IN THE DISTRICT OF COLUMBIA COURT OF APPEALS

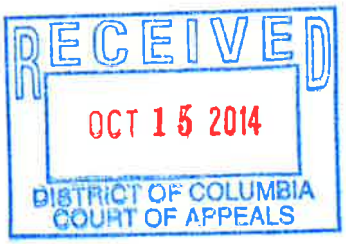
MICHAEL PATRICK MURRAY, *et al.*,

Respondents,

v.

MOTOROLA INC., *et al.*,[1]

Applicants/Petitioners.



From an Order of the Superior Court for
the District of Columbia, Civil Division
Superior Court Case No. 2001 CA 008479 B

COMBINED APPLICATION FOR PERMISSION TO APPEAL ORDER ON EXPERT WITNESS ADMISSIBILITY AND PETITION FOR HEARING EN BANC

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[1] This Application and Petition relates to *Murray* and the following twelve related cases (collectively, the "Murray Cases"): *Schofield v. Motorola, Inc.*, Case No. 2002 CA 001371 A; *Cochran v. Audiovox Communications Corp.*, Case No. 2002 CA 001369 A; *Keller v. Nokia*, Case No. 2002 CA 001372 A; *Schwamb v. Qualcomm Inc.*, Case No. 2002 CA 001370 A; *Agro v. Motorola, Inc.*, Case No. 2002 CA 001368 A; *Marks v. Motorola, Inc.*, Case No. 2010 CA 003206 B; *Kidd v. Motorola, Inc.*, Case No. 2010 CA 007995 B; *Prischman v. Motorola, Inc.*, Case No. 2011 CA 002113 B; *Bocook v. Motorola, Inc.*, Case No. 2011 CA 002453 B; *Brown v. Nokia, Inc.*, Case No. 2011 CA 006710 B; *Solomon v. Motorola, Inc.*, Case No. 2011 CA 008472 B; *Noroski v. Samsung Telecomm America, LLC*, Case No. 2011 CA 008854 B.

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[2] (1) *Brooks v. Mitsubishi Electric and Electronics USA, Inc.,* Case No. 2012 CA 003241 B; (2) *Jones v. Motorola, Inc.,* Case No. 2012 CA 003981 B; (3) *Cobb v. Motorola Mobility, Inc.,* Case No. 2012 CA 004068 B; (4) *King, et al. v. Motorola Mobility, Inc.,* Case No. 2012 CA 008533 B; (5) *Butler v. Motorola Mobility, Inc.,* Case No. 2012 CA 008537 B; (6) *Gonzalez v. Motorola Mobility LLC,* Case No. 2013 CA 005115 B; (7) *Phillips v. Nokia, Inc.,* Case No. 2013 CA 004542 B; and (8) *Anderson v. Nokia, Inc.*, Case No. 2013 CA 006641 B; (9) *Rice v. Motorola Mobility LLC,* Case No. 2013 CA 007805 B; (10) *Riepen v. AT&T Mobility LLC,* Case No. 2013 CA 007804 B; (11) *Zelcer v. LG Electronics USA, Inc.,* Case No. 2013 CA 007620 B; (12) *Marks v. Motorola Mobility LLC,* Case No. 2013 CA 008192 B; (13) *Ferguson v. Nokia, Inc.,* Case No. 2013 CA 007957 B; (14) *Savoury* v. *Motorola Mobility LLC,* Case No. 2014 CA 001425 B; (15) *Abrams Vervoort v. Motorola Mobility, LLC,* Case No. 2014 CA 002521 B; (16) *Reilly v. LG Electronics MobileComm USA Inc.,* Case No. 2014 CA 002797 B; and (17) *Kasperski v. AT&T Mobility, LLC,* 2014 CA 0004171 B.

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RULE 28(a)(2) CORPORATE DISCLOSURE STATEMENT

Apple Inc. has no parent corporation or publicly traded subsidiaries, and no publicly held corporation owns 10% or more of its stock.

AT&T Inc. has no parent company and no publicly traded subsidiaries. No publicly traded corporation owns 10 percent or more of AT&T Inc. stock.

AT&T Corp. is a subsidiary of AT&T Inc. AT&T Corp. has no publicly traded subsidiaries, and no publicly traded corporation owns 10 percent or more of its stock.

AT&T Mobility LLC does not issue stock. Its ultimate parent corporation is AT&T Inc.

AT&T Wireless Services, Inc. n/k/a New Cingular Wireless Services, Inc., has no publicly traded subsidiaries, and no publicly traded corporation owns 10 percent or more of its stock. Its ultimate parent corporation is AT&T Inc.

Audiovox Communications Corporation does not have any subsidiaries, and the only publicly held company that owns 10 percent or more of the stock of Audiovox Communications Corporation is Audiovox Corporation.

Bell Atlantic Mobile, Inc. ("BAM") was the managing general partner of Cellco Partnership d/b/a Verizon Wireless from July 1994 until April 2000, but is no longer an active entity.

Cellco Partnership d/b/a Verizon Wireless ("Cellco") is a general partnership formed under the laws of the State of Delaware. Cellco has four partners in total. These partners are Bell Atlantic Mobile Systems LLC, a Delaware limited liability company; GTE Wireless Incorporated, a Delaware corporation; PCS Nucleus, L.P., a Delaware limited partnership; and JV PartnerCo, LLC, a Delaware limited liability company. Verizon Communications Inc. indirectly, wholly owns Cellco. As far as Cellco is aware, no publicly traded corporation owns more than 10 percent of Verizon Communications Inc.

Cingular Wireless LLC n/k/a AT&T Mobility LLC has no publicly traded subsidiaries, and no publicly traded corporation owns 10 percent or more of its stock. Its ultimate parent company is AT&T Inc.

Cellular One Group, n/k/a Cellular One, LLC has no subsidiaries and no publicly-traded company owns 10 percent or more of its stock. Cellular One, LLC is a limited liability company formed under the laws of the State of Nevada and is owned by PN Cellular, Inc. d/b/a Trilogy Partnership.

Cricket Communications, Inc. is an indirect, wholly-owned subsidiary of AT&T, Inc. Other than as indicated herein, no publicly traded corporation owns more than 10% of the stock in Cricket.

CTIA-The Wireless Association, sued in these cases as "Cellular Telecommunications & Internet Association" and "Cellular Telecommunications Industry Association," has no parent corporation or subsidiaries, and no publicly held corporation owns 10 percent or more of its stock.

HTC America, Inc. HTC America, Inc.'s parent company is HTC Corporation, headquartered in Taipei, Taiwan; HTC Corporation is a public corporation whose stock is traded on the Taiwan Stock Exchange (TWSE).

LG Electronics MobileComm U.S.A., Inc., ("LGEMU") is a wholly-owned subsidiary of LG Electronics U.S.A., Inc., which is a wholly-owned subsidiary of LG Electronics, Inc. LGEMU does not issue stock.

Microsoft Mobile Oy, (formerly Nokia, Inc.) a Finland corporation, is a wholly owned subsidiary of Microsoft Luxembourg USA Mobile S.a.r.l, a Luxembourg corporation, which is a wholly owned subsidiary of Microsoft Luxembourg International Mobile S.a.r.l, a Luxembourg corporation, which is a wholly owned subsidiary of Microsoft Corp., a publicly held company incorporated in Washington, United States. Microsoft Mobile Oy has no publicly traded subsidiaries.

Motorola, Inc. On January 4, 2011, Motorola Mobility, Inc. was separated from Motorola, Inc., and Motorola, Inc. was renamed Motorola Solutions, Inc. On June 22, 2012, Motorola Mobility, Inc. became Motorola Mobility LLC. Motorola Mobility LLC is a Delaware limited liability company. Motorola Mobility LLC is the operating entity and wholly owned subsidiary of Motorola Mobility Holdings LLC. Effective May 22, 2012, more than 10% ownership of Motorola Mobility LLC was acquired by Google Inc. There is no parent corporation or other publicly held company that owns 10% or more of Motorola Solutions, Inc. stock.

Qualcomm Incorporated has no parent company or publicly traded subsidiaries, and no publicly held company owns 10 percent or more of its stock.

Samsung Telecommunications America, LLC ("STA") is a wholly-owned subsidiary of Samsung Electronics America, Inc. ("SEA") and no publicly held corporation owns 10% or more of STA's stock. SEA is a wholly-owned subsidiary of Samsung Electronics Co., Ltd., which is a Korean corporation that is publicly traded on the Korean Stock Exchange.

Sony Electronics Inc. is an indirect wholly-owned subsidiary of Sony Corporation of America ("SCA"). SCA is an indirect wholly-owned subsidiary of Sony Corporation, which exists under the laws of Japan. Sony Corporation's American Depository Receipts are traded on the New York Stock Exchange. No other public held company owns 10 percent or more of Sony Electronics Inc. Sony Electronics has no publicly traded subsidiaries.

On July 10, 2013, **Sprint Nextel Corporation** changed its name to "Sprint Communications, Inc." Sprint Communications, Inc. is a private company. It is a wholly-owned subsidiary of Sprint Corporation, a publicly-traded corporation. More than 10% of Sprint Corporation's stock is owned by SoftBank Corporation, also a publicly-traded corporation. h

Sprint Spectrum L.P. is an indirect wholly owned subsidiary of Sprint Communications, Inc., a private company. It is a wholly-owned subsidiary of Sprint Corporation, a publicly-traded corporation. More than 10% of Sprint Corporation's stock is owned by SoftBank Corporation, also a publicly-traded corporation.

T-Mobile USA, Inc., a Delaware corporation, is a wholly-owned subsidiary of T-Mobile US, Inc., a Delaware corporation. T-Mobile US, Inc. (NYSE: TMUS) is a publicly-traded company listed on the New York Stock Exchange ("NYSE"). Deutsche Telekom Holding B.V., a limited liability company (besloten vennootschap met beperkte aansprakelijkheidraies) organized and existing under the laws of the Netherlands ("DT B.V."), owns more than 10% of the shares of T-Mobile US, Inc. DT B.V. is a direct wholly-owned subsidiary of T-Mobile Global Holding GmbH, a Gesellschaft mit beschränkter Haftung organized and existing under the laws of the Federal Republic of Germany ("Holding"). Holding, is in turn a direct wholly-owned subsidiary of T-Mobile Global Zwischenholding GmbH, a Gesellschaft mit beschränkter Haftung organized and existing under the laws of the Federal Republic of Germany ("Global"). Global is a direct wholly-owned subsidiary of Deutsche Telekom AG, an Aktiengesellschaft organized and existing under the laws of the Federal Republic of Germany ("Deutsche Telekom"). The principal trading market for Deutsche Telekom's ordinary shares is the Frankfurt Stock Exchange. Deutsche Telekom's ordinary shares also trade on the Berlin, Düsseldorf, Hamburg, Hannover, München and Stuttgart stock exchanges in Germany. Deutsche Telekom's American Depositary Shares ("ADSs"), each representing one ordinary share, trade on the OTC market's highest tier, OTCQX International Premier (ticker symbol: "DTEGY").

Telecommunications Industry Association has no parent corporation or subsidiaries, and no publicly held corporation owns 10 percent or more of the Association.

United States Cellular Corporation is a nongovernmental corporation, the parent of which is Telephone and Data Systems, Inc. ("TDS"). TDS is the only publicly held corporation that owns 10% or more of U.S. Cellular's stock.

Verizon Wireless, Inc. is a Delaware corporation with its principal place of business in New Jersey. Verizon Communications, Inc. is Verizon Wireless, Inc.'s parent corporation. No other publicly held corporation holds 10% or more of Verizon Wireless, Inc.'s stock.

I. COURT OF APPEALS RULE 35(b)(1) STATEMENT

This proceeding presents a question of exceptional importance:

> [W]hether the District of Columbia Court of Appeals, sitting *en banc*, should discard the antiquated *Frye* test and join the majority of jurisdictions that have adopted Federal Rule [of Evidence] 702 or *Daubert* (or have modernized their *Frye* rule to permit consideration of both methodology and scientific reliability).

Order Amending August 8, 2014 Memorandum Opinion and Order to Include Certification for Interlocutory Appeal (Super. Ct. Judge Frederick H. Weisberg) ("Cert. Order," Exhibit A hereto) at 2 (referencing *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993)).

The undersigned Applicants/Petitioners hereby request permission under D.C. Code § 11-721 (d) and D.C. App. R. 5 to immediately appeal the Superior Court's Amended Memorandum Opinion and Order on Expert Witness Admissibility ("Order," Exhibit B hereto), as amended and reentered by Judge Weisberg in the Cert. Order. By this pleading, Applicants/Petitioners also petition the court for hearing en banc under D.C. App. R. 35.

II. INTRODUCTION

Plaintiffs in the thirteen Murray Cases (*see* footnote 1) and seventeen other related cases allege that they or a decedent developed a brain or other tumor as a result of exposure to radiofrequency (RF) emissions from cellular phones. *See* Order at 5. Because of the "novel scientific issues" raised by these cases, the Superior Court bifurcated discovery in the Murray Cases to address first the issue of general causation. *Id.* After expert discovery, Judge Weisberg held a four-week evidentiary hearing to determine the admissibility of Plaintiffs' expert testimony. *Id.* at 6.

Judge Weisberg applied D.C.'s admissibility criteria, and in particular the third prong of the standard in *Dyas v. United States*, 376 A.2d 827, 832 (D.C. 1977), which, the court held,

focuses entirely on the *Frye* test of the general acceptance of the expert's stated methodology, disregards whether the expert applied that method properly, and ignores the scientific invalidity of the proffered opinion. Order at 19-20. Under that test, Judge Weisberg held that "some, but not all," of Plaintiffs' proffered testimony was admissible. Cert. Order at 1.

That outcome did not result from any finding that the proffered opinions are scientifically valid. To the contrary, Judge Weisberg found that, on the question of whether cell phones cause brain cancer, he "could not conclude, based on the present record, that there is enough evidence for *any* scientist to answer the question 'yes' with the requisite degree of scientific certainty." Order at 4 (emphasis original). Rather, the admissibility of certain experts' general causation testimony was driven by strict application of the *Frye* standard.

Judge Weisberg offered several reasons for replacing *Frye*. *First*, Judge Weisberg held that the *Frye* test "is not a good gatekeeper for inductive sciences such as epidemiology or psychology," which "necessarily require[] the subjective judgment of the expert to infer from premises to conclusions." *Id.* at 28. As a result, in cases that present novel general causation issues involving an expert's subjective judgment, "*Frye* does not seem like the best way to ensure a just result." *Id.* *Second*, he observed that the *Frye* standard is likely to result in the admission of "bad science." *Id.* at 26. *Third*, Judge Weisberg contrasted *Frye* with the *Daubert* standard (embodied in Federal Rule of Evidence 702) and stated that the proffered opinions admissible under *Frye* "would almost certainly be excluded under *Daubert*." *Id.* at 25.

Judge Weisberg certified his Order for interlocutory appeal because it "satisfies the section 11-721(d) criteria in all respects." Cert. Order at 2. He identified the controlling question of law for which there is substantial ground for a difference of opinion as "whether the District of Columbia should adopt Federal Rule of Evidence 702 (or a revised *Frye* standard) for

the admissibility of expert evidence." *Id.* at 5. Immediate appeal could materially advance the termination of the underlying litigation because, "[i]f the adoption of a new standard results in the exclusion of Plaintiffs' general causation experts, Plaintiffs do not have a case." *Id.* at 2.

As Judge Weisberg concluded, the issue presented here "require[s] *en banc* consideration." Cert. Order at 4; *accord*, *Pettus v. United States*, 37 A.2d 213, 217 n.4 (D.C. 2012) (noting that en banc review is necessary to consider whether D.C. will "depart from the *Frye* test"). Whether D.C. should adopt a Federal Rule of Evidence or otherwise modernize its law on admission of expert testimony is "a question of exceptional importance." D.C. App. R. 35 (a)(2); *see, e.g.*, *Johnson v. United States*, 683 A.2d 1087 (D.C. 1996) (en banc) (adopting FRE 403); *Hernandez v. Banks*, 65 A.3d 59, 63, 61 (D.C. 2013) (en banc) (replacing long-standing rule with "modern" "majority approach").

The court's interlocutory and en banc review of this issue is particularly important given the backdrop of this litigation. Cell phones are ubiquitous in the United States, with over 335 million wireless subscriber connections (a number larger than the U.S. population).[3] As a result, the safety of cell phones has been extensively studied. The international consensus of governmental health agencies is that there is not an adequate or reliable basis to conclude that cell phones cause adverse health effects. U. S. federal regulators agree and have declared that cell phones "are safe."[4] And all other U.S. courts to consider expert testimony challenging the safety of cell phones have excluded it. Thirty cases pending in the Superior Court (none of

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[3] *See* http://www.ctia.org/your-wireless-life/how-wireless-works/annual-wireless-industry-survey (last visited October 10, 2014).

[4] *Murray v. Motorola*, 982 A.2d 764, 778 (D.C. 2009) (quoting *Bennett v. T-Mobile USA, Inc.*, 597 F. Supp. 2d 1050, 1053 (C.D. Cal. 2008)).

which involves a D.C. resident) challenge the safety of cell phones and, as Judge Weisberg noted, the number of cases is likely to grow. Cert. Order 2-3.

For these and other reasons, this court should accept Judge Weisberg's findings and permit an interlocutory appeal and en banc hearing. An immediate appeal presents a unique opportunity to consider a controlling and exceptionally important legal question, to align judicial outcomes with the state of the science, and to align D.C. jurisprudence with the overwhelming majority of jurisdictions.

III. FACTUAL BACKGROUND

A. Plaintiffs' Claims

Plaintiffs claim that RF emitted by cell phones causes two types of brain tumors: gliomas and acoustic neuromas.[5] As Judge Weisberg found, "Many common objects, and certainly all electronics, give off some form of radiation." Order at 7. Though a form of electromagnetic radiation, RF is very different from the "radiation" known to harm human cells, such as x-rays.[6] RF from cell phones is similar to radiation from other electronics, such as baby monitors, garage door openers, and radio/TV signals. The safety of RF from cell phones has been the subject of worldwide scientific study, mainly because of their wide proliferation.

Judge Weisberg described the state of the science based on the views of "[m]any . . . governmental agencies and other independent organizations": "All have concluded that the evidence at this time is insufficient to establish causation with any degree of confidence approaching a scientific certainty." Order at 15. That consensus includes the National Cancer

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[5] Although acoustic neuromas are not precisely brain tumors, by convention and for ease of reference this pleading uses "brain tumors" to apply to both gliomas and acoustic neuromas.

[6] *See* National Cancer Institute, Fact Sheet, Cell Phones and Cancer Risk, http://www.cancer.gov/cancertopics/factsheet/Risk/cellphones (last visited October 10, 2014).

Institute, Federal Communications Commission, Food and Drug Administration, World Health Organization, International Agency for Research on Cancer, and many others. The science considered by those organizations includes cancer trend data, which show that, during the twenty-year period in which cell phone usage skyrocketed rare to nearly 100% of the population, the rate of brain cancer diagnoses per year has remained flat, if not fallen slightly. Order at 13; 34-35.

Consistent with the scientific consensus, Judge Weisberg recognized that "[n]o American court has yet found that cell phones can cause brain tumors." Order at 5. Most prior lawsuits were voluntarily dismissed when scheduling orders required plaintiffs to present expert evidence. In the few cases in which the plaintiffs did present causation experts, the courts excluded their testimony. *See, e.g.*, *Newman v. Motorola*, 218 F. Supp. 2d 769 (D. Md. 2002), *aff'd* 78 F. App'x 292 (4th Cir. 2003); *Reynard v. NEC Corp.*, 887 F. Supp. 1500 (M.D. Fla. 1995).

B. Prior Proceedings in This Litigation

The Murray Cases were grouped together and ultimately assigned to Judge Weisberg. Seventeen virtually identical later-filed cases are also pending before Judge Weisberg, but were stayed pending the admissibility decision in the Murray Cases.[7] As Judge Weisberg observed, "[t]he number [of cases] is continuing to grow as Plaintiffs' counsel sign up new claimants." Cert. Order at 2-3. Plaintiffs have sued the entire cell phone industry – 28 defendants – including manufacturers (*e.g.*, Motorola, Apple, Microsoft Mobile, HTC), service providers (*e.g.*, AT&T, Verizon Wireless, Sprint, T-Mobile), and trade organizations. None of the Plaintiffs in the thirty pending cases resides in D.C.

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[7] The individual stay orders provide that the admissibility decision in the Murray Cases would apply to the seventeen related non-Murray cases.

In 2007, the Superior Court dismissed the six then-filed cases based on federal preemption. On appeal, this court largely affirmed, holding that Plaintiffs' claims "conflict with the FCC determination that 'wireless phones that do comply with [the FCC's] RF standards are safe for use by the general public and may be sold in the United States.'" *Murray*, 982 A.2d at 778 (quoting *Bennett*, 597 F. Supp. 2d at 1053). The court remanded for further proceedings, and the cases continued based on Plaintiffs' allegations that their phones did not comply with the FCC RF standards.

The Superior Court stayed general discovery and initiated a Phase I proceeding in the Murray Cases on general causation: whether cell phones are capable of causing brain tumors. Order at 5. Plaintiffs proffered "general causation" experts. Defendants proffered rebuttal experts and moved to exclude Plaintiffs' experts on the grounds that their opinions were inadmissible under both the *Dyas/Frye* and *Daubert* standards. Judge Weisberg conducted four weeks of hearings, receiving evidence from both sides on the state of the science and Plaintiffs' experts' methodologies and opinions.

C. Judge Weisberg's Order on the Admissibility of Expert Testimony

On August 8, 2014, Judge Weisberg issued his admissibility Order. He was "clear" on his view of the state of the science:

> Can cell phones cause brain cancer? . . . Although there are a few isolated strands of data pointing in the direction of causation, the court could not conclude, based on the present record, that there is enough evidence for *any* scientist to answer the question "yes" with the requisite degree of scientific certainty.

Order at 4 (emphasis in original). Judge Weisberg stressed that "[t]here is entirely too much controversy in the scientific community to entrust that question to a jury of laypersons." *Id.*[8]

Nevertheless, Judge Weisberg felt constrained by *Frye*, and admitted general causation testimony from some expert witnesses that it believed passed *Frye*'s low threshold for admissibility, which the court explained in detail. The court held that *Frye* "'does not ask – or even permit – the court to ascertain scientific validity for itself.'" *Id.* at 19 (quoting *The New Wigmore: A Treatise on Evidence*, § 5.3 at 161 (2004)). Instead, the court held, "[o]nce the court determines that the expert's methodology has been suitably identified and is generally accepted, the *Frye* inquiry ends"; thus, an expert's testimony is admissible under *Frye* even when the expert incorrectly applied the method and even when the expert opinion is not scientifically reliable. *Id.* at 22. Judge Weisberg noted, "[w]hether or not [an expert] properly applied that methodology is a question for the factfinder and is beyond the scope of a *Frye* inquiry." *Id.* at 43. Thus, for example, the court was constrained to admit testimony from an expert even though the court found his testimony "problematic," scientifically "thin," and noted that the expert "appears to apply his scientific knowledge as an advocate." *Id.* at 44.

Judge Weisberg contrasted D.C.'s "orthodox" *Frye* test with *Daubert*, explaining that *Frye* is more likely to admit "bad science." *Id.* at 25-26. The court highlighted that "the [*Frye*] test is not a good gatekeeper for inductive sciences such as epidemiology or psychology," which "necessarily" require greater use of "subjective judgment." *Id.* at 28. Thus, "[a]t least where the

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[8] Judge Weisberg acknowledged that the third *Dyas* prong discusses the "state of . . . scientific knowledge," but did not exclude the testimony under that prong because of his view that "subsequent case law . . . restrict[s] the trial court's inquiry to the narrow review of methodology under the *Frye* test." Order at 28 n.36 (citing *Ibn-Tamas v. United States*, 407 A.2d 626, 638 (D.C. 1979)); *compare Dyas*, 376 A.2d at 832.

science is as fraught with doubt as inferences of causation in epidemiology can be, *Frye* does not seem like the best way to ensure a just result." *Id.*

Judge Weisberg amended and reentered its Order on October 1, 2014, to permit interlocutory appeal on the controlling legal question of "whether the District of Columbia Court of Appeals, sitting *en banc*, should discard the antiquated *Frye* test and join the majority of jurisdictions that have adopted Rule 702 or *Daubert* (or have modernized their *Frye* rule to permit consideration of both methodology and scientific reliability)." Cert. Order at 2. The court held that the § 11-721 (d) criteria were met and gave several reasons why this court should not "wait for" a final judgment. Cert. Order at 2, 4. The court found that the number of similar cases "is continuing to grow," that review now "could save the court and the parties years of unnecessary and prohibitively expensive litigation," and "the record on general causation is about as well developed as it is ever going to be." *Id.* at 2-4. Judge Weisberg *sua sponte* stayed all proceedings in the thirty cell phone cases on its docket, holding that "any delay incident to the appellate process would be justified for the reasons the court has already enumerated." *Id.* at 5.

IV. CONTROLLING QUESTION OF LAW

Whether the District of Columbia should adopt Federal Rule of Evidence 702/*Daubert* (or a revised *Frye* standard) for the admissibility of expert evidence? *See* Order at 5.

V. ARGUMENT

A. The Court Should Permit Interlocutory Appeal for the Reasons Set Forth in Judge Weisberg's Orders.

An immediate appeal is warranted because, as Judge Weisberg held, the expert admissibility Order satisfies the statutory criteria that such an appeal "involves a controlling question of law as to which there is a substantial ground for a difference of opinion and . . . an immediate appeal . . . may materially advance the ultimate termination of the litigation." *See*

Cert. Order at 2 (quoting D.C. Code § 11-721 (d)). *First*, the operative expert admissibility framework is a question of law that controls the extent to which Plaintiffs have admissible expert proof necessary to their claims. *Second*, although District of Columbia Court of Appeals divisions have applied *Frye* previously, retaining *Frye* is subject to a difference of opinion given *Frye*'s recognized limitations, the ongoing debate concerning *Frye* and *Daubert*, and an overwhelming national shift from the former to the latter. *Third*, a decision to adopt FRE 702/*Daubert* or modernize the *Frye* standard is likely to end or narrow considerably this litigation, thereby saving countless hours and resources.

The § 11-721 (d) standard requires "a certain flexibility," and "[t]here can be no rigid formulation of the standards implicit in that doctrine." *Plunkett v. Gill,* 287 A.2d 543, 544 (D.C. 1972). Interlocutory appeal is appropriate when "the disadvantages inherent in piecemeal review [are] substantially outweighed by the possibility of mitigating what might otherwise be protracted and expensive litigation." *Plunkett*, 287 A.2d at 544; *accord*, *Reese v. BP Exploration (Alaska) Inc.*, 643 F.3d 681, 688 n.5 (9th Cir. 2011) (rejecting "formalistic" standard that "could lead to unnecessary, protracted litigation and a considerable waste of judicial resources").[9]

Interlocutory appeal is available to manage complex litigation efficiently when threshold legal issues "affect the scope of the evidence in a complex case" and should be addressed before massive resources are wasted. *Garner v. Wolfinbarger*, 430 F.2d 1093, 1097 (5th Cir. 1970) (reviewing privilege framework on interlocutory appeal of shareholder litigation); *accord*, *In re Air Crash Disaster near Chicago,* 701 F.2d 1189 (7th Cir. 1983) (reversing trial court evidentiary rulings on interlocutory appeal in multi-plaintiff consolidated tort litigation). Indeed,

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[9] Section 11-721(d) was modeled on the federal interlocutory appeal statute, 28 U.S.C. § 1292(b), and as with many such rules, District of Columbia courts look to federal law for guidance. *Plunkett*, 287 A.2d at 544.

a state appellate court previously granted interlocutory appeal to address this issue of cell phones allegedly causing brain cancer. *See Motorola v. Ward*, 478 S.E.2d 465, 466 (Ga. Ct. App. 1997).

