion, and is within the standard of error. *Id.* at 251-252. He was asked about one potential cleanup zone depicted on a map from which only 8 to 10 soil samples were taken. Of these, only two exceeded the cleanup level (41 ng/kg), so he was asked why he opined that the whole area needed remediation. He stated that the ArcView program was appropriate for determining the area to be cleaned, which produced the cost estimate. *Id.* at 255-256. He was asked about other areas with similar results, i.e. no samples taken yet topsoil removed and replaced and offered the same rationale. *Id.* at 257. He defended his assertion that even if a small portion of the samples in an area yielded results above the demolition level, that every home in that area would be demolished, regardless of level. *Id.* at 265-267. He also testified that the program decided the distance from a sample to extend a remediation zone. *Id.* at 269. [163]

Mr. Carr stated that in reviewing data from his various sources, if he could not determine the actual square footage of a residence he assumed a living area of 1,837 square feet, a building footprint of 1,381 square feet and a parcel frontage value of 576 feet. *Id.* at 296. He agreed that in the property records obtained from the Assessor' Office, 100 Series codes represented

[163] This line of questioning continued through several proposed cleanup zones.

residential property, and a subset of the 600 series represented schools. He indicated that every piece of property with a 100 code had a residence on it. *Id.* at 297-298.

For the purposes of his estimate, he assumed that even the soil in wooded areas would be capped, if it was in areas that were zoned residential. *Id.* at 305-306. He did not consider eliminating areas because of the topography or because the area was wooded. *Id.* at 307. He did not include areas that were zoned as agricultural in his estimate. *Id.* at 308. He also stated that there were areas where the houses would be demolished but the soil not remediated. This is based on dust and soil samples. *Id.* at 309-311. He also testified that he did not independently verify or review the veracity of the information received from the county assessors. *Id.* at 312.

Various anomalies were pointed out in the data: by way of example, Mr. Carr was questioned about a lot that measured 2 feet by 163 feet, for a total square footage of 327 square feet, yet which he estimated contained a house with the default measurement of 1,837 square feet of living space. He noted that there were "several properties, as noted in here, where averages and assumptions were made based on the lack of records." *Id.* at 316-317.

Mr. Carr testified that he used Class 4 estimates to establish reserves and budgets for companies when they have limited data. They are used for early or mid-level decision-making options. *Id.* at 337. He also testified about how much soil would need to be remediated under his various scenarios, and the method and length of time for soil disposal/treatment. *Id.* at 338-352. The amount of soil to be treated was reduced when the cleanup goal was set at $1x10^{-5}$ as opposed to the *de minimis* level of $1x10^{-6}$ *Id.* at 343.

Defense counsel then questioned Mr. Carr at length about the various estimates he used for several of the expenses, including brokerage fees, appraisals, house cleanup costs, etc. *Id.* at 352-380. He was also questioned about how he anticipated replacing the soil on hillsides,

particularly since his plan did not take into account terrain, trees, etc. *Id.* at 382-386. He stated that if property was zoned and deemed residential, then he used the formula from the State of West Virginia to calculate the risk. *Id.* at 390-393.

Mr. Carr testified that Drs. Flowers and Sawyers provided the criteria to evaluate the risk. They determined "what was acceptable risk to be protective of human health of residents." *Id.* at 396. This led to the use of the 1×10^{-5} risk level. *Id.* at 397. He also testified that he believed his estimate was between 5 to 10% complete. *Id.* at 411. He used Dr. Flowers' report for home dust samples and applied the program to the soil samples. *Id.* at 412. He could not estimate how much additional data he would need to refine his estimate or increase its level. *Id.* at 425-426.

On July 7, 2010, Mr. Carr was re-deposed. (dkt. no. 2980). He stated that he used information from a cleanup involving the Woolfolk Chemical Works to add a plan to clean attics in his remediation zones. *Id.* at 463-472. In calculating the cost estimate he assumed that all of the homes had attics but that the schools did not. *Id.* at 474. The attic cleanup added $30,000,000 to the total cost. *Id.* at 476. The age of the home, i.e. when it was built, would not make a difference in deciding whether or not to demolish it. *Id.* at 478-479. He was not able to get complete data from Kanawha County. *Id.* at 480-482.

Mr. Carr was not familiar with the April 18, 2007, ATSDR report, prepared by the West Virginia Department of Health and Human Resources as discussed, *infra*. He did not know whether to agree or disagree with their findings as he is not a toxicologist. *Id.* at 485-488. He described the *de minimis* standard as one representing an increased cancer risk of 1 in 1,000,000, and that it could represent a cleanup level or a trigger for more investigation. *Id.* at 490-494. He included remediation of the Nitro schools and community center even though the ATSDR did not find them likely to create adverse health effects to children or adults. *Id.* at 496-498.

He used Dr. Flowers' information to determine the area for attic cleanup, and not the 3TM data taken from South and East of the plant. *Id.* at 505-509. The cost of attic remediation was derived from the Woolfolk Record of Decision. *Id.* at 509. He found that document after reviewing the EPA website. *Id.* at 510. He described the various components of the attic cleanup process, and calculated the cost to clean each attic at $1,942. This did not include post-cleanup testing. *Id.* at 514-515. He agreed that in the Woolfolk site remediation, the acceptable risk was 1×10^{-4} or 1 in 10,000, while he was using 1×10^{-6} or 1 in 1,000,000, as the goal for the class area. *Id.* at 519-520. He is not offering an opinion as to whether cleaning of the residences and schools is required; only what the cost would be if it were required. *Id.* at 529-532. He agreed that some areas within the class area did not need remediation. *Id.* at 530.

Mr. Carr testified about his Addendum No. 2 report, stating that it was offered to provide the costs to clean the area to the *de minimis* standard. However, he was not trying to establish a cleanup goal. *Id.* at 548. He recognized that this estimate of $1,909,000,000 was a 600% increase over his original estimate of $315,080,000. This was based on a different cleanup goal. However, he was not giving an opinion as to which was more appropriate, but rather "to present the cost given the different scenarios and the cleanup scenarios." *Id.* at 550.

He discussed the various scenarios, including the *de minimis* goal, with the toxicologists in February 2010. He wanted to use the *de minimis* standard but the toxicologists thought the proper exposure level should be 1 in 100,000, rather than the 1 in 1,000,000 represented by the *de minimis* standard. *Id.* at 551-552. He went back to the 1 in 1,000,000 *de minimis* standard at the request of counsel. *Id.* at 546, 553,-555. He knew that the *de minimis* standards are standards where contaminants exist at levels that do not present a significant risk to human health, and that anything above that standard is based on site-specific information. However, he

stated that the fact that there was a site-specific standard in which a government agency used a risk factor of 1 in 10,000 in not finding a hazard would not alter his report, as he was not determining the cleanup levels, but merely the costs. *Id.* at 558-559.

Mr. Carr stated that the cost of attic cleanup presented in Addendum 1 would have to be added to the cost presented in Addendum 2, as it was merely a re-statement of his original workup, which was not used after his consultation with the toxicologists, *supra*. *Id.* at 563-566. He used Dr. Flowers' area for attic cleanup, but could not find what risk level Dr. Flowers used. *Id.* at 564-566. He explained that he opined that four (4) inches of topsoil should be added to the areas with readings between 3.9 ng/kg and 39 ng/kg because that would add in a factor of 10 times the standard to account for subsequent mixing of the soil. The areas with readings higher than 39 ng/kg would have six (6) inches of soil removed and treated. This soil would be replaced with six (6) inches of new soil. *Id.* at 567-570. He did not include commercial property in his estimate. *Id.* at 573. If a property was considered residential and within the four (4) inch soil addition area, every open part of the parcel would receive the additional soil, regardless of terrain or accessibility to the residence. *Id.* at 575. If there was no access to the property and it was not remediated, it would have to be rezoned. *Id.* at 576-577. His proposed work would require access with a bulldozer and a front end loader. *Id.* at 577. He testified that there was no correlation as far as the numbers go between Addendum 2 and Dr. Flowers' report. *Id.* at 582.

Mr. Carr conceded that the toxicologists agreed upon the criteria levels set out in his February report, and that none of the toxicologists stated that 3.9 ng/kg was the appropriate

remediation level. He was not aware of any witness in this case who was prepared to testify that figure represented the appropriate remediation goal. *Id.* at 630-631.[164]

F. The Defendants' Expert Evidence

Monsanto had a number of experts who were prepared to contest Class Counsel's expert witness opinions. These included Christopher R. Arrington, P.E., and Douglas G. Smith, Sc. D., in opposition to Mr. Auberle and Dr. Reeser on the air modeling; Michael E. Ginevan, Ph. D., who critiqued the work of Drs. Bell, Auberle, Flowers, Sawyer, Wade and Mr. Carr; Ray K. Forrester, B.S., in opposition to Dr. Bell; Donald G. Patterson, Jr., Ph. D., in opposition to Dr. Sawyer; George Maldonado, Jr., Ph. D., in opposition to Drs. Carpenter and Olson;

Jay Goldman, Esq., in opposition to Robert Carr; Phillip Guzelian, M.D., in opposition to Drs. Sawyer and Werntz; and John Henshaw in opposition to Steven Amter.

1. The Defendants' Air Modeling Evidence

a. Christopher Arrington, P.E.

Christopher Arrington, P.E., was offered to counter Mr. Auberle and Dr. Reeser, the Plaintiff's air model experts. *Report of Christopher Arrington, P.E.,* dated August 16, 2010. (dkt. no. 3190).[165] Mr. Arrington worked for thirteen years for the West Virginia Department of Environmental Protection as an Air Dispersion Model and Air Quality Engineer. He reviewed

[164] Mr. Carr provided a four-page affidavit dated June 11, 2012. *See* Ex. B (dkt. no. 3156). Mr. Carr stated that he had no opinion regarding what degree of dioxin contamination in indoor dust or remediated soil would warrant the need to remediate such property. He opined that the two-stage remediation proposal by Foth for the *Bibb* settlement was substantially similar to the three-stage remediation he proposed for indoor, living area-area dust. He also reviewed a recent HUD-funded study which concluded that there were no significant differences in clean-up outcomes between the two and three stage remediation process for interior dust. Had he proposed a two-stage process, the expected range of cost for his Class IV estimate would have been correspondingly lower. *passim*

[165] Mr. Arrington holds a B. S., in Electrical Engineering from West Virginia University and a Masters in Science in Environmental Engineering from Marshall University.

air dispersion modeling performed within West Virginia to ensure that it was conducted according to state and federal guidelines, and generally accepted scientific practice.

He had extensive experience in AERMOD, and co-authored the AERMOD Implementation Guide. He co-developed the original AERSURFACE tool for AERMOD. This preprocessor allows the user to input United States Geological Survey (USGS) land use data into the AERMET meteorological preprocessor. *Id.* at 1-6.

Mr. Arrington reviewed Mr. Auberle's report, noting that the AERMOD model was actually run by Dr. Reeser. He stated "I found major conceptual and application errors at every stage of the modeling process. The Plaintiffs did not follow the procedures and guidance issued by the USEPA and the WVDEP, and therefore the results cannot be considered consistent with regulatory requirements, or conducted in a generally accepted scientific manner." *Id.* at 1-8, 1-9. He further stated that "much of the data used within the model were assumptions or conjectures of uncertain accuracy. The information needed to accurately simulate the pollutant dispersion over this period, either never existed or no longer exists." *Id.* at 1-9.

Mr. Arrington cited twenty-one (21) major conceptual and application errors in the Plaintiff's air modeling:

1. Receptor density is not adequate to resolve peak concentration gradients due to emission source type characteristics.

2. Receptor density is not adequate to resolve peak concentrations and concentration gradients due to highly variable terrain elevations in the modeling domain.

3. A lower resolution terrain dataset was used, DEM data, instead of the available high resolution NED dataset.

4. Even by the receptor network's own design standards, the South Charleston open burning site was placed in the least accurate or dense portion of the receptor network.

5. The on-site Nitro meteorological dataset should have been chosen for this analysis.

6. The Charleston airport data is not the most representative meteorological data available.

7. The Charleston dataset does not meet the 90% Quality Assurance requirement, in either 2004 or 2005.

8. The Charleston dataset has an unusually large number of calms, and is not representative of the historical conditions at either the Charleston Airport or other meteorological stations within the Kanawha Valley.

9. The surface characteristics used by the Plaintiffs, during the AERMET processing, do not meet current guidance from the US EPA or the WV DEP.

10. Dry deposition parameters used were from an incinerator study, not for open burning sources, as needed for this analysis.

11. Meteorological files did not contain any precipitation, and therefore wet deposition was not computed correctly.

12. Tee Pee Burner characteristics used in modeling are not clearly representative of the characteristics of the burner used at the Monsanto Nitro facility.

13. Area and volume sources within AERMOD do not contain thermal buoyancy and therefore, these sources in the model are incorrectly characterized.

14. The model contained incorrect calculation of SIGMA Y and SIGMA Z variables for the area and volume source within the model.

15. Hours of operation of the pollutant sources within the model do not adequately represent the true diurnal variation of the operations at the Nitro facility.

16. The WWI Building source, the largest source of emissions within the modeling, is incorrectly located within the model.

17. The 1948 to 1952 emissions were 500% too high within the model run.

18. The 1962 WWI Building Emissions are 33% too high within the model run.

19. The model runs do not account for TCDD destruction within the Tee Pee Burner.

20. No data supports the source apportionment by year, leading to inconsistency of model representativeness.

21. The isopleths within the figures do not seem to reflect the model results, due to the lack of equivalent concentrations around the outlying open burning sites, or "islands" of concentrations.

Id. 1-9 to 1-11.

Mr. Arrington gave a detailed analysis of each of these twenty-one (21) criticisms in the discussion portion of his report. With regard to receptors, he stated, "in complex terrain such as in West Virginia, high density receptor networks are critical due to the rapidly changing elevations. These elevation changes affect the model calculations due to the terrains effect on pollutant plume paths." *Id.* at 2-2. He described the receptor grid used by Mr. Auberle. He believed that "the optimal design must include a high density receptor network close to the pollutant sources derived from high quality terrain data within the modeling domain." *Id.* at 2-4. He further stated that it was not uncommon in projects with complex terrains, complete with area and volume pollutant sources, for there to be total receptor counts in the range of 10,000 as opposed to the 900 in this model. *Id.* at 2-5. He was also critical of the terrain data used, stating that the new datasets available could have provided 1,111 data points for each 100 meter by 100 meter area with terrain height measurement available for every 3 meters on the ground, as opposed to the Plaintiff's dataset which produced 9 data points per 100 x 100 meter area, with a

terrain height measurement every 30 meters on the ground. *Id.* at 2-6. He attached a series of figures to depict the receptor grids used by the Plaintiffs, and the difference in accuracy of a representative cross-section of the Plaintiff's terrain model with that which he cited.

Mr. Arrington next addressed the meteorological data. He cited the Guideline on Air Quality models for the proposition that site-specific data is preferred over National Weather Service sites, and that all data has to meet quality assurance procedures. *Id.* at 3-2. He also discussed the treatment and importance of calm-wind conditions, citing the resource that stagnant conditions that include extended periods of calm often produce high concentrations over wide areas for relatively long average periods. *Id.* at 3-3. He cited the same reference that required that the meteorology database be 90% complete, and that four (4) consecutive quarters with 90% recovery are required for an acceptable one year database. *Id.* at 3-4. He described the various sites that were available to provide data, focusing on a site located in Nitro from 1992 through 2005, which was immediately adjacent to the Monsanto facility. He stated that five of the on-plant or adjacent sources were within 800 meters of the station, and four of the distant open burning sites were less than 8 kilometers away. "Over the period of 1948 to 1969, (according to Mr. Auberle's report), over 72% of the total TCDD emissions were emitted within 800 meters of the meteorological collection site." *Id.* at 3-7. Mr. Arrington attached another series of exhibits depicting the different data available from Institute, Nitro, and Charleston to substantiate his opinion that the on-site Nitro meteorological dataset should have been chosen for this analysis.

In the next section, Mr. Arrington focused on the AERMET processing of the Charleston 2004-2008 data. He stated that AERMET is run in three stages. In the first stage, meteorological data is extracted from the archive data files and processed through various quality

assessment checks to determine if the data being processed meet the requirement of 90% completion for each of the year's four quarters. In the second stage all data from the first stage for 24 hour periods is merged and stored in a single file. The third stage reads the merged meteorological data and estimates necessary boundary layer parameters for use by AERMOD. AERMET then writes two output files for AERMOD: the first consists of hourly boundary layer parameter estimates, and the second file contains observations of wind speed and direction, temperature, and standard deviation of the fluctuation components of the wind. Additional site-specific characteristics are required for Stage 3. *Id.* at 4-1 to 4-2.

Mr. Arrington had specific criticism of two stages of the process. These included, for Stage 1 – Data Quality Assurance Procedures and Calm Winds Frequency. There were several periods between 2004 and 2008 which did not meet the appropriate quality level. Also, the treatment of calm/light winds "poses a special problem in model application since steady-state Gaussian plume models assume that concentration is inversely proportional to wind speed." *Id.* at 4-5. Mr. Arrington believed that the 2004 to 2008 Charleston Airport dataset consistently contained 2-4 times the number of calms as all three historical datasets in the Kanawha Valley (Charleston Airport 1982-1992: calm 15.94%; Institute 1992-2006: calm 12.6%; Nitro 1992-2005: calm 10.4% as opposed to Charleston Airport 2004-2008: 43.55%). *Id.* at 4-6. He also criticized Surface Parameter Selection in Stage 3, stating it did not meet current guidance from the US EPA or WV DEP.

Deposition modeling was the next topic reviewed by Mr. Arrington. He described the process of "Dry Deposition" and "Wet Deposition", defining the former as the process where the pollutant falls from the ambient air due primarily to gravitational settling, and is deposited on the surface, while the latter is where the pollutant is "washed" from the air by moisture and some

form of precipitation. The processes should be calculated independently in AERMOD. He stated that dry deposition required the user to input the particle size distribution, the particle density and the mass function of the total pollutant. Wet deposition required the user to input hourly precipitation data into the AERMET pre-processor. Mr. Arrington stated that without precise data for these inputs, deposition calculations would be highly inaccurate and unsuitable for drawing legal or regulatory conclusions. *Id.* at 5-1 to 5-3.

Mr. Arrington criticized the Plaintiff's choice of dry deposition input, noting that they used the data from an incinerator study, specifically the University of Michigan Dioxin in Exposure Study Incineration Placement Dispersion Protocol, as opposed to uncontrolled open burning, which was appropriate here. With uncontrolled open burning of widely varying industrial wastes, he stated that the particles would be relatively much larger, and distributed more evenly within appropriate size categories. The Plaintiff's model treats the particles as extremely small, essentially a gas. With this input, the TCDD within the model settles out very slowly over a wide area due to the very small particle size and the density. The Plaintiffs modeled 99% of the particles as Particle Size I, with a diameter of 1.26 microns. The other choices were 6.78 and 21.5 microns for Particle Sizes II and III. *Id.* at 5-2.

As to the wet deposition model, he opined that the Plaintiff's expert used inaccurate or incomplete precipitation data. He criticized the methodology by which each was modeled. *Id.* at 5-4. He believed that in most models, wet deposition is a much more important component of total deposition than reported by the Plaintiff. *Id.* at 5-4. He specifically stated that "the output files reported that there was zero (0) precipitation in the meteorological data files for the entire data period of 2004 to 2008. Therefore, the wet deposition portion of the analysis was deeply flawed as it did not contain any precipitation, and therefore no wet deposition." *Id.* at 5-5.

Mr. Arrington was also critical of Mr. Auberle's "source characterizations." He characterized source data as "one of the most sensitive inputs to the model, if not the most sensitive." *Id.* at 6-7. It includes data such as the coordinates or location of the source, the emission rate of the pollutant, the stack height, the exit temperature of the pollutant, and others. He criticized the lack of data for the "tee pee burner". He discussed the definition of "point source", "area source", and "volume source". A point source models releases from stacks, vents, and other kinds of sources. An area source models low level or ground level releases with no plume rise. A volume source models releases from a variety of sources, such as building roof monitors, multiple vents, and conveyer belts. He leveled specific criticisms at Mr. Auberle's characterization of these sources. *Id.* at 6-10 to 6-11 & 6-14.

