UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

MARY PISKURA, *et al,*	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 1:10-cv-00248
	)	**ORAL ARGUMENT REQUESTED**
TASER INTERNATIONAL, INC., *et al,*	)	
	)	
Defendants.	)	

DEFENDANT TASER INTERNATIONAL, INC.'S BRIEF SUPPORTING EXCLUSION OF TENDERED EXPERT DR. DOUGLAS P. ZIPES

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[1] Pursuant to local rule, these summaries have been combined within the table of contents. A table of authorities follows, with the benefit of an executive introduction.

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EXECUTIVE INTRODUCTION

"[T]he courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1247 (11th Cir. 2005). The proposed expert testimony of Dr. Douglas P. Zipes ("Zipes") related to the TASER®[2] X26™ electronic control device ("ECD") should be excluded under Fed.R.Evid. 702 and *Daubert v. Merrill Dow Pharms., Inc.*, 509 U.S. 579 (1993), on several independent grounds.

At best, Zipes' theory that an ECD caused ventricular fibrillation ("VF") in Mr. Kevin Piskura ("Piskura") on April 19, 2008, who was agitated and otherwise had lethal levels of alcohol in his system, is mere guesswork. Not until May 15, 2009 did Zipes participate in a debate at the Heart Rhythm Society ("HRS") Annual Conference and *propose* "the recognition that [ECDs] can—on occasion—produce ventricular fibrillation and cardiac arrest," and that exactly how often ECDs can cause "fatal ventricular arrhythmias" was "not clear and may never be known with accuracy" [Ex4].[3] Shortly thereafter, Zipes testified that the he had not calculated the probability of an ECD causing VF in a human, that the frequency was unknown, that he did not "know how low" the probability was, and that "you can't get accurate probabilities" [Ex2pp43:24-44:7,47:12-16,137:4-8].

Nearly four years later, Zipes has done no studies or testing of his own to support his hypothesis from May 15, 2009. This year, in this case, at a rate of $1200 per hour, Zipes testified that, as of January 3, 2012, the likelihood of negative cardiac consequences from an X26 ECD at the human chest cannot be accurately determined and "is not calculable" [Ex1p114:3-12]. Despite study after study demonstrating the cardiac safety of ECDs on humans—and those human studies have been extensive—Zipes has not put science to theory to confer any reliability on his "incalculable" and untested theory. He has just relied on his "say-so" over the last three years. That incalculable

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[2] X26 is a trademark of TASER International, Inc., and TASER® is a registered trademark of TASER International, Inc., registered in the United States.

[3] TASER has compiled all exhibits in one global appendix to which these citations refer.

say-so is exactly the type of opinion that the Sixth Circuit has warned against. *See Hirsch v. CSX Transp., Inc.*, 656 F.3d 359, 362-64 (6th Cir. 2011) (finding one-in-a-million theory to be "legally insignificant").

Zipes does not dispute that his theory stands against *all* epidemiological data and prospective human studies. This year, in this case, Zipes testified that, as of April 19, 2008, the date of the Piskura incident, and also as of January 3, 2012, in the absence of one unusual anecdote (Cao) of an implanted cardiac pacemaker with electrical leads surgically implanted directly into the heart, no peer-reviewed literature has ever found that an ECD causes cardiac capture, cardiac arrest, ventricular tachycardia ("VT"), VF, or lethal cardiac consequences in humans [Ex1pp108:19-109:22,112:16-25]. And, in the one (Cao) pacemaker anecdote, the subject was not injured and did not experience VF. Just as the pacemaker authors said, Zipes cannot state that the subject would have experienced any cardiac effects without the presence of the implanted pacemaker [Ex5p22]. His admissions are repeated time and time again [Ex3pp102:19-103:3,105:19-24; Ex5pp21:13-22:24,151:1-13; Ex1pp182:25-183:6; Ex6pp652:12-19,652:24-653:3,655:4-6].

For this specific case, the analytical gaps in his methodology reveal it to be nothing less than unreliable and unhelpful under *Daubert*:

- Zipes admits he cannot opine that an electrical circuit capable of delivering an electrical charge to Mr. Kevin Piskura ("Piskura") was ever completed—a necessary premise to his theory.
- Zipes admits that his theory overlooks undisputed forensic evidence specific to this case—including the TASER Cam™ video—which cannot be disputed as a matter of law. *See Scott v. Harris*, 550 U.S. 372, 379 n.5, 380 (2007).
- Zipes admits that his theory ignores forensic evidence in the form of undisputed metallurgic analysis of the ECD probes and cartridge wires that demonstrate that no electrical circuit was completed between the ECD and Piskura.
- Zipes admits that his theory ignores undisputed forensic evidence gathered in the course of the medical examiner's autopsy that showed only probe mark, not the two needed to confirm an electrical circuit.

- Zipes admits that his theory ignores undisputed signal analysis of the ECD function demonstrating that there was an open circuit, not a closed circuit.
- Zipes admits that his theory ignores undisputed forensic optical microscopy and scanning electron microscopy analysis of the ECD function establishing (with probe analysis) that no energy ever traversed the ECD to reach Piskura.
- Zipes admits his theory must ignore eyewitness statements that demonstrate open arcing of the ECD, and no completed circuit to Piskura.
- Zipes admits that his theory must ignore undisputed testimony that Oxford Police Department ("OPD") Detective (and EMT) John Jones found a radial pulse in Piskura.
- His method fails to rule out the alternative and obvious cause that Piskura's severe intoxication caused his death, though the automated external defibrillator ("AED") applied to Piskura showed a shockable rhythm consistent with alcohol-induced VF.
- His theory ignores that all peer-reviewed human studies and epidemiology has never found that an ECD causes VF in humans.

This is no other case; these case-specific analytical gaps render his opinion here unreliable. *See, e.g., Smelser v. Norfolk S. Ry. Co.*, 105 F.3d 299, 303 (6th Cir. 1997) (holding that district court erred in admitting causation theory when expert had not examined or explained conflicting evidence).

To make matters worse, Zipes is no expert on the effects of ECDs on humans. He has *never* published on ECD effects. He has *never* completed any research studies on ECD effects on humans. He has *never* tested ECD effects on humans. He has *never* treated a person following an ECD exposure. Zipes concedes, as he must, that his made-for-litigation opinions have *never* been scientifically validated. His opinion amounts to mere *ipse dixit* (his bare say-so), whereas the actual scientific work on ECDs, which has shown the human safety of ECDs, has the benefit of scientific rigor and peer review.

Zipes' speculative opinion should be excluded—the same as other unreliable ECD opinions. *See Neal-Lomax v. LVMPD,* 574 F. Supp.2d 1193, 1199-1207 (D. Nev. 2008) (Pro, J.), *aff'd*, 371 Fed. Appx. 752 (9th Cir. 2010) (excluding unreliable experts and finding no evidence of causation); *Walker v. LVMPD*, No. 2:07-CV-0740, trans. at 23-29 (D. Nev. 2009) (Dkt. 129) (Pro, J.) (excluding

electrophysiologist because, like Zipes, lacking support in science, lacking validation in peer-reviewed literature, and citing unreliable pig studies) [Ex32]; *see also Oliver v. TASER*, 2011 U.S. Dist. Lexis 58127, 28 (M.D. Fla. 2011), *aff'd* 2012 U.S. App. Lexis 1712 (11th Cir. 2012) (excluding expert and concluding that "record does not support a finding that the [ECD] was capable of causing [the] death"); *Gilliam v. City of Prattville*, 667 F. Supp.2d 1276, 1296-99 (M.D. Ala. 2009) (excluding opinion that ECD caused cardiac arrest because physician used insufficient data and lacked scholarly support, peer review, or other validation); *TASER Int'l, Inc. v. Kohler*, 2009 Ohio 1519, ¶¶1-66 (Ohio Ct. App. 2009) (affirming exclusion of unreliable testimony that ECD contributed to three deaths, and affirming order requiring medical examiner to amend each cause of death accordingly); *Glowczenski v. TASER*, 2012 WL 976050, 8 (E.D.N.Y. 2012) (finding expert unqualified and unreliable on the specific subject of ECDs).

Zipes is a recognized expert on cardiac rhythms and has an impressive publication record of books and articles. He is also a recognized skilled expert witness with extensive experience that admitted that he has never turned down a case from the Plaintiffs' counsel in this case. Zipes simply knows nothing about the science of ECDs.

