IADC Mid-Year Conference 2019

Internal CLE Presentation:

What's Up with IARC?
Dealing with IARC Decisions in Product and Tort Litigation

William L. Anderson, Crowell & Moring LLP
Deirdre McGlinchey, McGlinchey Stafford
Brent Kerger, Exponent

This CLE presentation will focus on the impact of International Agency for Research on Cancer ("IARC") determinations in product and tort litigation in recent years, with a particular focus on the California glyphosate lawsuit earlier this year in which IARC's category 2A glyphosate determination played a central role. To support that CLE, the presenters offer this summary of recent and key case law involving IARC determinations. As an overview, some courts, including the recent federal glyphosate MDL judge, have recognized the flaws in allowing experts to rely on certain IARC determinations and excluded either the IARC materials themselves or the experts relying heavily or exclusively on them. These cases provide a solid basis for similar motions in other courts. A number of other courts, however, have let these materials and testimony in, on the ground that although IARC's determinations are not conclusive of causation, they constitute "some evidence" and can form part of the jury's consideration. More recently, largely due to the work of the defense attorneys in the Monsanto glyphosate litigation, the focus has turned to the IARC process and the influence of plaintiff litigation over IARC's determinations. Notwithstanding significant evidence of a biased decision process for glyphosate, however, neither the federal court in the glyphosate MDL nor the state court in the *Johnson* glyphosate trial excluded the IARC evidence.

IARC continues to have an outsized influence on litigation, at the same time that its processes and determinations are becoming ever more one-sided and misleading. The case law summary here will assist the reader and attendees at the presentation in capturing the scope of the law on this subject and preparing for a defense against IARC determinations in litigation.

I. The Monsanto Glyphosate Litigation Rulings

***In re Roundup Prod. Liab. Litig.*, 2018 WL 3368534 (N.D. Cal. July 10, 2018).**

In the recent California Monsanto glyphosate litigation, defendant Monsanto challenged the plaintiffs' experts' reliance on the IARC category 2A classification in the federal MDL proceeding via a motion for *Daubert* exclusion and summary judgment. The defense attorneys in this litigation conducted depositions of two panel members from the IARC Working Group who were both testifying experts in the cases, and the discovery of potential bias in the decision process seem to offer an even stronger basis for excluding this evidence. The court, however, only struck the testimony of the experts who relied almost exclusively on IARC without adding other scientific evidence to their opinions.

The federal MDL currently includes several thousand cases alleging that exposures to Roundup®, Monsanto's glyphosate product, caused cancer, primarily Non-Hodgkin's Lymphoma ("NHL"). IARC in 2015 reclassified glyphosate as a Category 2A carcinogen in a highly contentious and widely criticized proceeding. This flood of federal lawsuits, accompanied by many state lawsuits not part of the MDL, followed. In the MDL, Plaintiffs presented six experts, all of whom relied to some degree on the IARC classification. The motions filed by defendant Monsanto focused on expert exclusion to be followed by summary judgment. IARC was a particular focus, but the briefs, week-long testimony, and court ruling also dealt extensively with glyphosate epidemiology and animal and mechanistic study evidence. Two of the experts relied heavily, and in fact almost exclusively, on the IARC decision and did not even attempt to bolster that finding with additional scientific evidence.

This case thus tees up the critical issue as to whether an IARC 2A "probable human carcinogen" classification, based on only "limited human evidence," is sufficient to serve as the basis for expert causation testimony. The court in this ruling recognized that an IARC 2A determination is not sufficient for courtroom causation, in some very strong language that will be useful for other defendants dealing with this issue:

> "The distinction between glyphosate's capacity to cause NHL at any hypothetical dose and its capacity to cause NHL, at a human-relevant dose is important here, in light of the plaintiffs' heavy reliance on IARC's classification of glyphosate. … Plaintiff's experts seem to have operated under the assumption that they can clear the general causation hurdle simply by showing that IARC's decisions to designate glyphosate a probable human carcinogen is scientifically sound. Accordingly, they have put forward some expert opinions that largely parrot IARC's analysis and conclusions. But whether glyphosate is 'probably carcinogenic to humans' as IARC defines that phrase is not what's directly at issue here." (*9)
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> "IARC conducts its inquiry at a higher level of generality than what the Court must do here." (*11)
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> "As a result, expert opinions that simply parrot IARC's analysis and conclusions are somewhat off topic and are unduly limited, rendering them insufficient to satisfy the plaintiffs' burden at the general causation phase…." (*12)
>
> "[E]xpert opinions that go no further than IARC's analysis will be excluded. An expert opinion of this sort may not 'fit' the general causation inquiry closely enough to be helpful to the jury…." (*Id.*)

As a result of these findings, the court held that IARC determinations are not sufficient for causation proof. The court excluded two experts in whole and one in part because of over-reliance on IARC. Ultimately, however, the court allowed three of the experts to testify, including with partial reliance on IARC, because they presented substantial additional testimony on epidemiology and other studies, and thus the court denied summary judgment. This opinion thus can be cited in future cases if a plaintiff expert leans too heavily on an IARC determination. Unfortunately, because the court will let three of the experts testify in upcoming trials, the jury

will likely be allowed to hear the IARC evidence, and that evidence may well have an oversized impact on the outcomes.

In the California state case *Johnson v. Monsanto,* which initially produced a $289 million verdict (reduced to $78 million in post-trial motions), the motions practice did not focus on the IARC determination, but plaintiffs made it a central element of the trial. Monsanto challenged aspects of the IARC issues in its post-trial motions, but those motions focused significantly on the punitive damages verdict.

II. Other Cases Analyzing the Admissibility or Expert Use of IARC Pronouncements

Allen v. Pennsylvania Engineering Corp., 102 F.3d 194 (5th Cir. 1996)

The *Allen* case is one of the first to address IARC findings in the context of a toxic tort litigation. We include it here as a leading case that has been cited since by other courts addressing IARC issues.

Plaintiff died of brain cancer and alleged that his hospital maintenance work exposure to a sterilizing agent ethylene oxide was the cause. The experts produced no epidemiological study finding a statistically significant link with brain cancer, nor did they provide evidence of the dose involved. The court excluded all three experts. The experts claim to have used a "weight of the evidence" analysis as utilized by EPA, OSHA, and IARC to reach their determinations. The court found that the methodology used by IARC (and other agencies) is intended for preventative public health determinations and prophylactic rules, and the same methodology is not suitable for "more likely than not" causation determination in tort law. The IARC portion of this opinion is only a partial reason for exclusion of the experts, and the exclusion was based on the experts' attempts to use the IARC weight of the evidence approach, not on a specific IARC carcinogenicity determination.

Lightfoot v. Georgia-Pac. Wood Prod., LLC, 2018 WL 4517616 (E.D.N.C. Sept. 20, 2018).

Plaintiff pursued an action claiming his sinonasal cancer resulted from his exposure to wood dust working in his father's woodworking shop throughout his childhood. Defendants sought to exclude plaintiff's experts' testimony under Pennsylvania's *Frye* standard. Plaintiff's expert relied heavily on IARC monographs from 1981, 1995, and 2012. In the 2012 IARC study, upon which Dr. Aronson "heavily relied," IARC concluded, based upon a "synthesis" of studies worldwide: "Wood dust causes cancer of the nasal cavity and paranasal sinuses." (Dr. Aronson Rep. (DE 137-2) at 2; IARC Monograph 100C (2012) (DE 137-6) at 443 & 459). Defendants did not specifically challenge the reliance on IARC for general causation but instead asserted that the IARC monographs and other studies were not sufficient to support general causation for plaintiffs' specific type of cancer (as well as asserting lack of sufficient dose). The court repeatedly accepted the experts' reliance on IARC, coupled with citations to other studies, as sufficient and rejected the challenge.

Harris v. CSX Transp., Inc., 232 W.Va. 617 (2013).