He also expressed concerns about the assumption that the waste was continually burned by day and night, and about the placement of the WWI building, which produced the majority of total emissions (67%) from 1960 to 1969, the period of highest production. *Id.* at 6-14 to 6-18. He attached eleven exhibits depicting photographs and a map of the actual site during the time period in question, and exemplars of types of emission sources and a tee pee burner to support his conclusions.

The next areas reviewed were Emission Calculations and Model Input. Mr. Arrington began by assuming that Dr. Bell's calculations were correct. However, he noted that the amount of waste produced in 1948 to 1952 was 500% greater than what was shown in Dr. Bell's table. He stated that Mr. Auberle combined the data for these five years in a single model run, and did not run a model for each year as he did from 1953 to 1969. Mr. Arrington noted that the emissions were calculated at 38.31 pounds per year, when Dr. Bell's table showed average

emission of 7.71 pounds per year. Mr. Arrington assumed that Mr. Auberle failed to divide the total by five.

He also believed there was an over calculation for one year (1967) of waste burned at the WWI Building Source. He also mentioned that although Mr. Auberle believed some TCDD was destroyed in the Tee Pee burner, this was not reflected in the model. He also questioned the methodology chosen to apportion burning sources stating that "these assumptions ensure that the model results are concentrated, and centered within the more populated valley regions. While the actual distribution of the waste to the various sites is unknown, it is highly unlikely that Dr. Bell's apportionment is representative of the actual distribution on a year to year basis." *Id.* at 7-2 to 7-5.

Finally, Mr. Arrington criticized the post-processing and mapping. He stated that AERMOD does not create maps with isopleths, but outputs tables of concentration values at discrete points, specifically, the receptor locations. These outputs are then run through a program that creates a map based on high density receptor networks. Here, he stated there was no quality assurance performed, nor could Mr. Auberle or Dr. Reeser provide details on the methodology used, other than to state that the "Natural Neighbors Method" was used. *Id.* at 8-1-to 8-2.[166] Mr. Arrington used the Plaintiff's files to attempt to independently produce isopleths similar to those in Mr. Auberle's report. He could not recreate them, but instead, got additional isopleths around the outlying and more distant open burning sites. He examined the Plaintiff's files and found an original set of maps which were very similar to those created by him. He opined that "it is highly likely that the outlying 'island' isopleths lines were removed." *Id.* at 8-1 to 8-3. He attached the various isopleths to support his opinions.

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[166] *See* note 126.

Mr. Arrington was deposed on September 30, 2010. (dkt. no. 1514). He testified that he uses AERMOD on a weekly basis. *Id.* at 7. He reviewed and criticized air models and generated his own on a regular basis. *Id.* at 9. He worked on permits involving the air dispersion of 2, 3, 7, 8 TCDD but does not have the expertise to generate the value of the 2, 3, 7, 8 TCDD being modeled. *Id.* at 13-15. He was born and raised in Nitro and Cross Lanes, graduating from Nitro High School in 1986. *Id.* at 16. He agreed that air modeling could be used to determine a company's past impacts. *Id.* at 21-23. Mr. Arrington agreed that AERMOD and another model were each applicable, and had their own strengths. *Id.* at 34.

Mr. Arrington had serious concerns as to whether there was sufficient data to run the air model in this case. Among his primary concerns was not being able to use the actual meteorological data from 1948 to 1969, as it did not exist in its entirety. *Id.* at 40. He also had issues with the mass emissions calculations, and with how the emissions were allocated to the various sources. *Id.* at 40-41. He repeated the specific criticisms he raised in his report throughout the depositions[167].

Mr. Arrington highlighted several areas of concern in answering questions about his criticisms of the Plaintiffs' air modeling. As to the general question of receptor networks, he suggested that "there should have been one very large dense grid over the entire area where all the sources are, and the area of interest, which in this case would be the population in that part of the Kanawha Valley." *Id.* at 54. He stated that the Nitro meteorological data was the most

[167] The criticisms may be further found in the deposition on the following pages: Criticism 1: *Id.* at 45-48; Criticism 2: *Id.* at 48-49; Criticism 3: *Id.* at 49-52; Criticism 4: *Id.* at 52-73; Criticism 5: *Id.* at 73-76; Criticism 6: *Id.* at 76-78; Criticism 7: *Id.* at 76-78; Criticism 8: *Id.* at 78-98; Criticism 9: *Id.* at 98-108; Criticism 10: *Id.* at 114-117; Criticism 11: *Id.* at 117-122; Criticism 12: *Id.* at 122-127; Criticism 13: *Id.* at 127-131; Criticism 14: *Id.* at 131-137; Criticism 15: *Id.* at 137-144; Criticism 16: *Id.* at 144-149; Criticism 17: *Id.* at 149-158; Criticism 18: *Id.* at 158-161; Criticism 19: *Id.* at 161-163; Criticism 20: *Id.* at 163-173; Criticism 21: *Id.* at 173-192.

appropriate, but conceded that if all of the Nitro data was inappropriate, the Charleston data could be considered. *Id.* at 78. He also believed that the Charleston data was less representative, because it reflected a ridge top instead of a river valley. *Id.* at 80.

As to the effect of what he believed to be an overestimate of the amount of periods of calm in Mr. Auberle's model, Mr. Arrington stated that the model would not perform calculations during those periods, therefore creating higher impacts on each side of the calm. This would lead to an overestimation of dispersion. *Id.* at 93. He also believed that the inability of the model to input thermal buoyancy for an area source was one of the weaknesses of using AERMOD in this analysis. AERMOD turns these sources into virtual point sources. *Id.* at 128-129.

He questioned the modeling of emissions operating continuously for 22 years, at 24 hours per day. He believed that this type of operation would have occurred principally during the day, when there is more turbulence and higher wind speed, as opposed to night time, when the air is more stable and the wind is slower. He agreed that the information from Monsanto workers was not clear on this point. *Id.* at 137-138. This would cause the model to show less dispersion which would increase the dosage or the concentration as applied to certain places and groups of people. He agreed with the statement that, given the same amount of material being disbursed, disbursement over a wider area creates a lower concentration. *Id.* at 143. Mr. Arrington stated that the photographs in his report came from Randy Horsak's materials. *Id.* at 148.

Beyond these critiques, he also discussed the SCREEN model, describing it as "a very quick analysis to get a very conservative worst case answer that takes much less input and time to perform than the refined model." *Id.* at 207. It would not apply to the type of analysis done here. *Id.* at 208.

b. Douglas C. Smith, SC.D.

The Defendants also offered the opinions of Douglas G. Smith, Sc. D., as an expert witness on the issue of air modeling. He authored a report dated August 2010 and titled *"Report on Use and Misuse of Air Dispersion Models and Relationship to the Bibb, et. al. v. Monsanto, et. al. Case"* (dkt no.1533).[168]

To summarize Dr. Smith's opinions:

1. There are large uncertainties in the TCDD source information provided for the modeling of environmental distribution with AERMOD – assumed geometries, mass distribution among identified locations, and emissions characteristics, such as height and temperatures – and especially their variation with time. These approximate data cannot be relied upon to provide the AERMOD with the quality of input data necessary for accurate simulation.

2. AERMOD results are based on a mathematical simulation and simplification of reality, and thus its results are predictive estimates, not facts.

3. AERMOD was intentionally designed to generally produce conservative (over-estimates) of maximum air concentration and related deposition rates in an area, and results are not expected to represent the value that would be measured at any particular point location. It thus makes it more difficult to predict values that would match, or highly correlate with, comparative measurements.

4. When AERMOD operational protocols originated by its developers are not carefully followed, the modeler must explain the deviations and what effect they will have. The Plaintiffs' consultants did not explain such deviations.

5. Dr. Reeser relied upon a 2006 Dioxin study from the University of Michigan which includes estimates of particle

[168] Dr. Smith has a "Sc. D." in Environmental Health Science-Industrial Hygiene and a Master of Science in Environmental Health Sciences – Radiological Health/Air Pollution from the Harvard School of Public Health. A "Sc.D."or a Doctor of Science, is an academic research doctoral degree awarded by research universities. It is considered as the equivalent to a Ph.D

> sizes associated with the incinerator emission of dioxins and furans, and not the 2009 University of Michigan replacement which considered the differences between vapors and particles for all dioxin and furan congeners used in their modeling analysis. The 2009 table was available and not used.

Id. at 3-4.

Dr. Smith discussed each of these points in detail in the body of his report, stating that AERMOD specifically overestimated as it was used to build in a margin of safety for regulatory purposes. *Id.* at 4. However, studies have shown that for near-ground and elevated sources, and in either flat or rolling hill terrain, typical predictors from AERMOD may often overestimate short-term values by a factor of 4 or more. He stated that "[t]he cumulative effect of these overestimated levels, when projected over many years would also be expected to be overestimated for locations of highest impact. Therefore, relying on a model designed to be conservative for short-term impact assessment, will bias upward the long-term averages; this will lead to chronic errors in predicting air concentrations and soil deposition patterns." *Id.* at 8. He opined that AERMOD estimates of air and soil concentrations are not a reliable predictor of previous exposures. *Id.* at 14. Dr. Smith also questioned Dr. Reeser's efforts to "fit" the area originally designated for the Class definition, and stated this "illustrates the high degree of uncertainty that exists in identifying what sources and what emission rates would be relevant to such a decision." *Id.* at 16.

He concluded by stating that the proposed use of AERMOD modeled air concentration results as the basis for reliable estimates of historical exposure and any related risk is inadequate and unjustifiable. He based this upon: (1) highly questionable source emission rates for multiple source locations with speculative documentation; (2) use of oversimplified meteorological data with questionable representativeness of wind flow patterns for the area and periods selected for

their exposure estimates; (3) selection of a period of meteorological input data that includes so many calm hours (42%), since these are excluded from the modeling analysis, raising a question about the bias that would be introduced by this procedure; (4) the assumption that the AERMOD predictions are precise enough to use for case inclusion boundary decisions, when recent field testing indicates that AERMOD, in conjunction with the AERMET preprocessor program may lead to frequent overestimates of concentrations by a factor 150% to 400%; and (5) lack of congener speciation and particle size information needed to predict deposition with any reliability. He also stated that the Plaintiff's analysis did not make meaningful comparisons with the geographical distribution of measured soil and dust concentrations to that period.[169] *Id.* at 16-17.

2. The Defendants' Evidence on the Amount of 2,3,7,8, TCDD Produced and its Fate: Ray K. Forrester, B. S.

Ray K. Forrester was offered as an expert by the Defendants on the issue of the amount of 2, 3, 7, 8-TCDD produced in Nitro and its fate. He was offered to counter the testimony of Mr. Pape and Dr. Bell as to the amount of 2, 3, 7, 8-TCDD produced, and of Mr. Carr on the property remediation program.[170] Throughout his involvement, Mr. Forrester rendered five reports in this case, dated; March 20, 2007, August 2010, October 5, 2010, December 2010, and January 2011.

The first report, of March 20, 2007, contains Mr. Forrester's initial opinions. (dkt. no. 1547). After reviewing a series of documents associated with the site and visiting the Nitro site and surrounding areas, he performed a material balance to reach them. He reviewed the

[169] The Court could not find any deposition transcripts in the record for Dr. Smith.

[170] Mr. Forrester holds a Bachelor of Science degree from the University of Missouri – Rolla. His resume states that he has 30 years of experience working in the specialty-chemical, pharmaceuticals, and environmental industries.

production process and determined that there were three major manufacturing stages for TCDD, specifically 1948 to 1952, 1953 to 1963, and 1963 to 1969. *Id.* at 2-1 to 2-3.[171] He calculated the amount of NaTCP, 2, 4, 5-T and the mass of TCDD produced during each year. The production figures for NaTCP and 2, 4, 5-T allowed him to calculate the amount of TCDD in the final 2, 4, 5-T product and in the NaTCP slurry. *Id.* at 2-5. He also performed estimates of dust emissions, assuming that the composition of the dust was equal to that in the product. He noted that there were two distinct periods of operation for the estimates of dust emissions relating to the drying and packing of the product: 1948-52 at 1953-1969. He analyzed various potential emission points. He noted that "waste solids from filtration or centrifugation may be removed and sent to a disposal area such as a landfill or be washed down the sewer." *Id.* at 2-5 to 2-7. Also "[s]pills and leaks of solids or liquids are typically contained within a building and can be cleaned up or washed down the sewer for treatment . . . Damaged packing may be sent to a landfill or burned in an incinerator, if available. Combustible waste streams whether they be gaseous, liquid or solid are sometimes incinerated provided adequate incineration capability and capacity are available." *Id.* at 2-7 to 2-8.

He next described the physical properties of TCDD, noting that it has "unique properties, because it is a totally symmetrical molecule." *Id.* at 2-8. It is a solid that melts at 305° C. It is exceedingly insoluble in water, has a very strong affinity to absorb to solids, especially organic solids, and has an extremely low vapor pressure. *Id.* at 2-8. Its low vapor pressure of 10^{-13} atmospheres makes it exceedingly unlikely to escape to the atmosphere via fugitive emission.

In conclusion, he stated that:

[171] He attached a series of Exhibits which depicted each process in Appendix C to his report.

> TCDD is extremely unreactive under most chemical conditions. In summary, the physical-chemical properties of TCDD indicate a chemically inert compound stable to temperature above 500° C; a chemical of low volatility that adheres to surfaces, especially particulate matter; and a compound that concentrates in organics.

Id. at 2-9.

Mr. Forrester described how TCDD was made as a byproduct of the manufacture of 2, 4, 5-T. He specifically stated that it was formed in the reaction of TCB with sodium hydroxide in the presence of methanol in a pressure reactor at 170° C. The amount of TCDD that is formed depends on the temperature condition, the ratio of reagents, and the rate of TCB addition. TCDD formation increases with time at temperatures above 160° C and if the preferred ratios of methanol/TCB and sodium hydroxide/TCB are low. He believed it is likely that the TCDD content varied from batch to batch. *Id.* at 2-9. He believed that approximately 25% of the TCDD went in to the product, and 75% of the TCDD went to land disposal or process sewers. *Id.* at 2-10. He estimated total TCDD production from 1948 to 1969, to be 2,186.03 pounds, of which 635.40 pounds went in the product and 1,550.62 pounds went to the waste stream. *Id.* at 2-11, Table 2.

Mr. Forrester believed that solids from filtration or tank cleanout were likely disposed of in a landfill. He thought that disposal in a sewer was possible, but felt that burning in a boiler or incinerator was unlikely because of the highly corrosive nature of the material and the low heat value. Any TCDD passing through filtrate or washes was likely to have been in the form of very fine particles or associated with other solids passing through the filtration. The product was recycled. He believed that any liquid was discharged in the sewer. *Id.* at 2-12. He believed a minimum amount would have been lost during packaging in dust which escaped the control devices, calculating this to be 1.40 pounds over the entire period. *Id.* at 2-14, Table 3.

He stated that damaged packaging materials would likely have been sent to the landfill or burned in the tee pee incinerator between 1958 to 1962. Filter cloths, filter bags, filter cartridges and other similar materials would also likely have been sent to the landfill. Although he recognized that an internal publication, the "Monsanto Backgrounder," dated June 23, 1983, mentioned that filters, dust bags, and flow sweepings were burned in the plant incinerator in the 1950's – 1960's, he did not see this substantiated in any of the other documents that he reviewed. *Id.* at 2-12 to 2-13.

As a result of his workup, which has been very briefly highlighted above, Mr. Forrester expressed five opinions, which are set out herein with a brief discussion of the supporting reasoning for each:

"Opinion 1: All but trace quantities of the TCDD generated in the Site's 2, 4, 5-T process were removed in the process or went out with the product and not the atmosphere."

Mr. Forrester reiterated that 25% of the TCDD went in the product and 75% went to various disposal locations. He believed that these were most likely washed down the sewer to the waste treatment process or sent to a landfill for disposal. He thought it very unlikely that they were burned in the plant incinerator or boiler, for the reasons mentioned above. He relied upon the testimony of a witness named Kleive who stated that the only waste material burned at the site from the 2,4, 5-T process were empty paper bags burned between 1958 to 1962. *Id.* at 2-15 to 2-16. He discussed sewer disposal, stating that later measurements of sludge from treatment basins found that TCDD was present but at a low parts per billion level, consistent with the small amount of TCDD discharged in the sewers over time. He believed that waste water streams contained 5 to 15% of the TCDD. *Id.* at 2-16.

Vapor emissions from the process would have been unlikely to contain measurable quantities of TCDD. He believed it likely that the filter cloths, cartridges, and dust cloths were sent to the landfill. He relied heavily on the Kleive deposition in reaching this conclusion. He discussed an instance where some dust bags were burned on site. He discounted the information in the "Monsanto Backgrounder." He also believed that the heavy filter cloth bags and bag-house dust bags would not have been easily burned and would more likely have gone to the landfills. *Id.* at 2-15 to 2-18.

"Opinion 2: From 1948 until 1969, when the 2, 4, 5-T process shut down, approximately 1.4 pounds of TCDD could potentially have been released to the atmosphere."

He noted that his calculations for the period from 1948 until 1952 assumed that all of the fugitive dust was released to the atmosphere, when it was likely released in the building. His estimates of TCDD in dust from 1953 to 1963 exceeded the estimates made by the Plaintiff's expert, and the TCDD in dust from 1964 – 1969 is within the same range as the Plaintiff's expert. *Id.* at 2-18.

"Opinion 3: The March 8, 1948, (sic) incident would have released an insignificant amount of TCDD to the atmosphere."

Based on his review of the event and on the deposition testimony of a witness named Durland, any TCDD would have likely remained in the autoclave or in the building. The cloud moved in an east-northeast direction away from the town of Nitro. *Id.* at 2-18 & 2-19.

"Opinion 4: The remediation performed at the Site has been appropriate and effective in dealing with trace levels of TCDD and other similar compounds."

Mr. Forrester stated that although most levels of TCDD detected on the site were below the original US EPA residential cleanup value of 1 part per billion, the Site was fully remediated.

This was done by capping, which he called a good choice for TCDD contamination. This prevents any TCDD from migrating offsite by erosion. He cited a Monsanto news release claiming that 30 offsite samples indicated that there was no migration off the site. *Id.* at 2-19 to 2-20.

"Opinion 5: The presence of the 2, 4, 5-T process at the Site, its approximately 20 years of operation and the remediation of the Site did not significantly contribute to the levels of TCDD found in the town and surrounding areas of Nitro, West Virginia."

Mr. Forrester believed that the levels of TCDD found by the Plaintiff's expert were not significantly different from background levels found in other places in the United States. He identified other potential sources for the TCDD. He believed that much of the 1.4 pounds of dust emission settled on the Site. He also stated that ultraviolet light would degrade the TCDD while airborne or as it lay on the surface of the soil. He did not believe that the 1948 (sic) incident or the remediation program would have contaminated the community. In the latter case, he stated that the levels measured on the site were very low and did not represent a threat to the community, based on accepted cleanup values. *Id.* at 2-20.

Mr. Forrester filed a second report dated August 2010.[172] (dkt. no. 1547). He began this report with an executive summary containing seven opinions. The first five opinions basically repeated his earlier opinions, with some minor clarification. Specifically, Opinion 1 remained the same. Opinion 2 was restated as follows: "[f]rom 1948 until 1969, when the 2, 4, 5 T process shut down, approximately 1.28 pounds of TCDD could potentially have been released to the

[172] The first report was filed by him as part of "The Forrester Group," but the next was filed by him on behalf of Foth Infrastructure and Environment, LLC. His resume noted that he sold his business to Foth in 2009.

atmosphere from manufacturing related dust emissions." *Id.* at iv. Opinion 3 was modified to correct the year of the autoclave incident to 1949. Opinions 4 and 5 remained the same.

Mr. Forrester added two additional opinions, specifically:

> Opinion 6: The types of open burning or use of a teepee burner at the Nitro facility or other off-site locations are very different than standard industrial, hazardous waste incineration such as the Dow Chemical incinerator in Midland, Michigan.
>
> Opinion 7: The mass balance calculations presented in the Expert Report of Bruce Bell, dated February 15, 2010 differ from the calculations prepared in this report but are reasonable based upon the data available and the assumptions used. Thus, it is reasonable to assume that the total TCDD production is within the range of the values estimated by Forrester and Bell.

Id. at iv.

