Applied American Exceptionalism

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According to the Wikipedia entry (OK, maybe not the most reliable source, but it is the fastest), "American exceptionalism" is the notion "that the United States is qualitatively different from other nations." The first person to say so (although not in those exact words) wasn't even American, but French – Alexis de Tocqueville. While sometimes thought of as a doctrine embraced mostly by isolationists and others on the right wing of the political spectrum, according to Wikipedia, internationalist Communists were there first to coin the phrase, as an excuse for why the supposedly historic inevitability of Communism was such a miserable failure in the United States

We occasionally see American exceptionalism at work in prescription medical product liability litigation. Sometimes it takes a raw, rather nasty incarnation – as when plaintiffs' lawyers attempt to incite nativist suspicions, or worse, in juries when the defendant is a company based in Europe, Japan, or more frequently these days India or China. In one recent example, a plaintiff offered an "expert" in "Chinese culture" who could "'see beyond the facade in China' in a way that others cannot," for the purpose of saying that the defendant should never have bought anything Chinese made. In re Heparin Product Liability Litigation, 2011 WL 1059660, at *9 (N.D. Ohio March 21, 2011). Fortunately, the court resoundingly rejected this rank attempt to appeal to anti-foreign prejudices. First, they were purely a product of the expert's prejudices, and had nothing to do with the facts of the case:

"[The expert's] opinions with regard to the common practices of Chinese manufacturers and suppliers have not been tested or subjected to peer review or otherwise corroborated. At his deposition, [he] asserted that his conclusions are based on "common knowledge" and incapable of support by statistical data . . . .

[The expert's] opinions are entirely personal, based on his own and, to be sure, relatively extensive, experience with a broad range of businesses in China. But [the expert] sees those experiences and the views they have created through the lens of subjectivity. . . . [He] has no basis to apply his opinions reliably to the pharmaceutical industry. He has no professional experience with pharmaceutical . . . manufacturing outside of this litigation. . . . [N]owhere does he explain how his observations about Chinese business practices relate to the Defendants."

Id. at *10-11. Second, the entire subject was simply a blatant appeal to juror prejudices, and had no business in a product liability trial:

"Whatever slight probative value his opinions might have is substantially outweighed by the risk of unfair prejudice. His generalized opinions about Chinese culture and business practice have no link to the parties involved in this case and have a serious risk of prejudicing the jury. Courts repeatedly exclude this type of testimony because the risk of racial or ethnic stereotyping is substantial, appealing to bias, guilt by association and even xenophobia. Accordingly, Defendants' motion shall be granted." Id. at *11 (citation omitted).

Another aspect of American exceptionalism in product liability litigation, however, is not only more benign but also substantially accurate. That's the reluctance of courts to allow juries to hear about foreign regulatory activities. After all, it's demonstrably true – going back to the Thalidomide tragedy of the early 1960s, if not before – that the regulatory standards of various countries differ significantly. For better or worse (mostly for better), prescription medical products in the United States are regulated by the FDA, and not bound by disparate standards imposed by regulators in other countries.

We've touched upon the issue of admissibility of foreign regulatory activities before, but never in a systemic fashion. We think we'll try to kill it today.

The first appellate cases dealing with attempts to import the product regulations of other countries into American product liability litigation didn't involve drugs. In Tews v. Husqvarna, Inc., 390 N.W.2d 363, 366 (Minn. App. 1986), the plaintiff tried to have his expert testify about Swedish standards for chain saws in order to imply that the Swedish defendant manufacturer should have followed Swedish rather than American regulations for saws sold in this country. The trial court excluded the purported evidence, and on appeal was affirmed:

"[T]he trial court did not err in excluding testimony concerning the legal requirements for chain brakes in foreign jurisdictions . . . . [W]hile technology available in other jurisdictions is relevant, legal standards in other jurisdictions are not. We cannot say that the trial court abused its discretion in excluding this evidence."