The trial court in this case criticized a plaintiff expert for relying on an IARC publication that did not even contain a causation statement, but the West Virginia Supreme Court reversed in

a long opinion that establishes a very weak gatekeeping approach in that state. The case involved a railroad worker who died from multiple myeloma, allegedly from diesel fume exposure, and who brought suit under the Federal Employers' Liability Act and the Locomotive Inspection Act. One of the plaintiff experts relied in part on an IARC "Technical Publication" that appears to express only a research agenda. Defendant CSX criticized this reliance, among many other attacks on the experts, and the circuit court issued a thorough and detailed opinion demonstrating the flawed approach of the experts, including reliance on the IARC publication. The West Virginia Supreme Court, however, criticized the court's effort and analysis and held that the court greatly exceeded its gatekeeping role. The IARC publication is not a monograph, and in most instances it is unlikely a reasonable court would let an expert rely on it. This ruling may be viewed as perhaps an outlier reflecting the particular view of this state supreme court at the time in regard to expert gatekeeping.

***In re Actos (Pioglitazone) Products Liability Litigation*, 2014 WL 60324 (W.D. La. Jan.7, 2014).**

This case involved the assertion by plaintiffs' expert Dr. Schneeweiss that a certain drug (pioglitazone or Actos®) caused urinary bladder cancer. The expert submitted a 52-page report with many citations to epidemiology and other studies, and the court ultimately rejected defendants' challenge to the testimony. A relatively small portion of defendant's challenge focused on the expert's reliance on IARC's Category 2A classification of this drug for bladder cancer – based on limited human epidemiology but sufficient animal study evidence. The court's review is thus instructive because it illustrates how courts might address a 2A classification, which should not be sufficient for courtroom causation.

The defendant pointed out that IARC "was unable to consistently rule out confounding and bias related to disease severity and detection," and that the Working Group's conclusions were reached on "limited evidence." Thus, the expert should not have been allowed to cite to or use IARC as a basis for causation in this case. The court's response, however, showed a willingness to let even this inconclusive statement of causation into evidence: "Certainly, both of these elements of the IARC Determination should engender care in any epidemiologist seeking to rely upon that Determination as supporting evidence for an opinion. However, this court has found no evidence – nor have the Defendants pointed to anything in the record suggesting – that Dr. Schneeweiss has failed to acknowledge the IARC Determination's inherent limitations or otherwise misapplied its conclusions." (*17). According to the court, the defendants challenged the expert's use of the IARC determination *for any purpose*, and the court held that the expert properly included it for a limited purpose of some evidence of causation. The record in this case apparently involves a significant amount of epidemiology and Bradford Hill analysis, and thus does not present a situation where an expert attempts to rely solely or primarily on an IARC finding. Nevertheless, the defense was unsuccessful in keeping the IARC evidence out or in leveraging the expert's use of it for disqualification.

***Thompson v. Kinder Morgan Altamont, LLC*, 2018 WL 5257631 (D. Utah Oct. 22, 2018).**

Plaintiff Clayton Thompson claimed his chronic myeloid leukemia ("CML") resulted from his being exposed to benzene. Plaintiff presented an expert witness, Dr. Peter Infante, to offer causation testimony focusing on "near-complete reliance on the literature review process

espoused by IARC. That organization has recently deployed that methodology to conclude that benzene is in fact 'associated' with CML." Consequently, defendant sought to exclude Dr. Infante's testimony in part based on Dr. Infante's reliance on IARC's methodology, but the federal court rejected that challenge. The court found that Dr. Infante had properly relied on some studies showing statistical significance while adequately justifying his reliance on others that were not statistically significant and ignoring those finding no link. The court did not carefully analyze or discuss the IARC determination and methodology.

***Goodrich v. John Crane, Inc.*, No. 4:17CV9, 2018 WL 4677773 (E.D. Va. Sept. 28, 2018**).

Plaintiff Harry Goodrich claimed he contracted malignant mesothelioma as a result of being exposed to defendants' asbestos-containing products while serving in the United States Navy. Plaintiff's expert witness employed statements from various government organizations—including IARC—to establish the requisite causation. Defendant sought to preclude any testimony regarding statements from such government regulatory or private policy organizations, or, alternatively, a limiting instruction. The court concluded defendant failed to identify what evidence is sought to preclude with sufficient specificity to deny the motion. Additionally, the court recognized defendant's ability to cross-examine or object to such testimony.