A review of the sections supporting each of his first five opinions indicates limited revisions, for the most part. However, several revisions require comment. Because of a change in ratio of TCDD in the product to TCDD sent to the waste streams in the 1960's, those estimates changed. In each report, roughly 2,186 pounds of TCDD was estimated to have been created (2,186.03 in 2007 report v. 2,186.0 in 2010 report). However, the amount sent out in the product decreased from 635.40 pounds to 578.5 pounds. At the same time, the amount placed in the waste stream increased from 1,550.62 pounds to 1,607.5 pounds. *Id.* at 9, Table 2-2. Additionally, the amount of 2,4, 5-T dust emissions decreased from 1.4 pounds to 1.28 pounds. *Id.* at 12.

Opinion 1 was modified to add a provision that of the estimated 1,607.5 pounds of TCDD removed in the process, it was either (1) material adhered to filter cake, (2) material adhered to solids removed from settling tanks or (3) material adhered to solids suspended in waste water streams. He believed that the waste in 1 and 2 could potentially have been sent to a landfill for

disposal but would not have been incinerated for the reasons stated before. *Id.* at 14. He also noted, in Opinions 4 and 5, that since Monsanto's onsite remediation and release of data for offsite samples, that "limited evidence indicates that at least one property very near the Site has elevated levels of TCDD in soil. However, blood levels of residents are below levels of concern." *Id.* at 16-17.

Mr. Forrester then offered substantiation for his two additional opinions. As to Opinion 6, Mr. Forrester stated that open burning is a very inefficient means of burning materials such as paper bags, wooden pallets, or general trash. It does not generate sufficient temperatures to thoroughly burn wet, corrosive salt cakes with traces of TCDD, wet filter cloths or heavy canvas bags. He also stated that while the tee pee burner would have been more efficient than open burning, it would still not be sufficiently effective to have any significant increased ability to burn these types of materials. He then described how an incinerator like that used by Dow Chemical in Midland, Michigan worked, contrasting it with open burning or tee pee burners. He noted that even operators of purpose-built industrial hazardous waste incinerators are reluctant to receive significant quantities of very water-wet material, salts of various soils, and other corrosive materials due to the adverse effect that they have on the operation of the unit and corrosion to its metal parts. He concluded that open burning and tee pee burning were significantly different from burning in the Dow incinerator. *Id.* at 17-18.

Finally, in Opinion 7, Mr. Forrester compared the calculations he used to produce his estimates to those of Dr. Bell. They both agreed on using total phenols as the source to calculate TCDD concentration. He found two factors that could account for the difference. First, he calculated total TCDD production based upon the total NaTCP production for each given year using the assumption that NaTCP comprised the majority of total phenols on which TCDD

concentration was based, while Dr. Bell used a 1965 Monsanto document to calculate total phenols value based upon NaTCP as a percentage of total phenols. Thus, Dr. Bell's basis gave results that were 10% greater than his.

Second, Dr. Bell and Mr. Forrester used different values for TCDD concentration in the NaTCP slurry in the methanol recovery still, which is the basis for calculating TCDD production. He believed that both values were reasonable *Id.* at 18-19.

Mr. Forrester filed an additional report dated October 5, 2010, which supplemented his report of August 16, 2010. (dkt. no. 3190). With one exception, specifically, an amendment to the number of off-site test sites reported by Monsanto in Opinion 4, reducing those sites from 30 to 19, the rest of the changes were Bates reference numbers for documents or exhibits in or attached to his report.

In December, 2010, Mr. Forrester filed another report. (dkt. no. 3190). This report was offered to counter the opinion of Plaintiff's real estate damage/remediation expert, Robert J. Carr. He reviewed Mr. Carr's proposed remediation program contained in the latter's report dated February 11, 2010, with addendums dated April 16, 2010 and May 26, 2010. He found it to be "unprecedented in the history of remediation," . . . "based on flawed assumptions, biased data and impractical remediation methods." He also commented on the failure of either the USEPA or the WVDEP to express interest in Mr. Carr's proposed action. *Id.* at iii.

Mr. Forrester offered four opinions in regard to the Carr plan, namely:

> Opinion 1: Based on the information provided in opinions 2-4, I do not consider the Engineering Opinion-of-Cost to be a reasonable estimate.
>
> Opinion 2: Soil and dust sampling are inadequate to support or justify Carr's extensive proposed remediation.

> Opinion 3: Remedial action objectives were selected without consideration of land use and topography.
>
> Opinion 4: The opinion-of-cost does not appear to have evaluated the effectiveness, implementability, and cost effectiveness of the remedial alternatives for which the cost estimate has been prepared.

Id. at iii-iv.

Mr. Forrester began with a background section and a GIS data evaluation based on Mr. Carr's presentation of two remediation zones – one based on a level of 41 ng/kg and another on a lower limit of 3.9 ng/kg. He determined what percentage of each of these zones was in steep slope or forested. *Id.* at 2.

He supported his first opinion by stating that the cleanup levels proposed by Mr. Carr were too low. Mr. Forrester believed that they should have been set at higher levels, based upon an appropriate risk-based valuation and accepted cleanup levels of 1000 ng/kg residential and 5000 to 20,000 ng/kg for commercial real estate. He stated that all of the Missouri dioxin sites, including Times Beach, were remediated to those levels. He also opined that Mr. Carr's cleanup values of 41 ng/kg and 3.9 ng/kg are less than various background values measured throughout the world, and that the 3.9 ng/kg West Virginia *de minimis* standard cited by Mr. Carr was not a cleanup value, but a number which indicates when further investigation may be warranted. He also said the samples were biased toward dust deposition in non-traffic areas of homes where opportunities for exposure are extremely infrequent, it at all. He also believed that Mr. Carr based his opinions upon limited data which is not representative of a high percentage of land that has been identified for remediation. There were several area issues raised by him, including his opinion that large areas of the proposed cleanup area were forested and/or steep slopes. After reviewing Mr. Goldman's work, he believed that Mr. Carr grossly overstated the number of

impacted dwellings, *infra*. He also questioned whether Federal and State authorities would approve the plan. He also stated that the plan would require 100% participation by all landowners. *Id.* at 3-5.

His remaining three opinions were offered for the following reason: "to more fully demonstrate this overall conclusion, I have prepared the following opinions to support each of these reasons in greater detail . . ." *Id.* at 5.

Mr. Forrester's second opinion of four opinions concerned his belief that the soil and dust sampling data were inadequate, in that the soil samples were collected from easily accessible areas. He stated that the dust samples were taken from non-traffic areas with little chance of exposure. He relied upon the Risk Assessment Guidance for Superfund provided by the USEPA.

> In evaluating monitoring data for the assessment of soil contact exposures, the spatial distribution of the data is a critical factor. The spatial distribution of soil contamination can be used as a basis for estimating the average concentrations contacted over time if it is assumed that contact with soil is spatially random (i.e. if contact with soil in all areas of the site is equally probable). Data from random sampling programs or samples from evenly spaced grid networks generally can be considered as representative of concentrations across the site. At many sites however, sampling programs are designed to characterize only obviously contaminated soils or hot spot areas. Care must be taken in evaluating such data sets for estimating exposure concentration.

Id.

He cited this as authority for his belief that Mr. Carr is projecting remediation areas over vast tracts of land surface that have not been characterized at all. He also noted that Mr. Carr recommended demolition of homes that had not even been sampled. He also cited the August 30, 2005 EPA memorandum from Dawn A. Ioven to Marjorie Easton and Randy Sturgeon

concerning samples taken from the Nitro Community Center and Schools, *supra.* (dkt. no. 3190). He was also critical of the failure to determine background level data.

Finally, he stated that the soil remediation zones did not correlate to the presumed emissions from waste burning. He noted that two of the landfills were outside the Class Action Remediation Area and that four landfills were outside the extreme or high soil concentration zones or the Sub Chronic dust zones. He also stated that the "relatively low amount of 2, 3, 7, 8 TCDD compared to other congeners is further evidence that the 2, 4, 5-T process represented an insufficient contribution to the environment, if any." He cited other potential sources for dioxin congeners, such as historical industrial processes that burned wood and trash, residential burning of household trash, the Nitro tire fire of May 4, 2006, vehicle combustion, rubber manufacturing, and coal burning. *Id.* at 8-9.

Concerning Opinion 3, Mr. Forrester stated that Mr. Carr's total area for remediation at 41 ng/kg is 6,600 acres, and the total area at 3.9 ng/kg is 63,400 acres. This represents an area that Forrester states is 81% covered by steep slopes and 72% to 78.4% covered by forest. He again cited the Risk Assessment Guidance for Superfund from the USEPA which states that "samples from areas where direct contact is not realistic (such as where a steep slope or thick vegetation prevents current access) should not be considered when estimating current exposure concentration for direct contact pathways." *Id.* at 9.

Lastly, Opinion 4 states that Mr. Carr did not appear to have evaluated the effectiveness, implementability and cost effectiveness of the remedial alternatives for which the cost estimate was prepared. He stated that typical site progression towards final closure included site characterization, risk assessment and a feasibility study prior to selection of a final remediation approach. He did not believe that the site investigation here was adequately implemented. He

opined that Dr. Sawyer's risk assessment did not conform to a standard CERCLA risk assessment, and that it did not support Mr. Carr's program. He stated that Mr. Carr chose two extremely low values which do not properly address the potential for exposure in the areas of concern. *Id.* at 10.

He questioned both the long term and short term effectiveness of the program. He noted that background levels of dioxin were likely two orders of magnitude higher than the proposed *de minimis* level of 3.9 ng/kg, especially in urban or industrial areas. He believed that following the proposed house cleaning, background dust would re-accumulate in the houses, rendering or eliminating that benefit. *Id.* at 11.

He discussed the sheer physical magnitude of the proposed cleanup. He believed that it would require 25 million cubic yards of soil to place a 4 inch cover over the 3.9 ng/kg Remediation Zone, which he stated was the same volume as that of the debris cleared in Mississippi as a result of Hurricane Katrina. The remediation area would be the size of 35,000 football fields. He also stated that "the risk assessment performed by Dr. Sawyer does not conform to a standard CERCLA risk assessment, however his assessment does not support Carr's radical remediation program. Carr did not select his cleanup values based upon a risk evaluation. Carr sought out two extremely low values for his cleanup numbers which do not appropriately address the potential for exposure throughout the areas of concern. Therefore, the risk associated with the dioxin measured in the environment has not been evaluated." *Id.* at 10-13.

Mr. Forrester's supplemental report on the Class Representatives' serum samples was issued in January 2011. (dkt. no. 3190). He reviewed serum data received from Axys Analytical Services, Ltd., from eight Class representatives. Based on that review he opined that:

> Opinion 1: Based on new serum data in the Axys Analytical Services, Ltd., Report dated January 7, 2011, the eight Class Representatives serum levels for dioxins and furans are well within background serum levels thus confirming earlier results and that Carr's remediation program is necessary.
>
> Opinion 2: The new serum data referenced in Opinion 1 also supports my previous opinion that there have been no significant releases of 2, 3, 7, 8-TCDD to the community from the 2, 4, 5-T process.

Id. at 6-7.[173]

3. The Defendants' Evidence on the Plaintiffs' Exposure: Donald G. Patterson, JR., Ph. D.

Donald G. Patterson, Jr., Ph. D., was also offered as an expert witness for the Defendants.[174] His *Amended Report, Summary of Opinions Regarding the Claims of Bibb et al. v. Monsanto et al.*, is dated January 17, 2011. (dkt. no. 1793) . His resume states that he was a member of the Senior Biomedical Research Service in the Organic Analytical Toxicology Branch for the National Center for Environmental Health at the Centers for Disease Control and Prevention (CDC). He has authored or co-authored 383 papers and 15 book chapters in the area of human exposure to environmental chemicals.[175] He was offered to answer the opinions of Dr. Sawyer and Dr. Abraham Brouwer.[176] He explained his role as

> [T]o review the levels of polychlorinated-dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) and how they were measured as biomarkers in the blood of the Plaintiffs and community residents. This assessment will include a comparison of the levels measured to levels calculated by Plaintiff's expert using an exposure modelling approach. This

[173] The Court cannot find that Mr. Forrester's deposition(s) were filed in the record.
[174] Dr. Patterson has a Ph. D., from Arizona State University in Chemistry, Organic Chemistry and a B. A., in Chemistry, Biochemistry from the University of Northern Colorado.
[175] *See* Dr. Patterson's C.V., attached to this report as Appendix A.
[176] Dr. Brouwer was offered by the Plaintiff on the sole issue of CALUX testing.

> review will involve assessing the levels as they relate to the suitability of the test and to normal background exposures that all persons in industrialized societies experience. This review will also include assessing the validity of the use of the U. S. National Reference Ranges used as a comparison population as well as other issues set forth later in this document.

Id. at 1.

He reviewed a list of documents that he examined, primarily consisting of data, materials submitted by Richard A. Parent, and items relating to Drs. Sawyers and Brouwer.[177] He also reviewed various references.

His previous experiences included epidemiologic health assessment studies of Agent Orange exposure in Vietnam Veterans ground troops; U. S. Air Force *Operation Ranch Hand* Vietnam Veterans; Times Beach, Missouri; and Seveso, Italy, dioxin exposures. Dr. Patterson stated that he:

> [P]ublished the two most recent articles (Patterson, et. al., 2008, 2009) from the U. S. Centers for Disease Control and Prevention (CDC) establishing the U. S. Population reference ranges for persistent organic pollutants (POP's) such as pesticides polychlorinated dibenzo-p-dioxins (PCDD's), polychlorinated dibenzofurans (PCDF's) and polychlorinated bipheryls (PCB's). These studies establish U. S. reference ranges for these POP's that are a statistically valid representative sampling of the U. S. Population. These reference ranges are described by geometric means and percentiles and are categorized by age, sex, and race/ethnicity. The samples for the U. S. reference ranges were collected as part of the National Health and Nutrition Examination Survey (NHANES), which is administered by the CDC's National Center for Health Statistics (NCHS).

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[177] Mr. Urban submitted a letter from Dr. Parent in support of the former's *Supplemental Memorandum of the Urban and Falk Plaintiffs in opposition/Objection to Proponent's Proposed Settlement of the Property and Medical Monitoring Classes' Claims* (dkt. no. 3133). Dr. Parent holds a Ph. D. from Rutgers University, an M. S. from Northwestern University, and a B. S. from the University of Massachusetts. His letter supported the criticism made by James Dahlgren, M.D. of the proposed medical monitoring settlement. He stated that he was involved in the early stages of the investigation, but had not been involved in recent years. His letter did not reference any of his earlier activity in this matter. He believes the settlement to be "very beneficial to Mr. Calwell but of very limited value to the exposed population." *Id.* at 4.

Id. at 3.

Dr. Patterson's executive summary of his opinions states that:

- The named plaintiffs and community residents' PCDD and PCDF individual congener concentrations are within the normal range of the U. S. population.

- The named plaintiffs and community residents' TEQ concentrations are within the normal range of the U. S. population.

- Documented workers at the Monsanto Nitro plant have elevated 2, 3, 7, 8-TCDD levels in their blood.

- The pattern of PCDD and PCDF congeners in the blood of named plaintiffs and community residents is the normal pattern of the U. S. population.

- The ratio of key dioxin congeners in named plaintiffs and community residents is within the normal range for the U. S. population. Documented workers at the Monsanto plant have dioxin ratios higher than the normal range for the U. S. population.

- There is no pattern of "Monsanto" exposure in the blood of the named plaintiffs and community residents.

- Modelling by Dr. Sawyer of Body Burden levels for Residents in the Class Area Produces Unrealistic Estimates.

- It is not possible to identify the source of the PCDDs and PCDFs in the plaintiffs' or community resident's blood with the exception of 2, 3, 7, 8-TCDD in the documented plant workers. The PCDDs and PCDFs found in the plaintiffs' and community residents' blood did not come from the Monsanto plant, but are from the same sources as in average Americans.

- Back extrapolation of PCDD levels and PCDF levels is not warranted . . . when levels are within the normal range of the U. S. Population.

- The CALUX Bioassay was never intended to be used as a quantitative tool in human risk assessment.

Id. at 3-4.

Dr. Patterson's opinions were based upon the reported levels of PCDDs and PCDFs in the Plaintiffs' and community residents' blood contained in a letter from Richard A. Parent dated November 27, 2006 summarizing blood data from Axys Analytical Services.[178] He stated that the method most used as of the date of his report for detection and quantification is a high-resolution mass spectrometer that can separate compounds based on their mass. He believed this to be critical because of the presence of a large group of compounds not related to the operation of the Monsanto facility which are found everywhere in the environment, food supply, and blood of the U. S. population. He listed these compounds on pages 5 and 6 of his Amended report. He referenced to the congener specific methods for dioxin congener analysis as "the gold standard of environmental dioxin measurements." (*Id.* at 6).

He explained the development of testing for dioxins, first in fat tissue, then in serum. He also referenced studies which documented that measuring dioxin levels in environmental media and then using these levels to model the dose levels for human exposure assessment (external dose) does not work well. The trend is to measure the actual chemical in human tissue or blood (internal) to provide the best dose measurement for human exposure. In this regard, he observed that Dr. Sawyer's position on the importance of the current levels of PCDDs and PCDFs in the blood of the Plaintiffs and community members had changed during this case. *Id.* at 6. He explained the concepts of TEF and TEQ, then stated that he would be comparing the

[178] This letter was not included in his report.

plaintiff/community data to that contained in data obtained from NHANES. *Id.* at 7. *See* IV. B, *supra*, for a discussion of NHANES.

Dr. Patterson plotted the various congeners for the named plaintiffs along with the median and upper 95% confidence interval of the 95th percentile for each congener from the U. S. National population ranges for 2003-2004. He disagreed with Dr. Sawyer's assessment that the "Monsanto congeners" were statistically significantly elevated for the vast majority of the plaintiffs tested. He believed that the "Monsanto congeners" were well within the normal range for the U. S. population, and he depicted this opinion on several attachments. *Id.* at 7-8. He also conducted the same analysis for community residents' congener levels, and for the PCDD/PCDF levels of both Plaintiffs and Community Residents' PCDD/PCDF TEQ levels, reaching the same conclusions. *Id.* at 8.

He found that four community residents who had documented work experience at the Monsanto Nitro plant had elevated 2,3, 7, 8 TCDD levels above the 95th percentile for the U. S. population. However, one of the four plant workers has only a slight elevation of 2, 3, 7, 8-TCDD. Three of the four plant workers have no other congeners elevated above the 95th percentile while one of the four had other congeners slightly higher than the 95th percentile. These results are consistent with the Monsanto Nitro facility producing 2, 4, 5-T with a by-product of mainly 2, 3, 7, 8-TCDD. He found three of the four workers had TEQ levels above the 95th percentile, primarily due to elevated 2, 3, 7, 8-TCDD. *Id.* at 8-9.

Dr. Patterson disagreed with Dr. Sawyer's conclusion that certain residents of Nitro, West Virginia were exposed to large amount of PCDDs and PCDFs over a long period of time from the Nitro plant. He stated that while several workers did have high levels of 2, 3, 7, 8-TCDD, which is consistent with 2, 4, 5-T manufacturing at the plant, the other community

residents were well within normal background levels of PCDDs and PCDFs. He also stated that all of the named plaintiffs and community residents were within the range of the U. S. reference range ratio for 2, 3, 7, 8-TCDD and 1, 2, 3, 7, 8-PeCDD. He concluded this section by stating that "if there had been some past high exposure in these individuals to the process at the Monsanto plant, these ratios would be abnormal as is the case for the four Monsanto plant workers who were all above the range for the U. S. population." *Id.* at 9. He also concluded that the pattern of PCDD and PCDF congeners in the blood of the named plaintiffs and community residents matched the pattern of these congeners in the normal U. S. population. The Monsanto plant workers also matched the U. S. background levels with the exception of 2, 3, 7, 8-TCDD, and in one worker small deviations in three other congeners. *Id.* at 9.

Dr. Patterson stated that back extrapolation of Human serum levels for risk assessment would also require that the reference range levels also be extrapolated since both represent normal background levels. Before back extrapolation was done for risk assessment purposes, there would have to be a demonstrated exposure that led to an actual abnormal dose. He concluded that the current normal PCDD and PCDF congener levels in the blood of the plaintiffs and community residents demonstrate that there is no massive ongoing exposure to PCDDs and PCDFs in dust and soil, so extrapolating dust ingestion levels is not valid. If there had been large exposure in the past the ratio between 2, 3, 7, 8-TCDD and 1, 2, 3, 7, 8-PeCDD would still be outside the normal range. *Id.* at 9-10.