Under a standard identical to § 11-721 (d), the Tenth Circuit used interlocutory appeal twenty years ago to consider whether to abandon the then-established *Frye* standard. *See Wilson v. Merrell Dow Pharms., Inc.*, 20 F.3d 379 (10th Cir. 1994). States' highest courts also have granted interlocutory appeals to alter expert admissibility standards in favor of *Daubert*. *See McDaniel v. CSX Transp., Inc.*, 955 S.W.2d 257 (Tenn. 1997); *Christian v. Gray*, 65 P.3d 591 (Okla. 2003). The Murray Cases similarly turn on a threshold legal framework that is "problem[atic]" in the "present context." Order at 28. Guidance from this court on the admissibility standard is essential now, and this case meets the standard for interlocutory appeal.

1. Whether the District of Columbia Should Adopt FRE 702/*Daubert* or a Modern *Frye* Equivalent Is a Controlling Question of Law.

The question for immediate appeal is whether this court should "discard the antiquated *Frye* test" and adopt FRE 702/*Daubert* or a "modernized" *Frye* standard. Cert. Order at 2. That is a classic "abstract legal issue . . . [that] the court of appeals 'can decide quickly and cleanly without having to study the record,'" and is therefore the sort of "pure" question of law for which interlocutory review exists. *McFarlin v. Conseco Services, LLC,* 381 F.3d 1251, 1258 (11th Cir. 2004) (citing *Ahrenholz v. Bd. of Trustees of Univ. of Ill.*, 219 F.3d 674, 677 (7th Cir. 2000)).

The operative expert admissibility standard "can be outcome determinative" because "[t]he opinions offered in this case that may be admissible under the District's 'methodology only' application of *Frye* would almost certainly be excluded under *Daubert*." Order at 25; *see also* Cert. Order at 1 ("[M]ost, if not all, of Plaintiffs' experts would probably be excluded under the Rule 702/*Daubert* standard based on the present record."). If that expert testimony is excluded, "Plaintiffs do not have a case." Cert. Order at 2. Indeed, Plaintiffs conceded below

that the "*Daubert* versus *Frye*" issue is a "question of law," and that the issue "might have been controlling."[10] That, by itself, is enough to meet the § 11-721 (d) standard: a legal question is controlling for interlocutory appeal purposes if it is even "*potentially* dispositive." *Mineo v. Port Auth. of N.Y. & N.J.*, 779 F.2d 939, 942 (3d Cir. 1985) (emphasis added).[11]

The question is ripe now, and Judge Weisberg has considered how he would manage the application of a new operative standard on remand. Cert. Order at 4. To the extent further discovery is necessary "to place Plaintiffs in a fair position to litigate" under FRE 702/*Daubert*, Judge Weisberg explained that on remand he "could then allow whatever additional discovery might be necessary." *Id.* That, however, does not stand in the way of this court's consideration of a pure question of law, which this court can do largely apart from the existing record.

2. Substantial Ground for a Difference of Opinion Exists on the Proper Standard for Evaluating Expert Testimony in Cases Like This.

As the Superior Court recognized, "*Frye* prevails until [the] Court of Appeals *en banc* decides to adopt *Daubert*." Order at 25 (citing *Pettus*, 37 A.3d at 217 n.4). There is, however, substantial ground for a difference of opinion as to whether D.C. should continue to apply *Frye*. The numbers tell that story.[12] Forty states have joined the federal courts in adopting the FRE 702/*Daubert* standard requiring trial courts to scrutinize the scientific validity of expert

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[10] *See* Plaintiffs' Memorandum of Points and Authorities in Opposition to Defendants' Motion to Amend Memorandum Opinion and Order on Expert Witness Admissibility to Certify for Interlocutory Appeal, filed Sept. 9, 2014 ("Opp."), at 16.

[11] *Accord, Van Straaten v. Shell Oil Prods. Co.*, 678 F.3d 486, 491 (7th Cir. 2012); *Klinghoffer v. S.N.C. Achille Lauro Ed Altri-Gestione Motonave Achille Lauro in Amministrazione Straordinaria*, 921 F.2d 21, 24 (2d Cir. 1990) ("Although the resolution of an issue need not necessarily terminate an action in order to be 'controlling,' it is clear that a question of law is 'controlling' if reversal of the district court's order would terminate the action.") (citations omitted).

[12] *See* Exhibit C hereto (map of expert admissibility standards in the United States).

testimony. *Cf. Johnson*, 683 A.2d at 1099-1100 (en banc) (adopting FRE 403 because, *inter alia*, "at least forty of the states" had embraced that rule in relevant part).

Most of the eight states that still nominally apply *Frye* have modernized the general-acceptance test to incorporate *Daubert*-like reliability scrutiny.[13] Maryland is a prominent example. *See Blackwell*, 971 A.2d at 255 (citing Supreme Court's admissibility standards to modify *Frye* so that "[g]enerally accepted methodology . . . must be coupled with generally accepted analysis"). The District of Columbia is one of only three jurisdictions that maintain what Judge Weisberg called an "orthodox approach" to *Frye*. *See* Order at 25 n.29.

Explaining the overwhelming departure from *Frye* among U.S. jurisdictions is an almost universal recognition that FRE 702/*Daubert* is the better standard for ensuring that only reliable scientific evidence is admitted. *See, e.g.*, *State v. Reid*, 757 A.2d 482, 486 (Conn. 2000) ("[T]he flexible *Daubert* approach [is] a better approach than the test of general acceptance in the scientific community."). This case presents a perfect opportunity to consider whether D.C. will continue to adhere to the distinctly minority, orthodox *Frye* test or adopt a more flexible approach that is better suited to analyze the scientific reliability of expert opinions in modern tort litigation. *See Hernandez*, 65 A.3d at 61, 65 (en banc) (replacing long-standing rule, which only "a minority of jurisdictions continue to follow," with "modern" "majority approach").

3. An Immediate Appeal Will Materially Advance This Litigation.

Judge Weisberg confirmed that granting this interlocutory appeal "could save the [trial] court and the parties years of unnecessary and prohibitively expensive litigation." Cert. Order

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[13] **California**: *Sargon Enters., Inc. v. Univ. of S. Cal.*, 55 Cal. 4th 747, 77-72 (2012); **Maryland**: *Blackwell v. Wyeth,* 971 A.2d 235, 252 (Md. 2009); **Minnesota**: Goeb *v. Tharaldson,* 615 N.W.2d 800, 809-810 (Minn. 2000); **New York**: *Parker v. Mobile Oil Corp.*, 857 N.E.2d 1114, 1120 (N.Y. 2006); **Pennsylvania**: *Betz v. Pneumo Abex, LLC,* 44 A.3d 27, 53 (Pa. 2012).

at 3. If Plaintiffs' expert opinions are inadmissible under FRE 702/*Daubert*, as is "almost certainly" the case, this litigation is over. Order at 25-26; Cert. Order at 2 (Plaintiffs will "not have a case."). The efficiency gains from immediate review would be substantial.

Deferring decision on this issue until final judgment, on the other hand, "would mean greater delay and expense than would be caused by the interlocutory review itself." *Plunkett*, 287 A.2d at 545. Delaying review may require the trial court "to manage thirty (or more) individual cases through pretrial discovery and trial," which could all be for naught if this court adopts FRE 702/*Daubert* or a modernized version of *Frye* after a final judgment. Cert. Order at 3; *see also Weisgram v. Marley*, 528 U.S. 440, 443 (2000) (affirming appellate court reversal of a plaintiff's verdict because "[s]horn of the erroneously admitted expert testimony, the record evidence is insufficient to justify a plaintiff's verdict"). If the cases move forward, it will be necessary to conduct individualized discovery on, for example, the alleged non-compliance of each plaintiff's phone(s) with the governing FCC standard, and on each plaintiff's medical history, cell phone use, and awareness of and reliance on alleged misstatements. *See* Cert. Order at 3. Plaintiffs will seek discovery from 28 defendants. And, as they have in the past, Plaintiffs will no doubt again try to serve discovery on institutions like the FCC, FDA, EPA, and the World Health Organization. That discovery could take years to complete.

Once discovery is finally completed, additional admissibility hearings will likely be needed on specific causation (the alleged cause of a particular Plaintiff's tumor). Although the thirteen cases were consolidated specifically for the *Frye* proceedings, "the thirty cases have not been, and cannot be, consolidated for purposes of specific causation discovery or trial," and each trial could take weeks. *See* Cert. Order at 3. Even if Plaintiffs' cases could survive under FRE

702/*Daubert* or a modernized *Frye* standard, immediate review will minimize litigation costs and maximize scarce court resources by providing a clarified admissibility framework.

Section 11-721 (d) exists precisely for this kind of situation. Deciding the admissibility framework issue now will simplify, if not dispose of, this litigation and potentially avoid the waste of millions of dollars and thousands of hours of the parties' and the court's time.

B. En Banc Review is Appropriate Because Whether D.C. Should Adopt FRE 702/*Daubert* Is a Question of Exceptional Importance.

This case clears the high hurdle for en banc review under D.C. App. R. 35. Whether D.C. should join the overwhelming majority of jurisdictions that apply the principles of modern scientific evidence law embodied in FRE 702/*Daubert* is a "question of exceptional importance" appropriate for en banc review. D.C. App. R. 35 (a)(2). That is particularly true in medical causation cases to which *Frye* is not well-suited and where its application risks "erroneous decisions on liability and enormous, unnecessary, litigation costs." Order at 27. More generally, whether precedent "should be modified in light of subsequent developments" in the law "is a matter not for the panel but for an *en banc* petition." *U.S. v. Thompson*, 234 F.3d 74, 78 n.5 (1st Cir. 2000); *accord*, *Estate of Millikin v. CIR*, 125 F.3d 339, 343 (6th Cir. 1997) (granting en banc review "[i]n light of developments in the law"); *Mitchell v. JCG Industries, Inc.*, 753 F.3d 695, 699 (7th Cir. 2014) (Judge Posner, concurring) (equating "issues that affect . . . the development of the law" with "questions of exceptional importance").

This court has previously granted en banc review to modify precedent in light of "the development of the law." *Hedgepeth v. Whitman Walker Clinic*, 22 A.3d 789, 792 (D.C. 2011) (en banc) (modifying "zone of physical danger test"). Just last year, the court sat en banc to "modern[ize]" D.C. law. *Hernandez*, 65 A.3d at 61 (en banc). The en banc court analyzed the continued validity of D.C.'s 120-year-old rule that made contracts with mentally ill people void

and replaced it with the modern, "majority approach that such contracts are voidable," because the "voidable standard better comports with modern [] law and modern [science]." *Id.*

Additionally, the court has historically granted en banc review to align D.C. law with other Federal Rules of Evidence. *See, e.g.*, *Johnson*, 683 A.2d at 1090 (en banc) (FRE 403); *In re Melton*, 597 A.2d 892, 901 (D.C. 1991) (en banc) (FRE 703); *Rogers v. United States*, 566 A.2d 69, 75 (D.C. 1989) (en banc) (FRE 405(a)); *Laumer v. United States*, 409 A.2d 190, 192 (D.C. 1979) (en banc) (FRE 804(b)(3)); *see also Eason v. United States*, 704 A.2d 284, 285 n.3 (D.C. 1997) (en banc) (noting that "this court has looked for guidance to the principles underlying the federal rules of evidence concerning expert testimony"). In *Laumer*, the en banc court reviewed the history of a long-standing D.C. evidentiary rule, the criticisms of that rule, and noted its rejection by the Supreme Court and numerous states before ultimately rejecting the rule and adopting the relevant Federal Rule of Evidence. 409 A.2d at 194-95. That same analysis justifies en banc review and adoption of FRE 702.

Importantly, this court en banc has never affirmed *Frye*, nor has it sat en banc to consider adopting FRE 702/*Daubert*. Divisions of the court have continued to apply *Frye* because "*Daubert* has not been adopted in this jurisdiction," *Benn v. United States*, 978 A.2d 1257, 1269 n.44 (D.C. 2009), and "a division of this court lacks the authority to supplant *Frye* with *Daubert*." *Bahura v. S.E.W. Investors*, 754 A.2d 928, 943 n.15 (D.C. 2000). Past adherence to *Frye*, however, is no reason not to review that standard's continued relevance and reliability now. This court revises D.C. law and adopts majority approaches where it will gain "the advantage that uniformity with the federal rule and the vast majority of state rules affords for interpretation and application." *Johnson*, 683 A.2d at 1100. It should do so here.

C. The Court Should Take This Opportunity to Consider Whether to Align the District of Columbia with the Principles of FRE 702/*Daubert*.

The court should act now to consider adopting FRE 702/*Daubert*, which is widely recognized as a better standard for ensuring that verdicts are based on what Judge Weisberg called "good science." Order at 26; *see, e.g.*, *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1197 (11th Cir. 2002) ("The *Daubert* trilogy, in shifting the focus to the kind of empirically supported, rationally explained reasoning required in science, has greatly improved the quality of the evidence upon which juries base their verdicts."); *Miss. Transp. Comm'n v. McLemore*, 863 So. 2d 31, 39 (Miss. 2003) (adopting *Daubert*, to "provide[] a superior analytical framework for evaluating the admissibility of expert witness testimony"). By contrast, "the *Frye* standard [has been] subjected to critical analysis, limitation, modification, and finally, outright rejection."[14] As *Daubert* itself noted, "[t]he merits of the *Frye* test have been much debated." 509 U.S. at 586.

For many years, courts and commentators have confirmed that "*Frye* has become outdated and inadequate for modern litigation, where many cases involve sophisticated scientific data and knowledge." *State v. Coon*, 974 P.2d 386, 392 (Alaska 1999) (describing the state's arguments in favor of *Daubert*, and adopting *Daubert*).[15] Judge Weisberg similarly identified *Frye* as "antiquated," Cert. Order at 2, echoing former Chief Judge Newman, who has long called for this court to reject the "antiquated standard" of *Frye* and join the majority of states

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[14] 1 C. McCormick, Evidence (7th Ed. 2013) § 203, p. 1148. McCormick's is the original source of the *Dyas* expert standard. *See Dyas*, 376 A.2d at 832. The "state of the science" prong that *Dyas* quoted from the McCormick 1972 edition still exists in the most current edition, but is now glossed by the history of *Frye* general acceptance having been largely replaced by *Daubert*. *See* 1 McCormick, § 13, pp. 97-98.

[15] *See also* Giannelli, Frye v. United States – *Background Paper Prepared for the National Conference of Lawyers and Scientists*, 99 F.R.D. 188, 192 (1983) (noting that commentators have "labeled *Frye* 'archaic,' 'a sport,' 'infamous,' and 'antiquated on the day of its pronouncement'").

"that have already adopted the Federal Rule on this issue." *Taylor v. United States*, 661 A.2d 636, 651-52 (D.C. 1995) (Senior Judge Newman, dissenting); *see also Drevenak v. Abendschein*, 773 A.2d 396, 418 n.32 (D.C. 2001) (noting Senior Judge Newman's description of *Frye*).

Frye also is "potentially capricious because it excludes scientifically reliable evidence which is not yet generally accepted, and admits scientifically unreliable evidence which although generally accepted, cannot meet rigorous scientific scrutiny." *Coon,* 974 P.2d at 393-94. Judge Weisberg agreed, noting that "under *Frye,* as applied in this jurisdiction, even if a new methodology produces 'good science,' it will usually be excluded, but if an accepted methodology produces 'bad science,' it is likely to be admitted." Order at 26. Because "*Frye* may exclude scientifically reliable evidence while admitting unreliable evidence . . . [i]t is desirable to replace [it] with a rule not suffering from these deficiencies." *Coon*, 974 P.2d at 394. FRE 702/*Daubert* is such a rule, providing trial courts the flexibility to admit reliable evidence even if the methodology is not yet generally accepted. *See* Order at 26.

The Superior Court detailed yet another *Frye* weakness that is compelling in this case: "the [*Frye*] test is not a good gatekeeper for inductive sciences such as epidemiology and psychology" because an opinion based on those sciences "necessarily requires the subjective judgment of the expert to infer from premises to conclusions." Order at 28. A mechanical test like *Frye* does not permit a flexible approach for scrutinizing subjectivity or even for analyzing whether the expert properly applied the stated methodology. Thus, *Frye* does not bar testimony even where, as here, an expert applies his stated methodology in an unscientific manner and "appears to apply his scientific knowledge as an advocate." Order at 44.

In contrast, FRE 702/*Daubert* not only allows but requires a trial court to scrutinize the expert's case-specific application of the method. FED. R. EVID. 702 (requiring that "the expert

has reliably applied the principles and methods to the facts of the case"). Thus, under FRE 702/*Daubert*, "when an expert purports to apply principles and methods in accordance with professional standards, and yet reaches a conclusion that other experts in the field would not reach, the trial court may fairly suspect that the principles and methods have not been faithfully applied." FED. R. EVID. 702, adv. comm. notes (citing *Lust v. Merrell Dow Pharms., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996) (Bendectin case)). Because *Frye* does not permit that comparison to "'real world'" scientific assessments, Judge Weisberg concluded that in cases like this one, "*Frye* does not seem like the best way to ensure a just result." Order at 28.

Judge Weisberg's conclusion is firmly based in reality. In that regard, the *Oxendine* Bendectin litigation is a cautionary tale. It took four appeals and fourteen years to align the result in that litigation with the state of the science. Like these cases, *Oxendine* involved general causation evidence that relied heavily on epidemiology. The trial court there determined that "no [causation] conclusion one way or another [could] be drawn" based on the state of the science. *Oxendine v. Merrell Dow Pharms.*, 506 A.2d 1100, 1103 (D.C. 1986) (quoting trial court). This court reversed the trial court's j.n.o.v., order, but the reinstated verdict was so at odds with the science that the case dragged on for another eight years (during which the Supreme Court issued *Daubert*). On the fourth appeal, this court applied a novel procedure to align the verdict with the science by permitting the defendant to prove that the "scientific fact [general causation] on which the verdict relies is wrong." *Oxendine v. Merrell Dow Pharms.*, 649 A.2d 825, 832 (D.C. 1994). As Judge Schwelb observed, "[I]n this instance, our adversarial system has not been an unqualified success." *Id.* at 833 (Judge Schwelb, concurring).

Indeed, the lack of adequate procedural tools to assess the validity of the scientific evidence admitted in *Oxendine* placed D.C. courts out of step with the federal and state courts

adjudicating other Bendectin cases. *See Turpin v. Merrell Dow Pharms.*, 959 F.2d 1349, 1351 (6th Cir. 1992) (surveying Bendectin litigation results and identifying *Oxendine I* as the "only . . . reported case finally upholding a finding of causation"); *Merrell Dow Pharms. v. Havner*, 953 S.W.2d 706, 710-11 (Tex. 1997) (citing *Oxendine I* as the "only appellate decision we have found, state or federal, that has upheld a verdict in favor of a plaintiff in a Bendectin case," and recounting the "somewhat extraordinary" subsequent history of that case).

Serious social and economic consequences result when trial courts lack procedural tools to manage scientific evidence consistent with the state of the science. *Cf. General Electric Co. v. Joiner*, 522 U.S. 136, 148-49 (1977) (Justice Breyer, concurring) (explaining that "*Daubert* gatekeeping" will "assure that the powerful engine of tort liability . . . points toward the right substances and does not destroy the wrong ones"). Indeed, two weeks after the $750,000 *Oxendine* verdict, Bendectin was removed from the market, with the manufacturer noting that insurance premiums had grown to three times income.[16] The drug's removal was followed by "increased hospitalization for nausea and vomiting in pregnancy" – the dangerous conditions that the medical and regulatory community had deemed Bendectin safe and effective to prevent. *Id.*

Consistent application of *Daubert* has proven that general causation testimony with no scientific validity should be and is excluded. *See, e.g.*, *Meister v. Med Eng'g Corp.*, 347 U.S. App. D.C. 361, 369, 267 F.3d 1123, 1131 (2001) (highlighting "a landscape of litigation in other federal districts in which judges were unanimous in rejecting" general causation testimony on silicone breast implants and autoimmune diseases); *Rider*, 295 F.3d at 1203 (noting exclusion of general causation testimony on anti-lactation drug and hemorrhagic strokes "is in conformity

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[16] Hale & Niebyl, *Bendectin: How a Safe and Effective Drug was Removed from the Market by Our Legal System*, American College of Obstetricians & Gynecologists Clinical Reviews (2012) (Exhibit D hereto).

with numerous other decisions"). The same holds true when *Daubert* is applied to expert testimony that cell phones cause cancer. *See Newman*, 218 F. Supp. 2d at 783. Exclusion of such unreliable testimony furthers the basic goals of our civil justice system: that cases are "justly determined," and that "the truth may be ascertained." *Joiner*, 522 U.S. at 149 (Justice Breyer, concurring).

VI. CONCLUSION

To bring "the law in the District of Columbia into conformity with that of the large and growing number of jurisdictions," and with the state of the science on cell phones and cancer, the court should not wait, but should seize this "appropriate occasion" for considering whether to reject *Frye* and adopt FRE 702/*Daubert*. *Rogers*, 566 A.2d at 71. Defendants respectfully request that the Court grant permission to immediately appeal from the trial court's *Frye* Order and consider initially en banc the controlling legal question of whether the District of Columbia should adopt Federal Rule of Evidence 702 (or a revised *Frye* standard) for the admissibility of expert evidence. Defendants welcome oral argument if the Court determines it would be helpful.

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CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of October, 2014, a copy of the foregoing **COMBINED APPLICATION FOR PERMISSION TO APPEAL EXPERT ADMISSIBILITY ORDER AND PETITION FOR HEARING EN BANC** was sent via first class mail, postage prepaid, to below-listed persons at the stated addresses.

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Exhibit A

IN THE SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA
CIVIL DIVISION

MICHAEL PATRICK MURRAY, *et al.*, *Plaintiffs,* v. MOTOROLA, INC., *et al.*, *Defendants.*	Case No. 2001 CA 008479 B Judge Frederick H. Weisberg Calendar 3
BALDASSARE S. AGRO, *et al.*, *Plaintiffs,* v. MOTOROLA, INC., *et al.*, *Defendants.*	Case No. 2002 CA 001368 A Judge Frederick H. Weisberg
GILBERT COCHRAN, Individually, and as Personal Representative for the Estate of Pamela Cochran, *Plaintiffs,* v. AUDIOVOX COMMUNICATIONS CORP., *et al.*, *Defendants.*	Case No. 2002 CA 001369 A Judge Frederick H. Weisberg
RICHARD SCHWAMB, *et al.*, *Plaintiffs,* v. QUALCOMM, INC., *et al.*, *Defendants.*	No. 2002 CA 001370 A Judge Frederick H. Weisberg

DINO E. SCHOFIELD, *et al.*, *Plaintiffs,* v. MOTOROLA, INC., *et al.*, *Defendants.*	No. 2002 CA 001371 A Judge Frederick H. Weisberg
DAVID C. KELLER, *et al.*, *Plaintiffs,* v. NOKIA, INC., *et al.*, *Defendants.*	No. 2002 CA 001372 A Judge Frederick H. Weisberg
ALAN MARKS, *et al.*, *Plaintiffs,* v. MOTOROLA, INC., *et al.*, *Defendants.*	No. 2010 CA 003206 B Judge Frederick H. Weisberg
SHAWN KIDD, *et al.*, *Plaintiffs,* v. MOTOROLA, INC., *et al.*, *Defendants.*	No. 2010 CA 007995 B Judge Frederick H. Weisberg

CRISTIN PRISCHMAN, as Personal Representative of the Estate of PAUL G. PRISCHMAN, *Plaintiff,* v. MOTOROLA, INC. *et al.,* *Defendants.*	No. 2011 CA 002113 B Judge Frederick H. Weisberg
BRET KENYON BOCOOK and LAURA LYNN BOCOOK, *Plaintiffs,* v. MOTOROLA, INC. *et al.,* *Defendants.*	No. 2011 CA 002453 B Judge Frederick H. Weisberg
MINDY S. KEMP BROWN, individually and as Special Administrator of the ESTATE OF DANIEL TODD BROWN, *Plaintiffs,* v. NOKIA, INC., et al., *Defendants.*	No. 2011 CA 006710 B Judge Frederick H. Weisberg

MONIQUE SOLOMON, individually, and as the Special Administrator of the Estate of ANDREW J. SOLOMON, *Plaintiffs,* v. MOTOROLA, INC. *et al.*, *Defendants.*	No. 2011 CA 008472 B Judge Frederick H. Weisberg
ROBERT P. NOROSKI, individually, and as Personal Representative of the Estate of HEATHER LYNN NOROSKI, *Plaintiffs,* v. SAMSUNG TELECOMM AMERICA, LLC, *et al.*, *Defendants.*	No. 2011 CA 008854 B Judge Frederick H. Weisberg

ORDER AMENDING AUGUST 8, 2014, MEMORANDUM OPINION AND ORDER TO INCLUDE CERTIFICATION FOR INTERLOCUTORY APPEAL

On August 8, 2014, following a four-week evidentiary hearing, the court ruled that some, but not all, of Plaintiffs' proffered expert testimony on general causation is admissible under the *Frye/Dyas* evidentiary standard applicable in this jurisdiction. In its order, the court distinguished the *Frye/Dyas* standard from the Federal Rule 702/*Daubert* standard of admissibility applicable in the federal courts and some forty states and observed that most, if not all, of Plaintiffs' experts would probably be excluded under the Rule 702/*Daubert* standard based on the present record. The court did not include in its August 8 order a certification pursuant to D.C. Code § 11-721(d), which would enable Defendants to seek interlocutory review. The

matter is now before the court on Defendants' motion to amend the order to include a section 11-721(d) certification.

D.C. Code § 11-721(d) states, in pertinent part:

> When a judge of the Superior Court . . . shall be of the opinion that the ruling or order involves a controlling question of law as to which there is substantial ground for a difference of opinion and that an immediate appeal from the ruling or order may materially advance the ultimate termination of the litigation or case, the judge shall so state in writing in the ruling or order. The District of Columbia Court of Appeals may thereupon, in its discretion, permit an appeal to be taken from that ruling or order, if application is made to it within ten days after the issuance or entry of the ruling or order.

The court's August 8 order satisfies the section 11-721(d) criteria in all respects.[1] The question of whether the District of Columbia Court of Appeals, sitting *en banc*, should discard the antiquated *Frye* test and join the majority of jurisdictions that have adopted Federal Rule 702 or *Daubert* (or have modernized their *Frye* rule to permit consideration of both methodology and scientific reliability) is a "controlling question of law as to which there is substantial ground for a difference of opinion." If the Court of Appeals abandons *Frye* in favor of Rule 702, *Daubert*, or the more modern approach to *Frye*, the decision would "materially advance the ultimate termination of the litigation or case." If the adoption of the new standard results in the exclusion of Plaintiffs' general causation experts, Plaintiffs do not have a case.

There are other reasons why the Court of Appeals might choose to take up the *Frye* versus *Daubert* issue at this time. The thirteen cases that were consolidated for purposes of the *Frye/Dyas* hearing are merely a subset of the thirty individual cell phone cancer cases currently pending on the court's docket. The number is continuing to grow as Plaintiffs' counsel sign up

[1] Plaintiffs' argument that Defendants' motion is untimely because it was not filed within ten days of the court's order is without merit for the reasons stated in Defendants' reply brief. The same is true of Plaintiffs' argument that Defendants have waived their objection to the *Frye/Dyas* standard or should be judicially estopped from objecting because they "consented" to the applicability of that standard by participating in the proceedings to this point.

new claimants. These cases have not been filed as a class action pursuant to Rule 23, nor could a class properly be certified, because the type of cell phone and each user's cell phone habits vary widely from plaintiff to plaintiff, and the causation issue is heavily dependent on those two variables, among other individualized factors. For essentially the same reasons, although thirteen of the thirty cases were consolidated for the *Frye/Dyas* proceedings and the others were stayed pending the outcome, the thirty cases have not been, and cannot be, consolidated for purposes of specific causation discovery or trial.