Waite v. AII Acquisition Corp., 194 F. Supp. 3d 1298, 1304 (S.D. Fla. 2016).

In *Waite*, an automotive mechanic brought action against automobile manufacturer that used asbestos containing brake and clutch parts and chemical producer seeking to recover for injuries sustained from exposure to asbestos dust from products that were mined, processed, supplied, manufactured, and distributed by them. The defendant moved to exclude expert testimony regarding specific causation of plaintiff's cancer and for summary judgment. Plaintiff's experts claim to have followed the same weight-of-the-evidence methodology used by ("IARC, the World Health Organization , and the United States Agency for Toxic Substances and Disease Registry ("ATSDR"). Defendant claimed that the alleged lack of statistically significant epidemiological studies demonstrating an increased risk of mesothelioma to "mechanics" trumps all other evidence. However the court found that the defendant's argument that this one type of scientific evidence properly overcomes all others was unconvincing. The court agreed with Plaintiff that their experts had properly considered and evaluated a variety of scientific evidence concerning asbestos in formulating their opinions—including epidemiological studies, animal, cellular and molecular studies, and unbiased reviews of these materials by research agencies, such as ATSDR and IARC. Thus, the court held that proffered expert testimony regarding specific causation of Plaintiff's mesothelioma was admissible under *Daubert*.

***Burst v. Shell Oil Co*., No. CIV.A. 14-109, 2015 WL 3620111, (E.D. La. May 9, 2015), aff'd, 650 F. App'x 170 (5th Cir. 2016).**

In *Burst*, Defendants Shell Oil Company, Chevron U.S.A. Inc., and Texaco, Inc. moved to exclude the testimony of plaintiff's expert epidemiologist, Dr. Peter Infante. Plaintiff alleged that her husband's regular exposure to gasoline containing benzene during the years he worked as a gas station attendant and mechanic caused his acute myeloid leukemia.

The reported basis for Dr. Infante's opinion was his "review of the epidemiological and toxicological literature, plus internal industry documents, related to benzene exposure and risk of developing blood diseases." Dr. Infante stated he "followed the methodology of the International Agency for Research on Cancer (IARC) and of the Occupational Safety and Health Administration (OSHA) in evaluating epidemiological studies, case reports and toxicological studies of benzene exposure and its effect on the hematopoietic system." The court relied on precedent set previously by the Fifth Circuit in *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 198 (5th Cir.1996) that the conclusions and guidance of regulatory and advisory bodies that a substance is carcinogenic do not provide a reliable basis for establishing legal causation when examined alone. Thus, the Court granted defendants' motion because it found that Dr. Infante's general causation opinion was based on an unreliable methodology.

***McMunn v. Babcock & Wilcox Power Generation Grp., Inc.*, No. 2:10CV143, 2014 WL 814878 (W.D. Pa. Feb. 27, 2014).**

In *McMunn*, more than seventy-five (75) plaintiffs allege that defendants, Babcock & Wilcox Power Generation Group, Inc., B & W Technical Services, Inc. and Atlantic Richfield Co., as successors in interest to Nuclear Materials Corporation, were responsible for the release of radioactive uranium from a nuclear processing facility located in Apollo, Pennsylvania and operated from approximately 1953 to 1983. Plaintiffs further allege that inhalation of radioactive uranium from the facility caused the Plaintiffs to develop cancer. In order to prove personal injuries caused by the release of radiation, the Third Circuit has previously held that plaintiffs must establish that: (1) the defendants released radiation into the environment in excess of the levels permitted by federal regulations in effect in 1979; (2) the plaintiffs were exposed to this radiation (although not necessarily at levels prohibited by those regulations); (3) the plaintiffs have injuries; and (4) radiation was the cause of those injuries. The issues before the court in this case were related to the admissibility standard for expert witnesses under Rule 702 of the Federal Rules of Evidence as elucidated by the Supreme Court in *Daubert*.

