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The Impact Of Human Factors Experts In Medical Device Litigation

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Human factors is "the study of the interrelationships between humans, the tools they use, and the environment in which they live and work." Linda T. Kohn, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 63 (National Academy Press 2000) (emphasis omitted). The goal of the human factors professional is to eliminate user error through product design and labeling. *See*, *e.g.*, Neal I. Muni, M.D., *Challenges in Regulating Breakthrough Medical Devices*, 60 FOOD DRUG L.J. 137, 139-140 (2005). More and more frequently, human factors experts are relied upon to render opinions in product liability cases involving allegedly defective medical devices. While there are many instances where these experts are retained by defense counsel, they are most commonly used by plaintiffs to excuse user error. *See*, *e.g.*, Douglas R. Richmond, *Human Factors Experts in Personal Injury Litigation*, 46 Ark. L. Rev. 333, 338 (1993). This is because the focus in human factors is on "correcting" the actions of the manufacturer in designing the product (rather than on the user's negligent or even reckless conduct). *See*, *e.g.*, Michael Wiklund, *Defining and Designing for Worst-Case Users* (July 1, 2006), *available at* http://www.mddionline.com/article/defining-and-designing-worst-case-users) (a medical device must "withstand the actions and inactions of unprepared, unfit or impaired users"; in order to design an "error-tolerant" medical device, the product developers should consider the "characteristics of worst-case users."). The prevalence of human factors experts in medical device cases is due, in part, to this underlying philosophy.

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Because of its somewhat subjective nature, human factors can be a malleable science, providing the framework through which a plaintiff might try to justify his wrongdoing where his or her actions go beyond the pale of reasonably foreseeable user error. *See*, *e.g.*, *Graves v. Mazda Motor Corp.*, No. 08-0035, 2009 U.S. Dist. LEXIS 122414, at *55 (W.D. Ok. Dec. 17, 2009). Taken to its extreme, some plaintiffs might argue that human factors principles impose upon manufacturers the ultimate burden of fool-proofing their products, regardless of how remote or unlikely a misuse may be. Nonetheless, proper application of Fed. R. Evid. 702 (or the equivalent applicable evidentiary rule) and the principles of *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), will help ensure that the opinions of human factors experts are based, at the very least, on some objective scientific methodology rather than mere speculation.

The Admissibility Of Human Factors Expert Testimony In Product Liability Cases

Pursuant to Fed. R. Evid. 702 and *Daubert*, the court has an obligation to determine the reliability and relevance of proferred expert testimony and ascertain whether it is properly substantiated. While there do not appear to be any published decisions directly addressing the admissibility of human factors expert testimony in medical device cases, there are many decisions dealing with this same issue in other product liability cases.

As with any expert, human factors experts are permitted to testify only when it will "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. *See*, *e.g.*, *Simon v. Simon*, 260 Kan. 731, 738-740 (1996) (precluding expert testimony where it was clear that the expert was not necessary to describe the dangerousness of a meat grinder which was open and obvious). Most typically, human factors experts provide opinions regarding the adequacy and efficacy of warnings and/or the impact of human factors in the design of a product. While human factors principles may be somewhat subjective, a human factors expert should not be allowed to simply rely on his own "beliefs" regarding a warning or product design. He must be able to identify a reliable scientific basis for his opinion if his testimony is to be admitted. *See*, *e.g.*, *In re: Welding Fume Prods. Liab. Lit.*, No. 03-17000, 2005 U.S. Dist. LEXIS 46164, at *38 n.9, *41 (N.D. Oh. Aug. 8, 2005) (human factors expert precluded from expressing an opinion on "what plaintiffs would have done had they been given different warnings" because there was no stated methodology); *Hamilton v. Emer-*

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son Elec. Co., 133 F. Supp. 2d 360, 370-372 (M.D. Pa. 2001) (opinion that a brake on a miter saw was defective was precluded since the expert did not articulate a "discernible methodology" in support thereof); *Hotaling v. City of New York*, 866 N.Y.S.2d 117, 119 (App. Div. 1st Dep't 2008) (mere belief that design of doors deviated from "human factors" design standards, without pointing to any specifically applicable design standards, was fatal to human factors expert's opinion on design of doors in question); *Juarequi v. John Deere Co.*, 971 F. Supp. 416, 429 (E.D. Mo. 1997) (opinion on adequacy of warnings allowed because expert "was able to base his opinion on books, materials, and theories in the field of human factors and safety").