Deciding the standard of admissibility now could save the court and the parties years of unnecessary and prohibitively expensive litigation. Without interlocutory review, the court will be required to manage thirty (or more) individual cases through pretrial discovery and trial. If the the plaintiff prevails in first case to proceed to trial, all other parties would still have to wait for full appellate review and possible *en banc* consideration of the expert witness issue before the remaining cases could proceed; and, if the Court of Appeals then adopts *Daubert* or another more modern test for expert admissibility, all of the work in the lead case would have been for naught.[2] If the first trial results in a defendant's verdict, presumably there will be additional trials until one produces a plaintiff's verdict, from which the defendant could appeal.[3] Finally, under the posited scenario, even if defendants prevail in every trial, all of the costs to the court and the parties are potentially avoidable if the Court of Appeals entertains an interlocutory appeal and decides now that the time has come to adopt a more modern approach to expert

[2] Alternatively, if the other trials were to proceed during the pendency of the appeal of the first case, all of those additional resources will have been wasted in the event the Court of Appeals ultimately abandons *Frye* and adopts *Daubert* or something akin to it.

[3] If a defendant prevails at trial and the plaintiff appeals, the defendant could perhaps raise the expert admissibility issue on a cross-appeal, but the Court of Appeals would not be required to reach the issue if the rulings adverse to the plaintiff were affirmed in all respects.

witness admissibility in the District of Columbia and if, as a result, Plaintiffs are left without admissible expert testimony.

The court recognizes that ordinarily the Court of Appeals might prefer to wait for a complete record and a final judgment to decide an issue requiring *en banc* consideration. After all, the parties may reach a settlement, in which case there would be no need for appellate review. However, it seems exceedingly unlikely that these cases can settle without final resolution of the expert witness issue. On the one hand, the injuries to the Plaintiffs are severe and call for substantial compensation if liability is proven; on the other hand, Defendants adamantly deny causation (and hence liability) and believe all of Plaintiffs' experts should be excluded under the standard for expert witness admissibility they will urge the Court of Appeals to adopt whenever the occasion arises. In the meantime, despite Plaintiffs' protestations about needing additional discovery on general causation, the record on general causation is about as well developed as it is ever going to be, and the issue promises to be aggressively and effectively litigated by competent counsel on both sides. If the Court of Appeals decides now to adopt Rule 702/*Daubert* or a more modern *Frye* test, it would presumably remand for further proceedings on whether, under the new standard, testimony of Plaintiffs' general causation experts is admissible. The court could then allow whatever additional discovery might be necessary to place Plaintiffs in a fair position to litigate that issue.

Plaintiffs object to certification, arguing that after years of litigation, they should finally be able to move forward with discovery without having to endure the additional delay of an interlocutory appeal. However, if the court's August 8 order meets the standard of section 11-721(d), as it does, all this court is being asked to do is to give the Court of Appeals an opportunity to consider a controlling and potentially dispositive question of law now, rather than

later, to avoid the time and enormous expense of further litigation in the trial court, which might prove to be totally unnecessary. If the Court of Appeals elects not to take up the issue at this time, any interruption of further proceedings in the trial court will be relatively brief and will not significantly delay the final disposition of at least the first of these thirty cases in the trial court. On the other hand, if the Court of Appeals decides that the issue is deserving of *en banc* consideration on the present record, any delay incident to the appellate process would be justified for the reasons the court has already enumerated.

For all of the foregoing reasons, it is this 1st day of October, 2014,

ORDERED that Defendants' motion to amend the court's August 8, 2014, Memorandum Opinion and Order is granted; and it is further

ORDERED that the August 8 order is hereby amended to include a finding that the ruling and order involve a controlling question of law as to which there is substantial ground for a difference of opinion and that an immediate appeal from the ruling or order may materially advance the ultimate termination of the litigation or case so as to permit Defendants, pursuant to D.C. Code § 11-721(d), to seek interlocutory review of the question of whether the District of Columbia should adopt Federal Rule of Evidence 702 (or a revised *Frye* standard) for the admissibility of expert evidence; and it is further

ORDERED that the court's August 8, 2014, Memorandum Opinion and Order shall be deemed to have been reentered as of this date, as amended to include the foregoing finding; and it is further

ORDERED that all trial court proceedings in these cases and the seventeen related cases[4] are hereby stayed pending Defendants' application for an appeal pursuant to D.C. Code § 11-721(d) and the disposition of that application by the District of Columbia Court of Appeals or until further order of the court.

Judge Frederick H. Weisberg

Copies eServed to:
All Counsel listed in Case File Xpress

[4] The seventeen currently pending related cases are: Civil Action Nos. 2012 CA 003241 B; 2012 CA 003981 B; 2012 CA 004068 B; 2012 CA 008533 B; 2012 CA 008537 B; 2013 CA 004542 B; 2013 CA 005115 B; 2013 CA 006641 B; 2013 CA 007620 B; 2013 CA 007804 B; 2013 CA 007805 B; 2013 CA 007957 B; 2013 CA 008192 B; 2014 CA 001425 B; 2014 CA 002521 B; 2014 CA 002797 B; 2014 CA 004171 B.

Exhibit B

IN THE SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA
Civil Division

MICHAEL PATRICK MURRAY, *et al.*, Plaintiffs, v. MOTOROLA, INC., *et al.*, Defendants.	Case No. 2001 CA 008479 B Judge Frederick H. Weisberg
BALDASSARE S. AGRO, *et al.*, Plaintiffs, v. MOTOROLA, INC., *et al.*, Defendants.	Case No. 2002 CA 001368 A
PAMELA A. COCHRAN, *et al.*, Plaintiffs, v. AUDIOVOX COMMUNICATIONS CORP., *et al.*, Defendants.	Case No. 2002 CA 001369 A
DAVID C. KELLER, *et al.*, Plaintiffs, v. NOKIA, INC., *et al.*, Defendants.	Case No. 2002 CA 001372 A

SHAWN KIDD, *et al.*, Plaintiffs, v. MOTOROLA, INC., *et al.*, Defendants.	Case No. 2010 CA 007995 B
ALAN MARKS, *et al.*, Plaintiffs, v. MOTOROLA, INC., *et al.*, Defendants.	Case No. 2010 CA 003206 B
RICHARD SCHWAMB *et. al.*, Plaintiffs, v. QUALCOMM, INC., *et al.*, Defendants.	Case No. 2002 CA 001370 A
DINO E. SCHOFIELD, Plaintiff, v. MOTOROLA, INC., *et al.*, Defendants.	Case No. 2002 CA 001371 A

CRISTIN PRISCHMAN, as Personal Representative of the Estate of PAUL G. PRISCHMAN Plaintiff, v. MOTOROLA, INC., *et al.*, Defendants.	Case No. 2011 CA 002113 B
MINDY S. KEMP BROWN, individually and as Special Administrator of the Estate of DANIEL TODD BROWN Plaintiffs, v. NOKIA, INC., *et. al.* Defendants.	Case No. 2011 CA 006710 B
ROBERT P. NOROSKI, individually, and as Personal Representative of the Estate of HEATHER LYNN NOROSKI Plaintiff, v. SAMSUNG TELECOMM AMERICA, LLC, *et al.*, Defendants.	Case No. 2011 CA 008854 B

MONIQUE SOLOMON, individually and as the Special Administrator of the Estate of ANDREW J. SOLOMON, Plaintiffs, v. MOTOROLA, INC., *et al.*, Defendants.	Case No. 2002 CA 001371 A
BRET KENYON BOCOOK and LAURA LYNN BOCOOK Plaintiffs, v. MOTOROLA, INC., et al., Defendants.	Case No. 2011 CA 002453 B

MEMORANDUM OPINION AND ORDER ON EXPERT WITNESS ADMISSIBILITY

Can cell phones cause brain cancer? If that were the question confronting the court at this phase of the case, the answer would be relatively clear. Although there are a few isolated strands of data pointing in the direction of causation, the court could not conclude, based on the present record, that there is enough evidence for *any* scientist to answer the question "yes" with the requisite degree of scientific certainty. There is entirely too much controversy in the scientific community to entrust that question to a jury of laypersons on a case-by-case basis, to have one jury answer the question yes, only to have the next jury, presented with the very same evidence, come to the opposite conclusion.

The question presented, however, is not whether cell phones can cause cancer, but whether plaintiffs' expert witnesses, who have expressed the opinion "to a reasonable degree of scientific certainty" that cell phones more likely than not cause or promote certain brain tumors, should be permitted to testify to those opinions before the jury. In this jurisdiction, the court must answer that question under the test of *Dyas v. United States*, 376 A.2d 827 (D.C. 1977), *cert. denied* 434 U.S. 973 (1977), and *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), rather than *Daubert v. Merrill Dow Pharms. Inc.*, 509 U.S. 579 (1993). Under the *Dyas/Frye* test, the expert testimony is presumptively admissible if the subject is beyond the ken of an average layperson, the expert is qualified to offer an opinion on the subject, the expert uses a methodology that is generally accepted in the relevant scientific community to arrive at his opinion, and the probative value of the expert's testimony is not substantially outweighed by the risk of undue prejudice. *Ibn-Tamas v. United States*, 407 A.2d 626, 632 (D.C. 1979).

I. Procedural History

Plaintiffs are litigants in thirteen separate cases consolidated for purposes of the *Dyas/Frye* hearing.[1] Each plaintiff suffers from a brain tumor, or is suing on behalf of the estate of someone who died of brain cancer, allegedly caused by long-term exposure to cell phone radiation. The oldest and lead case, *Murray v. Motorola*, 2001 CA 8479, was filed in 2001, and many of the other cases have been pending for more than ten years. No American court has yet found that cell phones can cause brain tumors. Because of the novel scientific issues and the need for judicial economy, the court (Burgess, J.) bifurcated the litigation into two phases: general causation and specific causation. If plaintiffs' evidence is sufficient to get past the

[1] Sixteen additional cases have been stayed pending the resolution of the *Dyas/Frye* issue on general causation. The parties in those other cases, which are not formally consolidated with these thirteen, have agreed by stipulation to be bound by the *Dyas/Frye* ruling in these cases.

general causation phase of the litigation, the parties will proceed to phase two, with plaintiffs presenting their evidence of specific causation on a case by case basis.

To survive summary judgment on general causation, plaintiffs must present sufficient admissible expert testimony to place in dispute a genuine issue of material fact as to whether radiation from cell phones can cause two kinds of brain tumors, glioma and acoustic neuroma.[2] Again, because of the complexity of the issue, the general causation inquiry was itself bifurcated. The issue before the court at present is the admissibility of plaintiffs' experts under the standard applicable in this jurisdiction, which is derived from *Dyas* and *Frye*. If the court rules that the testimony of plaintiffs' experts – or some of them – is admissible, the parties will conduct broader discovery on the general causation issue (which has been stayed) before proceeding to specific causation.

In December 2013 and January 2014, the court conducted an evidentiary hearing to determine the admissibility of plaintiffs' experts. The court heard four weeks of testimony from plaintiffs' eight experts and defendants' four rebuttal experts, received approximately 280 exhibits containing thousands of pages of documents, and reviewed hundreds of pages of legal briefing both before and after the hearing.

II. Factual Background

A. *How Cell Phones and Radiation Work*

Some understanding of the basic science of radiation, cell phone technology, and human cancer is necessary to put the legal issues now before the court in their proper context.[3]

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[2] Gliomas are a type of malignant brain tumor that are nearly always fatal, whereas acoustic neuromas are non-malignant tumors which may be surgically removed or are otherwise treatable.

[3] Unless otherwise indicated, this background information comes primarily from the court's review of the record as a whole, including hearing testimony, exhibits, expert reports, and the parties' briefs. The court has done its best to learn enough of the science to be in a position to decide the legal issues and properly exercise its discretion.

Radiation is energy emitted by an object in the form of electromagnetic waves or particles. Many common objects, and certainly all electronics, give off some form of radiation. Energy radiates at different wavelengths depending on the nature of its source. The longer the wavelength, the lower the frequency; and the shorter the wavelength, the higher the frequency. The electromagnetic spectrum ranges from Extremely Low Frequency ("ELF") waves at the low end of the spectrum, all the way up to cosmic rays at the high end of the spectrum. Visible light is near the middle of the spectrum. At the high end of the spectrum are forms of ionizing radiation such as x-rays, gamma rays, and cosmic rays. At the low end of the spectrum, where cell phones operate, are forms of non-ionizing radiation such as microwaves, radiofrequency ("RF") waves, and ELF waves. Radiation can have thermal and non-thermal effects. The heat from a lit candle is a thermal effect; the light is a non-thermal effect of the flame's radiation.

For cancer to develop, there must first be a break in DNA molecules in the body. In natural processes, DNA strands are constantly breaking, but humans have numerous defenses to prevent those breaks from developing into cancer. It is generally accepted that *ionizing* radiation, such as x-rays and energy released by nuclear reactions, can cause cancer by breaking the chemical bonds of DNA molecules in the body. When DNA bonds are broken and not repaired, the frequency of genetic mutations increases. As mutations increase, the odds that cancer will develop increase as well. The accepted wisdom is that *non-ionizing* radiation is not powerful enough to break the chemical bonds that hold together DNA molecules. Plaintiffs' experts believe, however, that the non-ionizing radiation emitted by cell phones has a non-thermal adverse biological effect on the body's mechanisms for repairing naturally-occurring DNA breaks, which leads to an increased risk of cancer.

A cell phone functions by wirelessly transmitting data to and receiving data from nearby cellular towers. Those towers are networked with other components of telecommunications infrastructure, enabling one device connected to the network to communicate with another. A cell phone communicates wirelessly with the towers using a combination of RF and ELF waves, in a manner similar to other radio transmission devices. When a person uses a cell phone to make a call, connect to the internet, send a text message, or share photos, the phone transmits data packets to the network in the form of RF and ELF radiation. Depending on the type of communication and volume of data being transmitted, the phone will emit more or less radiation. Voice calls and video chats require the transmission of more data (and more RF and ELF radiation) than text messages and emails. As long as a cell phone is powered on, it must remain in constant communication with nearby cell towers so that the network can route data traffic to and from the phone, but when it is in its idle state, the phone emits less radiation than when it is in active communication. Communication with cell towers ceases only when the phone is turned off or in "airplane mode," meaning that its radio transmitters and receivers are deactivated.

When a cell phone emits RF and ELF waves in order to communicate with the network, it radiates in all directions. Consequently, when a phone is held up to a person's ear during a phone call, some of the radiation is directed toward the person's head. Some of that radiation will be absorbed by the head, and some will be reflected. The intensity of radiation dissipates over distance, so the closer a person is to a radiation-emitting device, the more radiation the person's body will absorb. Therefore, a person's head will generally absorb more radiation from a cell phone held up to one's ear than from a cell phone on a desk or from other devices in the room, like a Wi-Fi router or laptop computer, which also emit RF radiation.

At this phase of the litigation, the general causation question presented is whether the non-ionizing radiation from cell phones has a non-thermal effect that causes, promotes, or accelerates the growth of brain tumors, specifically gliomas and acoustic neuromas. The plaintiffs have proffered eight expert witnesses who, individually and collectively, purport to answer this question in the affirmative.

B. *State of the Science on Health Risks from Cell Phones*

At present, virtually all world-wide governmental health agencies that have studied the question have concluded that there is some, but not nearly enough, scientific evidence to conclude that cell phone radiation can cause or promote brain cancer. The World Health Organization's International Agency for Research on Cancer ("IARC") is widely recognized as the lead authority on the carcinogenicity of environmental agents, such as RF radiation. In 2011, its Working Group on the Evaluation of Carcinogenic Risks to Humans met in Lyon, France to evaluate the risks of cell phone radiation. Following its review of substantially all published research from a variety of fields, including epidemiology, cell biology, biophysics, engineering, and toxicology, IARC published a Monograph in 2013, summarizing the state of the science and concluding that "Radiofrequency electromagnetic fields are *possibly carcinogenic to humans (Group 2B)*." Ex. PX0062, IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, *Non-Ionizing Radiation Part 2: Radiofrequency Electromagnetic Fields*, Int'l Agency for Research on Cancer, Vol. 102, 419 (2013) (emphasis in original) (hereinafter "*IARC Monograph*").[4] This "Group 2B" classification, for "possible carcinogens," is in the middle of

[4] The pagination of plaintiffs' version of the IARC Monograph, Ex. PX0062, differs slightly from defendants' version, Ex. DX0049. The discrepancy is attributable to a section of the Monograph that has nothing to do with cell phone radiation or issues related to this case. *See* PX0062 at 173 and DX0049 at 168 (discussing Oberfeld 2008). As a result, the page numbers of the two different versions are off by about two pages in the second half of the Monograph. It is unclear to the court which version is the "correct" one, as both appear genuine, but there are no differences in the portions of the Monograph that are relevant to this case. In this order, the court's page citations are to the plaintiffs' version, PX0062.

IARC's classification hierarchy. Group 1 is comprised of known human carcinogens. Group 2A consists of agents that are "probably carcinogenic to humans." Most agents fall into Group 3, "not classifiable" as either carcinogenic or not carcinogenic to humans. Finally, a very small number of agents are classified in Group 4, "probably not carcinogenic to humans." *IARC Monograph* at 30. IARC classified RF radiation in Group 2B because "[t]here is *limited evidence* in humans for the carcinogenicity of radiofrequency radiation" and "[t]here is *limited evidence* in experimental animals for the carcinogenicity of radiofrequency radiation." *IARC Monograph* at 419 (emphasis in original).[5] The IARC Monograph is generally accepted by all parties and the court to be highly reliable and authoritative.[6]

The driving force behind IARC's "possibly carcinogenic" classification is the epidemiological evidence. Although "[p]ositive associations have been observed between exposure to radiofrequency radiation from wireless phones and glioma, and acoustic neuroma," the epidemiological evidence is "mixed." *IARC Monograph* at 419. The Working Group dismissed several early case-control[7] and cohort[8] studies as being "largely uninformative" due to

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[5] IARC defines "limited evidence" as "a positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence." *IARC Monograph* at 27. A minority of the IARC Working Group would have classified the epidemiological evidence as "inadequate" which, under IARC's criteria would have caused the overall classification of RF radiation to drop to Group 3 (carcinogenicity cannot be classified). *IARC Monograph* at 30, 419.

[6] The Monograph was published after the experts submitted their reports in this case. By the time of the hearing, all of the experts were able to testify about its contents and IARC's methodology.

[7] In a case-control study, epidemiologists identify people with a disease (the cases) and people without the disease (the controls) and question them on their exposure to the agent under consideration and other factors. The scientists attempt to control for all potential confounding variables to isolate particular associations between the disease and exposure to the environmental agent (or other factor). For example, to study whether cell phone radiation causes glioma, epidemiologists identify a representative population suffering from glioma (the cases) and another representative population that does not have glioma. The scientists quiz the two groups on a variety of factors, including past cell phone use. If the cases have a significantly higher past use of cell phones than the controls, all else being equal, then the epidemiologists may conclude that there is an "association" between cell phone use and glioma. In order to determine whether this association is causal, the epidemiologists need to control for bias, confounding variables, and chance.

[8] In a cohort study, epidemiologists track a representative population over a period of time (usually years or decades). The scientists survey the population to determine who is exposed to what environmental agents (such as cell phone radiation) and in what amounts. They also track who develops specific diseases, such as glioma. After

methodological shortcomings.[9] *IARC Monograph* at 419. The primary sources of epidemiological evidence were two sets of case-control studies, one from the INTERPHONE research group, and another from the Hardell research group. IARC described these two sets of studies as "the most robust evidence on the risk of tumours of the brain associated with wireless-phone use." *IARC Monograph* at 409. Nonetheless, IARC found that both the INTERPHONE and Hardell studies suffer from flawed study designs that do not fully control for bias, confounding, and chance, a view that is widely shared by most other organizations that have studied the subject.

INTERPHONE was an effort to study cell phone radiation exposures across thousands of cases and controls in multiple countries. In general, the INTERPHONE studies found that exposure to cell phone radiation for all but the heaviest users actually appeared to *reduce* the risk of glioma.[10] Like all case-control studies, participants were interviewed with questionnaires about their cell phone use, sometimes years in the past. This methodology can give rise to recall bias if the subject's recollection is not accurate, which can then distort the overall data.[11] *IARC Monograph* at 203, 216. For example, IARC found evidence that cases and controls estimated their past phone usage differently. *IARC Monograph* at 215. INTERPHONE defined a "regular" mobile-phone user as someone who had used a mobile phone for at least one call per week during the previous six months or more. *IARC Monograph* at 203. Because this definition of

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the period of time has expired and the results are compiled, the scientists may be able to identify if there is any association between an environmental exposure and disease incidence. Again, to determine if an association is causal, the epidemiologists must control for bias, confounding variables, and chance.

[9] For example, several of these early studies defined "exposure" as "having a cell phone subscription" with no measurement of how much a person actually used the phone. Some studies used unreliable self-reported histories of phone use. *IARC Monograph* at 408.

[10] As various experts pointed out at the hearing, if true this would mean that cell phone radiation actually protects against glioma. This is biologically implausible and indicates a flaw in the study design, which biased the results toward the "null."

[11] Recall bias occurs when the structure of the experiment influences, or results are influenced by, a participant's recollection of past events. For example, a patient with glioma on the left side of the head might misremember their past phone usage habits and report that they always used their phone on the left side of the head, if they are predisposed to think the two are related.

"exposure" is overly broad, the INTERPHONE results have been criticized as possibly being skewed "toward the null" by selection bias.[12] *IARC Monograph* at 203-16. If participants with relatively low phone use are defined as "exposed," they would dilute any possible association between phone use and cancer, resulting in underestimated odds ratios.[13] INTERPHONE may also suffer from participation bias[14] because its participation rates at some study centers varied widely, and there might not have been a fair representation of people who had never used cell phones. *IARC Monograph* at 215-16. When INTERPHONE did another analysis of its own data, recalibrating its definitions of "exposed" versus "unexposed" to try to account for bias, the resulting odds ratios were higher, indicating a positive association. *IARC Monograph* at 216. INTERPHONE's results and methodologies were largely similar for acoustic neuroma. *IARC Monograph* at 233.

The Hardell studies come from a research group led by Dr. Lennart Hardell in Sweden, also analyzing thousands of participants.[15] There are a number of Hardell studies and recombinations of Hardell data, but in general they point to a positive association between

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[12] Selection bias can occur if a researcher does not properly define the experimental and control groups when choosing individuals to participate in a study. For example, in a study designed to measure whether calcium intake is associated with bone growth, if a participant is classified as "exposed" if he consumed at least 1 mg of calcium a day and no association is found, the study might erroneously conclude that consumption of calcium had no effect on bone growth, even though an association might have been observable in the population that consumed more than 1000 mg of calcium per day. Theoretically, one could correct for this sort of selection bias by looking at the subset of participants who reported 1,000 mg or more per day; but doing this kind of retrospective analysis would require data from all participants on their actual daily consumption of calcium, and the sample of 1,000+ mg exposures would need to be large enough for statistical significance.

[13] An odds ratio is the method of defining the association between exposure to an element and disease incidence, relative to the control population. If an exposure results in an odds ratio of 1.00, that means that the exposed and unexposed groups develop the disease in equal proportions and there is no association. If the odds ratio is greater than 1.00 by a statistically significant margin, exposure to the agent is associated with higher rates of disease incidence relative to the control population. If the odds ratio is lower than 1.00 by a statistically significant margin, exposure to the agent is associated with lower rates of disease incidence relative to the control population.

[14] Participation bias occurs when the participants in the study are insufficiently representative of the population at large. Participation bias may occur in particular when the cases in a study participate at a greater rate than the controls.

[15] Dr. Hardell was a member of the IARC Working Group that produced the Monograph. IARC observed that Sweden was an appropriate location to study the risks of cell phone radiation, because that country had widespread use of cell phones much earlier than many other countries. *Id.* at 219.

exposure to cell phone radiation and the incidence of glioma and acoustic neuroma. *IARC Monograph* at 218-21, 233-34. This holds true even for users with relatively short periods of exposure (1-5 years). *IARC Monograph* at 204-14. Moreover, there seems to be some significant fluctuation between the odds ratios at varying levels of exposure in different Hardell studies, giving rise to criticisms that at least some of the studies suffer from methodological flaws. Like INTERPHONE, the Hardell studies also relied on questionnaires and interviews with cases and controls, which can result in recall bias. In particular, IARC noted that Hardell's questions about laterality (the side of the head on which one used the phone most frequently) could give rise to recall bias. *IARC Monograph* at 219. IARC commented that one strength of the Hardell studies was high participation rates, reducing the risk of participation bias. *IARC Monograph* at 220. However, others have criticized the Hardell studies for omitting certain categories of participants and distorting the participation rates. *See* Ex. DX0043, Indep. Advisory Grp. On Non-ionising Radiation, *Health Effects from Radiofrequency Electromagnetic Fields*, British Health Protection Agency 282-86 (Apr. 2012) (hereinafter "*HPA 2012*"). The HPA also criticized the later Hardell studies for under-representing cell phone users among both cases and controls relative to cell phone use in the overall population. *Id.* at 287.

IARC also examined the "ecological" evidence – the trends in disease incidence rates. In general, the incidence data do not show any significant increase in overall brain tumor rates, despite the widespread and ever-increasing use of cell phones. *IARC Monograph* at 192-99. There is some relatively new evidence of statistically significant increases for some tumors localized to particular regions of the brain. *See* Ex. PX0548, G. Zada et al., *Incidence Trends in the Anatomic Location of Primary Malignant Brain Tumors in the United States: 1992-2006*, World Neurosurgery 77(3-4): 518-24 (2012) (finding increased rates of a glioma subtype in the

frontal lobe, temporal lobe, and cerebellum) (hereinafter "Zada 2012"). But the overall incidence rates are mostly flat, or even trending downward. *IARC Monograph* at 192-99. This could be explained by long latency periods between the date of exposure and the incidence of cancer. Cell phones have been in widespread use for roughly twenty years. If cell phone radiation is carcinogenic, but it takes 30-40 years on average for cancers to develop, then cancers from cell phone radiation would not yet show up in large numbers in the incidence data. *IARC Monograph* at 199. On the other hand, some of the Hardell data are definitely inconsistent with the incidence trend data. In particular, Hardell found higher odds ratios after only a few years of cell phone use. If these findings were truly indicative of causation, then one would surely see a significant increase in certain brain tumors in the available incidence data; stated conversely, if long latency is the correct interpretation of the incidence data, some of Hardell's findings are most likely incorrect. Because the incidence data have not manifested the large spike in rates that the Hardell studies would predict, there is reason to doubt the reliability of those case-control studies, and one would look instead to bias, confounding, or chance to explain Hardell's results. *See* DX0264, M. P. Little, et al., *Mobile phone use and glioma risk: comparison of epidemiological study results with incidence trends in the United States*, BMJ 344:1-16, 3 (March 8, 2012) (hereinafter "Little 2012").[16] Likewise, the incidence data are inconsistent with the "protective effects" suggested by the INTERPHONE studies, reinforcing concerns of bias in those studies. *Id.*

In addition to human epidemiological studies, IARC also reviewed the experimental animal literature, including both *in vivo* and *in vitro* studies. *IARC Monograph* at 413-17. IARC concluded, "There is *limited evidence* in experimental animals for the carcinogenicity of

[16] The regional increases observed in the Zada 2012 study cannot sufficiently account for the predicted increase in rates derived from the Hardell data.

radiofrequency radiation." *IARC Monograph* at 419 (emphasis in original). When evaluating the mechanistic evidence, IARC generally found that there was only weak or insufficient evidence that RF radiation could have various cellular or molecular effects. *IARC Monograph* at 414-17.