Id. at 367. The same court had earlier rejected evidence of foreign standards concerning press brakes in Buzzell v. Bliss, 358 N.W.2d 695, 699 (Minn. App. 1984) ("its probative value was outweighed by its potential to confuse or mislead the jury"). Accord Garmon v. Cincinnati, Inc., 1993 WL 190923, at *2-3

(Tenn. App. June 4, 1993) (holding same foreign press brake requirements inadmissible under Tennessee law).

The identical issue in Tews also arose in Deviner v. Electrolux Motor, AB, 844 F.2d 769 (11th Cir. 1988). The trial court likewise held that "Swedish Standards are not relevant in a U.S. product liability case involving a saw sold in the U.S. in 1981." Id. at 771 n.3. The Court of Appeals affirmed, holding that "The District Court's desire to avoid confusing the jury with Swedish law and statistics cannot rightly be described as abuse of discretion, when the issues aris[e] under Alabama and federal law." Id. at 773.

A few years later, in Hurt v. Coyne Cylinder Co., 956 F.2d 1319, 1327 (6th Cir. 1992), the court followed Deviner in holding that expert testimony about safety features mandated in other countries should be excluded. "[F]oreign legal standards have been found excludable [in Deviner], and we will follow that holding." See also Sherry v. Massey-Ferguson, Inc., 1997 WL 480893, at *3 (W.D. Mich. June 5, 1997) (agreeing that foreign regulatory matters are irrelevant; fact that defendant used different design abroad could be used to establish alternative design).

Most recently in Katzenmeier v. Blackpowder Products, Inc., No. 4:06-cv-00169-RAW, slip op. (S.D. Iowa Nov. 25, 2008), the court excluded stricter European gun standards:

"[T]his case is governed by domestic law standards concerning which it is undisputed there is no [relevant] government or industry standard or procedure. . . . Evidence of stricter . . . European laws and regulations is likely to confuse and mislead the jury to defendants' unfair prejudice."

Slip op. at 5. On appeal, the Eighth Circuit tersely affirmed this ruling. Katzenmeier v. Blackpowder Products, Inc., 628 F.3d 948, 950 n.4 (8th Cir. 2010) ("evidence of foreign regulations in a case governed by domestic law has been found excludable because it likely leads to confusion of the jury").

Drug plaintiffs were not far behind in seeking to muddy the waters between what the FDA did and foreign regulatory activities that differed from the requirements of the FDCA. The issue first came up in an indirect context in birth control pill litigation. A bunch of plaintiffs from the United Kingdom sought to sue in the United States, despite their drugs being subject to an entirely different regulatory framework. The court threw them out because fairness required that a defendant be judged by the standards of the country where the drug in question was approved:

"[F]airness to the defendant mandates that defendant's conduct be judged by the standards of the community affected by its actions. . . . [I]t is manifestly unfair to the defendant, as well as an inappropriate usurpation of a foreign court's proper authority to decide a matter of local interest, for a court . . . to set a higher standard of care than is required by the government of the country in which the product is sold and used."

Harrison v. Wyeth Laboratories, 510 F. Supp. 1, 5 (E.D. Pa. 1980), aff'd, 676 F.2d 685 (3d Cir. 1982). Each country's regulatory standards reflect that country's "unique" political and social system:

"This balancing of the overall benefits to be derived from a product's use with the risk of harm associated with that use is peculiarly suited to a forum of the country in which the product is to be used. Each country has its own legitimate concerns and its own unique needs which must be factored into its process of weighing the drug's merits, and which will tip the balance for it one way or the other."

Id. at 4. Accord Doe v. Hyland Therapeutics Division, 807 F. Supp. 1117, 1129 (S.D.N.Y. 1992) ("[t]he forum whose market consumes the product must make its own determination as to the levels of safety and care required").

Quite a few years later, in multidistrict litigation, the same court that decided Hurt agreed – although, oddly, without even citing Hurt. Plaintiffs could not use a foreign regulatory decision, this time involving labeling, to create a triable issue about the adequacy of a U.S. drug's label:

"Plaintiffs also allege that the warning label for [the drug's] European equivalent contains more detailed instructions for the treating physician. Citing no authority, Plaintiffs argue that the difference in instructions creates a triable issue of fact. We disagree. American regulators have different priorities and deal with often more diverse populations than their European counterparts. . . . Plaintiffs have failed to make a showing of inadequacy such that a reasonable jury could find for the nonmoving party."