STANDARD

Expert testimony cannot be admitted merely on the expert's say-so. *See Kumho Tire v. Carmichael*, 526 U.S. 137, 157 (1998); *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). *Daubert* and later *Kumho Tire* established the district court as the "gatekeeper," entrusted with the duty to determine the reliability and relevance of expert testimony. The importance of the district court's gatekeeping role is "to make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152; *accord Gross v. Comm'r Internal Rev.*, 272 F.3d 333, 339 (6th Cir. 2001).

To withstand scrutiny under Rule 702, expert testimony must be both reliable and helpful. *Daubert*, 509 U.S. at 589, 591 (expert testimony that "does not relate to any issue in the case is not relevant, and . . . non-helpful"). Indeed, "the Sixth Circuit has long required judges to give a 'hard look' and carefully assess the scientific conclusions and reasoning of experts because jurors are frequently overly impressed by conclusory opinions of scientific experts paid by a party." *Downs v. Perstorp Components, Inc.*, 126 F. Supp.2d 1090, 1118 (E.D. Tenn. 1999); *accord Turpin v. Merrell Dow Pharms, Inc.*, 959 F.2d 1349, 1352 (6th Cir. 1992) (same).

Rule 702 requires that expert testimony satisfy four requirements to be admissible: (1) the witness must be "qualified as an expert by knowledge, skill, expertise, training, or education;" (2) the testimony must be "based upon sufficient facts or data;" (3) the testimony must be "the product of reliable principles and methods;" and (4) the witness must "appl[y] the principles and methods reliably to the facts of the case." Fed.R.Evid. 702. Expert testimony that fails to meet all of these criteria should be excluded. "[C]lose judicial analysis of expert testimony is necessary because expert witnesses are not necessarily always unbiased scientists." *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 252 (6th Cir. 2001) (quotations omitted). It is the burden of the party offering the expert testimony to establish admissibility, rather than the opponent's burden to establish inadmissibility.

See Nelson v. Tennessee Gas Pipeline Co., 243 F.3d 244, 251 (6th Cir. 2001). Plaintiffs cannot meet that burden here.

MEMORANDUM OF POINTS & AUTHORITIES

A. Zipes is not an expert on the human effects of ECDs.

"A witness is not an expert simply because he claims to be." *See Pride v. BIC Corp.*, 218 F.3d 566, 577 (6th Cir. 2000). A court is to examine "not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question." *Smelser v. Norfolk S. Ry. Co.*, 105 F.3d 299, 303 (6th Cir. 1997). Knowledge "connotes more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590; *see also Flores v. Johnson*, 210 F.3d 456, 464 (5th Cir. 2000) ("In the federal courts, one does not become qualified to provide 'expert scientific' evidence merely by virtue of possessing a medical or other advanced degree.").

Zipes is an electrophysiologist, but his experience has led him in directions other than ECDs such as cardiac drug therapy and *internal* stimulation with pacemakers and implantable cardioverters. In addition to admitting that he has no expertise in finite element modeling, Zipes concedes he is *not* an expert on *external* electrical stimulation of the human body:

> Q. Are you an expert in flow of electrical current through the human body by electrical stimulation externally such as by a TASER electronic control device?
>
> A. No.

[Ex3p114:15-19]. His honest response does not meet the *Smelser* standard of having the foundation to answer specific questions concerning ECDs.

Experts are made in the field, not in the courtroom. The Sixth Circuit has warned trial courts to remain "suspicious" of opinions "created for the purpose of litigation" and relied on that factor to exclude made-for-litigation theories. *Mike's Train House, Inc. v. Lionel, LLC*, 472 F.3d 398, 408 (6th Cir. 2006). The Sixth Circuit has called this a "very significant fact to be considered." *Id.* Zipes has

not published on ECDs, including any alleged human effects [Ex9p32]. He has never completed studies on ECDs [Ex9pp19,213]. None of his publications include the word "TASER" or "ECD" [Ex3pp217,226]. He has never treated a person following an ECD exposure [Ex3p87]. He has never done any research, testing, studies, or anything scientific vis-à-vis ECDs.

Before his first retention as a paid expert in a case against TASER in 2007, he had *no* experience with ECDs [Ex10pp29-31]. The first ECD-related writing Zipes ever did was as a paid expert in his first litigated matter against TASER [Ex10p75]. He did that at $1200 per hour for an approximate fee of $60,000. [Ex10pp43,49-50], and though he essentially has done nothing different by way of testing, studies, research, or anything scientific, he has continued to charge that handsome rate to earn hundreds of thousands of dollars in offering his opinion in cases against TASER [Ex2pp94-95,265; Ex9pp211-13; Ex3pp39-41; Ex10pp48-50]. There are many specialists who have done human ECD studies. Zipes is not one of them. He is not a scientist who has tested or formed his theories; it is just on-the-clock litigation. He should be excluded under *Smelser* and *Mike's Train*.

B. Zipes' theory lacks a sufficient factual basis and requires glaring speculative leaps that reveal his methodology to be unreliable.

For an expert's opinion to have a reliable foundation and to avoid analytical gaps, all expert testimony must be based on sufficient and known facts. *See* Fed.R.Evid. 702; *Daubert*, 509 U.S. at 590. But Zipes admits his theory is based on "insufficient data," with postulated "variables" all being "guesstimates," rather than being based on "absolute data" [Ex3pp145-46]. In this case, unlike any other, his analytical gaps are glaring.

1. Zipes admits he cannot opine that an electrical circuit capable of delivering an electrical charge to Piskura was ever completed—a necessary premise to this theory.

Based on undisputed facts about the probe-mode function of an ECD, without an intact electrical circuit, there could have been no electrical charge delivered to Piskura [*see* TASER's MSJ 4/12/12]. Zipes agrees there must have been a completed circuit to support his theory

[Ex1pp64,174]. Still, he concedes he is *not* an expert in this area [*Id.* 76]. He does not even know how close a probe would need to be (to the skin) to complete a circuit on a human (by arcing thru the air), or how many seconds of discharge is necessary to cause VF [*Id.* 47-48,64]. Instead, he invites a theoretical leap to his ultimate conclusion (based only on his say-so) contrary to *Kumho Tire*, 526 U.S. at 157.

Moreover, though the law governing experts requires a different standard, Zipes admits he cannot say to a reasonable degree of certainty that a second probe connected with Piskura, much less say to a reasonable degree of certainty that any probe penetrated Piskura's outer skin [Ex1pp168-69]. *See Novak v. United States*, 865 F.2d 718, 724 (6th Cir. 1989) ("because it involves a medical condition or illness, the plaintiff must show by a reasonable degree of medical certainty that the disease was caused by the . . . defective product"); *Provident Life & Accident Ins. Co. v. McCoy*, 2006 U.S. Dist. Lexis 100402, 32 (S.D. Ohio 2006) ("Under Ohio law, an expert is competent to testify only if the expert's opinion is held to a reasonable degree of scientific certainty."). By this law, and by his own admissions, Zipes cannot offer his unreliable opinion in this case.

2. Zipes admits that his theory overlooks undisputed forensic evidence specific to this case—including the TASER Cam™ video.

Forensic analysis of the TASER Cam video (including multiple still frames) of the incident show that there were no ECD probes in Piskura (whether in his chest or across his heart) to complete a circuit [Ex37; Ex46; Ex47pp2-3]. Assumptions cannot be made in the face of contradictory evidence. *See Smelser*, 105 F.3d at 305 (holding that district court erred in admitting causation theory when expert had not examined conflicting evidence). Unlike any other forensic evidence, the videotape cannot be disputed as a matter of law. *See Scott v. Harris*, 550 U.S. 372, 379 n.5, 380 (2007) (court "should not have relied on such visible fiction; it should have viewed the facts in the light depicted by the videotape"); *Hayden v. Green*, 640 F.3d 150, 152 (6th Cir. 2011) ("we reject

[] allegations to the extent they are clearly contradicted by a videotape capturing the events in question").