In other words, just because a human factors expert thinks that some change in the product might prevent injury does not *ipso facto* mean that there was a failure to warn or that the product is defective. Moreover, unlike other experts traditionally used in product liability cases (*e.g.*, engineers, physicians, psychiatrists), human factors professionals often draw their expertise from several disciplines. Thus, where a human factors expert's background is in, for instance, psychology but not engineering, that expert's opinions may be limited accordingly. *See*, *e.g.*, *id.* at 425 (human factors expert with background on psychology allowed to testify on adequacy of warnings but precluded from testifying regarding the defective condition of farming machinery because the expert had "virtually no relevant background in the design or function of products similar in function and operation" and his practical experience with agricultural machinery was negligible). *Cf. Graves*, 2009 U.S. Dist. LEXIS 122414, at *49, *54-56 (human factors expert with engineering degrees and automotive engineering experience sufficiently qualified to express opinion that gear shifter was defective, although opinion ultimately precluded because of flawed methodology).

FDA And AAMI'S Endorsement Of Human Factors Engineering In The Design of Medical Devices

The Food and Drug Administration ("FDA") is a strong proponent of the utilization of human factors principles in the design of medical devices, and human factors experts often point to this in expressing their opinions. Accordingly, it is important to be aware of the applicable FDA regulations and guidance documents pertaining to human factors in defending a medical device case.

Pursuant to the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.S. § 301, *et seq.*, the FDA established three classes of devices "intended for human use." *Id.* § 360c(a)(1). All three classes are subject to good manufacturing practices ("GMPs"). *Id.* §§ 360c(a)(1); 360j(f). The FDA's current GMPs are set forth in its Quality System Regulation, 21 C.F.R. § 820.1, *et seq.* Of particular note is § 820.30, which is applicable to all Class II and III devices and certain enumerated Class I devices. This section requires, among other things, that manufacturers implement procedures to ensure that design requirements are "appropriate" and address the intended use of the device. As the FDA has observed, "[t]he need for human factors techniques or data in the design process is implicit in paragraphs c, f, and g of Section 820.30 . . . ." *Human Factors Implications of the New GMP Rule Overall Requirements of the New Quality System Regulation*, *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/HumanFactors/ucm119215.htm. Consistent with § 820.30, the FDA recommends that manufacturers (1) consider human factors in developing the device user interface (what users "see, feel and hear"), which includes product labeling, (2) test the device for the potential for user error, and (3) consider user error in conducting a risk analysis. *Id.*

Moreover, there are two FDA guidance documents that directly address human factors in medical device design. Dick Sawyer, *Do It By Design, An Introduction to Human Factors in Medical Devices* (Dec. 1996), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm095061.pdf; Ron Kaye, *Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management* (July 18, 2000), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094461.pdf. *Do It By Design* is intended to "encourage manufacturers to improve the safety of medical devices and equipment" by introducing the intended reader (manufacturers, employees of the FDA and healthcare professionals) to human factors and its role in the design of medical devices. Similarly, *Incorporating Human Factors Engineering*, which is for medical device manufacturers and FDA premarket and design control reviewers, describes how user error should be addressed during the development and design of medical devices. In the words of the FDA, "human factors provides a variety of useful approaches to help identify, understand, and address use-related problems."

Human factors principles are similarly embraced by the Association for the Advancement of Medical Instrumentation ("AAMI") which has promulgated two voluntary human factors standards, *Human factors design process for medical devices, Standard HE-74* and *Human Factors Engineering — Design of medical devices, Standard HE-75*. ANSI/AAMI HE74:2001; ANSI/AAMI HE75:2009. The purpose of HE-74, which has been recognized by the FDA, is to "provide manufacturers with a structured approach to user interface design" and help manufacturers "interpret and respond effectively to national and international" human factors standards in the medical field. HE-75, which was only recently promulgated, was not available at the time of the writing of this article. It is anticipated, however, that it will be available at the time of this article's publication or shortly thereafter. The FDA has also recognized *Medical devices — Application of usability engineering to medical devices*, IEC 62366:2007, a European standard developed by the International Electrotechnical Commission ("IEC") and the International Organization for Standardization ("ISO") that addresses medical device user errors.

Conclusion

The use of human factors experts is on the rise in medical device cases. Although human factors can be subjective, this does not mean that an expert in the field is entitled to base his opinion on speculation. An understanding of the constraints placed on expert testimony and an awareness of the applicable FDA regulations, guidance documents, and industry standards relating to human factors will allow for more effective cross-examination of the human factors expert and help in the preparation of a strong defense.