One of Plaintiff's expert witnesses, Dr. Hu, testified that there is scientific consensus that alpha particles, from whatever source, can cause the biological changes that result in the development of cancer. Dr. Hu's testimony relied in part on the 2001 IARC conclusion that "[i]nternalized radionuclides that emit a-particles are carcinogenic to humans (Group I)." Dr. Hu also relied on an IARC assessment from 2012 in which IARC reiterated its assessment with regard to alpha particles. IARC concluded that it had found sufficient evidence to mandate a classification of uranium as "probably carcinogenic to humans."

In explaining the IARC 2012 report and its consistency with his opinions, Dr. Hu further explained:

> "[The report] defined limited evidence of carcinogenicity, sufficient evidence of carcinogenicity, inadequate evidence of carcinogenicity, and my opinions are aligned with their definition ... [T]he definition of limited evidence of carcinogenicity is the data suggests a carcinogenic effect, but are limited from making a definitive evaluation because, and then they list several of the reasons why they would categorize something as limited evidence.

> But again, we're in the realm of science wanting to make a definitive evaluation. Here we have a substance that's a known alpha emitter. They've already made a definitive statement on that. And in my view, coupled that with the evidence that exists, limited as it is, I feel very comfortable concluding that more likely than not enriched uranium, such as that exposed to residents around Apollo, is carcinogenic."

The Court reasoned that it was unable to find it scientifically unreliable or unreasonable to determine the existence of a risk of cancer for a particular radionuclide by reference to the body of science establishing the carcinogenicity of ionizing radiation. The court found that the alleged flaws in Dr. Hu's methodology go to the weight of Dr. Hu's opinion, not its admissibility. Moreover, because reasonable scientific minds can differ on the methodologies discussed, the motion to exclude the opinion of Dr. Hu was denied.

***Perry v. Novartis Pharm. Corp.*, 564 F. Supp. 2d 452 (E.D. Pa. 2008).**

This case arises from Andreas Perry's diagnosis of lymphoblastic lymphoma in October of 2003. Andreas's parents, plaintiffs in this action, allege that his use of Elidel, a prescription drug manufactured by defendant Novartis Pharmaceuticals Corporation, caused his lymphoma. The parties have completed discovery limited to the issue of causation and Novartis has filed a motion to exclude the testimony of plaintiffs' experts, Dr. Martyn T. Smith and Dr. E. Anders Kolb.

Dr. Smith's report, concluded that "pimecrolimus is a cause of non-Hodgkin lymphoma in humans." Dr. Smith bases that conclusion on his observations that: (1) pimecrolimus produced lymphomas in mice and monkeys and non-lymphoma tumors in rats; (2) cyclosporine and tacrolimus are well-described carcinogens in humans when used systemically to prevent transplant rejection; multiple case reports link dermal use of pimecrolimus to lymphoma; and (4) there exist biologically plausible mechanisms by which pimecrolimus could cause lymphoma. Dr. Smith's report goes on to examine possible mechanisms by which pimecrolimus exposure might induce lymphoma in humans. He begins by noting that immune deficiency, whether congenital, iatrogenic, or acquired, is a strong risk factor for NHL. Pimecrolimus is a calcineurin inhibitor and is known to suppress immune function. IARC has identified cyclosporine, another calcineurin inhibitor, as a known, or Group 1, human carcinogen. Dr. Smith hypothesizes that, were IARC to evaluate the data that he examined, it would conclude that pimecrolimus is a Group 2A carcinogen: a substance that "is probably carcinogenic to humans." Based on his review of animal studies and the IARC's categorization of comparable medication Dr. Smith concluded that "pimecrolimus is a cause of non-Hodgkin lymphoma in humans.