The Piskura TASER Cam video has undergone forensic analysis [Ex47]. The undisputed video and forensic video analysis establish that there were *not* two ECD probes striking Piskura, so there was *not* an intact electrical circuit [Ex37; Ex46; Ex47pp1-17]. Zipes "would not comment as to whether or not the probes are or are not visible in any of the TASER Cam video or still frames" in addressing this analytical gap with his theory [Ex1p67]. He concedes, however, that he cannot say that Piskura was neuro-muscularly incapacitated by the ECD (to any reasonable degree of certainty) that would demonstrate a completed electrical circuit [Ex1pp74-75]. His opinion cannot stand in the face of undisputed contradictory evidence. *See Hayden*, 640 F.3d at 152; *Smelser*, 105 F.3d at 305.

3. Zipes admits that his theory ignores forensic evidence in the form of undisputed forensic metallurgic analysis of the ECD probes and cartridge wires.

Undisputed forensic metallurgic analysis of the probes and ECD cartridge wires has demonstrated that the ECD wires were broken and could not deliver an electrical charge to Piskura [Ex7pp12-37]. Zipes concedes that his theory must ignore this finding [Ex1p172]. Again, his opinion cannot stand with the unreliable methodology of rejecting undisputed evidence. *See Hayden*, 640 F.3d at 152; *Smelser*, 105 F.3d at 305.

4. Zipes admits that his theory ignores undisputed forensic evidence gathered in the course of the medical examiner's autopsy.

Dr. Obinna R. Ugwu ("Dr. Ugwu"), the medical examiner, found only one mark on Piskura consistent with an ECD probe [Ex8pp62,63]. He looked extensively for a second probe mark, but found none [*Id.* 130]. That scientifically precludes any theory that the ECD formed an electrical circuit or discharged in Piskura. From the autopsy photographs, Zipes agrees that only one probe mark could be found on Piskura, consistent with the medical examiner's finding [Ex1pp169-70]. One probe applied to Piskura could not have completed an electrical circuit [Dkt69-10,pp11-19],

and again Zipes cannot offer an opinion soundly undermined by undisputed forensic evidence in this case. *See Smelser*, 105 F.3d at 305.

5. Zipes admits that his theory ignores undisputed forensic acoustical signal analysis of the ECD sound.

Undisputed forensic high-resolution acoustic signal analysis of the ECD sound has shown that there was an *open* circuit, not a completed circuit [Dkt69-10; *see also* TASER's MSJ 4/12/12]. An ECD remains significantly quieter when it completes a circuit (51 decibels at 1 meter) than when it misses its target (79 decibels at 1 meter) [Dkt69-10,pp16-17]. The scientific difference in sound emitted from an electrical arc has been well-studied to distinguish when an ECD has completed a circuit from when it has not [Dkt69-10,pp16-19]. Zipes admits that he has no evidence to dispute this opinion that there was no circuit made [Ex1pp75-76], and instead admits that the "sound [was] loud" and that the qualitative difference in sound represents an open versus completed circuit [Ex1pp20,75]. Once again, Zipes' continuing factual gaps are so glaring as to render his methodology unreliable.

6. Zipes admits that his theory ignores forensic microscopic probe wire analysis.

Undisputed forensic optical microscopy and scanning electron microscopy has shown that none of the 12 wire ends from the ECD cartridge exhibited evidence of arcing [Ex7pp12-16]. Coupled with probe analysis, this establishes that the wires were not part of an intact electrical circuit capable of delivering ECD discharge to Piskura [Ex7pp12-37]. Arcing activity would have resulted in visible changes to the wire tip and surface of the metal probe exposed to the arcing [*Id.*]. The absence of such arcing marks on the two metal probes indicates that no electrical circuit was ever established between the metal probes, and that the energy released by the ECD therefore never reached Piskura [Ex7pp12-37]. Zipes unreliably ignores this undisputed forensic evidence.

7. Zipes admits that his theory must ignore undisputed testimony that OPD Detective (and EMT) John Jones reported a radial pulse in Piskura.

When Detective Jones arrived on scene, OPD Officer Geoffrey Robinson ("Officer Robinson") still had not seen signs in Piskura of any medical distress or indications there was any medical emergency [Ex41p227]. Detective Jones measured Piskura's breathing and also detected a radial pulse [Ex44pp64,68]. Zipes admits that, to reach his opinion, he must reject Detective Jones' undisputed testimony reporting a radial pulse in Piskura [Ex1p170]. Electrically-induced VF would have caused Piskura to lose pulse and respirations immediately (within 5-15 seconds) [Dkt69-3,p13]. Zipes' opinion should be excluded without this proper factual basis. *See Smelser*, 105 F.3d at 305.

8. Zipes' theory must ignore eyewitness statements that are consistent with, open arcing of the ECD, and no completed circuit to Piskura.

Zipes' theory also ignores the statements by Mr. Casey Burns and Officer Robinson that show that no electrical circuit was completed between the ECD and Piskura and show just arcing across the front electrodes of the ECD. When Officer Robinson attempted to deploy the ECD toward Piskura he heard a "very, very loud crackling, continuous popping, crackling noise, much like the same noise you would hear when you spark test or do a spark test of the TASER [ECD]" [Ex41p209]. (A witness (Casey Burns) also "heard a crackling, like a sizzle and a crackle kind of noise" and saw blue arcing light for "at least 10 seconds" [Ex42pp46,143]. This is not consistent with the formation of an electrical circuit between Officer Robinson's ECD and Piskura.

9. Zipes' theory must ignore the alternative and obvious cause of alcohol toxicity based on the AED's detection of an alcohol-induceable "shockable" cardiac rhythm.

Alcohol can cause a shockable cardiac rhythm as interpreted by an AED [Ex36pp36:25-37:10]. As Zipes testified, high levels of alcohol can cause supraventricular or ventricular tachyarrhythmias that are detected as shockable by an AED. [Ex. 1p95:9-12]. As Nelson testified, alcohol can cause atrial fibrillation, AV block, and ventricular fibrillation that are detected as

shockable by an AED [Ex36p37:1-10]. Thus, the AED applied to Piskura showed a shockable cardiac rhythm inducible from alcohol toxicity—as confirmed by Zipes (and Plaintiffs' pharmacologist) [Ex36pp36:6-37:10;Ex1pp95pp158-59]. Zipes' theory must analytically and inappropriately leap over this fact.

10. Zipes admits that his theory ignores undisputed physical evidence.

Zipes claims that the ECD caused VF in Piskura. This cardiac rhythm is unlike any other. VF is when "the heart can no longer maintain a normal organized electrical event" and "disorganization occurs" [Ex9pp9-10]. VF is a chaotic heartbeat or when the heart fibrillates, it flutters, ranging from 400 to 600 beats a minute, with a heart monitor showing a "bunch of irregular up and down lines" [Ex1p175; Ex52p22]. Based on animal studies alone, and these are not supported at all by human studies, *see infra*, Zipes has theorized that ECD probes must be within 23 millimeters ("mm") (less than an inch) or even "less" to cause "cardiac capture" in a pig [Ex1pp203-04]. But this is just "cardiac capture" (or pacing), not VF. Zipes admits that causing VF is different from causing cardiac capture [Ex9p21:17 ("producing VF is a different thing")]. Since pigs fibrillate more easily than humans, *see infra*, Zipes does not actually know how close a probe would need to be to cause VF in a human, or how many seconds of ECD discharge would be necessary [Ex1pp47-48,64].

Even assuming the speculative leap from pigs to humans, even assuming the speculative leap from cardiac capture to VF, in this specific case Zipes admits that even the one probe mark he identified from the autopsy photographs was not within the 23 mm range needed to cause cardiac capture (in pigs, not humans), much less induce VF [Ex1pp169-70,203-04]. Zipes agrees that the one mark was "considerably farther than two centimeters from the right ventricle" of the heart [Ex1p146; *see also* Ex1pp167-68, "it's far from that" and "probably more than two centimeters"]. In

this respect, Zipes does not have sufficient factual backing to render his opinion reliably in this case, nor does the opinion even "fit" the facts of this case. His unreliable opinion should be excluded.

C. Zipes' theory is not the product of reliable principles and methods, just his say-so.

Zipes offers nothing of his own work that lends any credibility to his process. His "method" is a mere cite to his credentials as an electrophysiologist, it is so because "I" say it is so, with plaintiff-spun conclusions and cherry-picked literature. *See Daubert*, 43 F.3d at 1318 (district court must look at "soundness of his methodology"). This is far too scientifically slight to withstand the scrutiny of *Daubert*. Expert testimony cannot be admitted merely on the expert's say-so. *See Kumho*, 526 U.S. at 157; *Joiner*, 522 U.S. at 146 ("nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert").