He also criticized Dr. Sawyer's use of dust and historical ambient air modeling data to calculate daily dioxin TEQ doses for Kanawha Valley, West Virginia residents of various age groups and residence times within the Class area. He again stated that the best method to assess exposure to dioxin would be to measure the actual chemical in the body (internal dose) rather

than calculating a dose based on the environmental measurement and modeling (external dose), which he believed does not produce reliable body burden estimates. He compared the results of Dr. Sawyer's modeling method showing inhalation doses of 0.000020 ug TEQ/m^3 to the maximal class air level of 0.009 ug TEQ/m^3 with the measured blood levels in the six named plaintiffs and additional community residents. The calculated inhalation body burdens of residents from 1948 through 1968 were decreased over a period of four half-lives, using Dr. Sawyer's half-life value. He concluded that not only were all of the community residents within the normal U. S. population TEQ levels but none of the levels were within the range of high TEQ levels predicted by Dr. Sawyer's modeling approach: "These results demonstrate the exaggerated estimates produced by Dr. Sawyer's modelling approach." *Id.* at 10.

Finally, as to the usefulness of the CALUX Bioassay, Dr. Patterson believed it was designed to be a screening tool and was never intended to be used as a quantitative tool in human risk assessment studies. It responds to many other chemicals not associated with the Nitro Monsanto plant. He cited a USEPA study which demonstrated that the results of CALUX were biased high by an average of 514%, which he categorized as "clearly unacceptable for environmental measurements related to human exposure assessment. *Id.* at 11. He noted that the EPA study measured the PCDD/PCDF TEQ by CALUX and GC-HRMS TEQ methods. This was done with soil, sediments and extract samples. The comparison showed "that there are some samples with high differences in the PCDD/PCDF TEQ levels." *Id.* at 11. He reserved the right to amend his conclusions upon receipt of IME results for eight named plaintiffs, six of whom were previously measured. *Id.* at 12. 38 figures were attached which graphically demonstrated Dr. Patterson's opinions.

Dr. Patterson filed a supplemental report bearing the same date. *Supplemental Report. Summary of Opinions regarding the Class' of Bibb v. Monsanto, et. al.,* (dkt. no. 1793). This dealt with the blood sample results obtained from the eight class representatives, six of whom had already been measured. He provided an executive summary of the opinions reflected in his supplemental report. These included Opinions 1 through 6 and Opinions 8 and 9 from his Amended Report. They did not include Opinions 7 and 10. He added another opinion, specifically that "[T]he named plaintiffs and community residents' PCDD and PCDF levels are considerably lower than the levels reported in exposure studies in the scientific literature and within the background levels used as controls in these studies." *Id.* at 4.

He again stated that the high resolution gas chromatography – high resolution mass spectrometry used to evaluate the samples was the "detector of choice" and was "the gold standard of environmental dioxin measurements". He used the same set of NHANES data for comparison. He made the same comparisons for the plaintiffs' individual PCDD and PCDF congeners for the 2004 and 2010 data, and found that one of the plaintiffs had a 2, 3, 7, 8 TCDD level above the 95th percentile for her age. All of the other PCDDs and PCDFs were within the normal range of the U. S. population, which indicates that these persons obtained the dioxin from their food consumption. *Id.* at 5-7. He also noted that six (6) of the eight (8) plaintiffs had been tested in 2004 and 2010: "nearly all of the congener measurements are lower in 2010 as compared to 2004 . . . these results demonstrate that there is no significant on-going exposure to PCDDs and PCDFs in the area inhabited by the plaintiffs." *Id.* at 6-7.

He also plotted the plaintiffs' PCDD/PCDF TEQ levels as before. All were within the normal range of TEQ for the U. S. population. Of the six named plaintiffs who were tested in 2004 and 2010, three showed decreases in TEQ, two showed slight increases in TEQ and one

stayed nearly the same. He again concluded that there is no on-going significant exposure to PCDDs and PCDFs in the areas inhabited by the plaintiffs. *Id.* at 7. He also found that the levels of PCDDs and PCDFs in the bodies of the named plaintiffs are within and remain within the normal background levels of PCDDs and PCDFs in the U. S. population, with the one exception who is above the 95th percentile for the U. S. population for 2, 3, 7, 8-TCDD. All of her other congeners and TEQ are within the normal range for the U. S. population. *Id.*

As mentioned in his previous report, several documented workers at the Monsanto plant have higher levels of 2, 3, 7, 8-TCDD, which is consistent with the 2, 4, 5-T manufacturing process at the plant. All of the named plaintiffs, with one exception, have 2, 3, 7, 8-TCDD and 1, 2, 3, 7, 8-PeCDD ratios within the normal range for the U. S. population. *Id.* at 7. Dr. Patterson repeated his assertions that it was not possible to identify the source of the PCDDs and PCDFs in the plaintiff's blood. He also maintained his opinion that back extrapolating was not indicated. *Id.* at 8.

In a new section, Dr. Patterson compared the PCDD and PCDF levels with those found in other studies, specifically the Marshall University Medical Center Study, the Seveso, Italy Study, and other studies, including that of U. S. Air Force *Operation Ranch Hand* Vietnam Veteran Agent Orange herbicide sprayers. He did not plot the plaintiffs against the Marshall findings, but did against Seveso, Italy. He stated that "the 2, 3, 7, 8-TCDD levels in the plaintiffs and in the community residents are all within the background levels measured in zone-non ABR, and considerably lower than the levels measured in individuals residing in the various contaminated zones . . . The levels in the named plaintiffs are also compared to the background levels at various times over the years from the Seveso study . . . the named plaintiffs' 2, 3, 7, 8-TCDD

levels and the community residents' 2, 3, 7, 8-TCDD levels are similar to the median background levels in the Seveso study control non-ABR zone . . ." *Id.* at 9.[179]

Finally, as to the other studies, the named plaintiffs and community workers levels were considerably lower than those reported in those studies. *Id.* at 9-10. Dr. Patterson again included a series of attachments to demonstrate his conclusions.

4. The Defendants Contest the Plaintiffs Evidence as to the Source of 2,3,7,8-TCDD in Nitro and its Effect on Humans

a. George Maldonado, Ph.D.

George Maldonado, Ph. D., was offered as an expert by the Defendant on the issue of "does exposure to 2, 3, 7, 8 tetrachloradebenzo-p-dioxin (2, 3, 7, 8-TCDD) cause health effects in humans?"[180] His opinions are contained in a report titled *"2, 3, 7, 8-TCDD* and *Human Health,"* dated January 6, 2011. (dkt no. 1786). He stated that, unlike the International Agency for Research on Cancer (IARC), he was focusing his efforts on determining the health effects of 2, 3 7, 8-TCDD, and not those of higher chlorinated PCDDs. He also chose a different approach from the Institute of Medicine (IOM) in that the IOM did not limit their evaluation to the health effects of 2, 3, 7, 8-TCDD (they considered exposure to TCDD or herbicides sprayed in Vietnam), and they were charged by Congress with evaluating the scientific evidence for associations, not causal relations. *Id.* at 2.

He stated that the plaintiff's experts cited studies that did not meet the criteria of being human epidemiological studies with high and documented exposure to 2, 3, 7, 8 TCDD. He

[179] The Zone-non-ABR was a control zone established away from the Seveso accident site.
[180] Dr. Maldonado holds a Ph. D., in Epidemiology from UCLA, and was a member of the faculty at the University of Minnesota School of Public Health.

concentrated on those studies that focused on those areas. His conclusion, "based on an in-depth review of studies of human populations with high exposure to 2, 3, 7, 8 TCDD . . . is that (with the exception of chloracne) no health outcome has been established with a reasonable degree of certainty as being casually related to high exposure to 2, 3, 7, 8 TCDD." *Id.* at 3.

Dr. Maldonado explained his theory of counterfactualism as the tool by which he studied the cause and effect relationship between 2, 3, 7, 8 TCDD exposure and health effects. *Id.* at 6-20.[181] He reviewed certain studies which he believed were appropriate to this situation, which are listed on page 21 of his report. He also compared his analysis of these reports with that made by Dr. Carpenter. *Id.* at 22-56. After all of this analysis, he reached the conclusion stated above, adding "a plausible explanation for the few observed elevated relative risks reported in the studies reviewed above is a combination of random error and error due to study imperfection." *Id.* at 56.

Lastly, Dr. Maldonado examined "Other Studies cited by Plaintiff's Experts" *Id.* at 57-76. He described them as falling into several broad categories which did not meet his criteria of being human epidemiological studies with high and documented exposure to 2, 3, 7, 8-TCDD, specifically; he did not discuss any reports which dealt with non-human studies, or studies of exposure other than 2, 3, 7, 8-TCDD, or studies in which it was unclear if subjects were exposed to 2, 3, 7, 8-TCDD. He discussed human studies of 2, 3, 7, 8-TCDD which he placed into three sub-categories:

- Studies that examined the outcome of total cancer or one of the other outcomes that IOM (2009) categorized as "sufficient

[181] Dr. Maldonado explains counterfactual reasoning as allowing "for a clear and precise definition of casual-effect measure for human health studies, and consequently allowed us to understand quantitatively the combined impact on study results of imperfections in the design and conduct of epidemiologic studies." *Id* at 6.

evidence of an association" with herbicides used in Vietnam (2, 4-D, 2, 4, 5-T, TCDD, cacodylic acid and picloram).

- Studies that examined one of the outcomes that IOM (2009) categorized as "limited or suggestive evidence of an association" with herbicides used in Vietnam (2, 4-D, 2, 4, 5-T, TCDD, cacodylic acid and picloram).

- Studies that examined outcomes that IOM (2009) did not categorize as having "sufficient evidence of an association" or "limited or suggestive evidence of an association" with herbicides used in Vietnam (2, 4-D, 2, 4, 5-T, TCDD, cacodylic acid and picloram).

Id. at 57.

These reports were primarily presented by Drs. Carpenter and Sawyer. *Id.* at 57-78. At the conclusion, he summarized his findings of his review of the Plaintiff's expert's materials as:

- Some of the additional studies cited by the plaintiff's experts did not examine specifically the effect of 2, 3, 7, 8-TCDD or studied exposures other than 2, 3, 7, 8-TCDD (e.g. PCB's) and therefore they do not address the causal question I am answering in this report.

- Several of the studies cited by the Plaintiff's experts were very cautious in their conclusions, in my opinion lending little support to the plaintiff's experts (citations omitted).

- Several of the studies cited by the plaintiff's experts concluded that 2, 3, 7, 8-TCDD did not have an important effect on health, apparently contradicting the Plaintiff's experts (citation omitted).

Id. at 79.

His final conclusion was:

> Review of the additional studies cited by the Plaintiff's experts does not change my conclusion that was based on a review of studies of human populations with high exposure to 2, 3, 7, 8-TCDD. My final conclusion is as follows: (With the exception of chloracne) no health outcome has been established with a

> reasonable degree of certainty as being causally related to high exposure to 2, 3, 7, 8-TCDD. A plausible explanation for the few observed elevated relative risks is a combination of random error and error due to study imperfections.

Id. at 79-80.[182]

b. James C. Lamb, IV, Ph.D.

James C. Lamb, IV, Ph. D. was offered as an expert witness by the defense on the toxic effect of 2, 3, 7, 8 TCDD on humans. *Expert Witness Report of James C. Lamb, IV, Ph. D., DABT, Fellow ATS in Zina G. Bibb, et. al. v. Monsanto Company, et. al.*, January 3, 2011. (dkt no. 1761) . Dr. Lamb had work experience at the USEPA and the National Toxicology Program. He has published more than 100 book chapters and papers in peer-reviewed journals.[183] *Id.* at 2.

Dr. Lamb discussed general principles of toxicology and risk assessment. He defined toxicity as "the potential of a substance to cause adverse health effects'." He said that "'adverse' is generally defined as a finding that causes an overt change in the test subject's health, or ability to function or reproduce." *Id.* at 2. He specifically stated that the identification of biomarkers is indicative of exposure, but does not necessarily portend that adverse health effects will result." *Id.* at 3. He described the potential toxicity of a chemical as dependent upon both its structure and activity. The route of exposure is a factor. Exposure and toxicity data from one route of exposure may not be directly relevant to another route of exposure. He believed that the differences between animal and human species make it impossible to predict the response in humans merely by evaluating animal toxicity data alone. *Id.*

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[182] Apparently, only 12 pages of Dr. Maldonado's deposition testimony can be found in the record.

[183] Dr. Lamb's CV was not filed with his report in the Court file, and so there is no information available about his education.

Dr. Lamb stated that risk is a factor of toxicity, exposure and dose. He opined that exposure is not equivalent to dose in that exposure is the potential contact with a chemical, while dose is the amount of a chemical that enters and is absorbed into the body. He believed that "the dose determines the poison." *Id.* at 4. He concluded this section by stating that experimental data from animal studies provides support for biological plausibility, but cannot substitute for human data. The latter is necessary to establish causation. *Id.* at 4.

He then described the regulatory and legislative background, noting that regulatory agencies have a mandate to protect public health. Regulatory levels for compounds that are present in the environment to which people may be exposed have a large margin of safety. These agencies err on the side of caution. He noted that risk assessment is one of the methods for establishing regulatory levels and is conservative by design. He opined that "risk assessments rely on conservative exposure assumptions and conservative toxicity factors to derive concentrations of compounds to which individuals can be exposed without risk of adverse effects. Exposure assumptions and toxicity factors are multiplied together further compounding the conservative nature of the risk estimate. "Exceeding regulatory levels does not mean that adverse health effects will occur; nor can these levels be used to predict the potential increase risk from an exposure for a particular effect." *Id.* at 4. He stated that the initial EPA risk assessments for TCDD issued in 1985 have been criticized, and that substantial revisions have been suggested by the National Academy of Science (NAS). He also described the work of the NAS (IOM) on the Congressional mandate to the Department of Veterans Affairs to evaluate the "associations between specific health outcomes and exposure to TCDD and other chemical compounds in herbicides." *Id.* at 5. The Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides was formed by the NAS (IOM). At this point "the IOM has

determined that there is sufficient evidence for a positive association for only the following diseases: soft-tissue sarcoma, Non-Hodgkin's lymphoma (NHL), Hodgkin's disease, chronic lymphocytic leukemia (CLL), and chloracne." These do not represent casual associations. *Id.* at 5.

Dr. Lamb discussed how dioxin works in the body, binding to the aryl-hydrocarbon receptor (AhR). *Id.* at 6. He then described the path to other parts of the system, noting that "TCDD binding affinity for human AhR is approximately 10-fold lower than that of most experimented animal species." *Id.* at 7. He continued this review, further noting that "humans appear to be among the least sensitive to TCDD exposure compared to experimental animal species . . ." *Id.* at 9.

He also reiterated Dr. Thomas Starr's criticism of the EPA's use of the linear model as the default approach to derive regulatory limits for carcinogenic risk assessment. "This linear model approach results in any dose, no matter how small, being associated with some level of predicted toxicity. While this type of approach is conservative and protective of public health, it is not appropriate where mechanistic and dose-response data are available that demonstrate a threshold. In the case of dioxin, EPA utilized a linear model for the derivation of the cancer slope data available on the mode of action for TCDD (citations omitted)." *Id.* at 10.

He stated that the NAS did not support the use of a linear model in its review of the EPA's 2003 "Reassessment of Dioxin." It cited four factors to support its position that there was sufficient evidence available to support a threshold for TCDD-induced carcinogenicity. It recommended that the EPA reconsider the use of a non-linear model. *Id.* at 10-11. The NAS recently noted that the failure to include both a linear and a non-linear model was not consistent with EPA's own cancer risk assessment guidelines. *Id.* at 11. The EPA's conservative approach

that TCDD should be regulated as though it does not have a threshold is contrary to that of the World Health Organization (WHO) and the Scientific Committee on Food in the European Commission. *Id.* at 11.

Even though non-cancer effects are also thought to be related to the AhR, the default regulatory approach for non-carcinogens incorporates a threshold. He concluded that the scientific consensus is that TCDD effects, including cancer and non-cancer responses, are induced in a threshold manner such that adverse effects will not occur below a certain dose. *Id.* at 12.

Dr. Lamb concluded his report by reviewing the adverse effects claimed by the plaintiff's experts against his review of the data. He believed that chloracne is the only well-established adverse effect associated with TCDD exposure in humans. *Id.* at 13. In his opinion, liver toxicity is a hallmark of TCDD-indirect effects in experimental animals, for which a threshold exists. However, he did not believe that liver toxicity had been demonstrated in humans. *Id.* As to the other areas surveyed-Genotoxicity and carcinogenesis, reproduction and developmental toxicity, immunotoxicity, diabetes and cardiovascular disease – his opinions were that either the weight-of-evidence did not support the finding, or that there was a lack of clinically significant findings, or that the data was limited for demonstrating an association. *Id.* at 13-22.

5. The Defendants Offer Evidence Challenging Dr. Sawyer's Dose Group Opinions: Thomas B. Starr, Ph. D.

Thomas B. Starr, Ph. D., was offered as a defense expert to counter the opinions of Dr. Sawyer on the issue of the latter's dose groups.[184] His opinions are contained in a document entitled *"Expert Report of Thomas B. Starr, Ph. D. in the matter of Bibb v. Monsanto,"* January 7, 2011, (dkt. no.2140). He has worked in the field of quantitative risk assessment: "I have aimed consistently at effective incorporation of knowledge of toxic materials into the quantitative risk assessment process, and improving epidemiological methods for assessing adverse effects of chemicals on human health." *Id.* at 3. He stated that he had considerable professional experience directly related to dioxin-like compounds. *Id.*

His report focused principally on Dr. Sawyer's Human health risk assessment for residency (1948 – Present) (Sawyer 2010)

> [B]ecause this assessment was utilized to define the class for this case and to support the claim that future medical monitoring of class member for dioxin-related disease is warranted. Dr. Sawyer's assessment concludes that the cancer risk for all class members with residency, employment, or who attended Nitro schools for certain time period within a defined geographical boundary that he identified as the '0.000020 ug/m^3 TEQ isopleth' are characterized as being at excessive risk', i.e. subject to an increase in their lifetime cancer risk of at least 1.2 x 10^{-5}. Dr. Sawyer has stated (1) that his cancer risks estimates were calculated following 'generally accepted USEPA methodologies' and (2) that he selected input data in such a way that his resulting risk estimates were certain to underestimate the 'true risk', and (3) that these estimates provide only an 'absolute minimum floor of risk' for class members.

Id. at 1.

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[184] Dr. Starr holds a Ph. D., and an M. S. from the University of Wisconsin-Madison, and a B. A. from Hamilton College.

Dr. Starr began by reviewing Dr. Sawyer's risk assessment methodology. He noted that it had four basic components:

> 1. estimated environmental concentrations of dioxin-like compounds, either airborne or household dust, expressed in terms of dioxin TEQ;
>
> 2. "exposure factors", either inhalation rates or dust ingestion factors, adjusted by estimated body weight of the affected class members;
>
> 3. a cancer potency factor, exposure durations, representing the number of years spent within the defined geographic class boundary during the period 1948-1969 and/or 1969 to the present;
>
> 4. expressed as lifetime cancer risk per lifetime average pg dioxin TEQ intake per kg body weight per day.

Id.

Dr. Starr noted that "[T]he estimated environmental concentrations of dioxin-like compounds (DLC's) only represent 'opportunities' for exposure to DLC's, in the sense that individuals must be present at a site with a given airborne or dust concentration of DLC's, and they must also inhale the air or ingest the dust at that site at the rates specified by the exposure factors in order to actually be exposed." *Id.* at 4.

Dr. Sawyer calculated the amount of dioxin TEQ that each member took into their body per kilogram per day. The estimated daily intake was then multiplied by the ratio of the exposure duration (in years) to obtain the estimated intake over 70 years. This figure was then multiplied by the cancer potency factor to produce an estimate of a class member's lifetime cancer risk. By this means, Dr. Sawyer created his nine (9) risk groups. Five of these were based on inhalation only from 1948 to 1968; two were based on household dust ingestion, post

1968, and two were a combination of inhalation exposure from 1948 to 1968, and household dust ingestion, post 1968.