Many other governmental agencies and other independent organizations have examined whether cell phone radiation is a potential carcinogen. All have concluded that the evidence at this time is insufficient to establish causation with any degree of confidence approaching a scientific certainty, and most recommend that further research is needed. *HPA 2012* at 4 ("limitations to the published research [preclude] a definitive judgment," but so far there is not enough evidence of a risk); Ex. DX0050, *Mobile phones and cancer, Part I: Epidemiology and tumours in the head*, Health Council of the Netherlands, at 8 (June 3, 2013) (further study needed because "no clear and consistent evidence"); Ex. DX0051, Anders Ahlbom, et al., *Radiofrequency Electromagnetic Fields and Risk of Disease and Ill Health*, Swedish Council for Working Life and Research, 7-8 (June 2012); Paolo Vecchia, et al., *Exposure to high frequency electromagnetic fields, biological effects and health consequences (100kHz-300GHz)*, Int'l Comm'n on Non-Ionizing Radiation Prot., 353-54 (2009) (available evidence flawed and insufficient) (hereinafter "*ICNIRP 2009*"); Ex. DX0045, *Cell Phones and Cancer Risk*, Nat'l Cancer Inst. (June 25, 2013) ("more research is needed");[17] Ex. DX0044, *Cellular Phones*, Am. Cancer Soc'y (Feb. 23, 2012) (noting insufficient evidence at present and that "it is important that the possible risk of cell phone exposure continue to be researched using strong study methods, especially with regard to use by children and longer term use");[18] Ex. DX3115,

[17] http://www.cancer.gov/cancertopics/factsheet/Risk/cellphones
[18] http://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/cellular-phones

Wireless Devices and Health Concerns, FCC Consumer Facts (2012); Ex. DX0204, *No Evidence Linking Cell Phone use to Risk of Brain Tumors*, FDA Consumer Health Info. (May 2010).

Although not cited by any party, the Centers for Disease Control ("CDC") also takes a neutral, cautious position on the carcinogenicity of cell phone radiation. "There is no scientific evidence that provides a definite answer to that question. Along with many organizations worldwide, we recommend caution in cell phone use. More research is needed before we know for sure if using cell phones causes cancer." *Frequently Asked Questions about Cell Phones and Your Health*, CDC, June 9, 2014.[19] The consensus throughout the scientific community is that the present state of the science does not permit any definitive answer to the question of whether cell phone RF radiation causes cancer or any other adverse health effects. This is largely because many of the studies that have been conducted so far (including INTERPHONE and Hardell) have significant methodological shortcomings undermining their reliability, and most of the ecological evidence does not show a rise in brain tumors coinciding with the rise in cell phone use. Most organizations agree that there is a need for new, better, more controlled research to determine whether cell phone radiation poses a threat to human health.[20] In the meantime, the definitive evidence of causation is just not there.[21]

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[19] http://www.cdc.gov/nceh/radiation/cell_phones._FAQ.html. CDC also states "We don't know for sure if RF radiation from cell phones can cause health problems years later" and "It's too soon to know for sure [if cell phones cause health problems in children]."

[20] Plaintiffs argue that part of the reason the scientific research and literature is inconclusive is due to funding and sponsorship decisions by the telecommunications industry. Pl. Post-Hr'g Br. at 18-21. They argue that scientists funded by industry have a suspicious tendency to refute earlier positive findings, especially in the animal and *in vitro* studies. *See* PX0816, A. Huss, et al., *Source of funding and results of studies of health effects of mobile phones use: Systematic review of experimental studies*, 115 Envtl. Health Perspectives 1-4 (2007). This is a serious allegation, which the court is not in a position to assess.

[21] On May 9, 2014, French researchers published results from a new case-control epidemiological study. Their study found support for "a possible association between heavy mobile phone use and brain tumours," including glioma. Gaëlle Coureau, *et al.*, *Mobile phone use and brain tumours in the CERENAT case-control study*, Occupational & Envtl. Med., May 9, 2014 (*available at* http://oem.bmj.com/content/early/2014/05/09/oemed-2013-101754.abstract). Plaintiffs brought the study to the court's attention in a recent filing unrelated to the present motion. Because the study was published after the *Dyas/Frye* hearing and was not the subject of expert testimony at the hearing, the court is not able to assess its findings or its effect on the current state of scientific knowledge.

III. Legal Standard

In the District of Columbia, the court applies a three-part test when determining whether to admit expert testimony:

> (1) the subject matter "must be so distinctively related to some science, profession, business or occupation *as to be beyond the ken of the average layman*"; (2) "the witness must have sufficient skill, knowledge, or experience in that field or calling as to make it appear that his opinion or inference *will probably aid the trier in his search for truth*"; and (3) expert testimony is inadmissible if "the state of the pertinent art or scientific knowledge does not permit a reasonable opinion to be asserted even by an expert."

Dyas v. United States, 376 A.2d 827, 832 (D.C. 1977) (quoting *McCormick on Evidence*, § 13 at 29-31 (E. Cleary, 2d ed. 1972)), *cert. denied* 434 U.S. 973 (1977) (emphasis in original). Even if the proposed expert testimony satisfies the three-part test, the court will exclude the testimony if its probative value is substantially outweighed by its potential for unfair prejudice, including the risk of confusing or misleading the jury. *Ibn-Tamas*, 407 A.2d at 632; *accord Girardot v. United States*, __ A.3d __, slip op. at 4-5 n. 3 (D.C. June 12, 2014); *In re L.C.*, __ A.3d __, slip op. at 11 (D.C. June 5, 2014).

Expert witnesses are necessary to convey relevant scientific, technical, and other specialized knowledge to the court and the jury. Before an expert can testify, the court must determine that the expert has the proper qualifications and would aid the jury. "Because of the authoritative quality which surrounds expert opinion, courts must reject testimony which might be given undue deference by jurors and which could thereby usurp the truth-seeking function of the jury." *Smith v. United States*, 389 A.2d 1356, 1359 (D.C. 1978). The proper role of the trial judge, however, is to verify credentials and methodology, not to weigh the persuasiveness of the testimony. *Ibn-Tamas v. United States*, 407 A.2d at 638; *accord Benn v. United States*, 978 A.2d 1257, 1274 (D.C. 2009). The trial court has broad discretion to admit or exclude expert

witnesses, so long as it "take[s] no shortcuts." *Ibn-Tamas*, 407 A.2d at 635; *(James) Johnson v. United States*, 398 A.2d 354, 363-67 (D.C. 1979).[22]

A. *"Beyond the Ken"*

Under the first prong of *Dyas*, the court examines the subject matter of the proposed expert testimony to determine whether it is outside the knowledge or understanding of the average layperson. *Perkins v. Hansen*, 79 A.3d 342, 344 n. 7 (D.C. 2013) (expert testimony appropriate when subject matter is "'beyond the ken' of the average lay juror"). Even if the subject matter is appropriate for expert testimony, the court must confine the expert to opinions that do not invade the province of the jury to decide the ultimate issues of fact in the case. *Ibn-Tamas*, 407 A.2d at 632.

B. *Qualifications and Aid to the Factfinder*

Under the second prong of *Dyas*, the proponent of the testimony must establish the expert's qualifications and show that the opinion the expert offers is likely to aid the jury in its

[22] The court has reviewed pre-hearing briefs, four weeks of expert testimony, thousands of pages of exhibits, post-hearing briefs, various treatises on expert testimony and admissibility, and dozens of trial court and appellate decisions, including, *inter alia*: *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997); *Old Chief v. United States*, 519 U.S. 172 (1997); *Daubert v. Merrill Dow Pharms. Inc.*, 509 U.S. 579 (1993); *(William) Johnson v. United States*, 683 A.2d 1087 (D.C. 1996) (*en banc*); *In re Melton*, 597 A.2d 892 (D.C. 1991) (*en banc*); *Girardot v. United States*, __ A.3d __ (D.C. June 12, 2014); *In re L.C.*, __ A.3d __ (D.C. June 5, 2014); *Perkins v. Hansen*, 79 A.3d 342 (D.C. 2013); *Pres. & Dirs. of Georgetown College v. Wheeler*, 75 A.3d 280 (D.C. 2013); *Wilson Sporting Goods v. Hickox*, 59 A.3d 1267 (D.C. 2013); *Minor v. United States*, 57 A.3d 406 (D.C. 2012); *Robinson v. United States*, 50 A.3d 508 (D.C. 2012); *Pettus v. United States*, 37 A.3d 213 (D.C. 2012); *(Ricardo) Jones*, 27 A.3d 1130 (D.C. 2011); *(John) Jones*, 990 A.2d 970 (D.C. 2010); *Benn v. United States*, 978 A.2d 1257 (D.C. 2009); *Comford v. United States*, 947 A.2d 1181 (D.C. 2008); *Roberts v. United States*, 916 A.2d 922 (D.C. 2007); *United States v. Jenkins*, 887 A.2d 1013 (D.C. 2005); *Haidak v. Corso*, 841 A.2d 316 (D.C. 2004); *Bahura v. S.E.W. Investors*, 754 A.2d 928 (D.C. 2000); *Nixon v. U.S.*, 728 A.2d 582 (D.C. 1999); *United States v. Porter*, 618 A.2d 629 (D.C. 1992); *Allen v. United States*, 603 A.2d 1219 (D.C. 1992); *Street v. Hedgepath*, 607 A.2d 1238 (D.C. 1992); *Coates v. United States*, 558 A.2d 1148 (D.C. 1989); *(Nathaniel) Jones v. United States*, 548 A.2d 35 (D.C. 1988); *Sponaugle v. Pre-Term, Inc.*, 411 A.2d 366 (1980); *Ibn-Tamas v. United States*, 407 A.2d 626 (D.C. 1979); *Middleton v. United States*, 401 A.2d 109 (D.C. 1979); *(James) Johnson v. United States*, 398 A.2d 354 (D.C. 1979); *Smith v. United States*, 389 A.2d 1356 (D.C. 1978); *Dyas v. United States*, 376 A.2d 827 (D.C. 1977), *cert. denied* 434 U.S. 973 (1977); *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923); *United States v. Frazier*, 387 F.3d 1244, (11th Cir. 2004) (*en banc*), *cert. denied*, 544 U.S. 1063 (2005); *United States v. McBride*, 786 F.2d 45 (2nd Cir. 1986); *Western Indus., Inc. v. Newcor Can., Ltd.*, 739 F.2d 1198 (7th Cir. 1984); *Dollar v. Long Mfg., N.C., Inc.*, 561 F.2d 613 (5th Cir. 1977); *In re "Agent Orange" Prod. Liab. Litig.*, 611 F.Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2nd Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988).

search for the truth. The expert must possess specialized knowledge derived from education and research, practical experience, or a combination of the two. *McCormick on Evidence*, § 13 at 70 (6th ed. 2006). While certain subjects may require a member of a particular profession, specialization within the profession is generally not required. *Id.* For example, a medical doctor can ordinarily testify as an expert on any medical matter, even if it is not within her specialty. *In re Melton*, 597 A.2d 892, 897 (D.C. 1991) (*en banc*) (citing *Baerman v. Reisinger*, 363 F.2d 309, 310 (D.C. Cir. 1966)). The adequacy of the training and specialization of the witness generally goes to the weight the jury should give to the expert's testimony, not to admissibility. *Id.* at 897-98. In addition, the expert must show that his or her opinion *"will probably aid the trier in his search for truth."* *Dyas*, 376 A.2d at 832 (emphasis in original). "Implicit in that requirement is that the expert have a 'reliable basis for [his] theory' steeped in 'fact or adequate data,' as opposed to offering 'a mere guess or conjecture.'" *Perkins*, 79 A.3d at 345 (quoting *Haidak v. Corso*, 841 A.2d 316, 327 (D.C. 2004)); *accord Robinson v. United States*, 50 A.3d 508, 523 (D.C. 2012) (court may exclude "outright speculation").

C. *The Frye Test*

The third part of the *Dyas* test asks the question – first articulated in *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923) – whether the expert used a generally accepted methodology in reaching his or her opinion. The *Frye* test "does not ask – or even permit – the court to ascertain scientific validity for itself." *The New Wigmore: A Treatise on Evidence*, § 5.3 at 161 (2004). Instead, "satisfaction of the third *Dyas* criterion begins – and ends – with a determination of whether there is a general acceptance of a particular scientific methodology, not an acceptance, beyond that, of particular study results based on that methodology." *Ibn-Tamas*, 407 A.2d at 638; *accord Pres. & Dirs. of Georgetown College v. Wheeler*, 75 A.3d 280, 291

(D.C. 2013) (the witness' methodology, not conclusion, is the focus of the inquiry); *Wilson Sporting Goods Co. v. Hickox*, 59 A.3d 1267, 1272 (D.C. 2013); *Minor v. United States*, 57 A.3d 406, 420-21 (D.C. 2012); *(John) Jones v. United States*, 990 A.2d 970, 977 (D.C. 2010); *Benn*, 978 A.2d at 1274-75 (admissibility standard relies on adversarial system to guard against weak evidence).[23]

The *Frye* test focuses on whether the expert's methodology has been "generally accepted" within the pertinent field. The expert must be able to identify the methodology in question and must explain what he or she did to enable the court to determine that the expert actually used the methodology. *See Wilson Sporting Goods*, 59 A.3d at 1273 (expert adequately "explained his reasoning, step by step" even if he "did not fully explain every aspect"). A scientific method requires more than just "accumulation of observations and intuitively plausible deductions" – there must be a hypothesis, systematic data collection, careful documentation, and structured analysis. *(John) Jones*, 990 A.2d at 980; *see also Wilson Sporting Goods*, 59 A.3d at 1273 ("courts should exclude expert testimony that consists of mere assertions"). It is not sufficient for an expert to say, "I used the XYZ Method" without explaining the actual steps he took and *showing* that he used the XYZ Method. However, at the admissibility stage, the expert does *not* need to show flawless execution or generally accepted conclusions. Those are questions for the factfinder. *United States v. Porter*, 618 A.2d 629, 636 (D.C. 1992) ("Any failure by the scientists to adhere to the appropriate procedure is, of course, a proper subject of inquiry, but does not raise an issue which implicates *Frye*."); *see also Perkins*, 79 A.3d at 345-46

[23] The defendants have attempted to broaden the scope of the *Frye* inquiry. In their pre- and post-hearing briefs, as well as during the *Frye* hearing itself, defendants repeatedly challenged plaintiffs' experts on the ground that their conclusions and opinions are not generally accepted, equated holding a minority viewpoint with a failure to satisfy the *Frye* test, and argued that a flawed execution of an accepted methodology constituted a failure to use a generally accepted methodology. The *Frye* standard calls for a more limited inquiry; *Frye* is satisfied if the expert used a generally accepted methodology, even if the expert's execution of the methodology was flawed or the conclusion he reached is not generally accepted.

(expert's failure to consider relevant data in his analysis does not bar admission). Two qualified experts using the same generally accepted methodology can draw different inferences from the data, and both would ordinarily be permitted to testify under *Frye*. The court's proper and limited role is to ensure that the expert has collected, analyzed, and presented the data in accordance with a methodology, and then to determine if that methodology is generally accepted.

Determining whether a particular methodology is generally accepted by other experts in the relevant field is a *categorical* inquiry applying to all potential experts using that methodology. General acceptance means that the answer "does not vary according to the circumstances of each case." *(Nathaniel) Jones v. United States*, 548 A.2d 35, 40 (D.C. 1988) (quoting *Reed v. State*, 391 A.2d 364, 367 (Md. 1978)). The *Frye* test applies only to novel techniques and methodologies. *Minor*, 57 A.3d at 419; *Pettus v. United States*, 37 A.3d 213, 217 (D.C. 2012); *(Ricardo) Jones v. United States*, 27 A.3d 1130, 1137 (D.C. 2011). Once a methodology has been generally accepted, it is "presumptively reliable," and otherwise qualified experts using it should ordinarily be admitted. *Street v. Hedgepath*, 607 A.2d 1238, 1244 (D.C. 1992); *accord Minor*, 57 A.3d at 419 n. 8; *(Ricardo) Jones*, 27 A.3d at 1136; *(Nathaniel) Jones*, 548 A.2d at 39-40.

Moreover, general acceptance does not require unanimity; the issue is consensus versus controversy. *(Ricardo) Jones*, 27 A.3d at 1136; *(Nathaniel) Jones*, 548 A.2d at 42. This means there must be majority, though not necessarily universal, approval. *See* Giannelli & Imwinkelried, *Scientific Evidence*, § 1.06(c) (5th ed. 2012). However, "[i]t is not the court's role to resolve disputes within the scientific community. The very existence of a dispute precludes admission." *United States v. Jenkins*, 887 A.2d 1013, 1022 (D.C. 2005). A novel methodology will fail the *Frye* test if there are scientists in either number or experience who publicly oppose

it. *Minor*, 57 A.3d at 420; *Porter*, 618 A.2d at 634. The party offering the novel technique must prove general acceptance by a preponderance of the evidence. *Pettus,* 37 A.3d at 217; *Porter*, 618 A.2d at 633; *Scientific Evidence*, § 1.06 at 27. In determining general acceptance, the court may survey scientific publications and prior judicial decisions and may receive testimony from scientists as to the degree of acceptance of the methodology in the relevant scientific community. *Benn*, 978 A.2d at 1278; *(Nathaniel) Jones*, 548 A.2d at 41-42; *McCormick on Evidence*, § 203 at 828-29; *Scientific Evidence*, § 1.06 at 27.

Once the court determines that the expert's methodology has been suitably identified and is generally accepted, the *Frye* inquiry ends. *E.g.*, *(Ricardo) Jones*, 27 A.3d at 1136; *Ibn-Tamas*, 407 A.2d at 638. Because the *Frye* test is not applied on a case-by-case basis, and because generally accepted methodologies are presumptively reliable, the question of whether an expert used a particular generally accepted methodology correctly is not at issue when determining the expert's admissibility. Instead, the opposing party may challenge the application of the methodology by cross-examination designed to convince the jury to disregard or give little weight to the expert's opinion. *Minor*, 57 A.3d at 419 n. 8; *Pettus*, 37 A.3d at 218; *(Ricardo) Jones*, 27 A.3d at 1136; *Coates v. United States*, 558 A.2d 1148, 1152 (D.C. 1989); *Ibn-Tamas*, 407 A.2d at 638 n. 23. In general, "relevant, unprivileged evidence should be admitted and its weight left to the factfinder. . . . [Testimony] may be countered not only as erroneous in a particular case but also as generally so unreliable that it should be ignored." *In re Melton*, 597 A.2d at 899; *see also McCormick on Evidence*, § 13 at 833 ("Any relevant conclusions supported by a qualified expert witness should be received unless there are distinct reasons for exclusion.").

D. *Rule 403*

The District of Columbia has adopted Federal Rule 403[24] as the applicable rule of evidence in this jurisdiction. *(William) Johnson v. United States*, 683 A.2d 1087, 1099 (D.C. 1996) (*en banc*). Even if proposed expert testimony satisfies the *Dyas/Frye* criteria, the trial court has discretion to exclude the testimony if its probative value is substantially outweighed by the danger of unfair prejudice, including the risk of confusing or misleading the jury. *See, e.g.*, *Ibn-Tamas*, 407 A.2d at 632; *Middleton v. United States*, 401 A.2d 109, 131 (D.C. 1979) (trial court has discretion to exclude an expert if the testimony would cause undue prejudice). Evidence will be unfairly prejudicial if it creates an "undue tendency to suggest decision on an improper basis." *Comford v. United States*, 947 A.2d 1181, 1187 (D.C. 2008) (citing *Old Chief v. United States*, 519 U.S. 172, 180 (1997)); *see also Dollar v. Long Mfg., N.C., Inc.*, 561 F.2d 613, 618 (5th Cir. 1977) (prejudice not "unfair" simply because evidence is adverse to opposing party). The Rule 403 standard is a lenient one "admitting as much relevant evidence as it is reasonable and fair to include." *(William) Johnson*, 683 A.2d at 1100. "Probative evidence should not be excluded because of crabbed notions of relevance or excessive mistrust of juries." *Allen v. United States*, 603 A.2d 1219, 1224 (D.C. 1992) (citation omitted); *accord Comford*, 947 A.2d at 1187. But where the probative value of the testimony is weak and the potential for unfair prejudice is strong, the court's discretion under Rule 403 is properly invoked to protect the fairness of the proceedings.

Expert testimony, because of its powerful potential to mislead or confuse juries, can be excluded under Rule 403 even if it would otherwise meet the standard for admissibility. *United States v. Frazier*, 387 F.3d 1244, 1263 (11th Cir. 2004) (*en banc*) (trial court has more discretion

[24] Federal Rule of Evidence 403 states: "The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."

to exclude experts than lay witnesses because "expert testimony may be assigned talismanic significance in the eyes of lay jurors"), *cert. denied*, 544 U.S. 1063 (2005); *see also Middleton*, 401 A.2d at 131; *Smith*, 389 A.2d at 1359. The more "imprecise and unspecific" an expert's proffered opinion is, the greater the risk that it will confuse or mislead the jury. *Frazier*, 387 F.3d at 1266. However, "[t]he mere fact that there may be conflicting testimony by experts is not a sufficient basis" to find a risk of jury confusion and exclude the experts under Rule 403. *United States v. McBride*, 786 F.2d 45, 51 (2nd Cir. 1986); *see also In re L.C.*, __ A.3d __, slip op. at 15 (trial judge may not "exclude relevant and otherwise admissible expert testimony merely because it is against the expected weight of the evidence.") (citing *Western Indus., Inc. v. Newcor Can., Ltd.*, 739 F.2d 1198, 1202 (7th Cir. 1984)).

In assessing the application of Rule 403 to expert testimony, the court is guided in part by Judge Weinstein's thorough analysis in *In re "Agent Orange" Prod. Liab. Litig.*, 611 F.Supp. 1223, 1245 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2nd Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988).[25] In that case, Vietnam War veterans alleged that exposure to the herbicide Agent Orange caused various health problems. Judge Weinstein ruled that expert testimony should be excluded under Rule 403 if it is based on an inadequate scientific foundation because of an unacceptable risk that it would confuse the jury. 611 F. Supp. at 1243 (satisfaction of Rule 702 does not equate to satisfaction of Rule 403).[26] As Judge Weinstein aptly stated: "If the underlying data is so lacking in probative force and reliability that no reasonable expert could base an opinion on it, an opinion which rests entirely upon it must be excluded. The jury will not be permitted to be misled by the glitter of an expert's accomplishments outside the courtroom."

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[25] It is worth noting that Judge Weinstein literally wrote the book on the rules of evidence. *See* Jack B. Weinstein & Margaret A. Berger, WEINSTEIN'S FEDERAL EVIDENCE (Joseph M. McLaughlin ed., 2d. ed. 2010).

[26] *Agent Orange* was not in the same procedural posture as this case. Judge Weinstein was considering a motion for summary judgment, and the causation issues before him concerned both general and specific causation. In the present case, only admissibility of expert testimony on general causation is ripe for consideration.

611 F.Supp. at 1245; *see also In re Melton*, 597 A.2d at 903 (quoting this passage from *Agent Orange*).[27] This is especially true for disease causation issues. *Agent Orange*, 611 F.Supp. at 1249-50 (discussing experts' failure to properly assess epidemiological studies). After a thorough analysis of Rule 403 case law, Judge Weinstein excluded two experts whose testimony created a strong probability for jury confusion because of its "false aura of scientific infallibility, coupled with low probative value." 611 F.Supp. at 1255-56. The experts had low probative value in part because the epidemiological studies they relied upon were "virtually useless in establishing causation." 611 F.Supp. at 1238 [28]

E. *Frye versus Daubert*

The District of Columbia does not follow *Daubert*, which governs the admissibility of expert testimony in the federal courts and most states.[29] *See Pettus*, 37 A.3d at 217 n.4 (*Frye* prevails until Court of Appeals *en banc* decides to adopt *Daubert*); *(John) Jones*, 990 A.2d at 982 n. 38; *Benn*, 978 A.2d at 1269 n.44. However, the scientific dispute in this case illustrates that the choice of one approach over the other can be outcome determinative. The opinions offered in this case that may be admissible under the District's "methodology only" application of *Frye* would almost certainly be excluded under *Daubert* because the carcinogenicity of cell

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[27] In this section of the opinion, Judge Weinstein is discussing Rule 703, but the point applies equally to Rule 403.

[28] Although Judge Weinstein ultimately excluded the two experts, he found that they *had* satisfied the methodology requirements of pre-*Daubert* Federal Rule of Evidence 702. The experts' "general scientific technique consist[s] of making an inference from epidemiologic data and animal studies. . . [that] an affliction [is] causally connected to Agent Orange exposure. This technique has been accepted by a sufficient number of courts to allow judicial notice to be taken of its general acceptance." 611 F.Supp. at 1243 (citations omitted). Federal Rule of Evidence 702 was subsequently amended to conform to the *Daubert* rule.

[29] The so-called Daubert rule is actually from a trilogy of decisions, beginning with *Daubert v. Merrill Dow Pharms. Inc.*, 509 U.S. 579 (1993), and continuing through *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). Approximately forty states have adopted the federal rules of evidence, which incorporate *Daubert* in Rule 702, or have explicitly decided to follow the *Daubert* rule. Some of those jurisdictions have hybrid regimes and others have adopted *Daubert*, but not necessarily its successors, *Joiner* and *Kumho Tire*. *Scientific Evidence*, §1.11. It appears that a small minority of jurisdictions, including the District, continue to follow *Frye*, at least with respect to novel scientific discoveries or novel methodologies. The District's rule, focusing on methodology only, is perhaps the most orthodox approach. *Id.* at §§1.06(c), 1.11. Some *Frye* jurisdictions scrutinize the general acceptance of the underlying science as well as methodology. *Id.* at §1.06(c).

phones, *vel non*, is such an unsettled science. In a toxic tort case like this one, *Daubert* tends to insulate manufacturers from products liability by excluding expert testimony on causation until the scientific community has reached a clear consensus.[30] *Daubert* jurisdictions typically "scrutinize reliability more carefully and appl[y] stricter standards." Lloyd Dixon & Brian Gill, *Changes in the Standards for Admitting Expert Evidence in Federal Civil Cases Since the* Daubert *Decision*, RAND Inst. for Civ. Just., xiv-xx (2001);[31] *Scientific Evidence*, §1.08(h). The *Frye* test tends to make it easier for causation experts to get before the jury, even when they are in the minority and the underlying science on causation is still quite controversial. *See, e.g.* Margaret A. Berger, *What Has a Decade of Daubert Wrought?*, 95 Am. J. Pub. Health S59-S65 (Jul. 27, 2004) (discussing the disproportionate impact of *Daubert* on toxic tort plaintiffs versus defendants);[32] Margaret A. Berger & Aaron D. Twerski, *Uncertainty and Informed Choice: Unmasking Daubert*, 104 Mich. L. Rev. 257, 265-67 (2005) (discussing difficulty of admitting epidemiological evidence after *Joiner*). Put another way – and at the risk of over-simplification – if a reliable, but not yet generally accepted, methodology produces "good science," *Daubert* will let it in, and if an accepted methodology produces "bad science," *Daubert* will keep it out; conversely, under *Frye*, as applied in this jurisdiction, even if a new methodology produces "good science," it will usually be excluded, but if an accepted methodology produces "bad science," it is likely to be admitted.[33]

For the above reasons, if cell phones do not cause brain cancer (a question the court is not called upon to answer), exclusion of causation experts under a *Daubert* standard would protect

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[30] For better or for worse, *Daubert* also obliges judges to become "amateur scientists" in order to exercise their gatekeeping function, *Daubert*, 509 U.S. at 600-601 (Reinquist, C.J. concurring and dissenting); under *Frye* a judge does not need to understand the underlying science to determine admissibility. *(John) Jones*, 990 A.2d at 981.