"Without testing, all [Zipes] has done is identify a hypothesis. Even if it were a sound one, which it is not, the courts must necessarily lag behind science. Untested hypotheses, even if plausible, are insufficient to satisfy Rule 702." *Buck v. Ford Motor*, 810 F. Supp. 2d 815, 825-26 (N.D. Ohio 2011). A "working hypothesis" is not "admissible scientific knowledge." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010); *accord Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1202 (11th Cir. 2002) ("courtroom is not the place for scientific guesswork, even of the inspired sort").

Daubert, 509 U.S. at 593-94, identified the following factors to determine whether scientific testimony is reliably validated: (1) the theory can be (and has been) tested; (2) the theory has been subjected to peer review and publication; (3) there is a known or potential error rate; and (4) the theory is generally accepted in the relevant scientific community. *See also Pride*, 218 F.3d at 577 (failure to test or validate a hypothesis rendered opinion unreliable). In this case, Zipes' opinion likewise has not been tested; he cannot set forth an error rate (instead he says its "incalculable"); his theory has not been subjected to peer review; it is without explanation of the contrary existing peer-

reviewed and epidemiological human research; and it is not generally accepted. His "say-so," untested and unknown to the scientific community, should be excluded.

Quite aside from these dispositive failures, Zipes has not offered any reliable explanation for excluding the known and obvious explanation that alcohol causes cardiac arrest and that Piskura suffered from cardiac arrest because he was "out of his mind, blackout drunk" [Dkt71-2,Ex12p114:6-12], having consumed 24-25 alcoholic drinks [Ex36p66], with an undisputed blood alcohol level ("BAC") of at least 0.340 at the time of the incident with Officer Robinson[4] [Dkt69-5p7]. While not his expertise, Zipes concedes that mean levels above 0.30 BAC have been found to be lethal[5] [Ex1p13].

In addition to Zipes' and Nelson's testimonies, scientific literature demonstrates the risk of death—specifically cardiac arrhythmias—from acute alcohol toxicity. *See*, *e.g.*, G. Klein *et al.*, *Effect of Ethanol on Cardiac Single Sodium Channel Gating*, FORENSIC SCI. INT. (Sep. 2007;171(2-3):131-35) ("Alcohol in modest and higher doses has the potential to induce cardiac rhythm disturbances," including "cardiac arrhythmias."); K. Trejbal, *ECG Changes in Alcoholic Intoxication*, VNITR LEK (Apr. 2008;54(4);410-14) ("The higher the blood alcohol concentration, the higher the occurrence of a significant extension of ECG [electrocardiograph] intervals with possible manifestation of latent conduction disturbance or even sudden cardiac death."); J. Rehm *et al.*, *Alcohol-Related Morbidity and Mortality*, ALCOHOL RESEARCH & HEALTH (Vol. 27, No. 1, 2002) ("Heavy drinking appears to lower

[4] The undisputed evidence of Piskura's toxic alcohol levels, including the autopsy's finding that he had a BAC of 0.319 g/mL from a blood draw performed one hour after the incident [Ex60; Ex8pp154-55; Dkt69-5,p6; Ex36p70], has already been marshaled in detail in TASER's summary judgment brief.

[5] Plaintiffs' experts are 100% consistent in agreeing that Piskura's BAC was known to be potentially lethal. Their pharmacologist testified that "most any levels" of alcohol can induce cardiac arrhythmia according to the peer-reviewed literature [Ex36p41]. He says the scientific toxicology community "well know[s] what blood alcohol levels are associated with death," and, depending on tolerance levels, alcohol can be lethal from 0.25-0.50 BAC [Ex36pp22-23,114]. The medical examiner concurred that the potentially lethal range began at 0.24 BAC [Ex8p154].

the threshold at which the ventricular heart muscle begins a rapid contraction pattern: without prompt intervention, this pattern prevents normal heart function and results in death.").

That said, Zipes could not perform a differential diagnosis that ruled in the ECD and ruled out alcohol toxicity without a proper methodology and validation. *See*, *e.g.*, *Kolesar v. United Agri Prods., Inc.*, 246 Fed. Appx. 977, 980-81 (6th Cir. 2007) (excluding expert because had not ruled out other cause and theory lacked scientific literature); *Rolen v. Hansen Beverage Co.*, 193 Fed. Appx. 468, 474 (6th Cir. 2006) (excluding expert since he had not "engaged in the kind of methodological rigor that characterizes acceptable differential diagnoses"); *Ashburn v. General Nutrition Ctrs., Inc.*, 533 F. Supp. 2d 770, 774 (N.D. Ohio 2008) (doctor employing differential diagnosis excluded since theory not tested or peer reviewed, developed solely for litigation, and unsupported by foundational data). Zipes should be excluded as an expert as his say-so has not been reliably validated.

D. Zipes' theory does not fit this case.

Opinions must be tied to the facts of a particular case and reliably assist the trier of fact. *See Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000). A district court must determine whether an expert's "reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 593. There must be a "valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Daubert*, 509 U.S. at 591-92. This is what is commonly called "fit." *See id.* No opinion from Zipes reliably fits to assist the jury here.

1. Zipes admits his theory is "incalculable" such that it remains legally insignificant for a jury under *Hirsch v. CSX Transp., Inc.*, 656 F.3d 359 (6th Cir. 2011).

Just last year, in *Hirsch*, 656 F.3d at 362-64, a physician opined that exposure to a dioxin and other hazardous material fire from a train crash caused an additional 1 in a 1,000,000 risk of developing cancer for residents in that area. On appeal, the Sixth Circuit found that "a one-in-a-million chance is small. Indeed, it is proverbially small." *Id.* at 364. It compared this risk to many

other risks, including dying in a car accident (1:88), lightning strikes (1:84,000), and drowning in a bathtub (1:840,000)—all of which had far greater chance of causing death than what this expert opined from the dioxin fire. The court held that plaintiffs had consequently alleged "only a risk that borders on legal insignificance" and one that could not withstand summary judgment. *Id.*

Zipes presents an even more speculative and legally insignificant theory, so he would not assist a jury in this case under *Hirsch*. He has admitted this no less than five times. On February 22, 2010, Zipes testified that he had not calculated the probability of an ECD causing VF in a human, that the frequency was unknown, that he did not "know how low" the probability was, and that "you can't get accurate probabilities" [Ex2pp43-44,47,137]. On December 20, 2010, Zipes testified that he could not state to a reasonable degree of medical certainty the probability of ECD-induced "ventricular arrhythmia" and that he did not "know how low" the probability was [Ex9pp209-10]. On July 13, 2011, Zipes testified that the risk of VF from an ECD is "incalculable" [Ex6p655:6]. On December 21, 2011, Zipes again conceded that the likelihood of an ECD causing VF, cardiac arrest, or lethal cardiac consequences in a human was "incalculable" [Ex5pp140-41]. Zipes later confirmed in this case that, as of January 3, 2012, the likelihood of negative cardiac consequences from an ECD cannot be accurately determined and "is not calculable"[6] [Ex1p114].

This stands in sharp contrast to Zipes' testimony that the probability of death in informed consent advisements to patients of common procedures performed by cardiac electrophysiologists was a "pretty remote possibility" or "less than .1 percent" [Ex3pp90-92]. Zipes cannot even rate the alleged risk of ECD-induced VF as greater than ".1 percent." The "proverbially small" and "legally insignificant" theory that Zipes wants to advance in this case is thus not enough to surpass summary judgment under *Hirsch*, thus one that would be considered helpful to the jury under *Daubert* if it

[6] In contrast to the incalculable risk of VF from an ECD, and in the spirit of *Hirsch*, Plaintiffs' pharmacologist (Nelson) admits that (even assuming his data is true) the "fair probability" of Piskura's death from alcohol toxicity is between 1:1,000 and 1:10,000 [Ex36p118].

cannot even pass summary judgment muster. *See also Tamraz,* 620 F.3d at 670 ("working hypothesis" is not "admissible scientific knowledge"). A mere "scintilla of evidence" does not a jury trial make. *See Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 252 (1986); *Shropshire v. Laidlaw Transit, Inc.*, 550 F.3d 570, 576 (6th Cir. 2008) ("mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff"). He should be excluded.

2. Zipes had not even proposed the need for an alternative ECD warning until more than a year after Piskura's incident, so his retroactive theory does not assist the jury in this failure to warn case.