Dr. Starr then described Dr. Sawyer's reliance on Mr. Auberle and Dr. Flowers to provide the air concentration and living quarter dust measurements, and how they related to these groups. He pointed out that Dr. Sawyer interpreted the 0.000020 ug TCDD/m^3 concentration isopleth as a 0.000020 ug/TEQ/m^3 isopleth. This was important, because Dr. Starr believed that the DLC's coming from Monsanto for 2, 4, 5-T products would be virtually exclusively 2, 3, 7, 8-TCDD as observed from Ranch Hand Veterans, while the congener profile of soil and dust samples taken at the Nitro schools and community center was dominated by different congeners typical of general background exposures. This led Dr. Starr to question the actual source of the DLC's found in the soil and house dust.

Dr. Starr also questioned the methodology used by Dr. Sawyer in placing the dust readings in tiers in his determination that there is a "statistically significant" inverse correlation between the amount of dioxin found in the 58 samples of attic dust taken from homes and their distance from Monsanto. He believed that this completely masked the substantial within tier variation present in both TEQ levels and distances from the "primary emissions source." He believed that "in short, by hiding variation in both TEQ in the original dust samples and distance, Dr. Sawyer has greatly exaggerated the statistical significance of his estimated relationship between other dust TEQ and distance from the 'Monsanto primary emission source'." *Id.* at 5. He had other criticism of Dr. Sawyer's opinion, specifically focusing on his failure to consider measured blood concentrations for DLC's of the individual class members, and instead assuming that the standard exposure factors that he used applied uniformly to every Nitro Class member. *Id.* at 6.

Dr. Starr focused the balance of his report on Dr. Sawyer's use of "an entirely inappropriate linear no-threshold approach to estimate cancer risk that relied on a constant (dose-independent) upper band cancer potency estimate for DLC's of (130,000 per mg/kg-day)" *Id.* at 6. He traced the history of the USEPA's Carcinogen Risk Assessment practice from 1985 to 2010. In 1985 the USEPA released a Health Assessment for polychlorinated dibenzo-p-dioxins, which included a quantitative risk assessment of their potential human carcinogenic effect. This assessment has developed since its release. Updated guidelines for carcinogenic risk assessment were issued in 2005. *Id.* at 6.

> These new guidelines give risk assessors the additional flexibility that is necessary to reflect, as accurately as possible, whatever is known about the mechanisms by which chemicals cause toxicity, including cancer. As a result, the quantitative risk assessments, and related regulatory screening, guidance, and/or soil cleanup levels that result from application of the newly available risk assessment option can differ from one another, and from those that would be obtained with the earlier, simpler methodologies, by many orders of magnitude.

Id. at 6.

Dr. Starr stated that since 1983, the paradigm outlined in the National Academy of Sciences' "Red Book" has dictated the USEPA's risk assessment process for chemical carcinogens. This paradigm draws a clear distinction between risk assessment and risk management. Risk assessment contains four steps: Hazard Identification, Dose-Response Assessment, Exposure Assessment, and Risk Characterization. He explained the content of each of these steps. *Id.* at 6-7. Dr. Starr discussed the USEPA Carcinogenic Risk Assessment of 1985, which resulted in the classification of a substance's carcinogenity into six weight-of-evidence categories. He described the assessment behind these categories and which ones were appropriate for quantitative Dose-Response assessments. This involved animal and human data.

He noted that "because it was a default assumption, that absent evidence to the contrary, humans could be as sensitive to the carcinogenity of a substance as the most sensitive animal species, the data set yielding the largest estimate of carcinogenic potency (risk per unit dose), invariably was given the greatest emphasis." *Id.* at 8. For these reasons, the preferred model was "the 'linearized multistage' model, i.e. a linear no-threshold (LNT) model, because it generally produced the largest estimates of risk as a direct consequence of its inherent linearity at low doses." *Id.* at 8-9. This became the default dose-response model unless there was sufficient data to rule it out. It produced positively biased estimates of risk at low doses. *Id.* at 9.

Further, the USEPA's choice of daily dose, averaged over a 2 year rodent and 70 year human lifetime, as the preferred dose metric for carcinogenic risk assessment, allowed low doses of a carcinogen, received over a long period of time, to be equivalent in potency to high doses received over short period of time. "There was thus no 'threshold' daily dose for carcinogens. Every exposure to carcinogen, no matter how small, was presumed to confer at least some increase in the risk of developing cancer." *Id.* at 9.

Dr. Starr then reviewed Carcinogenic Risk Assessment under the 2005 Guidelines. This has led to the use of alternative means to assess risk, one branch leading to conventional linear low-dose extrapolation, and the other to multiple non-linear, possible threshold-like alternative approaches. *Id.* at 10. The new USEPA carcinogenic risk assessment guidelines instruct that dose-response modeling be conducted to determine whether linear or non-linear risk extrapolation, or other methods be used. The focus should be on using linear extrapolation for direct-acting mutagenic carcinogens; extrapolation using appropriate non-linear dose responses for carcinogens with non-linear modes of action; or Reference Dose and Margin of Exposure computation for carcinogens that exhibit a threshold. *Id.* at 11.

Dr. Starr examined the history and debate over which of these models is appropriate for studying the effects of dioxin. The default method, the linear no-threshold dose-response approach, was used in the 1985 document. Since then, additional assessments have been conducted by various groups. These have raised concerns about the quantitative risk assessment approaches that USEPA has taken in its evolving reassessment of DLC's. Because there are uncertainties, assumptions have been made to fill the significant data gaps that exist regarding the true toxicity and carcinogenity of DLC's to humans. "The gap-fitting assumptions that USEPA has in its risk assessments of DLC's have been intentionally conservative, i.e. health protective, in order to guard against any understatement of potential human health risks." *Id.* at 12.

Dr. Starr also stated that "[T]he NAS (2006) expert panel review roundly criticized USEPA for its failure to fully characterize the actual uncertainty (and variability) in its risk assessment of DLC's because this failure creates and conveys a false sense of precision and accuracy in the resulting hypothetical risk estimates and inferences. It is important to note that this false sense of precision and accuracy carries over directly into the risk estimates that have been generated by Dr. Sawyer for the plaintiff's class." *Id.* at 12-13. He explained these developments, stating that

> [O]ver the past 20 years, more and more evidence has continued to accumulate indirectly that DLC's are neither DNA reactive nor mutagenic, and operate via a receptor-based mechanism of action. The LNT model is simply not appropriate for DLC's because it does not reflect this new evidence indicating that DLC – induced endpoints, including cancer, are expected to have non-linear dose responses, and may well exhibit thresholds, i.e. exposure levels below which the risk of toxicity, including cancer, is actually zero.

Id. at 13.

Dr. Starr concluded his report by citing studies that estimated that the average American background intake of dioxin from 1948 to 1968 was ten times greater than that used by Dr. Sawyer to define class membership. The studies showed that even background intake in this decade, which has decreased dramatically since the 1960's, would be larger than the intake rate used by Dr. Sawyer to define class membership (*Id.* at 14). "These observations lead inescapably to the conclusion that the general U. S. population would qualify for class membership and also be at 'significant' risk of developing cancer from their background exposure to dioxin-like compounds if Dr. Sawyer's calculations were accurate." *Id.* at 14.

6.The Defendants Attack the Core of the Plaintiffs' Case: Michael E. Ginevan, Ph. D.

The defense offered Michael E. Ginevan, Ph. D., as an expert witness in the field of biostatistics.[185] *Report of Michael Ginevan in the Matter of Zina G. Bibb, et. al. v. Monsanto Company, et. al.* (dkt. no. 2973). Dr. Ginevan had over 30 years experience in the application of statistics and computer modeling to problems in public health and the environment, and in the conduct of environmental, epidemiological exposure assessment and risk assessment studies.[186]

Dr. Ginevan reviewed the work of Drs. Bell and Sawyer, Mr. Flowers, Mr. Auberle, Dr. Wade, and Mr. Carr. He also reviewed the reports of Mr. Arrington, Dr. Smith, and Mr. Forrester. He reviewed a series of documents, included EPA and ATSDR documents on dioxin cleanup levels and remediation goals. *Id.* at 5-6.

Dr. Ginevan's executive summary presents the following key conclusions concerning the opinions of a number of plaintiff's experts:

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[185] Dr. Ginevan received a Ph. D., in Mathematical Biology from the University of Kansas, an M. S., in Zoology from the University of Massachusetts, and a B. S., in Biology from SUNY-Albany.

[186] The Court record contains limited excerpts from Dr. Ginevan's April 20, 2011 deposition.

1. The source term defined by Bell and subsequently used by Auberle, is much too large and is not supported by the results of plaintiff's environmental sampling.

2. The plaintiff sampling does not have an overall plan and ignores the results of the source characterization and air modeling effects.

3. The sampling plan also fails to replicate measurements so it is impossible to tell how much variation is due to differences among properties and how much is due to simple random variation.

4. Dust sampling uses a weight/weight parts per billion determination of toxic material for dust measurements rather than concentration per unit area. This is a major conceptual error.

5. The plaintiff's dust and soil sampling show that, despite their claims to the contrary, household dust dioxin contamination could not have come from the Monsanto facility.

6. Plaintiffs experts try to apply soil dioxin criteria to attic and household dust. This is incorrect.

7. Plaintiff experts rely on CALUX dioxin TEQ measurements that their own data shows is not a quantitative measure of TEQ.

8. Plaintiff experts attempt to characterize Nitro as a rural area which is clearly incorrect.

9. Plaintiffs attempt to characterize the Nitro area as pervasively contaminated despite the fact that none of their dioxin TEQ data exceeds applicable EPA standards.

10. Plaintiffs claim that the dioxin blood serum levels of Nitro residents are elevated, but my analysis shows that this is not true.

11. Plaintiffs present an extensive set of Principal Components Analyses (PCA's) which attempt to show that the dioxin Nitro come from the Monsanto facility.
    a. This analysis ignores major features of the data.
    b. It presents the results in a way which is both incomplete and misleading.

c. A more correct PCA shows that the plaintiff samples are in fact different in dioxin composition than samples from the Monsanto facility.

Id. at 5.

Dr. Ginevan analyzed each of these points. As to the source term, he pointed out that Dr. Bell estimated that 954 pounds of dioxin was burned in landfills, and that 477 pounds of dioxin was emitted to the air. He stated that the Seveso, Italy release of 80 pounds of dioxin caused 197 cases of chloracne in the population surrounding Seveso, but at Nitro, apart from employees at the facility, no cases of chloracne were seen in the surrounding area.

He noted that this estimate was then used by Mr. Auberle in his air modeling. Dr. Ginevan calculated that if 477 pounds of dioxin were burned, then the soil concentration in a circle ten miles in diameter should be over 6,000 ppt. in the top six inches of soil. He then looked at the actual soil samples taken by the plaintiff's experts from the Nitro area, which were 77.6 ppt for the 90 samples analyzed by GC/MS (maximum 910) and 18.9 ppt for the 77 samples analyzed by CALUX (maximum 137.25). This led him to conclude that Mr. Auberle's proposed amount of dioxin lost to the air was not credible. *Id.* at 6-7.

He then reviewed the data samples submitted by the Plaintiff. He explained the difference between GC/MS and CALUX. He noted that GC/MS broke down the dioxin found into the 17 specific dioxin/furan congeners, of which 2, 3, 7, 8 TCDD is one. CALUX, conversely, measures in a different way, measuring not congener-specific concentrations, but an estimate of the overall TEQ. *Id.* at 7-8.

He next looked at the appropriate methodology on how to properly sample soil and dust. He stated that "the message here is that the exact process of sampling is as important as the actual number and locations of samples taken." *Id.* at 9. He then reviewed the plaintiff's 342

samples analyzed for dioxin levels, noting that 176 were CALUX samples, which give only TEQ, and 166 are GC/MS samples, which give both TEQ and the concentration of 17 dioxin and furan congeners. *Id.* at 11. Dr. Ginevan opined that the CALUX dust and soil sample locations were broadly dispersed over the area. The CALUX dust samples were living area dust samples while the GC/MS dust samples were primarily from attics. The GC/MS soil samples were clustered near the Nitro facility, with a number immediately adjacent to the site boundary. He also believed that there was an oversampling of GC/MS attic dust near the Nitro facility. *Id.* at 12.

Focusing on soil sampling, Dr. Ginevan again noted that the set of soil samples using GC/MS were collected from areas predominantly near the plant. While the highest sample was 910 ppt, the average was only 77.6 ppt. None of the samples exceeded the EPA preliminary remediation goal for soil of 1000 ppt. Only 6 samples exceeded a TEQ of 500. 4 of the 6 samples were collected at the same location. *Id.* at 13. When these are subtracted out, the mean TEQ for the remaining 84 samples is 30 ppt. While the CALUX soil samples were much better dispersed, the maximum TEQ was only 137 ppt and the average was 19 ppt. Several of these samples were collected from the roadside if access to the property was not available. *Id.*

Having reviewed the soil samples, Dr. Ginevan next turned to the household dust sampling, beginning with attic dust samples. He leveled various criticisms at whether this sampling was appropriate. He then discussed the fact that the plaintiffs used dust from living areas in the last batch of samples. He stated that these samples are typically taken to assess how much external environmental contamination is entering dwellings. However, Dr. Ginevan stated that these samples demonstrated that there are current dioxin sources in Nitro that have nothing to do with Monsanto. *Id.* at 14.

Dr. Ginevan was critical of the sampling strategy. He noted that there was no obvious connection between the predictions of Dr. Bell and Mr. Auberle as to the probable emission sources and the dispersion model of dioxin, respectively. He believed that the sampling should have been performed to match the modeling predictions. He discussed other ways he would have designed the sampling plan. *Id.* at 14.

Dr. Ginevan argued that Nitro was an urban, and not a rural area. He also stated that the plaintiff's dust sampling was measured in ppt mass/mass and not picograms TEQ per square meter. He noted that both the household dust and attic measurements were lower than the soil measurements. He also believed that house dust concentrations should be substantially lower than attic dust concentrations, unless there are unidentified, contemporary sources of high dioxin concentration dust that are driving both house and attic dust concentrations. *Id.* at 15-16.

Next, Dr. Ginevan leveled specific criticisms of several statistical issues raised in the plaintiff's various statistical reports. *Id.* at 16-19. Among them was the trend in dioxin concentration with distance from the alleged contaminated sources. According to him, both Drs. Flowers and Sawyer present analyses that apparently show that dioxin levels in dust decline with distance from the alleged contaminated sources associated with the Nitro facility. Dr. Ginevan posed the question as "do the patterns of decline from the alleged Nitro sources actually exist in the data and if the trends do exist, are they consistent with contamination patterns that might be expected from the Monsanto Nitro facility." *Id.* at 18. He analyzed the data, concluding that "while there are trends in dioxin TEQ with distance from Nitro, these are not evidence of widespread contamination resulting from the Monsanto facility. Indeed, the fact that trends are seen even for CALUX house dust, which could not be driven by contamination from 40 years ago, suggests that the facility is not the source of the observed trends." *Id.* at 19.

He also took exception with Dr. Sawyer's risk analysis. He disagreed with Dr. Sawyer's assessment that the region would merit the definition of a "public health hazard" under the ATSDR. He disagreed with Dr. Sawyer's assertion that the *de minimis* benchmark level for cancer risk is 1×10^{-6}. Instead many regulatory standards are set with target risks of 10^{-5} or 10^{-4}. *Id.* at 20.

Dr. Ginevan then reviewed Mr. Carr's report on remediation. He criticized the fact that, in his opinion, Mr. Carr used a single point of contamination as an indicator that large areas needed remediation. He noted that Mr. Carr suggested that an area should be categorized as "extreme" for soil contamination, when it was about 40% of the current EPA PRG (preliminary remediation goal). In short, "none of the dioxin concentrations are truly high, so Carr's characterizations of high and extreme are an effort to create an impression not a statement of fact." Also, "one needs multiple measurement points in a fairly small area to result in meaningful concentration estimates. Carr does not have such data, and as noted . . . relies extensively on CALUX data which, as used at Nitro, appears to be at best semi-quantitative." *Id.* at 21. He stated that Mr. Carr's area maps were flawed because they depicted remediation zones that have no apparent factual basis. Although houses with "elevated" measurements were dispersed among houses with higher dust TEQ levels, his dust remediation zone contained a number of homes that did not require cleaning or demolition by his own criteria. *Id.* at 21. He stated that the soil zones suffered from the same problems. *Id.* at 22.

Dr. Ginevan also took issue with the blood samples. He compared data from two NHANES surveys at the 90^{th} percentile of dioxin blood levels with the 31 blood samples drawn and found that "the dioxin blood levels are unremarkable. That is, the plaintiff's claim ongoing elevated exposure to dioxins but blood levels do not reflect such exposure." *Id.* at 24. He did

not use the samples of the four (4) persons who worked on the Monsanto site, but used the other samples to make comparison with attic dust samples. *Id.* at 24-27. His conclusion was that "serum dioxin levels in residents who had not been Nitro employees are within background levels, there is not compositional similarity between congeners in blood and congeners in dust, and there is no evidence of a positive association between TEQ levels in blood and TEQ levels in dust." *Id.* at 27.

Dr. Ginevan discussed what levels of dioxin in soil actually argue for remediation efforts. He did a detailed review of the dioxin risks and standards asserted by the plaintiff's experts. He noted that Dr. Sawyer suggested a *de minimis* soil cleanup TEQ of 4.5 (USEPA) and 3.9 (W. Va.) ppt. Mr. Carr suggested remediation efforts that begin at 41 ppt TEQ for soil and 90 ppt TEQ for dust. He contrasted this with the ATSDR's 2008 position it its *Update to the ATSDR Policy Guidelines for Dioxin and Dioxin-like Compunds in Residential Soil* "that health risks associated with levels of dioxins in soil below 1 ppb (1,000 ppt) would be low under most scenarios where the primary exposure pathway is incidental ingestion through direct exposure to soil and further set 50 ppt as a threshold for health evaluations. Of this evaluation threshold, ATSDR says 'the comparison value is not a threshold for toxicity and should not be used to predict adverse health effects.'" *Id.* He noted that the EPA's 2009 *Draft Recommended Interim Preliminary Remediation Goals (PRG's) for Dioxin in Soil at CERCLA and RCRA Sites* suggested levels of 72 ppt for residential soil and 950 ppt for commercial/industrial soil. Although lower than the 1,000 current EPA PRG of 1,000 ppt, even these numbers would not indicate a need for soil remediation at Nitro. *Id.* Dr. Ginevan also stated that for soil investigation, the EPA's recent draft PRG calculation used a target risk of 1 in 100,000 and assumes exposure for 70 years at 350 days per year. *Id.* He stated that the EPA questioned the

decision of those States that adopted the screening value as a cleanup level. Dr. Ginevan concluded the section by stating that "soil criteria are simply not relevant to dust exposure and there are severe mass balance problems involved in claiming that the contemporary household dust came from the Nitro facility that closed 40 years ago." *Id.* at 29.

The final section of Dr. Ginevan's report dealt with the Principal Components Analysis (PCA) performed by Dr. Wade. He described what PCA is and how it was used by Dr. Wade to identify Monsanto as the source of the environmental contamination. *Id.* at 29-38. At the end of his analysis of Dr. Wade's opinion, he summarized his criticism in seven points found on page 38 of his report, concluding that Wade's analysis was not valid. *Id.* at 38. He performed an "Example PCA" to conclude his report on this area. *Id.* at 37-44.

At the end of his report, Dr. Ginevan set out his final opinions as to each expert:

> A. Dr. Bell begins by identifying dioxin releases that are absolutely enormous. He postulates an ongoing environmental catastrophe that has left no evidence of its existence. Thirty plus years of sampling and modeling experience in environmental problems tells me that this is simply impossible.
>
> B. Dr. (sic) Auberle uses Dr. Bell's source terms and ½ his mass emission as a basis for air modeling. Again this assumes a dioxin mass that is simply untenable.
>
> C. Bell's source term and Auberle's models were apparently ignored in planning environmental studies.
>
> D. The Plaintiff's sampling has manifold deficiencies and is not adequate to characterize contamination in the Nitro area.
>
> E. Dr. Flowers characterizes rural samples by taking an upper bound on the mean of rural samples and then argues that the Nitro soil samples are contaminated because they exceed the upper bound. In fact there is about a 30% overlap between the rural and Nitro samples which suggests that since Nitro is not really a rural area, concentrations are quite low.