Meridia Products Liability Litigation v. Abbott Laboratories, 447 F.3d 861, 867 (6th Cir. 2006). That's a weird case name, by the way.

Those cases pretty well set the tone. In line with Tews, Deviner, Hurt, Katzenmeier, Harrison, and Meridia, foreign regulatory activity has mostly been declared off limits in prescription medical product liability litigation. In In re Vioxx Products Liability Litigation, 448 F. Supp.2d 741 (E.D. La. 2006), the

court essentially duplicated the Harrison decision throwing out foreign plaintiffs suing over foreign drugs taken in foreign countries. Foreign drugs are rightly subject only to foreign regulatory schemes:

"[T]he governments of [plaintiffs' home countries] approved and regulated the sale of [the drug] in those countries. . . . [T]rying the Plaintiffs' claims in the United States risks disrupting the judgments of [those countries'] regulatory bodies. . . . When a regulated industry, such as the pharmaceutical industry, is involved in an action, the country where the injury occurs has a particularly strong interest in the litigation. An American jury would also have no good means of evaluating whether a given foreign label or marketing scheme was adequate."

Id. at 748 (as always, various citations and quotation marks omitted).

In Jones v. Lederle Laboratories, 785 F. Supp. 112327 (E.D.N.Y. 1992), aff'd, 982 F.2d 63 (2d Cir. 1992), the court applied the same principle to a design defect case, holding as a matter of law that a differently designed vaccine – approved in Japan but not in the United States – could not, qualify as an "alternative design":

"The case illustrates some of the strengths and weaknesses of the American system for marketing drugs. Requiring strict proof of safety – both to comply with FDA regulations and to avoid tort liability – slows the availability of new products. The result may well be that dangers will be enhanced during the necessarily extended developmental period. . . .

The evidence is essentially uncontested that defendant could not have produced and marketed the safer [Japanese] vaccine that plaintiff's experts say would have avoided [plaintiff's] injuries. Once this conclusion is reached, there is nothing left to the case. The warnings were adequate. The production was not defective – it was in accordance with the design. No safer alternative design was available. . . . No basis for liability has been shown."
Id. at 1127.

The issue of foreign regulation most frequently comes up – as in Tews, Deviner, and Hurt – in the context of what evidence is relevant and admissible at trial. As we mentioned in our first post on the subject, the court excluded foreign regulatory activity in In re Baycol Products Litigation, 532 F. Supp.2d 1029 (D. Minn. 2007). Allowing experts to rely on inapposite foreign law would only confuse the issues:

"[T]he Court finds that allowing the admission of evidence of foreign regulatory actions, in a case that is governed by domestic law, would likely cause jury confusion. Given that notice is not dependent on governmental action, and to avoid jury confusion, the Court finds [expert] testimony concerning foreign regulatory actions must be excluded."
Id. at 1054.

We litigated the issue ourselves – and thus became intimately familiar with it – in the Seroquel litigation. In In re Seroquel Products Liability Litigation, 2009 WL 223140 (Mag. M.D. Fla. Jan. 30, 2009), the magistrate concluded that evidence of foreign regulatory non-approval was inadmissible:

"The foreign [drug] labels and the foreign regulatory actions have no relevance to Plaintiffs' main case. More importantly, whatever minimal relevance the foreign regulatory actions might have is clearly overwhelmed by the likelihood of jury confusion. . . . Plaintiffs' approach of allowing the evidence of foreign regulations and dispositions as to [the drug] – which the Court views as akin to evidence of foreign legal standards – even with Plaintiffs' proposed limiting instruction, will not alleviate the risk of jury confusion."