On May 15, 2009, over a year after the April 19, 2008 Piskura incident, in a debate at the HRS Annual Conference where Zipes was advocating the anti-TASER position, he was "*proposing* . . . the recognition that [ECDs] can—on occasion—produce ventricular fibrillation and cardiac arrest," and he says he told Tom Smith of TASER that since ECDs *might* cause cardiac effects TASER *should* issue a cardiac warning (but after the Piskura incident) [Ex4p37] (emphasis added). He was not even then reasonably certain that an ECD could allegedly cause VF in a human, but now claims the risk of cardiac arrest from an ECD was "well known prior to this [April 19, 2008] incident" [Ex33p1¶3]. His revisionist history does not aid the jury.

Under Ohio Rev. Code § 2307.76, the jury must determine whether the "manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product." If, according to Zipes, he were merely proposing for the first time—more than a year after the Piskura incident—the *recognition* that his theory was scientifically valid, and TASER *might* want to have a cardiac warning, he can hardly assist the jury in deciding whether TASER knew a year earlier that there was some alleged risk with its ECD. This is particularly so since Zipes admits that there is not a single article or study concluding then that an ECD causes VF in a human; the peer-reviewed scientific and medical research has never concluded that ECDs cause human VF [*e.g.*,

Ex1pp101,108-09,112; Dkt69-6,pp1,10; Dkt69-10,pp6,62]. Zipes should visit the laboratory before he visits a federal courtroom in Ohio. He cannot backdate his opinions at TASER's expense.

E. Zipes' "say-so methodology" remains inherently flawed by his failure to consider or address extensive epidemiological data and prospective human research on the cardiac safety of ECDs.

The effect of electricity on humans has been studied extensively for nearly a century, and no law enforcement force option has been studied more than ECDs. In sharp contrast to studies on alcohol toxicity—and Zipes concedes this in testimony—as of January 3, 2012, almost four years after the Piskura incident, there is not a single piece of medical, scientific, electrical, or engineering peer-reviewed literature, learned treatise, or statement from a professional association finding that an ECD causes cardiac capture, cardiac arrest, cardiac dysrhythmia, VT, VF, or other lethal cardiac consequences in humans [Ex1pp182:25-183:6; Dkt71-3,Ex13p112; *see also* Dkt71-4,Ex14pp101,105]. Indeed, human research studies on potential ECD effects are extensive and have never produced VF or other lethal cardiac consequence, despite probe vectors across the heart and continuous delivered ECD discharge durations up to 45 seconds.[7]

Indeed, so speculative is Zipes' opinion that just recently it was again debunked by a five-year study performed by the National Institute of Justice ("NIJ") of the United States Department of Justice, as well as a separate article published in the *Annals of Emergency Medicine*—both concluding that there is *no* current medical evidence that ECDs pose a significant risk of cardiac dysrhythmia or VF. *See* J. Laub, *Study of Deaths Following Electro Muscular Disruption*, NAT. INST. JUSTICE (May 2011); M. Pasquier, *Electronic Control Device Exposure: A Review of Morbidity and Mortality*, ANNALS EMERG. MED. (May 2011) ("No evidence of dysrhythmia or myocardial ischemia is apparent, even when the barbs are positioned on the thorax and cardiac apex.").

[7] To aid the Court, some of these extensive human studies and epidemiology have been marshaled in TASER's appendix of evidence, and summarized briefly for the Court's convenience in the addendum attached to this brief.

1. ECD review studies contradict Zipes as even he admits in testimony.

All human ECD review studies have been marshaled in the attached addendum. Zipes makes this discussion rather easy with his own testimony, however:

> Q. My question still is name any piece of medical, scientific, electrical engineering peer-reviewed literature that existed on or before September 30, 2009, that concludes that a TASER [ECD], including the X26 [ECD], applied to a human causes cardiac arrest or ventricular fibrillation.
>
> A. There are no peer-reviewed publications stating that, to the best of my knowledge.

[Ex3pp101-03; *see also* Ex1p112]. According to Zipes, no electrophysiology journal has published any peer-reviewed article concluding that ECDs cause VF in humans [Ex9p80 ("Not yet. Not yet.")]. His say-so methodology is thus unreliable and should be excluded.

2. Epidemiological (ECD field-use) studies also contradict Zipes as even he admits.

Zipes also admits that no epidemiological ECD field-use study supports his opinion that an ECD causes VF in humans:

> Q. Do any of the epidemiological studies that have been done support your opinion that TASER [ECDs] cause ventricular fibrillation or cardiac arrest in humans?
>
> A. They do not.

[Ex3p105; *see also* Ex9p69]. Inappropriately, he ignores this epidemiology. *See Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005) ("epidemiology is the best evidence of general causation"; "where epidemiology is available, it cannot be ignored"; "where there is a large body of contrary epidemiological evidence, it is necessary to at least address it with evidence that is based on medically reliable and scientifically valid methodology"). He should be excluded.

3. Prospective human laboratory studies also contradict Zipes.

The human research studies on potential ECD effects on humans are extensive and have never produced VF or asystole, despite trans-cardiac vectors of the probes and continuous discharge

durations up to 45 seconds. Zipes also completely ignores these peer-reviewed human studies. *See*, *e.g.*, Ho *et al.*, *The cardiovascular, respiratory, and metabolic effects of a long duration electronic control device exposure in human volunteers,* FORENSIC SCI. MED. PATHOL. 2010 Dec;6(4):268-74 (Epub May 26, 2010) (30-second exposures on anterior thorax showed *no* cardiac rhythm abnormalities) [Ex22]; Ho *et al.*, *Echocardiographic evaluation of TASER X26 [ECD] probe deployment into the chests of human volunteers*, AM. J. EMERG. MED. 2010 Jan;28(1):49-55 (close-range chest shots showed *no* cardiac capture) [Ex23]. All prospective human studies thus also stand against Zipes, who should be excluded as unreliable.

4. Animal studies are unreliable; those that Zipes cites do not "fit" this case, and even an author of one study criticizes Zipes for unfairly citing his work.

Federal courts in this circuit have appropriately looked askance at animal studies. *See Conde v. Velsicol Chem. Corp.*, 24 F.3d 809, 814 (6th Cir. 1994) (animal studies "not probative of medical causation"); *Turpin*, 959 F.2d at 1360 (animal study "insufficient to meet plaintiff's burden of proof" and "simply inadequate"); *Lee v. Richardson-Merrell, Inc.*, 772 F. Supp. 1027, 1033 (W.D. Tenn. 1991) (excluding expert based on difficulty of extrapolating animal studies to humans). While admissible under certain circumstances, animal studies *alone* are not enough to prove causation. *See Conde v. Velsicol Chem. Corp.*, 804 F. Supp. 972, 1027 (S.D. Ohio 1992), *aff'd*, 24 F.3d 809 (6th Cir. 1994) ("Animal studies are relied on by governmental agencies to determine public health risks; but animal studies alone are not, under the circumstances of this case, sufficiently reliable medical or scientific evidence to prove that a chemical causes human illness or disease."); *see also In re Heparin Prods. Liab. Litig.*, 2011 U.S. Dist. Lexis 79661, 35-36 (N.D. Ohio 2011) (requiring experts to "explain how such studies can be reliably extrapolated to prove comparable effects in humans").

Animal studies are not the stuff of reliable federal court *Daubert* proof. Extrapolation from animals to humans is inappropriate with ECDs, particularly when human studies have been voluminously done. *See also Joiner*, 522 U.S. at 143-47 (affirming district court's exclusion of expert based on animal studies); *Sorensen v. Shaklee Corp.*, 31 F.3d 638, 646, n.12 (8th Cir. 1994)

("extrapolating to humans from animal studies is problematic"); *Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp.2d 672, 683 (M.D.N.C. 2003) (disregarding animal studies); *In re Agent Orange Prod. Liab. Lit.,* 611 F. Supp. 1223, 1241 (E.D.N.Y. 1985) (animal studies "are of so little probative force and are so potentially misleading as to be inadmissible"). District courts in the Sixth Circuit have rejected non-epidemiological evidence as unreliable when there is an overwhelming body of epidemiological evidence to the contrary. *See, e.g., Turpin v. Merrell Dow Pharms.*, 736 F. Supp. 737, 743 (E.D. Ky. 1990) (animal studies inadmissible in light of over 30 epidemiological studies concluding no statistically significant risk of product).