F. Dr. Sawyer compares CALUX and GC/MS dioxin levels in 15 dust samples to show that they give almost the same level. In fact, the correlation between CALUX and GC/MS dioxin TEQ levels shows that CALUX is not a useful quantitative predictor of TEQ.

G. Dr. Sawyer also asserts that the dioxin compositions in blood and house dust are similar. My analysis shows that this is not the case.

H. Dr. Sawyer calculates elevated risk estimates by relying on the data from Auberle and by assuming that household dust is like soil. This ignores the fact that Auberle's estimates are grossly overstated and the evidence presented by the plaintiffs suggests that the household dust dioxin did not come from the Monsanto Nitro Facility.

I. Dr. Sawyer calls for medical monitoring for relative risks that are generally much less than 1.00025, which is contrary to any sound public health practice.

J. Dr. Sawyer also asserts that any risk in excess of 10^{-6} is considered "unsafe". This is clearly not true.

K. Carr makes sweeping conclusions from extremely limited data and in the process produces some maps which appear to contain errors. He also endorses such dubious positions as declaring that a house must be demolished on the basis of a single dust sample.

L. Dr. Wade's analysis attempts to use principal components analysis to show that the contamination must have come from Nitro, but makes numerous analytic errors that result in an analysis that is not consistent with a reasonable standard of professional care and is not a reliable basis for inferring the source(s) of contamination in the Nitro area.

Id. at 44

The plaintiff expert arguments are undermined by a wide range of quantitative mistakes and misrepresentations. For these reasons they cannot be taken as either accurate or reliable.[187]

7. The Defendants Present Evidence to Oppose the Plaintiffs' Medical Monitoring Program: Philip S. Guzelian, M.D.

The Defendants offered Philip S. Guzelian, M.D., as an expert witness on the suitability of medical monitoring as a remedy for the possible future health effects of exposure to chemicals in the environment. *Report of Dr. Philip S. Guzelian*, January 7, 2011. (dkt no.1847). Dr. Guzelian provided this report, and was deposed on April 7 and 8, 2011. The court record contains a "Declaration" from him filed on May 11, 2011. *Id.*[188] Additionally, there is a partial transcript of a deposition taken in this action on April 29, 2011, and filed on May 11, 2011. *Id.* Lastly, there is a transcript of a deposition taken of Dr. Guzelian in *Carter v. Monsanto* on September 7, 2007, and filed as Exhibit AA. *Id.*

Dr. Guzelian's deposition of September 7, 2007, though styled as taken in the *Carter* case, primarily involved Dr. Guzelian's contention that the *Bibb* action was not a proper subject for class certification. He testified that he was both a Medical Doctor, specializing in liver disease, and a biochemical toxicologist. *Id.* at 5-6. During his career he worked on the Times Beach case. *Id.* at 67-68. In that action, he concluded that there was no cause-and-effect relationship between the exposures to dioxin and the medical conditions at issue. *Id.* at 68.

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[187] Dr. Ginevan also presented his criticisms of Dr. Wade's principal component analysis in his *Affidavit in Support of Defendant's Motion in Limine to Exclude Testimony of Michael J. Wade, Ph. D.* dated November 5, 2010, (dkt no. 2973) and an *Affidavit Concerning Defendants Use of Serum Dioxin Levels, for a Total of 39 Blood Sample, as Evidence in the Matter of Zina G. Bibb, e. al. v. Monsanto Company, et al.* (dkt. no.2973).

[188] Dr. Guzelian obtained his M. D., degree from the University of Wisconsin at Madison, and served as Professor of Medicine and Pharmacology of the University of Colorado before his retirement in 2006.

Dr. Guzelian did not find the serum dioxin (TCDD) levels to be particularly unusual in the *Bibb* case. They and the serum TEQ levels were about what one finds as background levels, as compared to a situation he knew of in an occupational setting, where the amount of TCDD was very large relative to the TEQ. *Id.* at 94-95. He did not believe that this class should be treated homogeneously with regard to whether they should be medically monitored. *Id.* at 123. He agreed that soil samples taken from Nitro showed the presence of dioxin. *Id.* at 133. He supported the idea that there could be circumstances in which exposure-projected medical monitoring might be justified from a medical decision-making point of view. *Id.* at 143-144. Dr. Guzelian believed that an evidence-based threshold for the toxic effects of dioxin appeared to be one associated with a blood level in the range of 1,000 parts per trillion. *Id.* at 151. He did not believe that the medical monitoring claims of the named plaintiffs were medically typical of each other. *Id.* at 159-160. He examined the distances between the residences of some of the class representatives and the Monsanto plant. Some were close and some were far away. There was no relationship between the dose, as reflected by the blood level, and the distance from the plant. *Id.* at 162. Thus, there was not a homogenous relationship between the dioxin levels in people's bodies, and the decision about medical monitoring and the distance. *Id.* at 164. He stated that "there might be some people in that definition who should be monitored; there might be some who shouldn't; there might be some we can't tell. But it isn't going to be everybody. It's not going to be all. *Id.* at 170.

He agreed that dioxin is not a genetically produced molecule, so all the dioxin in the body is environmental, i.e. it is acquired from someplace. *Id.* at 173-174. There is a 40-fold range of dioxin in this case. *Id.* at 186. He also stated that when the VA recognized diseases as

associated with Agent Orange, it made the decision as a policy matter so that veterans would not have to prove individual causation. *Id.* at 195.

Dr. Guzelian's report dated January 7, 2011 contained his opinions as to the medical monitoring plan prepared by Dr. Werntz, *supra*. He acknowledged that health care preventive measures such as medical monitoring hold great intuitive appeal, but there are at least three criteria to guide the decision as to whether to submit one or thousands of patients, to supplemental medical testing, namely:

> 1. Early detection results in an improved outcome for the disease. (Benefit of early detection);
>
> 2. The test is accurate in the setting of medical monitoring, creating few false-negative or false-positive results. (Accuracy of early detection);
>
> 3. The prevalence (number of cases) of the latent disease in the particular groups to be monitored is high. (Likelihood of early detection).

Id. at 2-3

Further, in the specific context of exposure-prompted medical monitoring, which he believed the Plaintiffs were seeking, he opined that there were other criteria that should be met to justify medical monitoring:

> 1. It must be known that the chemical at the dose the person received can cause the disease to be tested for.
>
> 2. It must be known that the plaintiff was not only exposed to the chemical but also received from the exposure a sufficient dose of the chemical known to make causation of the disease a possibility.
>
> 3. The likelihood (i.e. expected frequency or "risk") that the chemical at the received dose will produce the disease must be known to be not just increased but increased high enough to make accurate medical testing of the class possible.

Id. at 3.

He had specific criticism of Dr. Werntz's failure, as he stated, to meet all of these criteria. At the conclusion of his summary, he stated that "it is impossible from the presented materials to conclude to a reasonable degree of medical and scientific certainty that the proposed medical monitoring program is necessary and appropriate." *Id.* at 4.

Dr. Guzelian stated that there are four indisputable steps to determine if a person may develop an injury or disease as the result of contact with a chemical substance in the environment:

1. Source – the chemical must have an origin.

2. Exposure – defined as physical contact with a chemical in the environment. The chemical must be released from its source in a form in which it is possible to reach a portal of entry into the human body. The key is not possible exposure, but actual exposure.

3. Dose – represents the amount of chemical to which the individual is exposed that actually traverses a portal of entry and is transported to the tissues, usually by way of the bloodstream.

4. Illness or Risk of Future Illness – this is often confused with "risk" as calculated for regulatory risk assessments. In this regard, he stated that "the US EPA itself considers calculated cancer risks falling into the range of 1×10^{-4} to 1×10^{-6} to be 'negligible' or *'de minimis'*.

Id. at 11-13.

He then reviewed Dr. Werntz's opinion that exposure to dioxin causes the diseases for which he proposes medical monitoring. Dr. Guzelian criticized Dr. Werntz for not conducting an evidence-based analysis of the literature. Instead, he believed that Dr. Werntz based the diseases chosen for monitoring on those diseases determined by the Veteran's Administration to

be statistically associated with exposure to Agent Orange. *Id.* at 16-28. Dr. Guzelian opined that effects from exposure to TCDD are unlikely to occur for serum levels of dioxin below about 1,000 ppt, a value far higher than the background level for the named plaintiffs for whom biologic testing results are available. *Id.* at 20.

Dr. Guzelian continued his review of Dr. Werntz's work, with numerous other criticisms about the methodology and efficiency of the proposed medical monitoring program. He looked at each of the proposed tests to determine how they would provide a meaningful screening for the diseases in question. *Id.* at 48-61. He reviewed whether the named plaintiffs, i.e. the Class Representatives, were themselves suitable for the proposed medical monitoring plan. He examined their detailed medical history, to include family history. He stated that none of them were, as they either already have one or more of the conditions for which they seek monitoring, or have a family history of one of these conditions, which may already place them at increased risk, or are already being monitored. *Id.* at 61-101. He concluded with a disease-by-disease review of the diseases for which the Class sought monitoring, noting that Dr. Werntz testified that most of the diseases he wanted to monitor for are not detected in an asymptomatic state. *Id.* at 101-103.

Dr. Guzelian was deposed over three separate days, April 7, 8 and 29, 2011.[189] He testified that he based his criticisms of Drs. Werntz and Sawyer on evidence-based reasoning. *Id.* at 7-8. He believed that the eight blood samples taken from the class representatives, would "[G]ive you a lot of information about what's likely to occur next. But it certainly doesn't tell you exactly what's going to happen next, no." *Id.* at 14.

[189] The record contains only a partial transcript of his last day of testimony.

He also believed that "if you want to know about the risk, if there is any, from exposure to dioxin, a blood level would be essential to trying to evaluate the risk for a given individual or for a group of individuals." *Id.* at 41. Dr. Guzelian opined that the blood samples of the other individuals in the class who were not tested would be similar to those of the 8 or 33 who were tested. *Id.* at 49. Based on the NHANES information and Patterson 2004 information, he believed that most of the blood readings were normal. *Id.* at 51. He would defer to Dr. Patterson as to what constituted a normal range. *Id.* at 52.

Dr. Guzelian also opined that the background level of dioxin if found in the everyday person is of no concern from a medical or toxicological standpoint. *Id.* at 61-62. He did not believe that Dr. Werntz justified the medical monitoring he proposed. *Id.* at 85. Dr. Guzelian believed that the ATSDR set out the accepted methodology for determining whether medical monitoring should be used. This is a three-step process. *Id.* at 91-92, and in his opinion Dr. Werntz did not address any of these criteria. He also stated that "of the 1200 CERCLA sites, I think there's only one or two where they've ever engaged in it. Most of the time these conditions are not met." *Id.* at 91-92. When the three-step process is properly used, the medical monitoring plan will emerge. *Id.* at 93. He criticized Dr. Werntz for not showing why the diseases were appropriate targets for medical monitoring. *Id.* at 97.

His criticism was also extended to Dr. Sawyer, whom he said "used the wrong method if his goal were to show that the risks for these patients, these plaintiffs, is significantly increased . . . So, what he did is . . . is worthless when it comes to the information Dr. Werntz needed to know to show that the risks to these patients were so increased, that is, not just increased at all, but actually were increased high enough, so that a decision to convert a person from "no, I wouldn't monitor her for this disease to yes, I would can be justified." *Id.* at 100-101. Dr.

Sawyer's big mistake was using EPA risk assessment methodology to determine the risk. *Id.* at 102. He stated that EPA risk assessments are useful for excluding risks, but are not useful for telling what the risk is. (*Id.* at 113). He stated that neither Drs. Werntz nor Sawyer attempted to calculate what dose resulted from the exposure and whether the dose was significant enough to trigger a medical monitoring decision. Dr. Guzelian did that, and did not believe that such a dose was received. *Id.* at 122-124.

He did not expect to see adverse health effects for any person until they had a serum lipid reading of at least 750 parts per trillion and then that would be for chloracne. *Id.* at 182-184. In other words, one would not see a biological response to dioxin in a human until the concentration of TCDD approaches 750 parts per trillion. *Id.* at 188-189. In his opinion, the only cause and effect relationship that has been established conclusively is chloracne. *Id.* at 231. He summarized his opinions about the named plaintiffs by stating "my published evaluation of the literature on TCDD concludes that effects are unlikely to occur for serum levels of dioxin below about 1,000 parts per trillion, a value far higher than the background values for the named plaintiffs." *Id.* at 241. Dr. Guzelian also opined that each individual should be examined by a knowledgeable person, in advance, who should take all of their individual characteristics into account. *Id.* at 283.

8. The Defendants Counter the Plaintiffs' Liability Evidence: John Henshaw, CIH

The Defendants also offered the opinions of John Henshaw, Certified Industrial Hygienist, on the issue of Monsanto's safe operation of its Nitro plant for the manufacturing

process for 2, 4, 5,-T.[190] He worked for Monsanto from 1975 to 2001. In 2001, he was confirmed to head the U. S. Department of Labor's Occupational Safety and Health Administration (OSHA). He was the subject of a *Motion to Strike Opinion Evidence"* filed by the Plaintiffs. (dkt. no.1516). The Defendants filed a reply, attaching a small portion of his opinion. (dkt. no. 1551). However, the Court cannot find any other material to review, and thus, cannot present any account of his opinions.

9. The Defendants Counter the Plaintiffs Property Damage and Remediation Evidence: Jay Goldman, Esq.

To principally oppose Mr. Carr, the Defendants presented Jay Goldman, Esq., as an expert witness. He provided his opinions in a document entitled *A Study to Determine Whether the Zuvic Associates, Inc., Consulting Engineering Report Correctly Interpreted the Assessor's Public Data and Whether the Potential Presence of Dioxin has an Effect on the Real Estate Market in the Zina Bibb, et. al. v. Monsanto Company, et. al.*, dated September 13, 2010. (*dkt no. 1546*). Mr. Goldman was retained by the Defendants "to determine if Robert J. Carr used the appropriate methodology to interpret publicly available data to estimate the cost to remediate real estate from alleged contamination and if the potential presence of dioxin has affected the real estate market in Putnam and Kanawha counties, West Virginia." *Id.* at 1.

Mr. Goldman compared the results obtained from his review of Mr. Carr's report with his own analysis from primary sources, including representatives of each counties assessor's offices and each county's planning director. He determined that Mr. Carr selected real estate with a Land Use Code 100 to determine residential property. Mr. Goldman determined that there are

[190] Mr. Henshaw has a Master's Degree in Environmental Health Administration and Industrial Health from the University of Michigan.

not single family homes on most of the Land Use Code 100 subdivision lots, and that most of the area is heavily wooded with varying terrain features. This physical fact would make soil remediation difficult. *Id.* at 3. He did not perform site visits to all the properties, but did research approximately 550 properties listed in the Carr report. *Id.* at 4.

Mr. Goldman opined that Mr. Carr made an invalid assumption when he chose to interpret Land Use Code 100 as representing real estate occupied by a dwelling. He stated that, by definition, Land Use Code 100 is vacant, residential property. He noted that Mr. Carr assumed that there was a 1,837 square foot dwelling on each of these lots: "The result of Mr. Carr's inaccurate and baseless assumption of the existence of dwellings on vacant residential lots is misleading and results in a greatly overstated calculation of alleged damages." *Id.* at 4. Mr. Goldman outlined his efforts to compare the Carr report findings with actual data. *Id.* at 5-8. Mr. Goldman noted that both Putnam and Kanawha County Assessor's Office personnel and employees of the West Virginia State Tax Department Real Estate Division defined Land Use Code 100 as residential vacant land. *Id.* at 8.

He interviewed twelve (12) appraisers who routinely work in Kanawha and Putnam counties, specifically in the subject area. None of these claimed to experience any issues with dioxin, and it was not brought to their attention. One of the appraisers lived in the Nitro area. *Id.* at 9. He also interviewed a local home inspector and realtors who had closed 15 transactions in the Nitro area in 2010. None of these brokers were aware of any dioxin issues. *Id.* at 10. He interviewed a Putnam County attorney who handles real estate closings in that county. He had never encountered a question about dioxin at a closing. *Id.* at 11. There were no disclosure statements concerning chemical contamination for any properties in the Kanawha Valley Multiple Listings. *Id.*

Mr. Goldman determined that there were 33 subdivisions cited by Mr. Carr in his report. In those 33 subdivisions, containing 553 Land Use Code 100 properties, 528 were vacant lots. He noted that "these 553 properties resulted in an estimate of approximately 1,015,861 square feet of dwellings that would be required to have remediation. Thus, there appears to be an error of approximately 95% of this sample, which overestimated approximately 979,000 square feet of phantom dwellings. *Id.* at 12. He could not give the same data for Kanawha County and reserved the right to revise his report when the data became available. *Id.* at 14. He concluded by stating that the information presented in the Carr Report was not reliable or credible and that the market did not consider the potential presence of dioxin on properties in the area to be a factor in sales. *Id.* at 15.[191]

V. The Proposed Settlements

Before discussing the details of the Settlement Agreements, the Court notes that this global settlement is the result of approximately eight years of highly contested litigation between the parties and their counsel. A thorough review of the record in this case reveals a docket of no less than 3200 entries, hundreds of pages of complex expert reports, extensive depositions and written discovery, a plethora of motions, writs of prohibition, removals and remands, notices of appeal, lengthy transcripts, and two mediations conducted by highly experienced mediators. As the court file will reflect, counsel for the parties "left no stone unturned" in their zealous representation of their respective clients. Also, there were numerous outbursts of personal animosity between the attorneys, and by attorneys with various witnesses. These issues were

[191] The report found in the Court file did not have exhibits attached.

apparent at hearings and in numerous depositions reviewed by the Court. It is for these reasons that any prospect of a settlement announcement was highly unexpected.

Despite this history, on January 17, 2012, Class Counsel and counsel for the Defendants advised the Court that a tentative global settlement had been reached. The global settlement included claims for the Medical Monitoring Class, the Property Class, and the personal injury cases. As part of the global settlement, the Defendants waived any and all objections to the property damage evidence and agreed to set aside the Order decertifying the Property Class, and include it in the settlement. On January 25, 2012, the Court conditionally vacated its November 3, 2011, Order decertifying the Property Class for the limited purpose of facilitating a settlement of the claims of the putative Property Class. On February 23, 2012, Mr. Urban filed a *Motion to Conduct Hearing Regarding Certification of Conditional Property Class*, arguing that the Court must conduct a Rule 23(a) hearing under *Amchem Products, Inc., v. Winsor*, 521 U.S. 591, 117 S. Ct. 2231 (1997), to determine whether all elements of Rule 23(a) had been satisfied for the conditional property settlement class. The Court found Mr. Urban's arguments unpersuasive as *Anchem* does not control the vacating of the decertification because the Property Class had "already been through a thorough Rule 23(a) analysis and another analysis was unnecessary". Furthermore, "the Property Class was decertified because damages could not be proven, and now, proof of damages is not at issue as such proof has been waived by Monsanto." *Order Denying Motion to Conduct Hearing Regarding Certification of Conditional Property Class.* (dkt. no. 3050).

On February 16, 2012, the Court received the Plaintiffs' Motion for Preliminary Approval and first Draft of the Medical Monitoring Class Settlement Agreement ("MMCSA") and the Property Settlement Agreement ("PCSA"). The Court thoroughly reviewed the

Settlement Agreements and held a hearing on February 23, 2012. As discussed in section II *infra*, the Court found that the Settlement had "some merit" but that issues existed that required re-drafting. Specifically, the Court stated that "there are certain aspects of both the medical monitoring and property class settlements that are of material nature that may call the agreement into question. The aspects in question are notice, standing to object, the claims administrator, and certain procedural aspects." *Id.* These also included the Triggering Event, the Committee which determined the Triggering Event, the Registration Period for both Medical Monitoring and Property Classes, and the details of the attorneys' fees and costs. After going through each issue, the Court stated that "if counsel is unwilling to inform the Court at tomorrow's hearing that these changes are acceptable, then we'll go forward with the trial on Monday, February 27th at 9:00 a.m." (Trial Tr. 2043:13-17, Feb. 23, 2012.) (dkt. no. 3029).