[31] *Available at* http://www.rand.org/content/dam/rand/pubs/monograph_reports/2005/MR1439.pdf.

[32] *Available at* http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2004.044701.

[33] However, the differences between *Frye* and *Daubert* vary greatly by jurisdiction. "'The choice is not between easy *Frye* and difficult *Daubert*; it is between strict and lax scrutiny.'" *Scientific Evidence*, §1.11 (quoting M. Redmayne, *Expert Evidence and Criminal Justice* 113 (2001).

defendants from erroneous decisions on liability and enormous, unnecessary, litigation costs. On the other hand, if cell phones do cause brain cancer, *Frye* increases the likelihood that cancer victims and their families can receive just compensation, without having to wait until the scientific community reaches consensus. Indeed, if cell phone radiation is carcinogenic, one would hope that courts would find a way to recognize that fact before a "phenomenal increase in the number of deaths attributed to cancer . . . provides one of the most striking changes in the pattern of mortality," and not forty years later. Richard Doll and A. Bradford Hill, *Smoking and Carcinoma of the Lung: Preliminary Report*, Brit. Med. J. 2(4682), 739 (Sept. 30, 1950).[34]

There is another limitation of the *Frye* standard in a case such as this. Proving causation depends – first and foremost – on epidemiology, which is largely an inductive, not deductive, science. Epidemiology depends on drawing inferences from observed conditions, both in nature and in the laboratory. There is nothing novel about the methodologies that are generally accepted in the field of epidemiology. Although they go by different names, most accepted methodologies rely heavily on, and share much in common with, Sir Austin Bradford Hill's famous nine causation factors. Ex. PX0107, A. Bradford Hill, *The Environment and Disease: Association or Causation?*, Sec. of Occupational Med., Proc. of the Royal Soc'y of Med., 7-12 (1965).[35] Whether an epidemiologist uses a literature review, or a weight of the evidence analysis, or directly applies the Bradford Hill criteria, all are attempting to answer the same question: does an exposure to a certain agent cause a particular biological effect in humans? Absent a known biological mechanism, this is often an attempt to know what cannot be proven definitively, and it is not unusual for competent epidemiologists to view the evidence, using the

[34] *Available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2038856/pdf/brmedj03566-0003.pdf.
[35] The Bradford Hill factors are: Strength, Consistency, Specificity, Temporality, Biological Gradient, Plausibility, Coherence, Experiment, and Analogy.

same accepted methodology, and come to opposite conclusions on causation, particularly in close cases.

Frye's targeted focus on the general acceptance of methodology works well enough for the deductive sciences: forensics, mathematics, applied physics, chemistry, and the like. But the test is not a good gatekeeper for inductive sciences such as epidemiology or psychology. Deductive reasoning employs fixed, quantifiable processes which, if applied correctly, should produce the same results regardless of the expert. Inductive reasoning, on the other hand, necessarily requires the subjective judgment of the expert to infer from premises to conclusions. In a litigation setting, it is difficult to separate the legitimate exercise of subjective judgment from the illegitimate advocacy of a biased, pre-determined opinion.

The problem with *Frye* in the present context – at least as applied here, where an accepted methodology is the be all and end all of admissibility – is that it does not distinguish between close cases and extreme cases. Under *Dyas/Frye*, if the methodology is accepted, the evidence generally comes in, and we trust the jury to decide based on competing experts on either side of the causation divide. Even if 99 out of 100 scientists come out on one side of the causation inference, and only one comes out on the other, as long as the one used a "generally accepted methodology," *Frye* allows the lone expert to testify for one party and one of the other ninety-nine to testify for the opposing party. If the jury finds the lone expert more persuasive, that party prevails, even though "in the real world" the evidence is overwhelming that the case should come out the other way. At least where the science is as fraught with doubt as inferences of causation in epidemiology can be, *Frye* does not seem like the best way to ensure a just result.[36]

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[36] When first articulated in *Dyas*, the third factor appeared to address "bad" science with the statement "expert testimony is inadmissible if the state of the pertinent art or *scientific knowledge* does not permit a reasonable opinion

One last preliminary observation may be in order. If there is even a reasonable possibility that cell phone radiation is carcinogenic, the time for action in the public health and regulatory sectors is upon us. Even though the financial and social cost of restricting such devices would be significant, those costs pale in comparison to the cost in human lives from doing nothing, only to discover thirty or forty years from now that the early signs were pointing in the right direction. As the inconclusive results of the IARC Monograph make clear, more research is necessary to answer definitively the fundamental question of carcinogenicity. If the probability of carcinogenicity is low, but the magnitude of the potential harm is high, good public policy dictates that the risk should not be ignored. *See* Richard Posner, *Catastrophe: Risk and Response* (2004). The court recognizes, however, that policy debates of this kind do not belong in the judicial branch. The question of admissibility before the court is a narrow one, and the court is bound by the precedents applying *Frye* unless and until an *en banc* decision of the Court of Appeals says otherwise.

IV. Plaintiff's Proposed Expert Witnesses

A. *Dr. Shira Kramer*

i. Field and Opinion "Beyond the Ken"

Dr. Shira Kramer is an epidemiologist. She studies the occurrence, patterns, and causation of disease in human populations. To determine disease causation, epidemiologists review multiple sources of scientific data coming from human case-control studies, human cohort studies, incidence data ("ecological analyses"), and *in vitro* and *in vivo* laboratory

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to be asserted even by an expert." 376 A.2d at 832 (internal quotations omitted) (emphasis added). Under that formulation, where the science is inconclusive, outlying minority views claiming science is capable of providing an answer could be excluded. However, subsequent case law quickly moved away from this broad language and restricted the trial court's inquiry to the narrow review of methodology under the *Frye* test. *See Ibn-Tamas*, 407 A.2d at 638 ("In summary, satisfaction of the third *Dyas* criterion begins – and ends – with a determination of whether there is general acceptance of a particular scientific methodology, not an acceptance, beyond that, of particular study results based on that methodology."); *accord Nixon v. U.S.*, 728 A.2d 582, 588 n. 14 (D.C. 1999).

experiments. Dr. Kramer offers her opinion, "to a reasonable degree of scientific certainty, that exposure to radiation from cellular phones is causally associated with increased risks of glioma and acoustic neuroma." Kramer Exp. Rpt. at 11. Dr. Kramer's field of expertise and her opinion are beyond the ken of a layperson, and she therefore satisfies the first requirement of *Dyas*.

ii. *Qualifications and Aid to the Factfinder*

Dr. Kramer received a masters degree in human genetics in 1975 and a PhD in epidemiology in 1979 from Johns Hopkins School of Public Health. From 1978 to 1984, she was an assistant professor of epidemiology at the University of Pennsylvania School of Medicine, where she taught courses and co-authored a textbook on epidemiology. During this same time period Dr. Kramer was also an epidemiologist at the Children's Cancer Research Center at the Children's Hospital of Philadelphia. She conducted research on childhood cancers using incidence data and case-control studies of potential risk factors. Since 1984, Dr. Kramer has worked for what is now known as Epidemiology International, Inc., a research and consulting firm she founded. Epidemiology International conducts epidemiological studies on a wide variety of diseases, including cancer, for clients in industry, academic institutions, federal and state agencies, and professional trade organizations. Dr. Kramer's past research has been funded by the National Institutes of Health, the EPA, the CDC, the FDA, the Department of Defense, and the State of Maryland, among others. She has been qualified to testify as an expert in epidemiology in both *Frye* and *Daubert* jurisdictions.

Defendants do not challenge Dr. Kramer's qualifications, and the court does not doubt her general competency. *See Haidak v. Corso*, 841 A.2d 316, 327 (D.C. 2004). While Dr. Kramer has not done any research specifically focused on glioma, acoustic neuroma, or cell phone radiation, an otherwise competent epidemiologist is qualified to testify on any matter

related to the field of epidemiology. *See In re Melton*, 597 A.2d at 897-98 (adequacy of specialization goes to weight, not admissibility). Dr. Kramer's proffered testimony satisfies the second requirement of *Dyas*.

iii. *General Acceptance of Methodology*

Dr. Kramer testified that she reviewed the relevant scientific literature and sifted it through a weight of the evidence ("WOE") analysis. There is such a thing as the WOE methodology, and in certain scientific circles it is generally accepted. Indeed, IARC uses a form of the WOE methodology in producing its Monographs. However, as Dr. Kramer plainly demonstrated at the *Frye* hearing, she did not faithfully or rigorously apply a true WOE methodology or, for that matter, any other generally accepted methodology. The preponderance of the evidence does not support Dr. Kramer's satisfaction of the third requirement of *Dyas*.

Before the court may determine whether a methodology is generally accepted, an expert must identify her methodology and establish that she actually did what she said she did. The expert must follow a scientific method, starting from a neutral position, by developing a hypothesis, systematically collecting relevant data, and subjecting all of the data – both that which supports the hypothesis and that which opposes it – to a carefully documented structured analysis. *See (John) Jones*, 990 A.2d at 980. The expert must "explai[n] his reasoning, step by step" but need not "fully explain every aspect." *Wilson Sporting Goods*, 59 A.3d at 1273. The preponderance of the evidence in the record makes clear that Dr. Kramer did not proceed in this manner. Dr. Kramer does not fail the *Dyas/Frye* test because her *conclusions* lack general acceptance or because she applied WOE, but did so poorly. Rather, the evidence and testimony at the *Frye* hearing show that what Dr. Kramer actually did to reach her conclusions was so far removed from what is generally accepted as a true WOE analysis that her methodology amounts

to little more than a subjective selection of sources and data to support her pre-determined causation opinion, to the exclusion of all contrary evidence, which is not WOE or any other generally accepted scientific methodology.

In scientific parlance, WOE sometimes refers to a methodology for answering scientific questions such as causation, but at other times it is a loose term that can mean different things in different contexts. It requires a concrete definition when used as a scientific methodology. Ex. DX3496, Douglas L. Weed, *Weight of Evidence: A Review of Concept and Methods*, 25 Risk Analysis 1545 (2005). Dr. Sheldon Krimsky, who has been cited favorably by both plaintiffs and defendants as an authority on scientific methods, describes WOE as "a process or method in which *all* scientific evidence that is relevant to the status of a causal hypothesis is taken into account." Ex. DX0091, Sheldon Krimsky, *The Weight of Scientific Evidence in Policy and Law*, 95 Am. J. Pub. Health, S129-S136, S129 (2005) (emphasis added). Many governmental bodies, such as the EPA, NCI, IARC, and the U.S. National Toxicology Program use some variant of the WOE method in their epidemiological evaluations. Kramer Exp. Rpt. at 25; Hr'g Tr. 1904:19-1905:2 Dec. 18, 2013. When used in the manner of these agencies, WOE is a generally accepted methodology. But because of the frequent lack of specificity and transparency as to what is included in a WOE analysis, proof of its rigor in any given case requires more than a bald assertion by the expert that "I used the WOE method." *See* Krimsky at S130. "Without an explication of how evidence is 'weighed' or 'weighted,' the claim WOE seems to be coming out of a 'black box' of scientific judgment." *Id.* at S131. Thus, unlike someone claiming to have employed the Bradford Hill criteria, conducted a literature review, or used another methodology that is not particularly amorphous, an expert asserting that she used the WOE method needs to supply more detail as to what her methodology entails.

In her report, Dr. Kramer writes that "[a] WOE analysis is the formal review and synthesis of a body of literature and data about a subject" that "evaluates trends in the literature based on consistency, biological plausibility, and convergence towards a particular conclusion." Kramer Exp. Rpt. at 10. "A WOE analysis utilizes evidence provided from a multitude of disciplines in order to assess causation, and causal conclusions are formed on the basis of the collective weight of the evidence." *Id.* at 23. Dr. Kramer reiterates again and again in her report that an investigator must use her best judgment when considering the weight of all of the evidence, the totality of the evidence, the convergence of the evidence, etc. "Inferences on disease causation are made on the basis of a logical deductive process that makes use of a mosaic of evidence, yet is not dictated by any single piece of evidence." *Id.* According to Dr. Kramer, a WOE analysis should examine all of the evidence from medicine, toxicology, epidemiology, and other sciences, which come in the form of animal studies, clinical case reports, randomized controlled trials, and observational epidemiological studies, among others. *Id.* However, WOE does not require a "specific weighting or ranking scheme" but instead ultimately comes down to a "subjective interpretation[n] of 'reality' implied by various lines of scientific evidence." *Id.* at 24.

In her report, Dr. Kramer states that she conducted a "systematic search of the epidemiological literature" as well as "relevant review articles and key primary research studies on the range of adverse effects of EMF radiation, particularly from cellular phones, in humans, animal models, and in genotoxicity and *in vitro* assays." *Id.* at 27. She reviewed epidemiological studies with positive, negative, and null association findings. *Id.* at 28. These included case-control studies done by INTERPHONE and Hardell, cohort studies, pooled and meta-analyses, and "ecological studies" of incidence data. *Id.* at 28-32. So far, so good.

But despite claiming to have "reviewed" all of the literature in all the relevant fields, Dr. Kramer supports her opinion almost exclusively with the INTERPHONE and Hardell epidemiological studies. Hr'g Tr. 2253:1-2254:3 Dec. 19, 2013. She testified that the heightened odds ratios from Hardell and portions of the INTERPHONE data show that cell phone radiation causes or contributes to the development of glioma and acoustic neuroma.[37] Dr. Kramer drew a sharp distinction between the publications she "reviewed" and the publications upon which she "relied" for her opinions.

Dr. Kramer disregarded or "did not rely on" animal or *in vitro* studies to support her opinion, Hr'g Tr. 2081:23-2082:19 Dec. 18, 2013, despite testifying and writing in her report that they are an important part of a WOE analysis in that they help determine biological plausibility. *E.g.* Kramer Exp. Rpt. at 36; Hr'g Tr. 2068:8-2069:1 Dec. 18, 2013. She testified that biological plausibility is unnecessary if the epidemiological evidence is sufficient, so she did not need to examine the largely negative data from the animal studies in depth. Hr'g Tr. 2082:20-2084:6 Dec. 18, 2013.

Dr. Kramer disregarded or "did not rely" on the reviews and reports of major bodies such as ICNIRP, HPA, or IEEE, Hr'g Tr. 2155:23-25, 2191:24-2192:22, 2258:16-2263:1 Dec. 19, 2013, despite testifying and writing in her report that such reviews are valuable to a WOE analysis. *E.g.* Kramer Exp. Rpt. at 28; Hr'g Tr. 2154:13-2156:11 Dec. 19, 2013. Dr. Kramer said that in general she thought it was more important to rely on primary data than review articles.

Dr. Kramer disregarded or "did not rely" on trends in the incidence data, Hr'g Tr. 2118:9-2122:12, despite writing in her expert report that such ecological studies are helpful epidemiological data. Kramer Exp. Rpt. at 27-32. One of the many difficulties with any opinion

[37] Dr. Kramer testified that she thought that parts of INTERPHONE's data were unreliable and other parts reliable.

that cell phone radiation can cause or promote brain cancer is that the worldwide incidence data for brain cancer are essentially flat during the same period when cell phone use across the globe has skyrocketed (IARC estimated 4.6 billion subscribers in 2009). Some causation experts have speculated that the incidence data remain flat because the latency period for glioma and acoustic neuroma may be so long (perhaps as long as thirty to forty years from exposure), there has not been enough time for the increased cancers from cell phones to show up in the data. Dr. Kramer, however, went so far as to testify that even if incidence data still showed no increase in brain cancer rates by 2040, she would reject the incidence data before she would question the correctness of her opinion that cell phones cause brain cancer. Hr'g Tr. 1934:2-1935:11 Dec. 18, 2013.[38] This does not accord with the WOE methodology, which seeks to "assemble a picture that is consistent with the majority of the clear and definite . . . and most relevant . . . evidence." Kramer Exp. Rpt. at 23-24. Likewise, Dr. Kramer disregarded or "did not rely on" meta-analyses and a host of other epidemiological studies and reviews. Hr'g Tr. 2210:3-2213:3 Dec. 19, 2013.

Dr. Kramer did not conduct a weight of the evidence analysis of the cancer risk from cell phones. Instead she looked at the broad range of data, picked out the pieces she preferred, and found convenient reasons to ignore the rest. Had Dr. Kramer actually conducted a WOE analysis similar to those undertaken by EPA or IARC, she would have followed a generally accepted methodology. But what she actually did is far removed from what those organizations do. Because plaintiffs failed to demonstrate that Dr. Kramer used any describable methodology at

[38] Dr. Kramer testified that she thought the incidence data were uninformative and speculated that some other factor might be "masking" the rise in brain cancer rates. But she could not identify any such masking agent. "[A] mere guess or conjecture" unsupported by adequate data will not be helpful to the jury. *Perkins*, 79 A.3d at 345 (quoting *Haidak*, 841 A.2d at 327).

all, much less a generally accepted methodology, her proffered testimony fails to satisfy the *Frye* test and the third requirement of *Dyas*.

iv. *Probative vs. Prejudicial*

In addition to concluding that Dr. Kramer's testimony does not satisfy the *Dyas/Frye* test, the court would also exclude her testimony under Rule 403, because the probative value of her testimony is substantially outweighed by the risk of misleading and confusing the jury. Fed. R. Evid. 403; *(William) Johnson*, 683 A.2d at 1099; *Ibn-Tamas*, 407 A.2d at 832; *Frazier*, 387 F.3d at 1263. In *Agent Orange*, Judge Weinstein ruled that a causation expert should be excluded under Rule 403 when the studies the expert relies upon are "virtually useless in establishing causation" because they lack any significant probative force. *Agent Orange*, 611 F.Supp. at 1238.[39]

Dr. Kramer relies almost entirely on the results of the INTERPHONE and Hardell studies, while brushing aside the mountains of other empirical data and analyses (most of which cast doubt on her fundamental conclusions). *See* Hr'g Tr. 2253:1-2254:3 Dec. 19, 2013. But scientists and agencies have roundly criticized the methodologies of both the Hardell and INTERPHONE case control studies. Plaintiffs tend to cite criticisms of INTERPHONE (which generally showed no association between cell phone radiation and brain cancer), while defendants tend to cite criticisms of Hardell (which showed some positive associations between cell phone radiation and brain cancer). Both camps admit that both sets of studies suffered from recall bias, selection bias, and participation bias. Hardell is criticized for producing results that have not been validated by other researchers and that are out of step with most other epidemiological evidence. INTERPHONE is criticized for methodological flaws producing a

[39] In *Agent Orange*, the experts relied primarily on animal studies and epidemiological studies of industrial accidents to extrapolate to causation in humans, while ignoring an extensive epidemiological literature with negative or inconclusive results. *Agent Orange*, 611 F.Supp. at 1230-34, 1237-38.

"bias toward the null," with critics pointing out that some of the INTERPHONE data could be interpreted to suggest that cell phone radiation has a protective effect *against* cancer, which is biologically implausible. Although IARC described Hardell and INTERPHONE as "the most robust evidence on risk of tumours of the brain associated with wireless-phone use," *IARC Monograph* at 409, its ultimate conclusion was that cell phone radiation could only be classified as a "possible carcinogen," based on the "limited evidence" to support causation. Every other major health agency or organization that has examined the issue has likewise concluded that the epidemiological evidence is inconclusive at best. Simply put, Hardell and INTERPHONE are of such limited probative force and reliability that a reasonable expert could not infer causation based solely on those sources. *See Agent Orange*, 611 F.Supp. at 1245. Dr. Kramer's testimony, relying almost entirely on these two sources, lacks substantial probative value.

Moreover, the risk that Dr. Kramer's testimony would mislead or confuse the jury is high. Because of the "talismanic significance" and "authoritative quality" that surrounds expert opinions, the court must be vigilant to prevent jury confusion caused by misleading testimony. *Smith*, 389 A.2d at 1359; *Frazier*, 387 F.3d at 1263; *accord Ibn-Tamas*, 407 A.2d at 632; *Middleton*, 401 A.2d at 131. Dr. Kramer perused the available scientific source material, chose those studies that she felt would best support the opinion she wished to convey, and then found "reasons" to disregard contradictory evidence. In some cases, data she relied upon (Hardell and the high exposure category of INTERPHONE) suffered from some of the same failings as studies she criticized (the rest of INTERPHONE). Other times, she disregarded entire lines of evidence that she herself had said were relevant to a disease causation determination. For example, after stating that biological plausibility is an important factor in determining causation, she disregarded all of the animal and *in vitro* studies that could be informative on this point.

Likewise, Dr. Kramer disregarded incidence data trends showing no significant overall increase in brain cancer, despite the fact that Hardell's studies, if correct, would predict that brain cancer rates should have already spiked upward. *See* Little 2012.

At a few points, Dr. Kramer even presented evidence in a manner that could hoodwink a jury. In her report Dr. Kramer quotes statements from some government agencies, including the FDA and FCC, and describes them as "precautions and advisories regarding the safety of cellular phones." Kramer Exp. Rpt. at p. 20-21. These quotes contain advice on how an individual can reduce exposure to cell phone radiation. In the context of her report, Dr. Kramer makes it sound like these agencies have concluded that such exposure could be dangerous. However, Dr. Kramer took these quotes unfairly out of context. The FCC[40] and FDA[41] documents from which Dr. Kramer lifted these quotes explicitly state that there is insufficient scientific evidence to establish a causal link between cell phones and cancer, but then go on to offer advice to consumers who are nonetheless apprehensive. Hr'g Tr. 2194:11-2203:22. In short, Dr. Kramer clipped statements that supported her position and used them, out of context, to distort the positions of these authoritative government agencies.

Although defendants are ably represented and have prestigious experts of their own, the court cannot be confident that effective advocacy can eliminate the risk that a jury would be misled by Dr. Kramer's testimony and reach a result on an improper basis. Because of the

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[40] Def. Ex. 203, *Wireless Devices and Health Concerns – FCC Consumer Facts*, FCC (2012) ("Even though no scientific evidence currently establishes a definite link between wireless device use and cancer or other illnesses. . . some consumers are skeptical of the science and/or the analysis that underlies the FCC's RF exposure guidelines. Accordingly, some parties recommend taking measures to further reduce exposure to RF energy. **The FCC does not endorse the need for these practices,** but provides information on some simple steps that you can take to reduce your exposure to RF energy from cell phones.") (emphasis in original). Dr. Kramer omitted this section of the document and just listed the exposure reduction steps that followed.

[41] Def. Ex. 204, *No Evidence Linking Cell Phone Use to Risk of Brain Tumors*, FDA (May 2010) ("Although evidence shows little or no risk of brain tumors for most long term users of cell phones, FDA says people who want to reduce their RF exposure can: reduce the amount of time spent on the cell phone; use speaker mode or a headset to place more distance between the head and the cell phone."). When quoting this passage, Dr. Kramer omitted the entire first clause and began with "…people who want to reduce."

significant risk that the jury would be confused or misled by her testimony, the limited probative value of Dr. Kramer's expert opinion is substantially outweighed by the risk of unfair prejudice, and her testimony is not admissible under Rule 403.

B. ***Dr. Michael Kundi***

i. *Field and Opinion "Beyond the Ken"*

Dr. Michael Kundi is a professor of epidemiology and occupational health at the Medical University of Vienna. Dr. Kundi offers his opinion, to a reasonable degree of scientific certainty, that cell phone radiation more likely than not causes an increased risk of brain tumors, including glioma and acoustic neuroma. Kundi Exp. Rpt. at 3, 15. Dr. Kundi's field and opinion are beyond the ken of a layperson, and he therefore satisfies the first requirement of *Dyas*.

ii. *Qualifications and Aid to the Factfinder*

Dr. Kundi received his PhD in psychology and mathematics from the University of Vienna in 1979. He received his medical habilitation degree in epidemiology and occupational health from the Medical University of Vienna in 1989.[42] He has been a professor of epidemiology and occupational health at the Medical University of Vienna since 1990. He was appointed head of the Department for Occupational and Social Hygiene in 1996, and head of the Institute of Environmental Health in 2004. He is the coordinator of the PhD program at the University. Dr. Kundi has taught courses in hygiene, microbiology, preventative medicine, occupational health and epidemiology, environmental and occupational medicine, public health, biostatistics, epidemiological research methods, and qualitative research methods. He researches the health effects of occupational and environmental factors and conducts epidemiological research of infectious diseases.

[42] A medical habilitation degree, a step above a PhD, is the highest academic degree one can obtain in many parts of Europe. In some countries, it is a prerequisite to supervise doctoral candidates.

Dr. Kundi is the deputy head of the Austrian Standards Committee for Electromagnetic Fields, head of the toxicology working group at the Austrian Ministry for the Environment, and a member of the EMF working group of the Highest Health Council at the Austrian Ministry of Health. He has been invited by the WHO to be a member of an advisory board to develop a research agenda for EMF. Dr. Kundi has authored or co-authored more than 300 peer-reviewed articles, including original epidemiological studies, meta-analyses, review articles, and other biomedical research. He has authored more than 30 articles relevant to the health effects of cell phone radiation.

Defendants do not challenge Dr. Kundi's qualifications, and the court has no reason to doubt his competency. *See Haidak*, 841 A.2d at 327. He is certainly qualified to render an opinion on the general causation issues in this case, and his proffered testimony satisfies the second requirement of *Dyas*.

iii. *General Acceptance of Methodology*

Dr. Kundi used what he calls the "Pragmatic Dialogue Method" ("PDM") to reach his opinions. Dr. Kundi explained PDM in a 2006 article, *Causality and the Interpretation of Epidemiologic Evidence.* 114 Envtl. Health Perspectives 969-74 (July 2006). In the article, Dr. Kundi discusses the Bradford Hill criteria and the ways in which scientists conduct causation determinations generally (not just in epidemiology), and he proposes a framework for systematic disease risk assessments. He highlights the logical fallacy of equating "insufficient evidence of causation" with "evidence of no causation," believes scientists sometimes apply the Bradford Hill criteria incorrectly, and describes a "dialogue approach" for applying Bradford Hill in a proper manner. Under this approach, scientists must start with epidemiologic evidence and examine what he calls 1) temporal relation, 2) association, 3) environmental equivalence, and 4)

population equivalence. If the evidence for a factor weighs in favor of causation and there are no valid counterarguments, then the examiner should consider that factor to be supporting causation. If epidemiologic evidence is insufficient to make a determination on its own, other types of evidence (such as *in vitro* and *in vivo* studies) should be weighed as well. Finally, if there is evidence of causation, Dr. Kundi believes that public health officials should not postpone action "until better evidence is available if our present knowledge appears to demand immediate measures for health protection." *Id.* at 969. He calls this the "precautionary principle."