Any animal study that Zipes could ever cite has been summarized in the attached addendum. On their face, these three pig studies cannot be extrapolated to Piskura. Indeed, extrapolation would be inappropriate since it remains undisputed that swine fibrillate *more easily* than humans [Ex55pp119-20; Dkt69-4,p11; Dkt69-3,pp16-17; Dkt69-6,pp11-13], particularly when the pig studies use artificial agents that can induce arrhythmia on their own [*Id.*; Dkt69-10]. *See Walker*, *supra,* trans. at 25-26 (Pro, J.) (finding that animal studies failed to account for the difference between human and pig hearts, or that pigs were artificially induced by anesthesia). Even Zipes admits in his 40 years of research that "one needs to be cautious jumping from the animal to the human. And ultimately if you're going to make opinions or decisions about humans, the studies need to be done in humans" [Ex10p187]. Despite this admission, he has not done so. His opinions are thus unreliable.

Even with pig studies, Zipes must analytically ignore most of what he cites to fabricate any support for his opinion. For instance, Zipes cites a swine study performed by Dr. Dhanunjay Lakkireddy. That study attempted to examine the VF threshold in anaesthetized pigs given cocaine, but the study did *not* produce VF at the standard X26 ECD discharge level even in a single pig or in a single event, even at the most sensitive trans-cardiac probe locations advanced by Plaintiffs [Ex38].

The study also cautioned against extrapolating from the study to humans. Now, in this case, Dr. Lakkireddy criticizes Zipes for unscientifically extrapolating from his study [Dkt69-3,pp23-25].

As another example, Zipes cites the Nanthakumar pig study, but again he must ignore the study's facts that only 1 out of 150 ECD discharges allegedly induced VF, and that one was in one out of 16 attempts to induce VF by the simultaneous infusion of high-levels of epinephrine to double the swine hearts' rates (which already fibrillate more easily than humans) [Ex39]. In other words, without high levels of epinephrine, there was no VF; and, even with high levels of epinephrine, there was no induction of VF 149 out of 150 ECD exposures [Ex39; Ex1p186]. What is more, the authors did *not* conclude a risk of VF, but instead recommended "further investigation in humans" [Ex39p804]. The authors concluded any alleged risk was "unknown" and that "there is no conclusive evidence to show whether stun-gun stimulation under certain electrophysiological conditions can result in cardiac arrhythmias" [Ex69p1456]. In fact, Nanthakumar later published that this presented a worst-case scenario, and that his results could *not* be extrapolated to humans [Ex39; Ex9p180; Ex1p191].

The addendum illustrates succinctly these analytical gaps by Zipes and the unreliability of his method. His opinions should be excluded.

5. Anecdotes (single-incident case reports) are not reliable.

Ohio district courts have "expressed skepticism of causation opinions based solely on adverse event reports, case series, case reports and case studies," admitting them only when "accompanied by other reliable scientific evidence." *In re Heparin Prods. Liab. Litig.*, 2011 U.S. Dist. Lexis 79661 at 36; *Glaser v. Thompson Med. Co.*, 32 F.3d 969, 972 (6th Cir. 1994) (only published studies and articles, and expert's own clinical and research experience, provided basis for case reports). Inapposite and random "anecdotes" or single-incident "case reports" on ECDs have been previously rejected by this and other federal courts as unreliable under *Daubert*. *See Walker*, *supra,*

trans. at 25-26 (noting that Kim and Franklin two-paragraph letter to the editor was "just that, it was a letter that had not been peer reviewed") [Ex32]; *Oliver*, 2011 U.S. Dist. Lexis 58127 at 16 (noting that case study related to ECD was "not reliable scientific literature"); *see also Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) ("case reports are not reliable scientific evidence of causation").

Also, for the Kim/Franklin letter, Zipes again attempts to ignore that the alleged "case report" is actually a two-paragraph letter to the editor; he does not know if it was peer-reviewed; he admits there is an error in the letter; and he must ignore the known facts that Paramedic Jill Hutchinson testified (per the EMS report) that, based on a fifteen-second vitals check, the subject had respirations of 16 and a pulse of 106 before he went into VF in the ambulance [*see* addendum below]. Again, Zipes must ignore these facts to get to his conclusion because he knows that, if electricity induces VF, the person will immediately lose pulse and respirations [Dkt69-3p13].

Zipes cites nothing but anecdotal case reports that he knows contain errors that do not reliably support his methodology and do not fit the facts of this case, so present no valid support for any causation opinion or any reason to assign scientific validity to his method. *See also Glastetter v. Novartis Pharm.,* 252 F.3d 986, 989-90 (8th Cir. 2001) (disregarding texts grounded on "case reports and other anecdotal information" since they "make little attempt to screen out alternative causes," "frequently lack analysis," and "often omit relevant facts about the patient's condition"); *Hollander v. Sandoz Pharma. Corp.,* 289 F.3d 1193, 1211 (10th Cir. 2002) (viewing case reports as scientifically insufficient); *Rider,* 295 F.3d at 1199 ("case reports alone ordinarily cannot prove causation"); *Soldo v. Sandoz Pharm. Corp.,* 244 F. Supp. 2d 434, 539 (W.D. Pa. 2003).

In this case, Zipes offered only one peer-reviewed human anecdote as supportive of his opinion:

> Q. [T]ell me any piece of peer-reviewed literature that has found, stated, or concluded that a TASER X26 [ECD] as applied to a human causes cardiac

> capture, cardiac arrest, ventricular tachycardia, ventricular fibrillation, or other lethal cardiac consequences other than the Cao pacemaker article?
>
> A. That's the only one.

[Ex1p112; *see also* Ex3pp101-03]. In short, this single case report (Cao) involved only cardiac capture (rapid pacing—*not* VF, and without injury to the person) in a prison inmate who had the unusual condition of having an implanted cardiac pacemaker with electrical leads surgically implanted directly into the heart which carried the ECD pulses directly into the heart [Ex3pp21,22]. Zipes has testified that, just as the Cao authors stated, he cannot state that the ECD would have had any cardiac effect without the presence of the pacemaker [Ex5p22]. Piskura did not have a pacemaker.

In addition, this Cao pacemaker anecdote concerned cardiac capture, not VF [Ex.9pp30, 37-38]. Again, Zipes admits cardiac capture is completely different [Ex9p21 ("producing VF is a different thing"); *see also* Ex3p102 ("Q. And capture is not the same as cardiac arrest; correct? A. That's correct."); Dkt69-4,pp111-12,154-56]. Consequently, even on brief review, no peer-reviewed human anecdote supports Zipes, or even helps him fit his theory to this particular case.

F. A final point: Zipes is not a warnings expert.

At points, Zipes appears to stray into a subsidiary role as a warnings expert. To the extent that Plaintiffs seek to convert their electrophysiologist into a warnings expert, that cannot occur. Zipes also admits that he is not an expert on warnings, including for law enforcement, weapons, and ECDs [Ex1p113; Ex9pp80-81,102]. None of his publications address law enforcement warnings [Ex2p109]. He has not published any articles on how to write product warnings [Ex2p266]. And, as stated earlier, it was not until May 15, 2009, over a year after the Piskura incident, that Zipes stated he told TASER's Tom Smith that TASER *might* want to have a cardiac warning. He should be excluded as an expert witness on this issue.

CONCLUSION

It is exactly Zipes' inexperience with the unique specifications and electrophysiological properties of ECDs that have led many other federal district courts to exclude proposed experts on ECDs. *See Smelser*, 105 F.3d at 303. Zipes also should be excluded. Plaintiffs have the burden of establishing the admissibility of his opinions, but have not done so. His unscientific and unsupported rhetoric and debate should be waged with his peers in presentations, studies, and in the laboratory. His "working hypothesis" is not "admissible scientific knowledge." *Tamraz*, 620 F.3d at 670. And this federal courtroom is no place for his guesswork. Pursuant to Fed.R.Evid. 702 and *Daubert*, his opinions should not be admitted.