In this case, the court found that Dr. Smith's testimony met the reliability requirement of *Daubert* but it failed to meet *Daubert's* fit requirement. The court found that Dr. Smith failed to address the disparity in the dosages Andreas Perry received and the dosages in the animal studies on which he relied. IARC, notably, performs only a "hazard" determination and does not take expected human doses into account. More specifically, the court reasoned that Dr. Smith's general causation conclusions are primarily based on the animal studies and his failure to satisfactorily address this analytical gap related to dosage levels undermines the usefulness of his conclusions to a jury. Further, the court found that the significant analytical gap dealing with

dosage meant that, even if the court were to find the specific causation conclusions reliable, it would still exclude Dr. Smith's testimony on fit grounds because Dr. Smith failed to form a scientifically-grounded chain of inference between their general causation finding and their specific causation finding. The court found that Dr. Smith's report did not meet *Daubert's* fit requirements and was inadmissible.

This opinion presents the rather unique situation in which an expert had no IARC review of the substance at issue to rely on, and instead hypothesized that IARC would reach a conclusion on that substance similar to its carcinogenicity finding on another, related material. That effort was unsuccessful. The outcome might have differed had IARC itself reached a determination on the substance at issue.

III. Workers' Compensation and Other Unique Circumstance Cases

***City of Philadelphia Fire Dep't v. Workers' Comp. Appeal Bd. (Sladek),* No. 13 EAP 2017, 2018 WL 5046516, (Pa. Oct. 17, 2018).**

This case is somewhat unusual in that involves a workers compensation claim and a state statute that specifically incorporates IARC determinations into workers compensation findings for firefighters. The statute in question requires firefighters to prove that they have a "cancer … which is caused by exposure to a known (Group 1) carcinogen." The burden then shifts to the employer, but the employer may not use epidemiology to demonstrate that the substances at issue do not cause cancer, contrary to the IARC findings. The statute only includes Class 1 carcinogens (those with sufficient epidemiology evidence) and thus would not incorporate lesser categories. But the court allowed the firefighter to demonstrate generally that smoke contained several such carcinogens, without proving that any single carcinogen or even all of them together actually caused his disease. This case has to be treated as an anomaly, first because it involves a statutory declaration, and second because it clearly involves a weakened standard for causation designed to benefit firefighters without requiring any traditional proof of causation.

***Peck v. Indus. Comm'n*, No. 1 CA-IC 17-0038, 2018 WL 3031636 (Ariz. Ct. App. June 19, 2018).**

This is another workers compensation case, but with a very different posture and outcome. Arizona, unlike Pennsylvania, does not incorporate IARC Category 1 determinations into its workers compensation statute, but instead requires full proof of causation from the occupational exposure. Plaintiff worked as a firefighter for the City of Goodyear and was diagnosed with sinonasal undifferentiated carcinoma ("SNUC"). The IARC monograph in this case was actually used by the *defense* to demonstrate a lack of connection between this type of cancer and firefighting: "Salganick stated that the IARC monograph related to firefighting showed only a possible relationship to all cancers generally and emphasized that the IARC monographs relating to wood dust, wood smoke, and soot in particular were irrelevant to firefighting and SNUC…. SNUC is 'not mentioned whatsoever'" in the IARC document. The reviewing court upheld the ALJ's rejection of this claim.

***Middlebrooks v. City of Bastrop*, 219 So. 3d 331 (La. App. 2 Cir. 1/11/17).**

Plaintiff Mark Middlebrooks served as a firefighter with the Bastrop Fire Department for over 19 years. In 2014, plaintiff was diagnosed with a brain tumor. Plaintiff sought workers' compensation benefits claiming his was exposed to carcinogenic substances as defined by IARC, while working as a firefighter. The statute specifically referenced IARC determinations as forming the required basis for a claim. The city rebutted the presumption with expert testimony of a questionnaire from Middlebrooks' physician conveying the cancer was of unknown origin. The Workers' Compensation Judge found the physician's statement sufficient to rebut the causation presumption. Nonetheless, on appeal, the court determined the physician's statement insufficient to demonstrate Middlebrooks' occupation had nothing to do with the cancer. Accordingly, the WCJ's judgment was reversed.