Defendants characterize PDM as a novel and not generally accepted methodology. They argue that other scientists have not explicitly used PDM to make a cancer causation determination. Defendants portray Dr. Kundi as someone seeking to "replace" Bradford Hill with PDM as the preferred methodology for inferring causation, even though no other scientist agrees with him. In particular, defendants argue that the "precautionary principle" pervades PDM and leads to a finding of causation, where the totality of evidence does not support causation under generally accepted epidemiological methodologies. According to defendants, unlike Bradford Hill, PDM starts with an assumption of causation and then seeks to disprove it.[43]

Defendants' characterization of Dr. Kundi's PDM methodology makes more of its differences with Bradford Hill than the facts will bear. Dr. Kundi's 2006 article and the writings of other scientists who cite to it demonstrate that PDM is not a novel alternative to Bradford Hill as much as it is an explanation of the way the Bradford Hill criteria should be considered. PDM looks at the same lines of evidence as Bradford Hill and interprets them in the same way, albeit with a slightly different vocabulary. The article itself purports to be a commentary on causation

[43] Defendants also argue that Dr. Kundi relied entirely on epidemiological evidence and that his failure to consider *in vivo* and *in vitro* studies was not "generally accepted." However, if PDM is a generally accepted methodology, the specific application of a generally accepted methodology is not an issue for the court under *Frye*. Moreover, virtually all accepted methodologies agree that if the epidemiological evidence in humans is strong enough, a causal inference can be drawn without reference to *in vitro* or *in vivo* studies.

and Bradford Hill generally; it is an attempt to standardize the causation discussion (i.e. "pragmatic dialogue"). Dr. Kundi testified that his goal was to "embrace the Bradford Hill criteria and giv[e] it structure, so that it cannot be arbitrarily used." Hr'g Tr. 99:10-12 Dec. 2, 2013. The article is not some groundbreaking new methodology, and it certainly does not appear to have provoked much controversy in the literature. Dr. Kundi's article is often cited together with other articles discussing the Bradford Hill approach and causation, largely without critical or other substantive commentary.[44] The handful of citations and lack of commentary do not signify, as defendants assert, that PDM lacks general acceptance. Rather, they show that the scientific community seems to regard PDM as something similar to, and not incompatible with, Bradford Hill, and for that reason PDM has not generated any significant controversy, outside of this litigation.

The "precautionary principle" is not a fundamental component of a disease causation assessment using PDM. Defendants' arguments to the contrary hold up no better than their attempt to debunk the methodology itself. As Dr. Kundi wrote in his article and explained in his testimony, the precautionary principle is a consideration for policy makers; it is not a component

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[44] Articles citing Dr. Kundi's 2006 publication include: Ex. PX0109, Adami, et al., *Toxicology and Epidemiology: Improving the Science with a Framework for Combining Toxicological and Epidemiological Evidence to Establish Causal Inference*, 122 Toxicological Sci. 223-243 (2011) (uses method similar to Dr. Kundi's); Ex. PX0633, Gallagher, et al., *Blood and Urine Cadmium, Blood Pressure, and Hypertension: A systematic Review and Meta-Analysis*, 118 Envtl. Health Perspectives 1676-84, 1681 (2010) (discusses Dr. Kundi and Bradford Hill); Ex. PX0634, Ward, *The role of causal criteria in causal inferences: Bradford Hill's "aspects of association,"* 6:2 Epidemiologic Perspectives And Innovations (June 17, 2009) (references Dr. Kundi and Bradford Hill); Ex. PX0635, Barbui, et al., *Perspectives on thrombosis in essential thrombocythemia and polycythemia vera: Is leukocytosis a causative factor?*, 114(4) Blood 759-763 (2009) (cites Dr. Kundi as an interpretation of Bradford Hill); Ex. PX0636, Schroeder, et al., *Food Allergy is Associated with an Increased Risk of Asthma*, 39(2) Clin. Exp. Allergy 261-270 (2009) (cites Dr. Kundi to define causality); Ex. PX0637, Uzoigwe, et al., *Epidemiological evidence for Mycobacterium avium subspecies paratuberculosis as a cause of Crohn's disease*, 135 Epidemiol. Infect. 1057-1068 (2007) (cites Dr. Kundi when defining causation). An article by Russo & Williamson quotes Dr. Kundi three times: to explain the Bradford Hill criteria, in a discussion of the history of disease causation determinations, and to critique philosophical definitions of causation that depend too much on probabilistic evidence while discounting the role of mechanistic evidence. Ex. DX3376, Federica Russo & Jon Williamson, *Interpreting Causality in the Health Sciences*, 21 Int'l Studies in the Philosophy of Sci. 157-70 (July 2007).

of a scientific inquiry by an epidemiologist. Hr'g Tr. 157:17-164:24 Dec. 2, 2013.[45] Basically, if a public health official is considering whether to regulate an exposure, and there is some evidence that the exposure might pose a health risk, the precautionary principle states that the official should "assume the worst" until more conclusive evidence is available. But an epidemiologic causation determination is a scientific endeavor that starts from the null position and then weighs the evidence, as Sir Bradford Hill prescribed.[46] This is what Dr. Kundi claims to have done in developing his opinions in this case.

Dr. Kundi might prefer to call his methodology the "Pragmatic Dialogue Method," but he is essentially doing a Bradford Hill analysis. A name change does not render an accepted methodology unacceptable. Because it cannot be disputed that use of the Bradford Hill criteria to determine causation is a generally accepted methodology, Dr. Kundi's methodology is generally accepted. Whether or not Dr. Kundi properly applied that methodology is a question for the factfinder and is beyond the scope of a *Frye* inquiry. *See*, e.g., *Minor*, 57 A.3d at 419 n.8; *Pettus*, 37 A.3d at 218; *Ibn-Tamas*, 407 A.2d at 638 n.23. Therefore, Dr. Kundi satisfies the third requirement of *Dyas*.

iv. *Probative vs. Prejudicial*

Admissibility of Dr. Kundi's testimony under Rule 403 is a close call. The causation opinions rendered by Dr. Kundi are probative as to the ultimate issue in this case. He has an

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[45] Whether or not Dr. Kundi allowed the precautionary principle to bias his own assessment of the evidence is an issue to be raised on at trial, which may affect the weight a jury gives to Dr. Kundi's testimony. But the specific application of an accepted methodology in a particular case is not part of a *Frye* inquiry. *See, e.g., Porter*, 618 A.2d at 636 ("Any failure by the scientists to adhere to the appropriate procedure is, of course, a proper subject of inquiry, but does not raise an issue which implicates *Frye*.").

[46] Dr. Kundi's "principle of pessimism," is different from his precautionary principle, and it played no role in his formulation of his opinions about RF radiation causing glioma and acoustic neuroma. As described by Dr. Kundi, the principle of pessimism states that if one has evidence that exposure A causes disease X, and disease Y is very similar to X but so rare as to be difficult to study, one should assume that A can also cause Y. In his report, Dr. Kundi explained that because there is sufficient evidence that cell phone radiation causes glioma, the principle of pessimism allows him to extrapolate that it likely also causes other similar, yet very rare, brain tumors. Because it played no role in the formation of his pertinent causation opinions, the principle of pessimism is irrelevant on the question of Dr. Kundi's admissibility.

impressive resume, a lengthy list of publications in the field, and significant experience researching EMFs. He is well-qualified to render an opinion on epidemiological issues generally and cell phone radiation specifically. Dr. Kundi believes that IARC misclassified the carcinogenicity of cell phone radiation; he would have classified it as 2A had he been on the IARC panel. But he also thinks the gap between 2A and 2B is quite narrow and that both meet the "more probable than not" evidentiary legal standard. Hr'g Tr. 143:24-144:15 Dec. 2, 2013.

Dr. Kundi's impressive credentials are precisely what make his causation testimony problematic. Any jury is likely to treat his opinions as authoritative and weighty even though the scientific basis for those opinions may be thin. Dr. Kundi believes the epidemiology alone is strong enough to support an inference of causation, even with only limited evidence from the animal studies and without a known biological mechanism. Hr'g. Tr. 326:22-327:10 Dec. 3, 2013. He testified as to why he supports the Hardell studies and thinks the INTERPHONE studies are partially biased toward the null. *See* Hr'g. Tr. 82:21-87:1 Dec. 2, 2013; Kundi Exp. Rpt. at 6-10. He discounts the absence of evidence in the incidence data because of the long latency periods of the tumors at issue in this case. *See* Hr'g. Tr. 254-10-255:21.[47]

Moreover, Dr. Kundi appears to apply his scientific knowledge as an advocate. It is apparent that he believes cell phone radiation poses a serious public health risk. While he asserts that the precautionary principle is not a component of his scientific methodology, it is not obvious that he is able to separate the two. He believes cell phone radiation is carcinogenic even though every authoritative government body has said the evidence is inconclusive at this point. Obviously he is entitled to hold his point of view and to express it in the realm of public policy. But in court, in the context of private civil litigation, he must be able to separate health hazards

[47] Unlike Dr. Kramer, however, Dr. Kundi at least accounted for the inconclusive incidence data, and he was willing to acknowledge that if the incidence data remained flat to the year 2040, he would need to rethink his causation opinion. Hr'g. Tr. 257:6-258:14 Dec. 3, 2013.

that are known with the requisite degree of scientific certainty from those that are not known, but may pose enough of a risk that policy makers should be willing to act on the available evidence. Because of the high magnitude of harm that would result if cell phones are carcinogenic, the precautionary principle instructs Dr. Kundi that action needs to be taken sooner rather than later. As was thoroughly discussed at the hearing, the probabilities and magnitudes of harm might support a policy proposal, but they are not a proper basis for a judicial determination on the science. Dr. Kundi's testimony poses a risk of prejudice, confusion, and misleading the jury.

Given the probative value of Dr. Kundi's proffered testimony and its potential for prejudice, the difficult question under Rule 403 is whether the probative value "is *substantially* outweighed by a danger of unfair prejudice." *See In re L.C.*, slip op. at 14 n. 24 (emphasis in original). Guiding the court's exercise of discretion is the principle that Rule 403 is designed to be a permissive standard that leans toward admitting relevant evidence and cautions not to exclude probative evidence because of "excessive mistrust of juries." *Comford*, 947 A.2d at 1187 (quoting, *(William) Johnson*, 683 A.2d at 1100, and *Allen*, 603 A.2d at 1224). The court cannot "exclude relevant and otherwise admissible expert testimony merely because it is against the expected weight of the evidence." *In re L.C.*, slip op. at 15 (citing *Western Indus. Inc. v. Newcor Can., Ltd.*, 739 F.2d 1198, 1202 (7th Cir. 1984) ("a judge in our system does not have the right to prevent evidence from getting to the jury merely because he does not think it deserves to be given much weight"). Courts must carefully scrutinize expert testimony because of its "aura of special reliability and trustworthiness." *Ibn-Tamas*, 407 A.2d at 632. Nonetheless, the Court of Appeals has clearly stated that exclusion should be a last resort to be used only when there is a substantial risk of jury confusion:

> The [Supreme] Court advised that judges should rely on the adversarial system, rather than on the exclusion of evidence, to guard against potential juror

> confusion from the presentation of scientific evidence, noting that "[vigorous] cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Any remaining concern a trial judge may have that admission of expert testimony could confuse or overwhelm the jury is more appropriately dealt with, not by exclusion, but by placing reasonable limitations on the expert's testimony and instructing the jurors that they – and only they – are the ultimate fact finders.

Benn, 978 A.2d at 1275 (citing and quoting *Daubert*, 509 U.S. at 596).

In this case, while risk of prejudice from Dr. Kundi's testimony is not insignificant, that risk does not "substantially" outweigh the probative value of his opinions. At trial, defendants will have every opportunity to cross-examine and impeach Dr. Kundi, challenge his overreliance on the "limited"epidemiological data, point to the "limited" results of the animal studies, criticize his interpretation of the *in vitro* data, present the contradictory incidence data, undercut the Hardell studies, and attempt to portray Dr. Kundi as a "Chicken Little." Defendants will also have the opportunity to present testimony from their own highly qualified, authoritative expert witnesses. These safeguards, along with proper jury instructions, should be sufficient to protect against the risk of unfair prejudice posed by Dr. Kundi's testimony. *See Benn*, 978 A.2d at 1275.

C. ***Dr. "Vini" Guatam Khurana***

i. *Field and Opinion "Beyond the Ken"*

Dr. Khurana is a neurosurgeon and associate professor of neurosurgery at the Australian National University in Canberra. He offers, to a reasonable degree of medical certainty, the following epidemiological opinions:

1. Radiation emitted from cell phones causes adverse effects in humans, including, but not limited to, increased risk of brain tumors.
2. A significant increase in brain cancer incidence has been observed and that a significant increase will be observed internationally within this decade, a substantial contributing cause of which is more probably than not related to cell phone usage.

Khurana Exp. Rpt. at 8. In his report, Dr. Khurana reviews epidemiological evidence, discusses the potential ways by which non-ionizing radiation can affect DNA and lead to cancer promotion, and asserts that incidence trend data in Australia show increased brain cancer rates, which will be observed in other international databases in the coming years.

Dr. Khurana's field of expertise and opinions are beyond the ken of a layperson, and his proffered testimony therefore he satisfies the first requirement of *Dyas*.

ii. *Qualifications and Aid to the Factfinder*

Dr. Khurana received his medical degree from the University of Sydney Medical School in 1994. He worked at the Mayo Clinic in Rochester, Minn., from 1996 to 2005, where he was a neurosurgery resident. In 2001, he earned a PhD from the Mayo Clinic and received accolades for his doctoral research. From 2005 to 2006, he was a fellow at the Barrow Neurological Institute and a neurosurgeon at St. Joseph's Hospital in Phoenix, Ariz., where he conducted research on brain aneurysms and tumors. Since 2006, Dr. Khurana has practiced as a neurosurgeon at The Canberra Hospital in the Australian Capital Territory, with a stint as a visiting neurosurgeon at the Royal Melbourne Hospital from 2010 to 2012. Since 2007, he has instructed and supervised medical students as an associate professor of neurology at the Australian National University. In his clinical practice, Dr. Khurana regularly treats and operates on patients with brain tumors and brain cancer. He also conducts clinical research and supervises graduate student research. He holds two U.S. patents related to gene delivery and genetic testing in relation to brain aneurysms. He has received a number of awards for his past work and research, and he has published dozens of journal articles.

Defendants challenge Dr. Khurana's qualifications to offer an expert opinion on epidemiology. They argue that he does not have sufficient "expertise to critically analyze

epidemiologic meta-analyses or to assess the impact of fundamental, basic epidemiological concepts" at issue in this case. Def. Post-Hr'g Br. at 81. Dr. Khurana is a practicing neurosurgeon and PhD, who routinely treats the very brain tumors and cancers at issue in this case. Although epidemiology is at the center of the causation issue, he demonstrated enough basic knowledge of epidemiology to render his opinion on the carcinogenicity, *vel non*, of exposure to RF from cell phones. Any gaps in the expert's understanding of the epidemiological issues in the case ordinarily go to the weight of his testimony, not its admissibility. *In re Melton*, 597 A.2d at 897-98 (citing *Baerman*, 363 F.2d at 310).

The court does not doubt Dr. Khurana's competency. *See Haidak*, 841 A.2d at 327. Because his opinions about cancer causation and incidence data are central to the general causation questions in this case and could aid the jury, Dr. Khurana satisfies the second requirement of *Dyas*.

iii. *General Acceptance of Methodology*

To the extent he articulated one, Dr. Khurana's methodology consisted of conducting a literature review of scientific and medical publications related to cell phone radiation and brain cancer. One of the main sources Dr. Khurana relies upon is a meta-analysis he co-authored with Dr. Hardell, Dr. Kundi, and Dr. Michael Carlberg, which reviewed epidemiological data from the Hardell and INTERPHONE studies. To reach his opinion on trends in incidence data, Dr. Khurana also reviewed data from Australia and from the Central Brain Tumor Registry of the United States ("CBTRUS"), which combines data from NIH and CDC to create a near-comprehensive list of reported U.S. cancers. Hr'g Tr. 917:1-13 Dec. 11, 2013. Dr. Khurana relied on published literature analyzing the incidence data, as well as his own analysis, to reach his opinions about trends in cancer incidence.

Defendants argue that a "literature review" is not a generally accepted methodology, and that Dr. Khurana's literature review was significantly flawed based on his choice of sources and his selective reading. In particular, Defendants argue that Dr. Khurana relied principally on his own writings (some of which were not published in peer-reviewed journals),[48] that his analysis of the incidence data was flawed, and that he cherry-picked the *in vivo* and *in vitro* studies. Many of defendants' criticisms would be the proper subject of cross-examination at trial; but in the context of the *Frye* test under the third prong of *Dyas*, defendants' arguments are misguided.

Drawing inferences from a review of published scientific literature has long been recognized as a generally accepted methodology. *See, e.g., Georgetown*, 75 A.3d at 292 ("reliance on relevant medical literature. . . as well as case studies appearing in that literature, [is] a 'generally accepted' method for forming an opinion regarding medical causation."); *Wilson Sporting Goods*, 59 A.3d at 1272 (experts may rely on published data of other experts); *Agent Orange*, 611 F.Supp. at 1243 (expert's methodology of making inferences from scientific literature was "generally accepted" despite relying on unreliable studies). Because a literature review is a generally accepted methodology, and Dr. Khurana adequately demonstrated that he did in fact do a literature review, his methodology is "presumptively reliable" and the *Frye* inquiry goes no further. *Hedgepath*, 607 A.2d at 1244; *accord Minor*, 57 A.3d at 419 n. 8; *(Nathaniel) Jones*, 548 A.2d at 40 (the *Frye* test "does not vary according to the circumstances of each case"); *Ibn-Tamas*, 407 A.2d at 638. If an expert uses a generally accepted methodology, the reliability and credibility of the expert is properly addressed by cross-examination and the testimony of opposing experts. *E.g. In re Melton*, 597 A.2d at 899; *Benn*, 978 A.2d at 1274-75.

[48] While most of the sources cited in his report are his own articles, Dr. Khurana testified that in forming his opinions he relied not just on his own writings, but also on the sources he cited in his own writings. Hr'g Tr. 974:4-22 Dec. 11, 2013. He claims the bibliography of his expert report does not give the full picture by itself.

Because Dr. Khurana used a generally accepted methodology, his testimony satisfies the third requirement of *Dyas*.

iv. *Probative vs. Prejudicial*

Although defendants are unable to knock out Dr. Khurana's methodology under the three-part *Dyas* test, their criticisms of his methodology are on firmer footing in the court's Rule 403 analysis. As discussed previously, and as elucidated by IARC, the Hardell and INTERPHONE studies provide only limited evidence of carcinogenicity. Dr. Khurana relies on those studies, but he supplements them with a number of his own publications, several of which are not formal academic writings published in peer-reviewed journals.[49] The abbreviated list of citations in Dr. Khurana's report supports defendants' allegation that he cherry-picked the studies on which he chose to rely.[50] Moreover, the methodologies of some of the articles cited by Dr. Khurana have been criticized by independent authorities.[51] Meanwhile, Dr. Khurana ignored the bulk of evidence and reviews from major health agencies like the HPA and many others, which have concluded that there is insufficient evidence of a causal link between cell phone radiation and cancer. It seems to the court that Dr. Khurana had his mind made up before he began his report, then went out and found a handful of publications (some of which are significant outliers, defendants argue) to support his predetermined position.

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[49] Dr. Khurana's first reference, *Mobile phones and brain tumours – A public health concern,* was published on www.brain-surgery.us, Dr. Khurana's website, which is not a scientific journal and is not peer-reviewed. While the paper is lengthy and written as a scholarly examination of cell phone radiation, the court is in no position to evaluate its scientific accuracy. Reliance on such unverified source material poses a substantial risk of misleading or confusing the jury. Three of the other references in Dr. Khurana's expert report are letters to the editors of scientific journals, one is a published debate with another scientist, and one is about cellular base stations, not phones. While these sources may have scientific merit, the first four are not peer-reviewed publications and the final one may or may not be relevant to cell phone radiation. When there is no shortage of substantive scientific literature on cell phone radiation, for Dr. Khurana to rely on these peripheral sources raises red flags about both the probative value of his testimony and the risk of confusing or misleading the jury.

[50] Defendants argue that Dr. Khurana ignored the bulk of animal studies, which found no significant effects from cell phone radiation, and instead cited a handful of outlier studies that defendants claim have failed replication.

[51] For example, Dr. Khurana cites the Weisbrot 2003 fruit fly study, which IARC criticized for using unreliable dosimetry. *IARC Monograph* at 341.

While Dr. Khurana's lack of expertise in epidemiology is not a disqualifier under *Dyas/Frye*, it is nonetheless a factor under a Rule 403 analysis. As Dr. Khurana freely acknowledged in his testimony at the hearing, he is not an epidemiologist and he is not particularly familiar with many of the tools of that trade, such as the calculation of odds ratios. Without a strong understanding of the nuances of odds ratios and the statistical side of the search for causation in epidemiology, his testimony on causation lacks strong probative value and carries with it a high risk that study results will be presented in a confusing, misleading, or inaccurate manner. For example, when combining the odds ratios from multiple studies, it is important to control for heterogeneity, failing which the amalgamated odds ratios may mask important inconsistencies in the underlying data. Moreover, Dr. Khurana brushed aside the inconsistencies in the epidemiological data from different studies, even though epidemiology, under any approach, including Bradford Hill, emphasizes the importance of consistency between studies to support a causation inference. Because a jury is likely to give Dr. Khurana's opinions on the epidemiological data an "aura of special reliability and trustworthiness," whether they are accurate and reliable or not, his proffered testimony carries with it a heightened risk of confusing or misleading the jury to reach a result on an improper basis. *Ibn-Tamas*, 407 A.2d at 832.

Finally, where the methodology leading to an opinion, not shared by most other scientists, that a particular agent *is* carcinogenic to humans is as amorphous as a "literature review," the risk of misleading the jury is significant. Dr. Khurana may be a first-rate surgeon, but he is not an epidemiologist, the field of science to which such opinions belong. A literature review cannot make him an epidemiologist, but a jury is likely to give his opinions on causation authoritative weight simply because they are pronounced by an expert of his obvious stature. Where the broad consensus from the expansive epidemiological literature is that there is not

enough evidence to conclude that cell phone radiation is carcinogenic to humans, the jury should not be misled into finding that it is carcinogenic simply because Dr. Khurana, a non-epidemiologist, tells them so based on his shallow and highly selective reading of that literature.

For the foregoing reasons, the court will exercise its discretion to exclude Dr. Khurana's testimony under Rule 403.

D. ***Dr. Igor Belyaev***

i. Field and Opinion "Beyond the Ken"

Dr. Igor Belyaev was a member of the IARC Working Group and is "a cancer research scientist with a focus on the biophysical effects and molecular mechanisms of non-ionizing and ionizing radiation." Belyaev Exp. Rpt. at 1. He offers seven opinions, to a reasonable degree of scientific certainty: 1) that RF cell phone radiation has non-thermal biological effects, including single and double strand DNA breaks and inhibition of DNA repair; 2) that these non-thermal biological effects are caused by known physical mechanisms; 3) that the effects and risks of cell phone radiation are proportional to the specific absorption rate ("SAR") and duration of exposure; 4) that the effects vary according to genetic and physiological variables and therefore some populations, like "young people," are more susceptible to cell phone radiation than others; 5) that RF cell phone radiation induces cellular mechanisms that produce carcinogenesis in human brain cells; 6) that ELF cell phone radiation produces effects and carcinogenesis similar to RF cell phone radiation; and 7) that ELF and RF cell phone radiation "cause and/or significantly increas[e] the risk of certain [unspecified] malignant and non-malignant head and brain tumors in humans." *Id.* at 5-6.

Unlike IARC, which placed RF from cell phones in its Group 2B – possibly carcinogenic to humans – Dr. Belyaev testified that he would place it in Group 2A – probably carcinogenic to

humans. Hr'g. Tr. 637:6-21 Dec. 4, 2013. When asked to explain why he did not hold out for a 2A classification when he was part of the IARC Working Group, Dr. Belyaev basically admitted that he did not have the votes. He claimed that IARC reaches its decisions by consensus and, for political reasons, he decided to accede to the 2B classification. *Id.*

Dr. Belyaev's field of expertise and opinions are beyond the ken of the average layperson, and he therefore satisfies the first requirement of *Dyas*.

ii. *Qualifications and Aid to the Factfinder*

Dr. Belyaev is the Head Research Scientist at the Cancer Research Institute at the Slovak Academy of Science in Bratislava, Slovakia. He received a masters degree in radiation physics and dosimetry from the Moscow Engineering Physics Institute at Moscow Technical University in 1981, a PhD in radiobiology from the Institute of Biophysics at the U.S.S.R. Academy of Science in 1986, and a D.Sc.[52] in genetics from St. Petersburg State University in 1994. From 1981 to 1994, Dr. Belyaev was an associate professor and held various academic research positions at the Moscow Engineering Physics Institute, culminating in the position of Head Research Scientist. From 1994 to 2006, he taught, conducted research, and directed research teams at Stockholm University in the areas of radiobiology, genetic and cellular toxicology, and microbiology. Since 2006, he has been at the Cancer Research Institute at the Slovak Academy of Science. Dr. Belyaev supervises a biophysics and radiobiology laboratory, which primarily studies the biological effects of RF and ELF radiation.

Dr. Belyaev was one of the thirty members of the IARC Working Group charged with classifying the carcinogenicity of cell phone radiation, which produced the 2013 IARC Monograph heavily cited in this case. He is on the editorial board of several scientific journals,

[52] A Doctor of Sciences degree is the highest post-graduate degree in Russia (and formerly in the Soviet Union), obtained after one has already obtained a PhD.

including *Electromagnetic Biology and Medicine* and *International Journal of Radiation Biology*. The journal *Bioelectromagnetics* awarded Dr. Belyaev and his research team Most Influential Paper from 2005 to 2009 for a study on the biological effects of RF on rat brains.

Defendants do not challenge Dr. Belyaev's qualifications, and the court has no reason to doubt his competency. *See Haidak*, 841 A.2d at 327. Dr. Belyaev's expertise and opinions are likely to aid the factfinder, and he therefore satisfies the second requirement of *Dyas*.

iii. *General Acceptance of Methodology*

Dr. Belyaev testified that he used the same methodology in reaching his expert opinions that IARC used in compiling its Monograph. Hr'g Tr. 369:12-370:1, 372:12-374:25 Dec. 3, 2013. He reviewed and evaluated the body of scientific literature that the IARC Working Group reviewed and evaluated when he was a member. While the IARC Monograph had not yet been published at the time Dr. Belyaev submitted his expert report, he had access to IARC's materials and drafts.[53] He said that he relied on the research that IARC had done on the topic. Dr. Belyaev reviewed epidemiological studies, animal studies, and *in vitro* studies. In essence, Dr. Belyaev conducted a literature review based primarily on research already compiled by IARC and supplemented with some additional sources.

Defendants criticize Dr. Belyaev's literature review as lacking the rigor of IARC, relying on allegedly flawed studies, and failing to analyze objectively the positive and negative studies. They argue that if Dr. Belyaev had properly applied IARC's methodology, he would have been unable to reach a conclusion different from IARC's 2B classification of possibly carcinogenic.[54]

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[53] IARC describes its methodology in great detail in the preamble to the Monograph. *IARC Monograph* at 9-31. The Working Group examines all relevant information and studies on a potential carcinogen, including epidemiological studies, whole animal experimental studies, mechanistic (*in vivo* and *in vitro*) studies, incidence data, and any other evidence. The Group then weighs the evidence and decides how to classify the agent. In contrast to Dr. Kramer, IARC is a true example of attempting to determine causation using a WOE methodology.

[54] Defendants lob variations of this argument at almost every one of plaintiffs' experts: that if the expert had properly applied Methodology X, the only possible conclusion would be "no causation;" and since the expert has a

While these critiques may be effective at trial, they go beyond the scope of a *Frye* inquiry. Whether one chooses to call it "IARC's Methodology," WOE, or a literature review, Dr. Belyaev's stated methodology is generally accepted. *Georgetown*, 75 A.3d at 292; *Wilson Sporting Goods*, 59 A.3d at 1272; *Agent Orange*, 611 F.Supp. at 1243. Therefore, it is "presumptively reliable" and the *Frye* inquiry goes no further. *Hedgepath*, 607 A.2d at 1244; *accord Minor*, 57 A.3d at 419 n. 8; *(Nathaniel) Jones*, 548 A.2d at 40 (the *Frye* test "does not vary according to the circumstances of each case"); *Ibn-Tamas*, 407 A.2d at 638.