Upon hearing the Court's concerns, counsel for the parties revised the first draft and provided a second draft of the Settlement Agreements to the Court on February 23, 2012, at 9:00 p.m. The Court reviewed the second draft of the Settlement Agreements until 1:00 a.m., and still had two concerns. On the morning of February 24, 2012, the Court staff contacted counsel with those two issues. (Hr'g Tr. 4, 1:16-17, Feb. 24, 2012.)

On February 24, 2012, the Court held another hearing and stated that all but two of the Court's issues had been fully addressed.

> The Court worked diligently reviewing the proposed changes until 1:00 a.m. . . . and determined that all but two of the Court's issues have been fully addressed. . . . These two issues dealt with notice and clarification of the settlement provisions in the medical monitoring area class -- or rather program.

(Trial Tr. 2056:12-23, Feb. 24, 2012.)

The Court further stated "[c]ounsel had diligently worked to address those issues and incorporate the changes into the final draft, which will be brought later today." (Hr'g Tr. 4:1, 17-20, Feb. 24, 2012.)

Furthermore, the Court stated,

> Based upon the general terms and subject to the two issues being finalized in the documents, the Court finds that the Motion For Preliminary Approval of Class Settlement falls within the range of reasonableness, of course subject to reviewing those two final changes which will be filed later today. After that review, the Court will enter an Order reflecting this ruling.

(Trial Tr. 2058:7-14, Feb. 24, 2012.)

The Court received the third and final draft later that evening and upon thorough review, the Court entered the *Order Preliminarily Approving Class Settlements* (dkt. no. 3028) at 8:10 p.m., that day.

A. The Medical Monitoring Class Settlement Agreement

The Medical Monitoring Class Settlement Agreement ("MMCSA") creates a medical monitoring program where members of the Medical Monitoring Class can register for and receive free medical examinations and testing performed by the physicians and professional staff at Thomas Healthcare System. *Memorandum of Law in Support of Motion for Preliminary Approval of Class Settlements* at 1. To begin this process, the MMCSA establishes a Medical Monitoring Fund ("MMF") within 30 days of the Effective Date. *Id.* at 9. Under the MMCSA, a Medical Monitoring Fund will be created to pay for medical examinations and testing of eligible Class Members over the course of the next 30 years. *Id.* at 6. The Fund shall operate as follows:

> (a) The Fund will be established in an interest-bearing account in a bank selected by the Defendants; (b) the Fund will be administered by the Medical Monitoring Fund Administrator for a fee negotiated

> by the Defendants to be paid out of the Fund; (c) defendants will be responsible for maintaining appropriate balances in the Fund as further outlined below; (d) payment for all examinations and testing will be dispersed from the Fund on a "pay as you go" basis. Any part of the Fund not used for medical monitoring during any Screening Period as set forth below will be returned to the Defendants.

Id. at 25.

The Medical Monitoring Program ("Program") has an Initial Screening Period ("Year 0") that will commence within 60 days of the Effective Date and follow this timeline:

> (1)Notice to the Class followed by a 120 day Registration Period, to coincide with the Property Class Registration Period; (2) thereafter, Participants will have 150 days to have testing performed as set forth in the Program; (3) thereafter, within 120 days of the completion of testing, the Hospital will issue Reports summarizing the test results and send them to the Participants and/or the Participant's primary care physician, at the Participants' election.

Id.

The Defendants will deposit $3 million to fund each of the 7 Screening Periods (i.e., Year 5, Year 10, Year 15, Year 20, Year 25, and Year 30), totaling $21 million dollars. In the event that the Fund has inadequate money to cover Program costs in Years 0, 5, or 10, the Medical Monitoring Fund Administrator may supplement the Fund as follows: for Year 0, the Administrator may direct the Defendants to add for use in Year 0, up to $1 million in funds previously designated for Year 30; for Year 5, the Administrator may direct the Defendants to add for use in Year 5, up to $1 million in funds previously designated for Year 25; for Year 15, the Administrator may direct the Defendants to add for use in Year 15, up to $1 million in funds previously designated for Year 20.

As mentioned *supra*, the Screening Period will take place every five years for a total of 30 years, except if a Triggering Event occurs. A Triggering Event will occur when greater than 25 percent of the participants sampled have dioxin TEQs greater than the background range. *Id.* at Ex. D, § 6.3. The background range is the Upper Confidence Limit of the 95th percentile of dioxin congeners established by the NHANES Survey and as published in Chemosphere 73 (2008), S261-S277. *Id.* at § 6.2.[192] The background TEQ is defined as levels at or below (1) 22.4 pg/g for participants aged 20-39 at the time the serum sample is drawn, (2) 37.5 pg/g for participants aged 40-59 at the time the serum sample is drawn, and (3) 62.2 pg/g for participants aged 60 and older at the time the serum sample is drawn. *Id.* In order to account for statistical chance and error, at least 100 participants' serum samples must be drawn and be capable of analysis following the procedure during any monitoring period for a Triggering Event to occur.

In the event of a Triggering Event occurring, during any Screening Period, the next Screening Period will occur within two years instead of five, and Defendants' contribution to the Fund for that next Screening Period will increase from the base amount to $5.4 million. *Id.* at 12. The total amount allocated for a Triggering Event would contribute an additional $63 million dollars, for a total maximum potential payment of $84 million dollars for medical monitoring testing. This is not a guaranteed payment of $84 million, but a series of payments depending on conditions.

The two-year interval screening and funding increase will occur only if a Triggering Event occurred during the immediately preceding Screening Period. If during that next Screening Period, a Triggering Event does not occur, the subsequent Screening Period will take place in five years following the last Screening Period and will return to the $3 million funding. *Id.* The

[192] *See* discussion *supra* IV.C.

determination of whether a Triggering Event has occurred will be made jointly by the Laboratory, the Medical Monitoring Program Administrator, the Class analytical scientist designee, and the analytical scientist designee. In the event of a disagreement about whether a Triggering Event occurred, the Medical Monitoring Administrator will so notify in writing Defendants' counsel, who will so notify the Court, which will decide if a Triggering Event has occurred. *Id.* § 6.4.

The participating Class Members will be given an initial evaluation, including a history and physical examination, and a battery of blood tests which include the following:

> (1) serum dioxin test (the Hospital will draw the blood and ship it to AXYS Laboratory; AXYS Laboratory will provide any protocols necessary and will send test results to the Hospital);
> (2) fasting glucose;
> (3) hemoglobin A1C;
> (4) fasting lipid profile;
> (5) erythrocyte sedimentation rate; and
> (6) cbc with differential[193]

Id. at Ex. E ¶ 6. The above-referenced tests will be repeated if the initial results are positive.

Criteria for entry into the program are those recommended by class experts, Dr. Werntz and William R. Sawyer, Ph.D. MMCSA at 7. The Class members must fit into one or more of Dr. Sawyer's "dose groups." Also, the Class member may not have worked at Monsanto's Nitro Plant previously. *Id.* The parties selected a geographical area encompassed by an isopleth calculated by plaintiffs' expert William M. Auberle, and then added 10% to that area as a "safety buffer." The Medical Monitoring Fund will operate on a "pay as you go" basis, and all funds not expended will revert to the Defendants. *Id.* at 8.

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[193] The congeners to be analyzed will be the seven (7) dioxin congeners for which there is a corresponding Toxic Equivalent Factor ("TEF"). *Id.* Ex. D.

B. The Property Class Settlement Agreement

The Property Class Settlement Agreement ("PCSA") creates a program that is designed to clean the interior surfaces of potentially thousands of residences in the community. *Memorandum of Law in Support of Motion for Preliminary Approval of Class Settlements*. at 8. It creates a Property Fund that will be used to clean eligible class members' residences over the course of three years. *Id.* Defendants will contribute $3 million per year to the Property Fund. The cleanup will be performed by Foth Infrastructure & Environment, L.L.C., an international engineering and environmental remediation corporation whose personnel have handled thousands of dioxin remediations. *Id.* The cleanup will encompass defined living spaces where there is potential for exposure. *Id.* Exterior surfaces such as soils are not included as the parties and their experts agree that these do not constitute an environmental or health hazard. *Id.*

The geographic area encompassed in the clean-up coincides with that incorporated into the medical monitoring program. *Id.* The area is based upon an isopleth calculated by the Plaintiffs' expert [Dr.] Auberle, plus an additional 10% added as a "safety buffer." *Id.* Up to 4,500 houses will be eligible for cleaning and funds not spent on remediation will revert to the Defendants. *Id.*

Eligible Class Members means all members of the Property Class who meet the Eligibility Criteria for participation in the Property Program. *Id.* at § 2.10. Specifically, all Property Class members who own a Residential Property located within the geographical area delineated in the Property Class Cleanup Area. *Id.* at § 2.11. The total amount of funds allocated to the Program will be $3,000,000 per year for 3 years for a total of $9,000,000.

The Property Program ("Program") shall operate as operate as follows:

> (a) The Property Program Administrator shall cause a public notice to be mailed by first-class to those to whom Class Notice was sent, notifying them of the opportunity to participate in the Program. Persons seeking eligibility to participate in the Program shall thereafter have 120 days to register with the Administrator; (b) Registration shall be on a form provided by the Administrator. The Administrator may require such additional information as the Administrator deems appropriate; (c) Property that is not registered during the registration period shall not be eligible for Property Cleanup; (d) Property that is determined by the Administrator to be eligible shall be cleaned on a first-come first-served basis. The Administrator shall have the right to make groupings of residences to be cleaned; (e) the cleanup program shall be conducted for up to three years. Not more than 4,500 residences will be cleaned; (f) The Administrator shall prepare a list of the eligible residences. The Administrator shall coordinate Property Cleanup with the contractor selected for the work. The contractor performing the work shall be selected by Defendants. (g) Defendants will deposit the amount of three million dollars ($3,000,000) to the Fund each year for three successive years. The Fund will operate on a pay as you go basis, any part of the Fund not expended in any given year will be returned to the Defendants. The maximum amount to be expended by the Fund each year will be three million dollars ($3,000,000).

Id. at § 4.5.

C. Attorneys' Fees and Costs

Class counsel petitioned the Court for reasonable attorneys' fees and costs payable by the Defendants. *Id.* Class counsel is seeking fees up to $22,500,000 approximating 18% of the value of the settlement as apportioned between the two Classes and in addition up to a total of $7,000,000 in reimbursable direct costs as apportioned between the two classes. *Id.* Defendants have agreed to pay up to a total of $29,000,000 as reasonable fees and costs in connection with

the proposed settlement. *Id.*[194] The instant Order will only generally refer to the *Petition for Attorneys' Fees and Costs.*

D. Notice to the Class

Rule 23(e) of the West Virginia Rules of Civil Procedure require that "[n]otice of the proposed dismissal or compromise shall be given to all members of the class in such manner as the court directs." Rule 23(e) of the Federal Rules of Civil Procedure requires that adequate notice must be given to all class and potential members. The parties designed a notice plan to be implemented upon issuance of the Preliminary Approval Order by the Court ("Notice Plan"). As the identity of the members of the Medical Monitoring Class are currently unknown to the parties, notice by national publication is the best practicable notice under the circumstances. The identities of the Property Class Members are known, in that they encompass occupied residences within the Property Class Cleanup Area. Reaching the Property Class members by first class mail is the best practicable notice under the circumstances.

Class counsel established a website, www.BibbClass.com, and it contained the Class Notices and Registration Forms for both classes. The website also contained sufficient information to allow individuals to determine whether they may be eligible to participate in the Medical Monitoring, and/or Property Clean-up Programs. Class counsel assumed the expense of all costs of Class Notice.[195]

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[194] The Court has contemporaneously entered its *Final Order Awarding Attorneys' Fees and Litigation Expenses and Awarding Class Representatives' Incentive Payment*, with this Order.

[195] The Court has contemporaneously issued its *Order Finding that Notice Requirements Set Forth in the Court's Preliminarily Approving Class Settlements Have Been Satisfied*, with this Order.

E. Standing to Object

The parties proposed that any class member who objects ("Objectors") be handled as follows:

> Any objection should explain why the Settlement Agreements should not be approved as fair, reasonable, and adequate and why final judgment should not be entered thereon. Moreover, the Parties propose[d] that any papers submitted in support of an objection shall be considered by the Court at the Fairness Hearing only if the Objector: (1) submits documentary proof that he or she is a member of at least one of the Settlement Classes; (2) states in writing the specific basis for each objection, including any legal support he or she wishes to bring to the Court's attention; (4) [sic] submits any evidence he or she wishes to introduce in support of his or her objection; and (5)[sic] provides any other information required by the West Virginia Rules of Civil Procedure. The parties propose that any objector who fails to comply with these requirements be forever barred from objecting to the Class Settlements.

Id. at 13.

The parties further proposed that any Objector who had retained counsel for the purpose of objecting on his or her behalf provide notice of appearance. Objectors were required to serve and file any written objections and serve a notice of intention to appear at the Fairness Hearing. The parties further requested that all objections and notices be postmarked no later than June 7, 2012 and sent to the Putnam County Circuit Clerk's Office.

F. The Claims Administrator

Thomas Flaherty, Esq., agreed to be the Claims Administrator for both the Medical Monitoring and Property Classes. As the Claims Administrator, Mr. Flaherty will oversee and manage how the Medical Monitoring and Property Class Funds will delivered to the Class. A

Class Administrator also ensures compliance with the Notice and Registration provisions of a settlement.

During the Fairness Hearing, Mr. Flaherty testified as to the details of how the two settlement programs will be administered, beginning with the Property Class Settlement. A storefront office in Nitro will be opened not later than the day following the first mailing of the class notice. (Fairness Hr'g Tr. 45:4-7, June 18, 2012.) This fully staffed office will remain open Tuesdays through Fridays from 10:00 a.m., until 6:00 p.m., and Saturdays from 9:00 a.m. through noon, excluding legal holidays over a period of 120 days calendar days from the last date that the last class notice is mailed. *Id.* at 46. As Mr. Flaherty was uncertain how many people will be present to register the first day or week, he plans to overstaff. Thereafter, he plans to accommodate staffing so that anyone who wants to take advantage of the settlement may do so. *Id.* His assistants and law firm will conduct some proactive outreach into the community to encourage participation in times when people are not coming in to the office. *Id.* Three runners will be available to transport people to the office to register for benefits if they do not have their own transportation. *Id.*

The determination of an eligible applicant will be based upon the information contained in the questionnaires and the accompanying exhibits. Mr. Flaherty intends to be "very, very liberal in making the benefits available." *Id.* at 48. He also intends to resolve any doubt of eligibility in the favor of an individual who believes they should receive benefits. In the event of a denial the following procedure will be followed:

> If there are appeals for denials as requested by the applicants, they'll be reviewed and in the event that the review confirms the denial, then the applicant can seek relief from the court, in which case we will provide a written explanation of the denial and an appearance in court will be provided regarding that issue.

Id. at 48:6-13.

Once a determination is made as to eligibility, all participating eligible class members will execute a right of entry and informed consent form prior to the actual cleaning to their homes. *Id.* at 48:15-18. The residences will be cleaned by Foth Infrastructure & Environmental in the order registered, with adjustments made to take into account the conveniences of scheduling and location. *Id.* at 50. The cleaning appointments will be scheduled during normal business hours but at the convenience of the home owners. *Id.* Foth will obtain a verification from the homeowner that it was completed and submit that verification to the office. *Id.* Any complaints from the property owners will be investigated and an attempt made towards resolution. *Id.* Mr. Flaherty testified that he relied on the affidavit from Bryan Simmons of Foth that states the following:

> There will be six four-person cleaning crews, each with a team leader. The six crews will be supervised by two full-time experienced supervisors. They will work approximately 240 days a year, 48 weeks, and each crew will clean two homes in one day. That's what the affidavit says.

Id. at 67. Brian Symons Affidavit. (Ex. D, PCSA).

The Medical Monitoring class follows the same timelines that are all triggered by the effective date of the settlement. After the effective date, Class Counsel will publish the class notice, with instructions on how to apply for medical monitoring. The implementation of the Property Class Settlement and the Medical Monitoring Settlement will be executed in the same manner. Both Settlement Classes will go to one Nitro office, publication of the class notice will be handled in the same manner, and guidelines for eligibility into the program will be identical.

Notice of eligible class members of the commencement of the initial screening period will be provided by first class mail and sent to those who sent notification of their intention to participate. *Id.* at 55. Assistance will be provided to those eligible class members in scheduling appointments at Thomas Health Systems in South Charleston. *Id.* The Nitro office will maintain a list of participants in the initial screening period and their addresses. Mr. Flaherty's office will maintain a back-up in the IT department. Participants will be notified in writing that they must notify Nitro Class Action Administrators, LLC. This name will be on the door of the office, along with a website, an 800 number, and a permanent post office address. In the event that low participation occurs, town meetings will be held to improve involvement. *Id.* at 57. On or about May 1 or each subsequent screening year, such as year 5, 10, 15, 20, 25 and 30, all participants in the initial screening period will receive by first class mail a notice of commencement of another screening period, with instructions on how to schedule testing. *Id.* at 58. The notice will be mailed more frequently in the event of a triggering event. Mr. Flaherty has also taken the steps to make certain that the Nitro Class Action Administrators, LLC will be staffed through the end of the class settlement period (i.e. 30 years). *Id.*

G. Limited Discovery to Objectors Limited Protective Order

On June 18, 2012, the Court held a Fairness Hearing in regards to the proposed settlement. During the hearing, the Class Administrator testified that he felt that the settlement was fair and adequate based upon his knowledge as mediator. Fairness Hr'g Tr. 36:7-11, June 18, 2012. On July 24, 2012, the Court entered *Order Granting Limited Discovery to Objectors and Granting a Limited Protective Order* (dkt. no. 3232) which granted the Motions for Protective Order with regards to discovery into confidential mediation pursuant to Trial Court Rule 25.12 and *Riner v.*

Newbraugh, 211 W.Va. 137, 563 S.E.2d 802 (2002). In order to avoid any unfairness to the Objectors, the Court struck the testimony offered by the Class Administrator during the fairness hearing in determining the fairness, adequacy, and reasonableness of the proposed settlement. Only the mechanics of administering the settlement will be considered by the Court.

VI. History of Medical Monitoring

The Court notes that the proposed settlement includes both a settlement of the medical monitoring claims and the property remediation claims. As to the first part, the history of medical monitoring is important for a complete understanding of this decision. As to the property remediation settlement, the law is clear and well established in that the available remedies for property damage include clean-up of the property if the cost of the repair does not exceed the fair market value, soil remediation, and punitive damages.

A. Brief History of Medical Monitoring Without Physical Injury

Prior to 1984, a claim for medical monitoring without physical injury was not a compensable claim. Adam P. Joffe, *The Medical Monitoring Remedy: Ongoing Controversy and a Proposed Solution*, 84 Chi.-Kent L. Rev. 663 (2009). As one commentator states, "[f]or decades, a central tenet of tort law has been that a plaintiff may not recover damages for negligence absent physical injury. *Id.* There are several reasons for such a rule. As explained by the Michigan Supreme Court:

> The requirement of a present physical injury to person or property serves a number of important ends for the legal system. First, such a requirement defines more clearly who actually possesses a cause of action. In allowing recovery only to those who have actually suffered a present physical injury, the fact-finder need not engage

> in speculations about the extent to which a plaintiff possesses a cognizable legal claim. Second, such a requirement reduces the risks of fraud, by setting a clear minimum threshold-a present physical injury-before a plaintiff can proceed on a claim. By requiring a prospective plaintiff to make a showing of an actual physical injury, present tort law thus excludes from the courts those who might bring frivolous or unfounded suits. In particular, the fact-finder need not be left wondering whether a plaintiff has in fact been harmed in some way, when nothing but a plaintiff's own allegations support his cause of action.
>
> Finally, and perhaps most significantly, the requirement of a present physical injury avoids compromising the judicial power. The exercise of the "judicial power" . . . contemplates that there will be standards-legally comprehensible standards that guide the judicial branch's resolution of the matters brought before it. The present physical injury requirement establishes a clear standard by which judges can determine which plaintiffs have stated a valid claim, and which plaintiffs have not. In the absence of such a requirement, it will be inevitable that judges, as in the instant case, will be required to answer questions that are more appropriate for a legislative than a judicial body: How far from [a contaminated site] must a plaintiff live in order to have a cognizable claim? What evidence of exposure to dioxin will be required to support such a claim? What level of medical research is sufficient to support a claim that exposure to dioxin, in contrast to exposure to another chemical, will give rise to a cause of action?