Respectfully submitted,

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EXHIBIT "ZIPES": ADDENDUM

A. ECD review studies.

Study/Source	Conclusions
March 2012 Kunz Article[8] [Ex64]	▪ "The majority of current medical research could not find acute clinical relevant pathophysiological effects during or after professional use of CEWs on human subjects."
May 24, 2011 NIJ (5 year) Study[9] [Ex11ppviii,9] (emphases added)	▪ "[T]he risk of human death due directly or primarily to the electrical effects of CED [synonymous with ECD] application has *not been conclusively demonstrated*." ▪ "[C]urrent *research does not support a substantially increased risk of cardiac arrhythmia in field situations, even if the CED darts strike the front of the chest*." ▪ "There is currently *no medical evidence* that CEDs pose a significant risk for induced cardiac dysrhythmia in humans when deployed reasonably."
May 2011 Pasquier Article[10] [Ex12]	▪ "[I]mmediate induction of ventricular fibrillation does *not* seem to be a likely mechanism of electronic control device–associated death." ▪ "[T]he role of electronic control device in mortality remains *speculative*."
January 2011 Vilke[11] [Ex13]	▪ "There were 140 articles on CEWs screened, and 20 appropriate articles were rigorously reviewed and recommendations given." ▪ "These studies did *not report* any evidence of dangerous laboratory abnormalities, physiologic changes, or *immediate or delayed cardiac ischemia or dysrhythmias after exposure* to CEW electrical discharges of up to 15s."

[8] S.N. Kunz, et al., *Acute pathophysiological influences of conducted electrical weapons in humans: A review of current literature*, Forensic Sci. Int. (2012), oi:10.1016/j.forsciint.2012.02.014 [Ex64].

[9] J. Laub, *Study of Deaths Following Electro Muscular Disruption*, Nat. Inst. Justice, viii, 9 (May 2011) [Ex11].

[10] M. Pasquier, *Electronic Control Device Exposure: A Review of Morbidity and Mortality*, ANNALS EMERG. MED. (May 2011) [Ex12].

[11] Vilke *et al.*, *Emergency Department Evaluation after Conducted Energy Weapon Use: Review of the Literature for the Clinician*, J. EMERG. MED. (In Press, Corrected Proof. Position Paper Approved by the American Academy of Emergency Medicine Clinical Guidelines Committee) (emphases added) [Ex13].

Study/Source	Conclusions
April 2010 International Association of Chiefs of Police ("IACP")[12] [Ex14]	▪ [94 ECD] research papers were reviewed during the preparation of this document. ▪ "The totality of information presently available suggests that [ECDs] do *not* create an increased risk of pacemaker malfunction, heart fibrillation, or death or serious injury, absent the legitimate concern of secondary injuries from falling down."
June 2009 American Medical Association ("AMA") White (Position) Paper[13] [Ex15]	▪ "Most studies undertaken by law enforcement agencies (and others) indicate that deploying CEDs relative to other use-of-force options, such as pepper spray, physical force, police dogs, and batons, reduces injuries to officers and suspects and reduces the use of lethal force." ▪ "Furthermore, *no evidence of dysrhythmia or myocardial ischemia is apparent, even when the barbs are positioned on the thorax and cardiac apex*."
January 2009 Bozeman Paper[14] [Ex16]	▪ "A rapidly evolving body of literature has examined a range of physiologic and cardiovascular effects of conducted electrical weapon exposure in human volunteers (Table 6)." ▪ "These studies, which include articles and published preliminary reports in abstract form, demonstrate *no evidence of dangerous respiratory or metabolic effects using standard (5-second), prolonged (15-second), and extended (up to 45-second) conducted electrical weapon discharges*."

B. Epidemiological studies (post-ECD field deployments with medical evaluation or force option field post-deployment injury studies).

Study/Source	Conclusions
2009 Bozeman letter following prior paper[15] [Ex17]	▪ "When this experience is combined with previous reports of medical outcomes after consecutive field use of conducted electrical weapons, including Eastman et al (n 426), Bozeman et al (n 1201), and a recent abstract by Angelidis et al (n 1101), there is a combined experience of 4,058 consecutively monitored conducted electrical weapon uses with an electrical shock delivered." ▪ "Serious injuries are clearly rare, *and there are no cases in any of the reports*

[12] Electronic Control Weapons, Concepts and Issues Paper, International Association of Chiefs of Police (IACP) National Law Enforcement Policy Center, April 2010 [Ex14].

[13] Carolyn B. Robinowitz, MD, Chair, *Report 6 of the Council on Science and Public Health (A-09), Use of Tasers® [Conducted Electrical Devices (CEDs)] by Law Enforcement Agencies* (Reference Comm. D, AMA) (emphasis added) [Ex15].

[14] W. Bozeman *et al.*, *Safety and Injury Profile of Conducted Electrical Weapons Used by Law Enforcement Officer Against Criminal Suspects,* ANNALS EMERG. MED. (January 2009) [Ex16].

[15] W.P. Bozeman, *Additional Information on TASER [ECD] safety*, Annals Emerg. Med. (Vol. 54:5 Nov. 2009) (emphasis added) [Ex17].

Study/Source	Conclusions
	suggesting sudden cardiac death related to the Taser."
2010 NIJ Study—Final Report (M. Smith)[16] [Ex18]	▪ "Across 12 agencies and more than 25,000 use of force cases, the odds of a suspect being injured decreased by 70 percent when a CED was used. Controlling for other types of force and resistance, the use of CEDs significantly reduced the probability of injuries." ▪ "In very rare cases, people have died after being pepper sprayed or shocked with a Taser, although *no clear evidence exists that the weapons themselves caused the deaths.*"
October 2009 MacDonald Study[17] [Ex19]	▪ "CEDs appear to be relatively safe when used on healthy individuals in clinically controlled research settings. Given the findings from this study, as well as those from previously published research, law enforcement agencies should encourage the use of OC spray or CEDs in place of impact weapons and should consider authorizing their use as a replacement for hands-on force tactics against physically resistant suspects." ▪ "Our findings suggest that the incidence of injuries from police use-of-force incidents can be reduced substantially when police officers use CEDs and OC spray responsibly and in lieu of physical force to control physically resistant suspects."
2009 Police Executive Research Forum ("PERF")[18] [Ex20]	▪ "Overall, we found that the CED sites were associated with improved safety outcomes when compared to a group of matched non-CED sites on six of nine safety measures, including reductions in (1) officer injuries, (2-3) suspect injuries and severe injuries, (4-5) officers and suspects receiving injuries requiring medical attention, and (6) suspects receiving an injury that resulted in the suspect being taken to a hospital or other medical facility." ▪ "Also within CED agencies, in some cases the actual use of a CED by an officer is associated with improved safety outcomes compared to other less-lethal weapons." ▪ "The evidence from our study suggests that CEDs can be an effective weapon in helping prevent or minimize physical struggles in use-of-force cases."

[16] M. Smith *et al.*, *A Multi-Method Evaluation of Police Use of Force Outcomes: Final Report to the National Institute of Justice* (US Dept. of Justice 2010) (emphasis added) [Ex18].

[17] John M. MacDonald, Robert J. Kaminski, and Michael R. Smith, "The Effect of Less-Lethal Weapons on Injuries in Police Use-of-Force Events," American Journal of Public Health, October 2009 [Ex19].

[18] Taylor B, Woods D, Kubu B, *et al.* Police Executive Research Forum (PERF), "Comparing safety outcomes in police use-of-force cases for law enforcement agencies that have deployed Conducted Energy Devices and a matched comparison group that have not: A quasi-experimental evaluation," September 2009 [Ex20].

Study/Source	Conclusions
	▪ "LEAs should consider the utility of the CED as a way to avoid up-close combative situations and reduce injuries to officers and suspects."
2008 Eastman[19] [Ex21]	▪ "[I]in addition to avoiding the use of lethal force in a significant number of circumstances [23 of 426 incidents, or 5.4%], the safety of CED use was demonstrated despite one death subsequently attributed to lethal toxic hyperthermia."

C. Prospective human laboratory studies.

Study/Source	Conclusions
May 2010 Ho Study[20] [Ex22]	▪ 30-second exposures on anterior thorax showed *no* cardiac rhythm abnormalities.
January 2010 Ho Study[21] [Ex23]	▪ Close-range chest shots showed *no* cardiac capture.
May 2009 Ho Study[22] [Ex65]	"Prolonged CEW application in an exhausted human sample did not cause a detectable change in their 12-lead ECGs. Theories of CEW induced dysrhythmia in non-rested humans are not supported by our findings."
July 2009 Bozeman Study[23] [Ex66]	▪ "CEW exposure produced no detectable dysrhythmias and a statistically significant increase in heart rate. Overall, Taser CEW exposure appears to be safe and well tolerated from a cardiovascular standpoint in this population. This study increases the cumulative human subject experience of CEW exposure with continuous ECG monitoring and includes 28 full 5-s exposures."