In addition to his literature review, Dr. Belyaev also relies on some of his own laboratory research. Based on that research, Dr. Belyaev believes that cell phone radiation inhibits mechanisms in human cells that repair double strand DNA breaks, which could lead to increased development of tumors. Pl. Post-Hr'g. Br. at 92-94; Hr'g. Tr. 377:20-379:16 Dec. 3, 2013. Some of these experiments used a technique called Anomalous Viscosity Time Dependence ("AVTD"). According to Dr. Belyaev, AVTD is similar to the comet assay, which is a widely used and generally accepted technique for measuring DNA damage in *in vitro* experiments. Hr'g Tr. 360: 12-20 Dec. 3, 2013. Dr. Belyaev invented and patented the AVTD method in the late 1980s in the Soviet Union. He testified that AVTD has been validated and accepted by the scientific community. Hr'g Tr. 357:23-358:1 Dec. 3, 2013; Hr'g Tr. 611:12-19 Dec. 4, 2013. IARC cited some of Dr. Belyaev's studies that used AVTD without comment, disapproval, or criticism of the methodology. Hr'g Tr. 611:3-612:6 Dec. 4, 2013; *IARC Monograph* at 297, 299, 307-09, 338, 340, 343, 346, 384-85. However, while AVTD may be a reliable method, there is

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different opinion, he must not have used a generally accepted methodology. This argument is without merit for two reasons. First, if an expert improperly uses a generally accepted methodology, any such errors go to the weight to be given to his testimony, not its admissibility, at least where the expert honestly followed the methodology as he understood it. Second, different scientists can look at the same sets of data, apply the same methodology, make no errors, and still reach different conclusions on the close questions. Disease causation inferences draw from myriad sources and are fundamentally subjective determinations requiring the application of the expert's judgment.

no evidence in the record that anyone outside of Dr. Belyaev's laboratory uses it, even though the technique is now more than twenty-five years old.[55] Hr'g Tr. 609:23-610:25 Dec. 4, 2013.[56] Moreover, at least some publications have characterized AVTD as being an unorthodox technique. *See* Ex. DX1038, SSI Report, *Recent Research on EMF and Health Risks*, Swedish Radiation Prot. Auth., April 2007, at 20 ("not a standard method generally used by other investigators"); Ex. DX1033, Andrei G. Pakhomov et al., *Current State and Implications of Research on Biological Effects of Millimeter Waves*, 19 Bioelectromagnetics 393, 397 (1998) ("not a conventional technique in cell biology").

On this record, plaintiffs have failed to show by a preponderance of the evidence that AVTD is a generally accepted methodology. *E.g. Jenkins*, 887 A.2d at 1021-22; *Porter*, 618 A.2d at 633. Consequently, to the extent that Dr. Belyaev bases his opinions on his own work using the AVTD methodology, those opinions are not admissible. However, to the extent that Dr. Belyaev formed his opinions using the generally accepted IARC methodology, his opinions satisfy the third requirement of *Dyas/Frye* and are admissible for that reason. *See, e.g., Benn*, 978 A.2d at 1275 (limiting testimony with proper jury instructions is preferable to exclusion).

iv. *Probative vs. Prejudicial*

Dr. Belyaev's opinions on the carcinogenicity of cell phone radiation will have significant probative value because of his expertise and his experience as a member of the IARC Working Group. As discussed above, defendants have a number of criticisms of Dr. Belyaev's opinions and methodology, including that he failed to examine the evidence with as much rigor as IARC, relied on unreplicated or methodologically flawed studies, and failed to assess the

[55] It is unclear whether Dr. Belyaev's patent on AVTD has expired or if his patent extended outside the Soviet Union. Hr'g Tr. 611:1-10 Dec. 4, 2013. There is no evidence in the record that other scientists would have used AVTD but for the patent protection.

[56] Dr. Belyaev testified that he had recently become aware of AVTD being used by a research team in Canada, but he was unable to provide any specific details regarding that research.

positive and negative results in an objective manner. They argue in particular that he disregarded the mechanistic studies and incidence data. Obviously defendants take issue with his general causation opinions, which are at odds with the majority of the scientific community.

With respect to IARC's 2B classification, Dr. Belyaev testified that he disagreed with IARC and would have held out for a 2A classification. He claimed, however, that IARC operates by consensus, and he could not convince the other Working Group members, who concluded that the "limited" epidemiological evidence precluded a 2A classification. Hr'g. Tr. 637:6-21 Dec. 4, 2013. Of course, Dr. Belyaev is free to disagree with IARC, but his claim that he was forced to go along with the majority to achieve consensus has a hollow ring to it. The Monograph itself notes conspicuously that while the majority of the Working Group favored the 2B classification, a minority thought cell phone radiation should be in Group 3 (evidence inadequate to classify carcinogenicity to humans). *IARC Monograph* at 419; Hr'g. Tr. 637:22-640:6 Dec. 4, 2013. This suggests not only that IARC's decision was not strictly dictated by consensus, but also that there was at least some debate about lowering the classification from 2B to Group 3. Even if the minority in favor of Group 3 consisted of only one member of the Working Group, IARC thought enough of that view to include it in the Monograph. Dr. Belyaev's claim that he would have asked IARC to include *his* minority position in favor of 2A had he known that option was available to him, sounds more like revisionism than history.

Under Rule 403, the court may not exclude expert testimony based on the court's view of its persuasive force or because it is against the expected weight of the evidence. *In re L.C.*, slip op. at 15 (citing *Western Indus. Inc. v. Newcor Can., Ltd.*, 739 F.2d 1198, 1202 (7th Cir. 1984) ("a judge in our system does not have the right to prevent evidence from getting to the jury merely because he does not think it deserves to be given much weight"). As long as the

testimony satisfies the *Dyas/Frye* test, as Dr. Belyaev's testimony does to the extent it is based on IARC's methodology, the testimony must be admitted unless its probative value is substantially outweighed by a risk of unfair prejudice. Defendants will have ample opportunity to cross-examine Dr. Belyaev about his disagreement with IARC and any other weaknesses in his testimony, and they will undoubtedly put on opposing expert testimony of their own. With these safeguards and proper jury instructions, the court cannot say that the probative value of Dr. Belyaev's testimony is substantially outweighed by the risk of unfair prejudice, confusion, or misleading the jury to reach a decision on an improper ground.

E. ***Dr. Wilhelm Mosgoeller***

i. *Field and Opinion "Beyond the Ken"*

Dr. Mosgoeller is a cell biologist and histologist. He researches effects on cellular biology under various conditions and conducts *in vitro* studies. He offers his opinions "to a reasonable degree of medical and scientific certainty" and summarizes them as follows:

1. Non-thermal radiation as emitted from cellular phones causes biological effects in some human systems and cells.
2. In principle these biological effects can be either beneficial, neutral, or adverse.
3. "A-thermal" radiation from cellular telephones causes an increase in DNA breakage in certain types of human cells resulting in an increased risk of cancer.
4. Some cells (*e.g.*, metabolically active cells) respond more strongly to non-thermal EMFs, a finding which is particularly concerning for children and youth, who have a greater percentage of metabolically-active, "growing" tissues.
5. Because of what we know about a-thermal effects, it is not possible to define new safety regulations based on the currently available data. Therefore, the recommendations for risk minimizing strategies focus on the "principle of prudent avoidance", *i.e.*, avoid and lower exposure whenever reasonably achievable.

Mosgoeller Rpt. 3. Dr. Mosgoeller testified that long-term exposure to radiation emitted from cell phones can cause adverse biological effects in human cells by increasing the

accumulation of unrepaired DNA breaks. It does this, he believes, by inhibiting a cell's DNA repair mechanism or by activating the reactive oxygen species of the cell thereby making the DNA more brittle. Hr'g. Tr. 680:3-682:6, 706:7-710:17, 726:8-13 Dec. 9, 2013.[57] It is generally understood that unrepaired DNA breaks can lead to an increased risk of cancer, although for cancer to develop from DNA breaks, other biological processes must occur. Dr. Mosgoeller is not able to say that exposure to cell phone radiation causes an increased risk of glioma or acoustic neuroma specifically. Hr'g Tr.731:22-732:9 Dec. 9, 2013. His opinion is therefore limited to biological plausibility, and constitutes only a building block for plaintiffs' overall causation theory.

Dr. Mosgoeller's field of expertise and opinions are beyond the ken of a layperson, and he therefore satisfies the first requirement of *Dyas*.

ii. Qualifications and Aid to the Factfinder

Dr. Mosgoeller is a tenured professor and medical doctor at the University of Vienna Medical School's Institute for Cancer Research. He received his medical degree from the University of Vienna in 1987. He is the head of the Cell and Tissue Culture Laboratory at the University of Vienna's Institute of Histology and Embryology and a senior histologist and cell biologist at SCIgenia Science Support GmbH, Ltd., a biomedical consultancy in Vienna, Austria. Dr. Mosgoeller is or has been a member of several scientific societies relating to cellular biology and regulatory affairs, especially as related to radiation and EMF, including the Austrian Standards Institute for Electromagnetic Safety Standards and an EMF committee within the Austrian Health Ministry. As a member of the Austrian Standards Institute, Dr. Mosgoeller helps craft regulations for permissible EMF exposure limits for workers and the general public.

[57] The parties and their experts seem to agree that non-ionizing radiation, such as that emitted by cell phones, cannot directly break DNA strands. They dispute whether non-ionizing radiation can lead to increased DNA breakage rates through other means such as inhibiting the repair of naturally occurring DNA breaks.

From 2002 to 2008, Dr. Mosgoeller was appointed by the Austrian Government's Workers' Compensation Board to investigate the non-thermal biological effects of weak EMFs and radiation. This research program, known as "ATHEM-1," produced numerous peer-reviewed scientific publications. Since 2011, Dr. Mosgoeller has been overseeing the "ATHEM-2" research program, which investigates genotoxic effects of exposure to RF radiation.

Defendants do not challenge Dr. Mosgoeller's qualifications,[58] and the court does not doubt his general competency. *See Haidak*, 841 A.2d at 327. Dr. Mosgoeller is qualified to testify as an expert in cell biology and histology. Because cellular biology, histology, and *in vitro* studies on cell phone radiation are relevant to the general causation issues presented in this case, Dr. Mosgoeller's expertise and opinions will probably aid the factfinder. Therefore, Dr. Mosgoeller satisfies the second requirement of *Dyas*.

iii. *General Acceptance of Methodology*

Dr. Mosgoeller relied on two methodologies to reach his opinions. First, he conducted a literature review of studies and publications. Hr'g Tr. 662:19-664:10 Dec. 9, 2013. Dr. Mosgoeller described his literature search as an extensive process in which he searched the library of the National Institutes of Health and screened "all possible papers, publications, peer-reviewed journals" to find the sources that were most relevant to answer the question at hand. Hr'g Tr. 662:19-663:8 Dec. 9, 2013. He also consulted his personal libraries. Hr'g Tr. 664:1-10 Dec. 9, 2013. Dr. Mosgoeller identified and reviewed 2,765 publications about EMF, *see* Ex. PX0890, and ultimately cited 39 publications in his expert report. Mosgoeller Rpt. 16-18.[59]

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[58] Defendants note that Dr. Mosgoeller is not an epidemiologist or geneticist, but Plaintiffs have not offered Dr. Mosgoeller as an expert in either of those fields. As noted earlier, as a medical doctor, Dr. Mosgoeller can testify as an expert on any medical matter, even if it is outside his specialty. *In re Melton*, 597 A.2d at 897.

[59] Dr. Mosgoeller's list of sources in PX0890 covers the literature on EMF generally, going well beyond cell biology and histology to include research in other disciplines, such as animal, human, and toxicology studies.

Defendants criticize Dr. Mosgoeller for "cherry picking" in his literature review. They argue that he largely ignored studies, reviews, or meta-analyses that showed no DNA damage or other negative effects and that he relied on studies that failed replication. Defendants assert that most studies have not found the types of biological effects Dr. Mosgoeller reports.[60] Additionally, defendants dispute Dr. Mosgoeller's position that finding DNA breaks in *in vitro* studies can be extrapolated to cancer promotion in humans. However, these criticisms are largely aimed at the conclusions Dr. Mosgoeller drew from his literature review, or the sources he chose to rely upon, not the categorical general acceptance of the methodology itself. A literature review is a generally accepted methodology. *Georgetown*, 75 A.3d at 292; *Wilson Sporting Goods*, 59 A.3d at 1272; *Agent Orange*, 611 F.Supp. at 1243. Because Dr. Mosgoeller used a generally accepted methodology, his testimony is admissible under *Frye*; arguments about the sources he chose to rely on and those he chose to reject raise questions for the factfinder, but they do not render his testimony inadmissible. *See Minor*, 57 A.3d at 419 n.8; *Pettus*, 37 A.3d at 218; *(Ricardo) Jones*, 27 A.3d at 1136; *Coates*, 558 A.2d at 1152; *Ibn-Tamas*, 407 A.2d at 638 n.23.

Dr. Mosgoeller's second methodology was to rely on the results of his ATHEM-1 laboratory research program, which conducted *in vitro* experiments. In his expert report, Dr. Mosgoeller describes in considerable detail the process by which his laboratory experiments were conducted. Mosgoeller Rpt. 3-9. The report describes the exposure apparatus, double-blind experimental design, exposure conditions, cell preparation, methods by which effects on proteins were analyzed, and statistical analysis of control samples. Plaintiffs argue that Dr.

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[60] Plaintiffs counter that some of these studies are funded by the telecommunications industry and that such studies have been shown to be more likely to find no effects, citing Anke Huss, *et al*, *Source of Funding and Results of Studies of Health Effects of Mobile Phone Use: Systematic Review of Experimental Studies*, 115 Envtl. Health Perspectives 1 (Jan. 2007). See note 20, *supra*.

Mosgoeller used generally accepted laboratory methodologies when conducting his experiments with ATHEM-1, citing to his testimony that his lab used the same processes as many other cell biology labs around the world. Hr'g Tr. 695:3-698:7 Dec. 9, 2013.

Defendants do not challenge any aspect of Dr. Mosgoeller's laboratory methodology as being not generally accepted on a categorical basis. Rather, defendants criticize particular studies and argue that the ATHEM-1 research does not support Dr. Mosgoeller's conclusion that RF can promote DNA breaks at the cellular level and that it increases the risk of cancer in humans.

In particular, defendants criticize three studies produced by ATHEM-1 and relied upon by Dr. Mosgoeller – the Gerner study (co-authored by Dr. Mosgoeller), the Diem study, and the Schwarz study. IARC itself cautioned that the Gerner study did not adequately confirm its results. *IARC Monograph* at 355, 357-58. With regard to the other two studies, a researcher outside the ATHEM-1 project, Dr. Alexander Lerchl, accused the Diem and Schwarz studies of scientific fraud. Those studies were published in peer-reviewed scientific journals. Investigations into the studies by the Austrian Commission for Scientific Integrity did not find any evidence of fraud, but also cautioned that the studies did not follow the rules of good scientific practice in that they did not provide the attention to detail necessary for the scientific community to understand their published data. Hr'g Tr. 1110:18-1112:5 Dec. 12, 2013. The studies were not retracted by the journals in which they were published. Dr. Mosgoeller testified that he believes Dr. Lerchl is funded by the cell phone industry and had ulterior motives for attempting to discredit ATHEM-1's work. Hr'g Tr.1186:16-1188:22 Dec. 12, 2013. It is noteworthy, however, that IARC commented that the mode of acquisition of data in the Diem

and Schwarz studies had been the subject of controversy and criticism in scientific journals and that the studies failed at least one attempt at replication. *IARC Monograph* at 313, 322.

Defendants' criticisms of Dr. Mosgoeller's reliance on ATHEM-1 do not go to the general acceptance of the methodology used by Dr. Mosgoeller or the ATHEM-1 laboratory. Rather, defendants criticize how those methodologies were employed and the conclusions Dr. Mosgoeller drew from ATHEM-1's research. The preponderance of the evidence shows that Dr. Mosgoeller and ATHEM-1 used generally accepted methodology in conducting their experiments. *See Pettus*, 37 A.3d at 217; *Porter*, 618 A.2d at 633. Whether Dr. Mosgoeller and his colleagues properly applied that methodology is not for the court to decide. *Ibn-Tamas*, 407 A.2d at 638 n.24. If Dr. Mosgoeller's lab did poor work or drew untenable conclusions, defendants can argue to the jury that his opinions are erroneous and "generally so unreliable that [they] should be ignored." *In re Melton*, 597 A.2d at 889; *(Nathaniel) Jones*, 548 A.2d at 40 (general acceptance "does not vary according to the circumstances of the case.").

Dr. Mosgoeller used generally accepted methodology both in his literature review and in his laboratory experiments. He therefore satisfies the third requirement of *Dyas*.

iv. *Probative vs. Prejudicial*

Dr. Mosgoeller's expert opinions are not "imprecise and unspecific." *Frazier*, 387 F.3d at 1266. He clearly states his views on the health risks associated with radiation emitted from cell phones. His opinions do not obviously lack scientific foundation. *See Agent Orange*, 611 F.Supp. at 1243, 1245. There is a dispute between the parties as to whether Dr. Mosgoeller's science is correct. It is not unusual to find scientists disagreeing about difficult questions of causation. Defendants' chief critique of Dr. Mosgoeller is that his opinions are out of the mainstream in the scientific community and inconsistent with the results of many studies. They

argue that he cherry picks the data he uses and ignores the fact that some of the research studies he relies on have not been replicated or have failed replication. These are legitimate issues for defendants to demonstrate by cross-examination at trial and by presentation of opposing experts. However, the probative value of Dr. Mosgoeller's testimony is not substantially outweighed by the risk of confusing or misleading the jury, and to exclude his testimony under Rule 403 on the grounds asserted by defendants would not be a proper exercise of the court's discretion.

F. ***Dr. Dimitris Panagopoulos***

i. *Field and Opinion "Beyond the Ken"*

Dr. Dimitris Panagopoulos is a biophysicist whose research focuses on non-ionizing radiation. His conducts *in vivo* experimental research with *Drosophila melanogaster*, the common fruit fly, in which he exposes fruit flies to cell phone radiation and measures any consequent health effects. Dr. Panagopoulos would testify "that it is more probable than not that cell phone radiation causes adverse health effects in humans." Panagopoulos Rpt. 7. The basis for Dr. Panagopoulos' opinion is that fruit flies are genetically similar to humans, they are generally more resistant to radiation than humans, cell phone radiation can damage DNA in fruit flies and injure their reproductive systems, and other studies have found similar effects in mammals and birds. Dr. Panagopoulos is not offering an opinion that cell phone radiation causes glioma or acoustic neuroma. Like Dr. Mosgoeller, his opinion is a building block in plaintiffs' general causation theory.

Dr. Panagopoulos' field of expertise and opinion are beyond the ken of a layperson, and therefore he satisfies the first requirement of *Dyas*.

ii. Qualifications and Aid to the Factfinder

Dr. Panagopoulos has a degree in physics and a PhD in biology from the University of Athens, focusing on biological effects of electromagnetic fields. He completed his PhD in 2001, and he has done post-doctoral research on cell death induction by non-ionizing radiation. Since 2002 he has been a researcher and lecturer in the Biology Department of the University of Athens, where he also founded the Radiation Biophysics Laboratory. Dr. Panagopoulos is a regular peer reviewer for several international scientific journals. The journal *Mutation Research* named him a "Top 10 cited Author in 2007 & 2008" for his article "Cell Death induced by GSM 900 MHz and DCS 1800 MHz Mobile Telephony Radiation." Dr. Panagopoulos has conducted and authored 22 peer-reviewed studies related to cell phone radiation and has given numerous presentations at conferences on the biological effects of EMFs. He is the founder and director of the Radiation and Environmental Biophysics Research Centre, a private research laboratory. He was invited to testify on the health effects of cell phone radiation before the Greek Parliament in 2005, and the Canadian Parliament in 2010. After testifying before the Canadian Parliament, the University of Athens took away his office and laboratory at the University. Hr'g Tr. 1423:7-1425:25 Dec. 13, 2013.[61] As of January 15, 2014, he began working at the National Centre for Scientific Research of Greece "Demokritos" (Institute of Radioisotopes, laboratory of Health Physics).

Defendants do not challenge Dr. Panagopoulos' qualifications as a biophysicist,[62] and the court does not have any reason to doubt his competency. *See Haidak*, 841 A.2d at 327. Because biophysics and *in vivo* studies of cell phone radiation are relevant to the general

[61] Dr. Panagopoulos testified that two other scientists who testified before the Canadian Parliament regarding health risks from cell phones, one French and one Swedish, suffered the same fate. *Id.*

[62] Defendants do argue that Dr. Panagopoulos is not qualified to be an expert on cancer causation because he is not a medical doctor, or a cancer specialist. But Dr. Panagopoulos is qualified in biophysics and related fields, and he is not offering an opinion on whether cell phone radiation causes glioma or acoustic neuroma.

causation determinations in this case, Dr. Panagopoulos' expertise and opinions would probably aid the factfinder. Therefore, Dr. Panagopoulos satisfies the second requirement of *Dyas*.

iii. *General Acceptance of Methodology*

Dr. Panagopoulos' opinions are derived principally from his own laboratory experiments exposing fruit flies to cell phone radiation. In these experiments, Dr. Panagopoulos (or another member of his research team) placed adult fruit flies, separated by gender, into test tubes, which contained standard fly food in the bottom and were sealed with cotton plugs to allow the flies to breathe but not escape. The researchers then positioned a commercially available cell phone against the test tube so that the antenna of the phone was touching and parallel to the tube. Dr. Panagopoulos testified that the researchers used a typical consumer cell phone for the experiments in order "to test the effects of the real thing." Hr'g Tr. 1249:17-1250:17 Dec. 12, 2013. The vials of flies were then exposed or sham-exposed to cell phone radiation.[63] Exposure consisted of a researcher reading a script into the phone during a phone call. For the sham-exposed group, the researcher read the same script, but the phone was turned off. Each exposure constituted a "dose," and the vials were dosed multiple times over the course of the experiment. After 48 hours, the male and female flies were combined into one vial to allow them to mate while exposures and sham-exposures continued for another 72 hours. The flies were then removed from the vials and the vials, containing developing embryos, were kept in a culture room for another six days without exposure to additional cell phone radiation. The researchers then counted the number of pupae in the exposed and sham-exposed samples to compare the reproductive capacity of each group. This count was blinded. The researchers also used the

[63] "Sham-exposure" is what a researcher does to the control group. To control for other variables, the sham-exposed group receives the exact same treatment as the exposed group, except for the variable being tested (in this case, cell phone radiation).

TUNEL assay and two other assays to analyze the ovaries of the exposed and sham-exposed female flies.

Based on these experiments, Dr. Panagopoulos found that exposure to radiation from cell phones caused severe DNA damage, impairing the flies' reproductive capacity.[64] Based on his knowledge of the literature and the genetic similarities between fruit flies and humans, Dr. Panagopoulos concluded that cell phone radiation more likely than not causes adverse health effects in humans. His opinion is that cell phone radiation can damage DNA in humans the same way it does in fruit flies, because the relevant cellular and genetic structures of humans and flies are similar.

Plaintiffs argue that Dr. Panagopoulos' experimental methodology was flawless and controlled for all possible confounding variables through his control of environmental factors, stress, temperature, and his use of sham-exposure. They note that all three assays used by Dr. Panagopoulos are common, generally accepted laboratory techniques for assessing various conditions. Dr. Panagopoulos developed his methodology back in 1999 and has used it to publish numerous peer-reviewed articles over 14 years. Hr'g Tr. 1260:6-12 Dec. 12, 2013. He testified that his methodology has never been publicly criticized and has been used by two other studies, Weisbrot 2003[65] and Margaritis 2013.[66] Hr'g Tr. 1260:13-21 Dec. 12, 2013.

Defendants argue that Dr. Panagopoulos' exposure methodology of holding a commercial cell phone next to a test tube is not generally accepted, and for that reason his expert testimony cannot satisfy the *Dyas/Frye* standard. Dr. Panagopoulos developed this methodology, and the

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[64] Dr. Panagopoulos has posited what he calls the "Ion Force Vibration Theory," a theory for a mechanism by which non-ionizing radiation could directly break DNA bonds. It is apparent from the record that this novel theory does not have a widespread following and is not generally accepted in the scientific community.

[65] Weisbrot D., *et al*, *Effects of mobile phone radiation on reproduction and development in Drosophila melanogaster*, J. Cell Biochem. 89(1): 48-55 (2003).

[66] Margaritis L.H., *et. al.*, *Drosophila oogenesis as a biomarker responding to EMF sources*, Electromagn. Biol. Med. Early Online, 1-25 (2013).

record shows that almost no one outside of the University of Athens uses it.[67] The British Health Protection Agency has criticized this exposure method based on its inconsistent levels of exposure and insufficient experimental control. *See HPA 2012* at 36. IARC likewise criticized Dr. Panagopoulos' experiments for having "several shortcomings related to the methods of exposure assessment and temperature control, which could have influenced the results." *IARC Monograph* at 291. The Monograph also noted that at least one of these studies used "unreliable dosimetry" by placing the vials adjacent to the phone antenna. *Id.* at 341.

Defendants point out that the Margaritis 2013 study should not count as independent acceptance of Dr. Panagopoulos' methodology, because Dr. Margaritis was a collaborator and co-author on Dr. Panagopoulos' studies. According to defendants, the only other evidence of "general acceptance" is the Weisbrot 2003 study, which IARC criticized for the same kind of methodological flaws that IARC found in Dr. Panagopoulos' work. *See IARC Monograph* at 341 ("Unreliable dosimetry: exposure by placing vials next to mobile-phone antenna"); *see also* ICNIRP 2009 at 176 (Weisbrot 2003 "difficult to interpret because of lack of RF dosimetry").

Dr. Panagopoulos' exposure methodology is a novel technique which, to the best of the court's knowledge, has not previously been scrutinized under *Frye* (or *Daubert*, for that matter). Even if his methodology produces valid results,[68] plaintiffs have failed to show by a preponderance of the evidence that his exposure methodology is generally accepted. *Pettus*, 37 A.3d at 217; *Porter*, 618 A.2d at 633. "It is not the court's role to resolve disputes within the scientific community. The very existence of a dispute precludes admission." *United States v. Jenkins*, 887 A.2d 1013, 1022 (D.C. 2005); *see also (Ricardo) Jones*, 27 A.3d at 1136;

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[67] Weisbrot 2003 is the only study in the record using this method outside of the University of Athens.

[68] Under *Frye* it is not the proper function of the court to determine whether Dr. Panagopoulos' exposure methodology produces scientifically valid results. *(John) Jones*, 990 A.2d at 981 (court need not understand underlying science to determine admissibility).

(Nathaniel) Jones, 548 A.2d at 42. A novel methodology will fail the *Frye* test if there are scientists in either number or experience who publicly oppose it. *Minor*, 57 A.3d at 420; *Porter*, 618 A.2d at 634. The record makes clear that the Panagopoulos exposure methodology of placing a cell phone next to a vial of flies has not obtained general acceptance. Few, if any, other scientists have adopted it, and it has been criticized or received negative comment from IARC, the HPA, and ICNIRP.

Dr. Panagopoulos' exposure methodology is central to his laboratory experiments and to the causation opinions for which plaintiffs have proffered him as an expert. Because he did not use a generally accepted methodology, Dr. Panagopoulos does not satisfy the third requirement of *Dyas*, and his testimony must be excluded.[69]

G. ***Dr. Abraham Liboff***

i. *Field and Opinion "Beyond the Ken"*

Dr. Abraham Liboff is a physicist and molecular biologist who has had a long and accomplished career studying electromagnetic effects on biological systems. Dr. Liboff concludes, to a reasonable degree of scientific certainty, that RF and ELF radiation from cell phones can cause non-thermal biological changes. Dr. Liboff does not offer an opinion on whether cell phones cause or promote glioma, acoustic neuroma, or any other type of tumor. Rather, his opinion is limited to biological plausibility, based on his belief that the RF and ELF radiation emitted by cell phones are "biologically interactive" and have produced various effects in cells and animals. Liboff Exp. Rpt. 3.