Henry v. Dow Chem. Co., 473 Mich. 63, 76-77, 701 N.W.2d 684, 690-691 (2005)(citations omitted).

Starting in 1984, however, a serious of cases redefined the tort of medical monitoring. These cases include *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816 (D.C. Cir. 1984), *Ayers v. Jackson Township*, 525 A.2d 287 (N.J. 1987), *In re Paoli* ("*Paoli I*"), 916 F.2d 829 (3rd Cir. 1990), *Hansen v. Mountain Fuel Supply*, 858 P.2d 970 (Utah 1993), *Potter v. Firestone Tire and Rubber Co.*, 863 P.2d 795 (Cal. 1993), and *In re Paoli* ("*Paoli II*"), 35 F.3d 717 (3rd Cir. 1994). These cases generally found that a cause of action for medical monitoring does not require a physical injury. As stated in *Paoli I*,

> The policy reasons for recognizing [a cause of action for medical monitoring without a physical injury] are obvious. Medical monitoring claims acknowledge that, in a toxic age, significant harm can be done to an individual by a tortfeasor, notwithstanding latent manifestation of that harm. Moreover, as we have explained, recognizing this tort does not require courts to speculate about the probability of future injury. It merely requires courts to ascertain the probability that the far less costly remedy of medical supervision is appropriate. Allowing plaintiffs to recover the cost of this care deters irresponsible discharge of toxic chemicals by defendants and encourages plaintiffs to detect and treat their injuries as soon as possible. These are conventional goals of the tort system as it has long existed . . . .

916 F.2d at 852. While not perfect, the idea behind the cause of action makes sense.

> Victims of toxic exposure rarely experience immediate symptoms; rather they may remain asymptomatic for years until illness develops. Or, the illness may never develop, but the victim must undergo periodic medical examinations to attempt to detect the onset of the disease. In such cases, the cost of such diagnostic treatment is necessitated by the defendant's conduct, and should be compensable.[196]

6 Litigating Tort Cases § 67:24 (2012).

B. History of Medical Monitoring Without Physical Injury in West Virginia

West Virginia's jurisprudence on medical monitoring without a physical injury began in the United States District Court for the Southern District of West Virginia. Eighteen former employees and two spouses of former employees of Joy Technologies brought suit for, *inter alia*, future medical monitoring. *Ball v. Joy Mfg. Co.*, 755 F.Supp. 1344 (S.D.W.Va. 1990). The

[196] There are several states that do not allow a claim for medical monitoring without a physical injury. Those states include Alabama (*Hinton v. Monsanto Co.*, 813 So.2d 827 (Ala. 2001)), Kentucky (*Wood v. Wyeth-Ayerst Lab.*, 82 S.W.3d 849 (Ky. 2002)), Michigan (*Henry v. Dow Chem. Co.*, 701 N.W.2d 684, 690-691 (Mich. 2005)), Mississippi (*Paz v. Brush Engineered Materials, Inc.*, 949 So.2d 1 (Miss. 2007)), Nevada (*Badillo v. American Brands Inc.*, 16 P.3d 435 (Nev. 2001)), North Carolina (*Curl v. American Multimedia, Inc.*, 654 S.E.2d 76 (N.C. App. 2007)), Oregon (*Lowe v. Philip Morris USA, Inc.*, 142 P.3d 1079 (Or. App. 2006)), and Louisiana (La. Civ. Code Ann. art. 2315)(2001).

plaintiffs alleged "that while employed at the defendant's corporate facilities in Bluefield, West Virginia, and Bluefield, Virginia, they were wrongfully exposed to and absorbed various toxic chemicals." *Ball v. Joy Tech., Inc.*, 958 F.2d 36, 37 (4th Cir. 1991). The United States District Court for the Southern District of West Virginia found that neither West Virginia law nor Virginia law allowed recovery for medical monitoring without present physical injury. *Ball*, 755 F.Supp. at 1364-1368. This ruling was upheld by the Fourth Circuit Court of Appeals in *Ball v. Joy Tech., Inc.*, 958 F.2d 36 (4th Cir. 1991). In upholding the District Court's ruling, the Fourth Circuit actually found that West Virginia law as to medical monitoring requires a present physical injury.

In *Bower v. Westinghouse Elec. Corp.*, 206 W.Va. 133, 522 S.E.2d 424 (1999), however, the West Virginia Supreme Court of Appeals came to a different conclusion. Based on a certified question from the United States District Court for the Northern District of West Virginia, the Supreme Court of Appeals found that a claim for medical monitoring does not require a present physical injury. *Id.* In making its determination, the Supreme Court of Appeals stated,

> We now reject the contention that a claim for future medical expenses must rest upon the existence of present physical harm. The "injury" that underlies a claim for medical monitoring—just as with any other cause of action sounding in tort—is "the invasion of any legally protected interest." . . . As one of the first courts to grapple with this subject observed:
>
> > It is difficult to dispute that an individual has an interest in avoiding expensive diagnostic examinations just as he or she has an interest in avoiding physical injury. When a defendant negligently invades this interest, the injury to which is neither speculative nor resistant to proof, it is elementary that the defendant should make the plaintiff whole by paying for the examinations.

Bower, 206 W. Va. at 139, 522 S.E.2d at 430 (citations omitted).

In *Bower*, the West Virginia Supreme Court of Appeals set forth a six prong test:

> In order to sustain a claim for medical monitoring expenses under West Virginia law, the plaintiff must prove that (1) he or she has, relative to the general population, been significantly exposed; (2) to a proven hazardous substance; (3) through the tortious conduct of the defendant; (4) as a proximate result of the exposure, plaintiff has suffered an increased risk of contracting a serious latent disease; (5) the increased risk of disease makes it reasonably necessary for the plaintiff to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of the exposure; and (6) monitoring procedures exist that make the early detection of a disease possible.

Syl. Pt. 3, *Id.* Every one of these elements must be established in order to sustain a claim for medical monitoring. *In re Tobacco Litigation*, 215 W. Va. 476, 480, 600 S.E.2d 188, 192 (2004).

The next change to medical monitoring came in 2010, when the West Virginia Supreme Court of Appeals barred punitive damages in medical monitoring causes of action. *Perrine v. E.I. du Pont de Nemours and Co.*, 225 W. Va. 482, 546-548, 694 S.E.2d 815, 879-881 (2010). After an extensive review, the Supreme Court of Appeals basically reasoned that in such actions plaintiffs "have not suffered any actual, present physical injuries from their alleged exposure to [chemicals], [therefore] punitive damages simply should not be available[.]" *Id.* at 547, 880.

VII. Standard of Review

It is uncontroverted that public policy and the law favor settlements. *See, eg., Sanders v. Roselawn Mem'l Gardens, Inc.*, 152 W. Va. 91, 104, 159 S.E.2d 784, 792 (1968). This is especially true of complex cases, such as class actions. *See* William B. Rubenstein, Alba Conte & Herbert Newberg 4, *Newberg on Class Actions* § 11:41, at 87 (4th ed. 2012). In fact, "[b]y their very nature, because of the uncertainties of outcome, difficulties of proof, and length of litigation, class action suits lend themselves readily to compromise." *Id.* at 87-88.

Complex class action lawsuits pose challenges to both class members and defendants because of the length of the litigation, the difficulty of proof, and the uncertainty of the outcome. These challenges frequently lead the parties to settle. *See* William B. Rubenstein, Alba Conte & Herbert B. Newberg 4, *Newberg on Class Actions* § 11:41 (4th ed. 2012).

The law favors settlement. *See, e.g., Sanders v. Roselawn Mem'l Gardens, Inc.*, 152 W. Va. 91, 104, 159 S.E.2d 784, 792 (1968). This is particularly true in class actions since the litigation is highly disputed, complex, and substantially taxing on judicial resources. *See* 4 *Newberg on Class Actions*, § 11:41; *see also Trombley v. Nat'l City Bank*, 826 F. Supp. 2d 179, 191 (D.D.C. 2011) ("the discretion to a reject a settlement is 'restrained by the principle of preference that encourages settlements.'").

Settlement spares the litigants the uncertainty, delay, and expense of a trial, while simultaneously reducing the burden on judicial resources. Rule 23(e) of the West Virginia Rules of Civil Procedure provides that a class action "shall not be dismissed or compromised without the approval of the court." W. Va. R. Civ. P. 23(e).

In effectuating any class action settlement, the role of the Court is to approve, disprove, or impose conditions on the settlement. The Court cannot rewrite the MMCSA and PCSA. Both ultimately must stand or fall in their entirety. *See* Federal Judicial Center, *Manual for Complex Litigation* § 21.61 (4th ed. 2004) (citing *Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1026 (9th Cir. 1998)).

In ruling on the fairness, adequacy, and reasonableness of a proposed class action settlement, courts observe that the focus must be on the information available to the parties when they negotiated the settlement. *See Trombley*, 826 F. Supp. 2d at 198 ("the terms of the

settlement agreement should be analyzed based on what information was known at the time the settlement agreement was reached. . . .").

"A settlement is by nature a compromise between the maximum possible recovery and the inherent risks of litigation. The test is whether the settlement is adequate and reasonable and not whether a better settlement is conceivable." *Muhammad v. Nat'l City Mortg., Inc.*, 2008 WL 5377783 at *5 (S.D. W. Va. Dec. 19, 2008) (quoting *In re Warfarin Sodium Antitrust Litig.*, 212 F.R.D. 231, 258 (D. Del. 2002) (citations omitted)).

West Virginia jurisprudence on the settlement of class actions is minimal. In the first place, Rule 23(e) of the WVRCP simply states "(e) Dismissal or Compromise. A class action shall not be dismissed or compromised without the approval of the court, and notice of the proposed dismissal or compromise shall be given to all members of the class in such manner as the court directs." *Id.* This rule, however, gives minimal guidance to a reviewing court. In terms of case law, after extensive research, the Court can find only one case from the West Virginia Supreme Court of Appeals that has discussed the procedures for approval in a class action settlement; *Bd. of Educ. of County of Monongalia v. Starcher*, 176 W.Va. 388, 343 S.E.2d 673 (1986). *See* Commonwealth's West Virginia Rules Manual, Rules of Civil Procedure, Rule 23, Editorial Staff Notes, Note 6 & 7 at 23-19 to 23-20 (2011). The majority opinion in that case, however, has been criticized as unconstitutional. *Id.* Even with this limited mandatory authority, class action settlements are not a new phenomenon and there is an extensive body of law available for the Court to use in its analysis. What follows is a discussion and summarization of that law.

First and foremost, the law is clear – a court must review and approve all class actions settlements. Rule 23(e) of the West Virginia Rules of Civil Procedure; *Bd. of Educ. of County of*

Monongalia v. Starcher, 176 W.Va. 388, 343 S.E.2d 673 (1986). The court's review and approval "is to protect the nonparty class members from unjust or unfair settlements affecting their rights when the representatives [or class counsel] become fainthearted before the action is adjudicated or are able to secure satisfaction of their individual claims by a compromise, abandoning the claims of the absent class members." 7B Charles Alan Wright, Arthur R. Miller, & Mary Kay Kane, *Federal Practice and Procedure* § 1797 (3rd ed. 2005) (footnotes omitted). The reviewing court must "act[]as a fiduciary and as a guardian of the rights of the absent class members." 32B Am. Jur. 2d *Federal Courts* § 1864 (2012)(footnotes omitted). This rule ensures that absent class members' rights have not been sacrificed for minimal to no gain. *See generally* Ann. Manual Complex Lit. § 21.6 (4th ed.).

The approval of a class action settlement is a three step process. The first step is preliminary review of the proposed settlement. Next, a reviewing court must ensure that notice of the proposed settlement was effectuated on the class. Finally, there is a fairness hearing to determine if the proposed settlement is fair, adequate, and reasonable.

A. Preliminary Review

Preliminary review is an "initial evaluation" where the court will determine if there are any "obvious deficiencies." 2 Joseph M. McLaughlin, *McLaughlin on Class Actions: Law and Practice* § 6:6 at 60 (8th ed. 2011). These deficiencies include "collusive negotiation, unduly preferential treatment of class representatives or segments of the class, or excessive compensation of attorneys . . . ."[197] *Id.*

[197] It is important to note that, "[a] settlement reached after a supervised mediation receives a presumption of reasonableness in the absence of collusion." McLaughlin, *supra*, § 6:6 at 62.

The preliminary review does not necessarily require notice to be effectuated on class members. *Manual for Complex Litigation* § 21.632 (4th ed. 2004).[198] Furthermore, there is no hearing required for preliminary approval. 4 *Newberg on Class Actions* 4th § 11:41 at 93. While this step is not necessarily required, it is highly recommended because it will let the proponents of a proposed settlement know if there are any obvious deficiencies that would prevent approval before undertaking the costly task of disseminating notice.

A reviewing court's preliminary determination does not have to be a simple yes or no. "The court may find that the settlement proposal contains some merit, is within the range of reasonableness required for a settlement offer, or is presumptively valid subject only to any objections that may be raised at a final hearing." *Id.* § 11:26. Making any one of these determinations "does not dilute the court's review on final approval . . . ." McLaughlin, *supra*, § 6:6 at 64. However, if the court determines that the settlement proposal is presumptively valid, "it does place the burden on any objectors of persuading the court that the proposed settlement is unreasonable." *Id.* If a reviewing court makes any other determinations, the burden is still on the proponents.

Ultimately,"[t]he judge must make a preliminary determination on the fairness, reasonableness, and adequacy of the settlement terms and must direct the preparation of notice... [of the] proposed settlement, and date of the final fairness hearing." MCL, *supra,* § 21.632.[199]

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[198] *Manual for Complex Litigation* § 21.632 (4th ed. 2004) will be referred to as "MCL" throughout the remaining Order.

[199] There is no requirement, however, that the Court "conduct [a] hearing[] to evaluate the adequacy of a settlement prior to ordering settlement notice." Newberg, *supra*, § 11:41 at 93.

B. Notice of Proposed Settlement

A reviewing court cannot approve a proposed class action settlement without proper notice informing the class of the proposed settlement. Rule 23(e) of the West Virginia Rules of Civil Procedure requires that notice of a proposed settlement "shall be given to all members of the class in such manner as the court directs." The purpose of this rule is to "ensure that absentee class members, for whom a settlement will have preclusive effect, have an opportunity to review materials relevant to the proposed settlement and to be heard or otherwise take steps to protect their rights before the court approves or rejects the settlement."[200] McLaughlin, *supra*, § 6:16 at 105-106.

A reviewing court should be aware of several issues that can affect the notice. What follows is a brief discussion of these issues.

1. Contents of the Notice of Settlement

The notice should contain the following information: (1) the essential terms of the settlement, (2) the effect on their rights, (3) the fairness hearing date, (4) objection procedures,[201] (5) proofs of claim or some other general enrollment or sign-up document, and (6) contact information. As to the level of specificity,

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[200] There is no requirement that the individual class members receive actual notice.

> Courts have repeatedly held that neither due process, Rule 23(c) nor Rule 23(e) mandates that class members *receive* actual notice in order to be bound by a class action settlement. The provision of notice reasonably calculated to apprise class members of the settlement is sufficient to bind class members to whom notice was directed.

McLaughlin, *supra*, § 6:16 at 115 (emphasis in original).

[201] "The notice of the fairness hearing should tell objectors to file written statements of their objections with the clerk of court by a specified date in advance of the hearing and to give notice if they intend to appear at the fairness hearing. Despite such ground rules, people who have not filed a written statement may be allowed to present objections at the hearing." MCL, *supra*, § 21.633.

> The notice of settlement must be sufficiently detailed to permit class members to determine the potential costs and benefits involved, or at least whether additional investigation into the matter would be an efficient use of their time. . . . *It is well settled that the notice is not required to provide a complete source of information.*

Newberg, *supra*, § 11:41 (emphasis added); *See also* MCL, *supra*, § 21.313.

For instance, the notice "does not need to set forth the exact formula by which monetary awards to individual class members will be calculated."[202] McLaughlin, *supra*, § 6:16 at 112. Furthermore, a precise distribution plan is not required to be in the notice. Newberg, *supra*, § 11:53 (citing *In re Agent Orange Product Liability Litigation MDL no. 381*, 818 F.2d 145 (2d Cir. 1987)). The only requirement is that the notice "must contain enough information about the settlement and its implications for participants to enable class members to make an informed decision about whether to be heard concerning the settlement . . . ." McLaughlin, *supra*, § 6:16 at 109.

A reviewing court should require a general enrollment or sign-up form – such as a proof of claim – to be included in the notice. A proof of claim is exactly that; a "claims form [that] provid[es] details about [the class members] claims and other information needed to administer the settlement." MCL 4th § 21.66. A proof of claim, however, cannot be distributed unless the claims procedure has been determined. As stated in the *Annotated Manual for Complex Litigation*,

> If the details of a claims procedure have been determined, and there is little indication of any serious challenge to or problems with the settlement, claims forms might be included with the settlement notice. Often, however, the outcome of objections to or

[202] It has also been stated that the notice does not need to contain "the reasons a class member might object to the proposed settlement." McLaughlin, *supra*, § 6:16 at 110. Furthermore, the notice does not need to "attach (a) the proposed settlement agreement or (b) an opt-out form." *Id.* at 111.

> concerns over the settlement terms and the details of allocation and distribution are not established until after the settlement is approved. In that situation, claims forms are distributed after the approval.

Ann. MCL 4th § 21.312. While this publication suggests that some type of sign-up form can be distributed afterwards, the better course is to include some type of general enrollment or sign-up form in the notice. This insures that another expensive class wide notice does not have to be sent should the settlement be approved.

2. Distribution of the Notice of Settlement

As to how the notice is to be distributed,

> District courts have considerable discretion in deciding the manner in which notice of settlement is provided to class members. In determining what manner of notice to provide, a district court ordinarily should consider the cost of giving notice, the difficulty of identifying class members, the timing of the notice and the likelihood of notice reaching potential class members. Neither the rule nor due process requires that individual notice of the settlement be provided to class members where notice of the pendency of the class action was previously provided under Rule 23(c)(2).

McLaughlin, *supra*, § 6:16 at 108. Ultimately, "settlement notices should be delivered or communicated to class members in the same manner as certification notices." MCL, *supra*, § 21.312.

3. Cost of the Notice of Settlement

As to the cost of notice, it has been stated that "[t]he defendant, as the party with the greatest interest in obtaining a broad *res judicata* effect for the settlement decree, should normally bear the costs of settlement notice." Newberg, *supra*, § 11:53. This averment, however, is not universally recognized. The *Manual for Complex Litigation* states that "[t]he parties

generally use the settlement agreement to allocate the cost of settlement notices. The costs are often assessed against a fund created by the defendants or to the defendant, in addition to any funds paid to the class." MCL, *supra*, § 21.312. While it should be aware of this information, a reviewing court only needs to involve itself if the cost of notice is to be paid out of the settlement agreement. This fact would go directly to the fairness, adequacy, and reasonableness of the proposed settlement, which is discussed below.

4. Opt-Outs and Opt-Ins

During the initial certification stage, a court can allow individuals to exclude themselves from the class; i.e., to opt-out. MCL, *supra*, § 21.321. If a class is certified under Rule 23(b)(3), however, the court must afford individuals class members the opportunity to opt-out. *Id.* Such an opportunity should be communicated to the class in the class certification notice.

The question becomes whether a court is required to allow a second opt-out. As with other aspects of a class action settlement, the West Virginia Supreme Court of Appeals has not discussed the issue. However, the federal jurisprudence is clear; a second opt-out is soundly within the discretion of the court. McLaughlin, *supra*, § 6:20. Courts are urged to use caution, though, in allowing class members to opt-out.

> "A second opt-out opportunity might inject additional uncertainty into settlement and create opportunities unrelated to the purpose of the second opt-out, potentially defeating some settlements and making others more costly." The [Rules] Committee acknowledge that the benefits of informed choice for class members should be weighed against the possibility that a second opt-out "would create an opportunity for dissatisfied or mercenary counsel to woo class members away from the settlement with the promise of a superior alternative settlement award."