[19] Eastman, A.L., *et al.*, *Conductive electrical devices: a prospective, population-based study of the medical safety of law enforcement use*, J. TRAUMA, 2008. 64(6): pp. 1567-72 [Ex21].

[20] Ho *et al.*, *The cardiovascular, respiratory, and metabolic effects of a long duration electronic control device exposure in human volunteers,* FORENSIC SCI. MED. PATHOL. 2010 Dec;6(4):268-74 (Epub May 26, 2010) [Ex22].

[21] Ho *et al.*, *Echocardiographic evaluation of TASER X26 [ECD] probe deployment into the chests of human volunteers*, AM. J. EMERG. MED. 2010 Jan;28(1):49-55 [Ex23].

[22] Ho JD, Dawes DM, Heegaard WG, Calkins HG, Moscati RM, Miner JR. *Absence of electrocardiographic change after prolonged application of a conducted electrical weapon in physically exhausted adults.* J Emerg Med. May 12 2009 [Ex65].

[23] Bozeman W, Barnes D, Winslow J, et al. *Immediate cardiovascular effects of the Taser X26 conducted electrical Weapon.* Emerg Med J. 2009;26(8):567-570 [Ex66].

Study/Source	Conclusions
August 2008 Ho Study[24] [Ex24]	▪ 10-second ECD exposures in an ideal cardiac axis application did *not* demonstrate concerning tachyarrhythmias using human models.

D. Unreliable or inapposite animal (pig) studies.

Source	Reasons Unreliable/Inapplicable
Lakkireddy/Tchou cocaine pig study [Ex38]	▪ Zipes admits that this study did not produce any fatal cardiac dysrhythmia from a normal application of an ECD [Ex1p238]. He also admits he has no evidence that it is even possible for an ECD to double the charge with its known power source [Ex1p238]. ▪ Anaesthetized pig study, not human study. Even the authors cautioned against extrapolation: "Extending animal data to human beings should always be done with caution" [Ex38; Ex9p114]. ▪ Study examining VF cocaine threshold did not produce VF at standard X26 ECD discharge level, even at most sensitive trans-cardiac probe locations [Ex38; Ex9pp109-10]. ▪ This experimental, most sensitive probe location on the pig was *not* the probe location on Piskura [Ex60; Ex1pp166-68]. Indeed, there was no electrical circuit completed capable of delivering an electrical charge in Piskura, and the one probe was not over the heart [Ex1pp166-68]. ▪ Lakkireddy's post-2006 porcine studies had no findings of VF even in a porcine model. "Swine heart needs 35% less current to go to [VF] in comparison to human heart from external stimulation" [Biria 2010]. ▪ In this case, Lakkireddy criticizes Zipes for unscientifically taking liberties with this study [Dkt69-3,pp23-25]. ▪ Lakkireddy also concludes that the ECD probes never penetrated Piskura's body, thus eliminating any possibility that the ECD induced cardiac arrhythmia [Dkt69-3,p12].
Nanthakumar pig study [Ex39]	▪ Pig study where there were a total of 150 ECD discharges of which 94 ECD discharges were applied with probes across heart of small, 110-pound pigs. Not a human study. ▪ Nanthakumar later published that this presented a worst-case scenario, and that his results could not be extrapolated to humans [Ex39; Ex9p180; Ex1p191; Ex68; Ex69]. ▪ This swine study does not "fit." No pig suffered VF from just an ECD exposure—something admitted by Zipes [Ex1p186, "Q. And

[24] Ho *et al.*, *Echocardiographic Evaluation of a TASER-X26 [ECD] Application in the Ideal Human Cardiac Axis*, ACAD. EMERG. MED. 2008 Aug 10 [Ex24].

Source	Reasons Unreliable/Inapplicable
	how many animals were put into VF by Dr. Nanthakumar during his testing without infusion of epinephrine? A. None."]. ▪ Instead, the study artificially stimulated swine hearts with epinephrine to run more rapidly (very discordant from an arrest scenario). Even then, out of 16 episodes with epinephrine infusion, only 1 pig out of 6 went into VF, and only one time [Ex39; Ex1pp185-88]. ▪ That one scenario involved a 15-second exposure with high levels of epinephrine—not the alleged 11-second application to Piskura without artificial stimulation of the heart [Ex1pp185-86; Ex39]. ▪ This study came out after (May 20, 2008) the incident with Piskura (April 19, 2008) [Ex1pp189,190]. ▪ The authors did not conclude a risk of VF (based on only one pig after epinephrine infusions), but instead recommended "further investigation in humans" [Ex39p804] (emphasis added). ▪ The authors concluded any alleged risk was "unknown" and that "there is no conclusive evidence to show whether stun-gun stimulation under certain electrophysiological conditions can result in cardiac arrhythmias" [Ex69p1456] (emphasis added).
Dennis/Walter pig articles [Ex40]	▪ Pig studies without fair extrapolation to humans. ▪ Anesthetized unventilated (during extended ECD exposure pigs received 80-second ECD applications (two 40-second applications with a 10-second interval), but were not allowed to breath during the ECD applications. No evidence that Piskura was likewise deprivated. ▪ Used small pigs of 22-46 kilogram ("kg") (48-101 lbs), but induced VF in only two very small pigs (29 kg and 31 kg) (64 lbs and 68 lbs). No swine study has shown VF induced from ECD for person weighing as much as Piskura (79.8 kg or 176 lbs) [Ex60]. ▪ Walter article (22-71 kg pigs) saw VF in only one 28-kg (62 lbs) pig with 80-second discharge and called likelihood "extremely low," noting that this study used SCh, a depolarizing muscle relaxant that can—by itself—cause bradycardia and junctional myocardial rhythms [Ex40pp70-71].

E. Unreliable or inapposite case reports.

Source	Reasons Unreliable/Inapplicable
Two-paragraph anecdote/letter to the editor from Kim and Franklin (Akeem Watson)	▪ Two-paragraph letter to the editor states that "no definite causative link between death and the use of a stun gun has been made" [Ex25]. ▪ Zipes admits that he cannot say this letter to the editor was ever peer reviewed [Ex1p103]. Just a two-paragraph letter anecdote; not peer reviewed. [Ex9p36; Ex1p267]. Zipes admits it contains an error.

Source	Reasons Unreliable/Inapplicable
[Ex25]	▪ Unchallenged testimony from the paramedic at the scene establishes that the suspect had a normal pulse, respirations, and cardiac rhythm after the ECD application, and again approximately two minutes later, both inconsistent with saying VF was caused by the ECD [Ex9pp33-35].
Greshmond Gray anecdote [Ex26]	▪ Greshmond Gray autopsy report states that the cause of death is physiologic stress of a physical altercation and due to heart enlargement and fibrosis with other significant contributors of non-recent cocaine use. The autopsy report also states that Gray had alcohol level of 0.145 g/100 ml and THC (marijuana metabolite). ▪ Zipes references testimony from Dr. Charles Swerdlow concerning this anecdote. This paper came out mid-2009 after Piskura's exposure. ▪ It describes only case that is "suggestive of" or "consistent with" VF, but not opining that an ECD exposure actually caused VF (or asystole). *Layton v. Yankee Caithness Joint Venture*, 774 F. Supp. 576, 580 (D. Nev. 1991) ("possibility alone is insufficient."). ▪ Swerdlow explains in deposition that he "had limited data on the Greshmond Gray case at the time [he] wrote this paper" [Ex54p101]. ▪ Zipes concedes that no peer-reviewed scientific or medical literature has indicated that a TASER ECD can cause VF in humans [Ex9pp77-78, "Not in humans. In pigs, well established."]. The Swerdlow paper should not be assigned more importance that Zipes attributes to it. ▪ Swerdlow also testified that the first time he discussed this anecdote with TASER was March 1, 2010—well after the Piskura incident [Ex1pp244-45; Ex54pp106-07].

CERTIFICATE OF SERVICE

The above signed attorney hereby certifies that a copy of the foregoing was served this 12th day of April 2012, through the Court's ECF system to all counsel of record.