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[69] Because Dr. Panagopoulos cannot satisfy the *Dyas* test, the court need not determine whether the probative value of his testimony would be substantially outweighed by the risk of prejudice under Rule 403. Nor is it necessary to consider defendants' other grounds for exclusion: (1) Dr. Panagopoulos does not offer a cancer causation opinion: (2) if he does hold such an opinion, he is not qualified to offer it; and (3) in any event, it is not generally accepted to infer cancer causation in humans from DNA damage in fruit flies, even if RF radiation, under proper conditions, were capable of causing DNA damage in fruit flies, particularly where Dr. Panagopoulos fails to account for the uniformly negative whole animal studies.

Dr. Liboff's field of expertise and the opinions he offers are beyond the ken of a layperson, and he therefore satisfies the first requirement of *Dyas*.

ii. Qualifications and Aid to the Factfinder

Dr. Liboff received his PhD in physics from New York University in 1964 and first began experimenting with magnetic fields in the late 1960s. From 1965 to 1972, Dr. Liboff was a researcher and professor in the NYU Department of Physics. For thirty years, from 1972 to 2002, he was a physics professor at Oakland University in Rochester, Michigan (he is now a professor *emeritus*), where he served as the Chairman of the Physics Department and the Director of the Doctoral Program in Medical Physics. From 2004 to 2010, he was a research professor in the Center for Molecular Biology and Biotechnology at Florida Atlantic University. At various times during his academic career, Dr. Liboff conducted research for General Electric and the Sylvania Corporation, and he served as a consultant to numerous government agencies and private corporations. He was a Management Fellow at the Department of Energy and a National Research Council Fellow at the Naval Medical Research Institute. From 1998-2010, Dr. Liboff was the Editor of *Electromagnetic Biology and Medicine*, a scientific journal. Dr. Liboff is a peer reviewer for many major scientific journals including *Science*, *Nature*, *Physical Review Letters*, *Neuroscience Letters*, *Bioelectromagnetics*, among others.

Dr. Liboff has been awarded 41 patents in the area of electromagnetic therapy, including patents for devices used today to repair bones using Ion Cyclotron Resonance, a theory he developed and introduced at a NATO conference in 1984. He has published more than 100 peer-reviewed articles, book chapters, and other reviews, and has given dozens of presentations on electromagnetic interactions with biological systems. In 1994, Dr. Liboff was a member of a five-person group responsible for preparing the Bioelectromagnetic Applications to Medicine

Report for the National Institutes of Health. Dr. Liboff also participated in the drafting of IARC's 2001 statement declaring that non-ionizing electromagnetic radiation is a possible carcinogen. Dr. Liboff testified[70] that despite his retirement, he continues to keep current with the developing science in his field.

Defendants do not challenge Dr. Liboff's credentials. Dr. Liboff is well-qualified to testify as an expert on matters relating to biophysics, electromagnetics, and the biological effects of cell phone radiation. Because these subjects are relevant to the general causation determinations in this case, Dr. Liboff's expertise and opinions will probably aid the factfinder.[71] Therefore, Dr. Liboff satisfies the second requirement of *Dyas*.

iii. *General Acceptance of Methodology*

Dr. Liboff's opinions are based on his review of the scientific literature, including peer-reviewed and published empirical studies (both his own and those of others), as well as his knowledge acquired through discussions with other scientists conferences and his experience as a peer-reviewer for many journals. Ex. PX0028 (Liboff 11/20/13 *de bene esse* Dep. Tr.) at 67:1-72:1. Dr. Liboff testified that he gave more weight to the publications of researchers he felt were more trustworthy and reliable, based on his years of experience in the field. *Id.* at 85:8-86:18. While defendants argue that Dr. Liboff does not have any describable methodology, most of their opposition to Dr. Liboff is directed at his conclusions, rather than at his methodology. Drawing conclusions from a fair qualitative and quantitative review of the published scientific literature is a generally accepted methodology. *Georgetown*, 75 A.3d at 292; *Wilson Sporting Goods*, 59 A.3d at 1272; *Agent Orange*, 611 F.Supp. at 1243. Surely such a methodology does not lose

[70] Dr. Liboff, who is in his eighties, lives in Florida and does not travel. He testified *de bene esse* and his videotaped deposition was played in its entirety at the *Frye* hearing.

[71] Defendants argue that Dr. Liboff's opinion that radiation from cell phones causes "biological change" is irrelevant to the issues of this case. However, the standard for relevance is quite permissive and Dr. Liboff's opinion on biological plausibility could be helpful to the jury. *In re LC*, slip op. at 11-15.

general acceptance when you add fifty years worth of scholarly experience on top of it. Dr. Liboff used a generally accepted methodology, and his proffered testimony satisfies the third requirement of *Dyas*.

iv. *Probative vs. Prejudicial*

Dr. Liboff's testimony will be probative on the issue of biological plausibility. His expert opinions are limited to the biological effects of cell phone radiation, and he cannot testify beyond that to the more specific issues relating to cancer causation, glioma, and acoustic neuroma. Defendants will have ample opportunity to cross-examine him and offer their own evidence in opposition, including evidence that the biological effects cited by Dr. Liboff are many steps removed from cancer causation in humans. There is little risk that Dr. Liboff's testimony will mislead or confuse the jury in a way that would result in undue prejudice. Therefore, the probative value of Dr. Liboff's testimony is not substantially outweighed by the risk of undue prejudice.

H. ***Dr. Laura Plunkett***

i. *Field and Opinion "Beyond the Ken"*

Dr. Laura Plunkett is a pharmacologist and toxicologist whose work focuses on human health risk assessment. Dr. Plunkett does not offer any opinions directed to the ultimate issue in this phase of the litigation, general causation of brain tumors, but instead she validates the methodologies of other experts and the inferences that can fairly be drawn from different lines of scientific evidence. She is essentially a support witness. Dr. Plunkett offers three opinions, expressed to a reasonable degree of scientific certainty: 1) "Weight of Evidence" is a generally accepted methodology for inferring disease causation; 2) it is generally accepted to extrapolate results from fruit fly and other *in vivo* studies to predict health effects in humans; and 3) it is

generally accepted to extrapolate findings from *in vitro* studies in human and mammalian cells to predict health effects in humans.

Dr. Plunkett's field of expertise and the opinions she offers are beyond the ken of the average layperson, and she therefore satisfies the first requirement of *Dyas*.

ii. *Qualifications and Aid to the Factfinder*

Dr. Plunkett received her PhD in pharmacology from the University of Georgia in 1984. From 1984 to 1986, she was a research fellow at the National Institute of General Medical Sciences, and she worked in a neurosciences laboratory in the National Institute of Mental Health. From 1986 to 1989, she was a researcher and professor of pharmacology and toxicology at the University of Arkansas medical school. From 1989 to 1997, Dr. Plunkett worked for the ENVIRON Corporation, where she consulted on regulatory matters before the Food and Drug Administration and Environmental Protection Agency. Since 2001, Dr. Plunkett has been a consultant with Integrative Biostrategies, LLC, where she advises companies on regulatory affairs and business decisions related to pharmacology, toxicology, and health risk assessment. She has conducted original laboratory research and has served as a peer-reviewer for scientific journals.

Defendants declined to cross-examine Dr. Plunkett at the *Frye* hearing and barely mention her in their post-hearing brief.[72] The court does not have any reason to doubt her competency. *See Haidak*, 841 A.2d at 327. Dr. Plunkett is qualified to testify as an expert in pharmacology, toxicology, and methods of assessing risks to human health, and her testimony

[72] In their initial memorandum in support of their motion to exclude plaintiffs' experts, defendants only briefly criticized Dr. Plunkett, and that criticism was largely aimed at her opinion on fruit fly research.

could aid the jury to the extent it is relevant and not merely cumulative. *See In re L.C.*, slip op. at 11-15.[73]

Dr. Plunkett's first opinion that WOE is a valid methodology is irrelevant because the court has concluded that Dr. Kramer's testimony should be excluded. Dr. Plunkett's second opinion on the value of fruit fly studies in determining human health risks is also irrelevant, because the court has concluded that Dr. Panagopoulos' testimony is not admissible under *Dyas/Frye*. However, because the court is denying defendants' motion to exclude Dr. Mosgoeller, whose opinions are based in part on the results of *in vitro* experiments, Dr. Plunkett's third opinion could aid the factfinder. Accordingly, Dr. Plunkett satisfies the second requirement of *Dyas*, with respect to her third opinion. *See Benn*, 978 A.2d at 1275 (court can limit the scope of expert testimony).

iii. *General Acceptance of Methodology*

Defendants do not challenge Dr. Plunkett's methodology. To reach her opinions, Dr. Plunkett conducted a systematic literature review and her conclusions about how toxicologists assess risks to human health are based on her experience as a toxicologist and pharmacologist. Dr. Plunkett used generally accepted methodology, and her testimony satisfies the third requirement of *Dyas*.

iv. *Probative vs. Prejudicial*

Dr. Plunkett's testimony to the jury will merely corroborate the opinions of other experts. She has offered no causation opinions, and therefore she cannot testify on the ultimate issue of whether radiation from cell phones can cause or promote glioma or acoustic neuroma. To the extent that her testimony is not excluded as merely cumulative, defendants will have ample

[73] For reasons unrelated to *Dyas*, it is not clear that Dr. Plunkett will be a trial witness. To the extent that she does no more than tell the jury that another expert used a valid scientific methodology, her testimony might be excluded.

opportunity to cross-examine her and offer their own evidence in opposition. The probative value of Dr. Plunkett's testimony is not substantially outweighed by the risk of undue prejudice.

ORDER

For the foregoing reasons, it is this 8th day of August, 2014,

ORDERED that Defendants' Motion to Exclude Plaintiffs' Proffered General Causation Expert Testimony is granted in part and denied in part; and it is further

ORDERED that the proffered expert testimony of Dr. Shira Kramer on general causation is excluded; and it is further

ORDERED that the proffered expert testimony of Dr. Michael Kundi on general causation is not excluded; and it is further

ORDERED that the proffered expert testimony of Dr. Guatam Khurana on general causation is excluded; and it is further

ORDERED that the proffered expert testimony of Dr. Igor Belyaev on general causation is not excluded, except that any opinions based solely on his laboratory research using the AVTD method are excluded; and it is further

ORDERED that the proffered expert testimony of Dr. Wilhelm Mosgoeller on general sausation is not excluded; and it is further

ORDERED that the proffered expert testimony of Dr. Dimitris Panagopoulos on general causation is excluded; and it is further

ORDERED that the proffered expert testimony of Dr. Abraham Liboff on general causation is not excluded; and it is further

ORDERED that the proffered expert testimony of Dr. Laura Plunkett on the general acceptance of predicting health effects in humans from *in vitro* studies of human and mammalian cells is not excluded; but her proffered expert testimony on the general acceptance of the "weight of the evidence" methodology and on the general acceptance of predicting health effects in humans from *in vivo* studies of fruit flies is excluded.

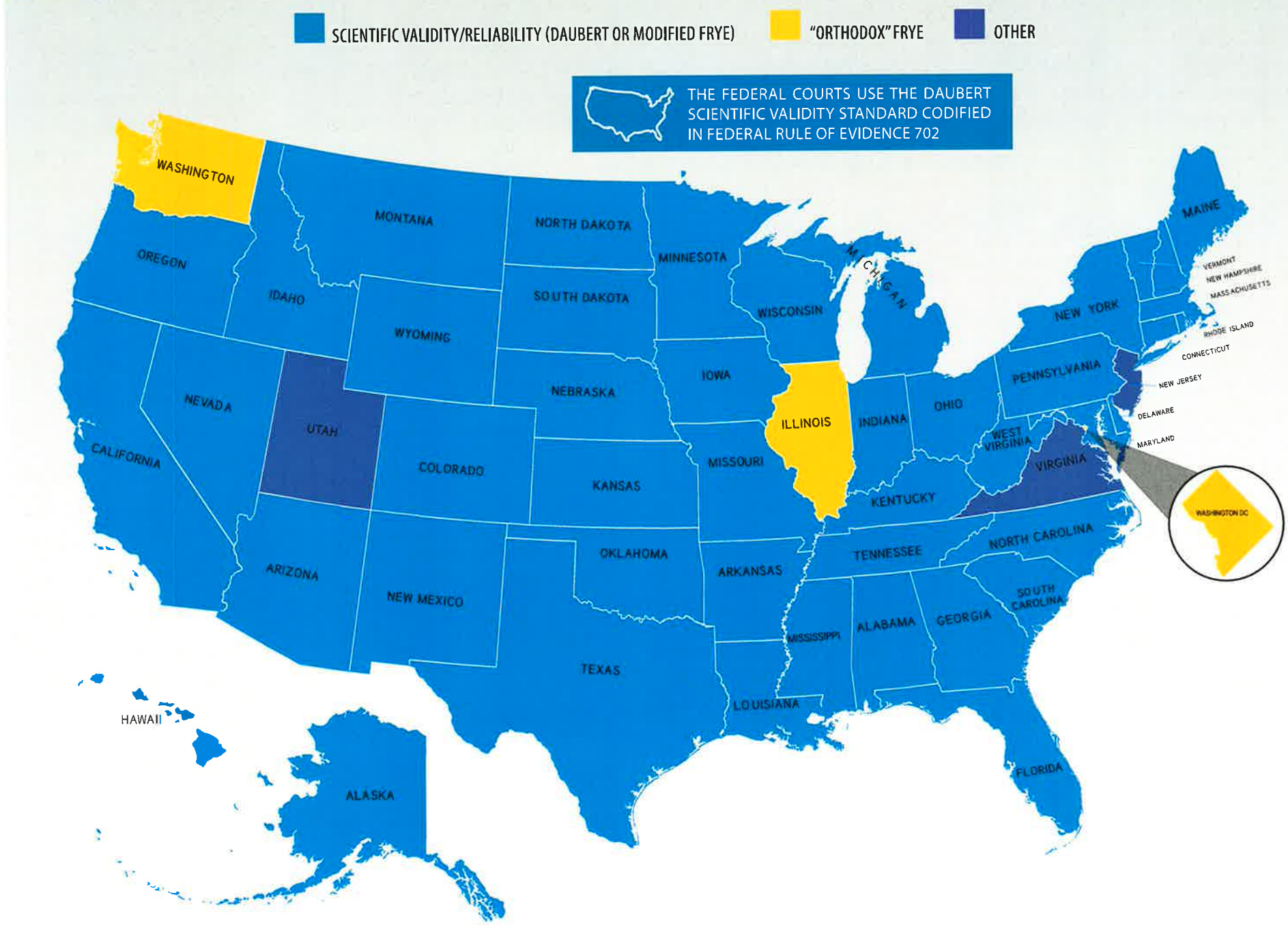
Judge Frederick H. Weisberg

Copies eServed to:

All Counsel listed in Case File Xpress

Exhibit C

EXPERT ADMISSIBILITY STANDARDS IN THE UNITED STATES



EXPERT ADMISSIBILITY STANDARDS IN THE UNITED STATES

DAUBERT/RULE 702 (40)

AL - *Thompson v. State*, __ So.2d __, 2012 WL 520873, *40 nn. 14 & 15 (Ala. Crim. App. Feb. 17, 2012)

AK - *State v. Coon*, 974 P.2d 386 (Alaska 1999)

AZ - *State v. Salazar-Mercado*, 325 P.3d 996 (Ariz. 2014)

AR - *Farm Bureau Mut. Ins. Co. of Ark., Inc., v. Foote*, 14 S.W. 3d 512 (Ark. 2000)

CO - *People v. Shreck*, 22 P.3d 68 (Colo. 2001)

CT - *State v. Porter*, 698 A.2d 739 (Conn. 1997)

DE - *M.G. Bancorporation, Inc., v. Le Beau*, 737 A.2d 513 (Del. 1999)

FL - *Zakrzewski v. State*, SC13-1825, 2014 WL 2810560 (Fla. 2014)

GA - *Mason v. Home Depot U.S.A., Inc.*, 658 S.E.2d 603 (Ga. 2008)

HI - *State v. Vliet*, 19 P.3d 42 (Haw. 2001)

ID - *Weeks v. Eastern Idaho Health Servs.*, 153 P.3d 1180 (Idaho 2007)

IN - *Turner v. State*, 953 N.E.2d 1039 (Ind. 2011)

IA - *Ranes v. Adams Labs., Inc.*, 778 N.W.2d 677 (Iowa 2010)

KS - Kansas Senate Bill 311 (effective July 1, 2014)

KY - *Goodyear Tire & Rubber Co. v. Thompson*, 11 S.W.3d 575 (Ky. 2000)

LA - *State v. Foret*, 628 So. 2d 1116 (La. 1993)

ME - *State v. MacDonald*, 718 A.2d 195 (Me. 1998)

MA - *Com v. Powell*, 877 N.E. 2d 589 (Mass. 2007)

MI - *Gilbert v. DaimlerChrysler Corp.*, 685 N.W.2d 391 (Mich. 2004)

MO - *State Bd. of Registration for Healing Arts v. McDonagh*, 123 S.W.3d 146 (Mo. 2003); *Goddard v. State*, 144 S.W.3d 898 (Mo. Ct. App. 2004)

MT - *State v. Price*, 171 P.3d 293 (Mont. 2007)

NE - *Schafersman v. Agland Coop.*, 631 N.W.2d 862 (Neb. 2001)

NV - *Hallmark v Eldridge*, 189 P.3d 646 (Nev. 2008)

NH - *Baker Valley Lumber, Inc. v. Ingersoll-Rand Co.*, 813 A.2d 409 (N.H. 2002)

NM - *State v. Alberico*, 861 P.2d 192 (N.M. 1993)

NC - *State v. Ward*, 694 S.E.2d 738 (N.C. 2010); see also *State v. McGrady*, 753 S.E.2d 361 (N.C. Ct. App. 2014)

ND - *State v. Hernandez*, 707 N.W.2d 449 (ND 2005)

OH - *Terry v. Caputo*, 875 N.E.2d 72 (Ohio 2007)

OK - *Christian v. Gray*, 65 P.3d 591 (Okla. 2003)

OR - *State v. O'Key*, 899 P.2d 663 (Or. 1995)

RI - *In re Mackenzie C.*, 877 A.2d 674 (R.I. 2005)

SC - *State v. Jones*, 681 S.E.2d 580 (S.C. 2009)

SD - *State v. Guthrie*, 627 N.W.2d 401 (South Dakota 2001)

TN - *McDaniel v. CSX Transp., Inc.*, 955 S.W.2d 257 (Tenn. 1997)

TX - *E.I. du Pont de Nemours & Co. v. Robinson*, 923 S.W.2d 549, (Tex. 1995)

VT - *985 Assocs., Ltd. v. Daewoo Elecs. Am., Inc.*, 945 A.2d 381 (Vt.2008)

WV - *San Francisco v. Wendy's Int'l, Inc.*, 656 S.E.2d 485 (W. Va. 2007)

WI - *State v. Kandutsch*, 2011 WI 78, 799 N.W.2d 865 (Wis. 2011)

WY - *Bunting v. Jamison*, 984 P.2d 467 (Wyo. 1999)

FRYE-MODIFIED (5)

CA - *Sargon Enters., Inc. v University of S. Cal.*, 288 P.3d 1237, 1252 (Ca. 2012) ("a court may inquire into, not only the type of material on which an expert relies, but also whether that material actually supports the expert's reasoning")

MD - *Blackwell v. Wyeth*, 971 A.2d 235, 255 (Md. 2009) ("Generally accepted methodology must be coupled with generally accepted analysis.")

MN - *Goeb v. Tharaldson*, 615 N.W.2d 800, 816 (Minn. 2000) ("The proponent of scientific evidence has the burden to establish the proper foundation for the admissibility of the test by showing that the methodology used is reliable and in the particular instance produced reliable results.")

NY - *Parker v. Mobil Oil Corp.*, 857 N.E.2d 1114, 1120 (N.Y. 2006) (scrutinizing both "the general reliability concerns of Frye" and "the specific reliability of the procedures followed to generate the evidence proffered and whether they establish a foundation for the reception of the evidence at trial")

PA - *Betz v. Pneumo Abex, LLC*, 44 A.3d 27, 53 (Pa. 2012) ("[A] Frye hearing is warranted when a trial judge has articulable grounds to believe that an expert witness has not applied accepted scientific methodology in a conventional fashion in reaching his or her conclusions.")

"ORTHODOX" FRYE (3)

DC - *United States v. Jenkins*, 887 A.2d 1013 (D.C. 2005)

IL - *Donaldson v. Cent. Illinois Pub. Serv. Co.*, 767 N.E.2d 314 (Ill. 2002)

WA - *Anderson v. Akzo Nobel Coatings, Inc.*, 260 P.3d 857 (Wash. 2011)

OTHER (3)

NJ - *Kemp ex rel. Wright v. State*, 809 A.2d 77 (N.J. 2002)

UT - *State v. Crosby*, 927 P.2d 638 (Utah 1996)

VA - *John v. Im*, 559 S.E.2d 694 (Va. 2002)

Exhibit D

HISTORICAL PERSPECTIVE

Bendectin: How a Safe and Effective Drug was Removed from the Market by Our Legal System

Ralph W. Hale, MD, and Jennifer Niebyl, MD

Approximately 50% of women have nausea and vomiting in early pregnancy, and an additional 25% have nausea alone (1, 2). In approximately 35% of women, nausea and vomiting are clinically significant, negatively affecting work time and family relationships. In approximately 1% of pregnant women, hyperemesis gravidarum occurs with dehydration, weight loss, and ketonuria. However, the period of organogenesis is from 4 weeks to 10 weeks from the last menstrual period, so a safe pharmacologic intervention is essential to treat this condition.

Multiple dietary and pharmacologic treatment regimens have been recommended over the years. In 1957, one pharmacologic treatment was thalidomide. Although it was never approved or licensed by the U.S. Food and Drug Administration (FDA) for use in the United States, clinical trials and access to the drug in other countries resulted in thousands of women in the United States using the medication. As a result, major anomalies appeared in the offspring of women who used the drug. The most common was phocomelia, extensive limb reductions. In 1961, the application to the FDA for approval of the drug was withdrawn, but the teratogenicity of thalidomide had a major influence on development or use of any medication during early pregnancy. In fact, it is always in the background when the story of Bendectin is discussed.

Bendectin was introduced in 1956 by the Wm. S. Merrell Co. of Cincinnati, Ohio. The main therapeutic indication was to treat nausea and vomiting in pregnancy. Its original formulation included doxylamine succinate (an antihistamine), pyridoxine (vitamin B_6), and dicyclomine. One of the first double-blinded placebo controlled studies was published in *Obstetrics and Gynecology* in 1959 (3). They reported a 90% success rate. This was followed by other studies, and the medication became a standard treatment for women with nausea or vomiting or both during pregnancy. In the 1970s, the National Academy of Sciences listed Bendectin as possibly effective, which then resulted in new and more detailed research. The outcome of these studies was that dicyclomine did not contribute to the efficacy of the medication and it was removed from the formulation of Bendectin in 1976 (4). This formulation of the medication was available until 1983. During the 1970s, it was estimated that 30–35% or more of women who were pregnant were taking Bendectin.

In the 1970s, a number of lawsuits were filed against the company alleging that Bendectin, like thalidomide, was responsible for congenital defects. However, unlike thalidomide, the claims against Bendectin were for multiple defects. It was impossible to assign any particular time of development to the etiology of the defects, which varied from cardiac, limb, and gastrointestinal defects and defects in virtually any other organ. Even though there was no scientific evidence to support any of these claims, a number of lawyers were actively seeking any types of cases for litigation. One of the first cases that received wide publicity was the Mekdeci case that alleged that Bendectin treatment resulted in Poland syndrome (unilateral limb reduction due to vascular disruption). In that case, the jury found that there was no evidence that Bendectin caused the defect, but they awarded $20,000 to the family because they felt the family needed something (4). Unfortunately, the award became publicized, but not the reasons for the award.

This verdict was later reversed in a subsequent trial for the defense. Of note, there were no epidemiologic data in the 1980s supporting the allegations that Bendectin could cause Poland syndrome (5), and it was not biologically plausible because drug exposure would cause bilateral limb reductions, not unilateral.

The next and possibly most important lawsuit was a class action suit filed with more than 1,000 plaintiffs in Ohio. The judge negotiated before the trial a $170 million settlement, but the plaintiffs rejected the offer. A significant aspect of this class action was the multitude of anomalies that were identified as being caused by Bendectin. The case went to trial and a verdict for the defense resulted. In spite of the lack of scientific evidence, a number of other cases followed. In actuality, the frequency of limb reductions, congenital heart disease, and other anomalies was the same when compared with the time span after Bendectin ceased to be available, but that would only be shown in subsequent years (4).

Despite the lack of scientific evidence, lawsuits continued to be filed. In 1983, the company, now called Merrell Dow Pharmaceuticals, elected to stop production of Bendectin. At that time, there were 300 pending claims and one case in Washington, DC, that was decided 2 weeks before the withdrawal and resulted in a $750,000 jury decision for the plaintiff. The company stated in their announcement that they were forced to stop production not because Bendectin was hazardous, but because their insurance premiums had soared to $10 million per year and that was only $3 million less than the income from sales (5).

Subsequently, several controlled trials confirmed that Bendectin is safe and effective for use in patients with nausea and vomiting in pregnancy (4, 6, 7). The Canadian equivalent of the FDA reviewed an identical medication in Canada (Diclectin) in 1995 and after receiving hundreds of research reports found no problems with safety or increase in anomalies. Therefore, the drug has continued to be available in Canada without any reports of it causing fetal anomalies in continuing reviews (4). The Atlanta Birth Defects Case Control study of 1982–1983 reviewed the incidence of congenital heart defects and found a reduced risk in women who used Bendectin for nausea and vomiting in pregnancy. They further quoted a 1994 meta-analysis that agreed with their findings and also reported a reduced risk of oral clefts (8). In 1999, the FDA confirmed this finding in a report released in the *Federal Register* (9).

In 2004, the American College of Obstetricians and Gynecologists published Practice Bulletin Number 52, *Nausea and Vomiting of Pregnancy*. When comparing hospital admissions for nausea and vomiting in pregnancy, before and after Bendectin was available, there were fewer hospital admissions when Bendectin was available than after it was no longer available. Further, it was reported that in more than 170,000 exposures, the combination of doxylamine and pyridoxine was safe (10).

What have obstetrician–gynecologists learned from the history of Bendectin? First, that in spite of numerous negative studies and three meta-analyses indicating its apparent safety, the legal profession was able to indict and remove a safe, effective medication from the market by filing unsubstantiated claims (11). The result has been increased hospitalization for nausea and vomiting in pregnancy. Second, in spite of studies showing no linkage between a medication and a birth defect, courts can, and do, rule otherwise. Attorneys can create hypotheses that contradict available scientific evidence and some scientists are willing to use junk science as justification for supporting legal claims that have no validity (4, 12). Sympathy awards can be given in cases because the child needs medical care and may not have sufficient health insurance, and the physician and drug company are perceived as being wealthy.

The history of Bendectin has shown that safe and effective medications can be adversely affected without good evidence when an abnormal outcome occurs,

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and legal actions can force the withdrawal of these drugs. Bendectin was truly a litigen, a drug that caused lawsuits, although there is much evidence that it was not a teratogen.

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