Id. at *5-6. The court adopted the magistrate's conclusion in In re Seroquel Products Liability Litigation, 601 F .Supp.2d 1313 (M.D. Fla. 2009), holding that even if foreign regulatory actions could be relevant to notice, they were prejudicial and inordinately time consuming. Without the necessary "context" the jury might be tempted to "defer to the negative decisions of . . . foreign regulators" concerning the drug. Id. at 1318. But providing the necessary context was, comparatively speaking, a waste of time:

"[A]llowing [defendant] to introduce this evidence would result in a series of "mini-trials" regarding the grounds for the decisions and the regulatory schemes of the three foreign countries involved. This would confuse the jury and waste everyone's time."

Id. A jury instruction would neither prevent waste of time nor alleviate potential prejudice. Id. See In re Trasylol Products Liability Litigation, 709 F. Supp.2d 1323, 1336 (S.D. Fla. 2010) (agreeing with Seroquel about foreign regulations, but excluding expert altogether for various additional reasons).

The same result was reached in In re Viagra Products Liability Litigation, 658 F. Supp.2d 950 (D. Minn. 2009). Relying on the Baycol decision, the court held that the plaintiffs' expert's proposed testimony about foreign regulatory conclusions was both irrelevant and confusing:

"The Court finds that any discussion of foreign regulatory actions is irrelevant to the current litigation and should therefore be excluded . . . . Further, the Court finds that to the extent that foreign regulatory information is relevant, its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury."

658 F. Supp.2d at 965-66.

Likewise, in Zammit v. Shire US, Inc., 415 F. Supp. 2d 760 (E.D. Mich. 2006), the court refused to allow an expert to opine on the basis of Canadian regulatory actions. Only the FDA's actions had any relevance in a case involving an American plaintiff taking an FDA-approved drug:

"The evidentiary value of these [Canadian] submissions is quite limited, however. . . . [O]nly the FDA approval process has any legal significance, and it is simply irrelevant whether some other government might have declined to authorize the sale of a drug in some other country, or whether the manufacturer's submission seeking such approval might have been deemed insufficient in some respect."

Id. at 767 n.6.

There's also Hogan v. Novartis Pharmaceuticals Corp., 2011 WL 1533467, at *13 (E.D.N.Y. April 23, 2011), where the court recently stated, while nonetheless denying a poorly supported in limine motion (suggestion for defense counsel – don't file crappy motions), "I do not see the relevance of foreign regulatory actions and materials." And in In re Rezulin Products Liability Litigation, 309 F. Supp.2d 531 (S.D.N.Y. 2004), the court recognized but dodged the issue – and was content to find the plaintiffs' experts incompetent on the subject of foreign law. Id. at 553. Finally, state trial courts have also excluded foreign regulatory matters. In re Vioxx Cases, 2007 WL 6652327, at part X (Cal. Super. June 1, 2007); Colangelo v. Novartis Pharmaceuticals Corp., 2002 WL 32153354, at *4 ¶3 (Ill. Cir. Dec. 17, 2002).

For the sake of completeness, there are a couple of negative cases that we know of. One is the execrable Gadolinium decision that we previously criticized here. The court didn't cite a thing – certainly not the Sixth Circuit's decisions in Meridia and Hurt – in deciding that unspecified "foreign regulatory events" "may be admissible and relied upon by" a plaintiff's expert, even though the expert was "not qualified to testify as an expert on foreign regulatory law." In re Gadolinium-Based Contrast Agents Products Liability Litigation, 2010 WL 1796334, at *17 (N.D. Ohio May 4, 2010). The other bad

decision is In re Levaquin Products Liability Litigation, 2010 WL 4676973 (D. Minn. Nov. 9, 2010), which allowed evidence of foreign regulatory matters upon finding them too "preliminary" for there to be a risk that the jury would be unduly influenced. Id. at *5. Say what? If they're so preliminary that a jury would ignore them, then they're correspondingly less probative, and have no business ever being placed before a jury in the first place.

Thus, to this degree we agree with American exceptionalism in the courts – where prescription medical products are governed by the FDA's regulatory scheme, that foreign regulators have come to differing, disparate results is not only irrelevant, but prejudicial and confusing as well, at least where the plaintiff is suing over a drug that was prescribed in this country.