Reducing Frivolous Litigation

Affidavits of Merit in Medical Device Litigation

By Michael R. McDonald, Kim M. Catullo and Michelle M. Bufano

Part Two of a Two-Part Article

In the first installment of this article, published last month, we discussed the problem of frivolous lawsuits against drug and medical device firms and how state legislatures have been moving to curb frivolous suits in another arena — professional negligence — through the introduction of a requirement for an affidavit of merit. This month, we look at how the lessons learned in the case of professional negligence suits could be applied to reduce the filing of unfounded complaints against drug and medical device makers.

Should Affidavits of Merit Be Required in Drug and Medical Device Litigation?

While the primary purpose of professional negligence affidavit-of-merit statutes is to reduce frivolous professional liability lawsuits, professional negligence suits are not the only actions prone to abuse. Frivolous litigation is also rampant in pharmaceutical and medical device mass tort litigations. See Damiani DJ: Proposals for Tort Reform in the Evaluation of Expert Testimony in Pharmaceutical Mass Tort Cases. 13 Alb. L.J. Sci. & Tech. 517, 518-519 (2003). Accordingly, if affidavit-of-merit statutes can successfully reduce frivolous professional liability actions, similar statutes should also successfully reduce frivolous pharmaceutical and medical device actions. In either type of litigation, affidavit-of-merit statutes require both the plaintiff and the attorney to invest time prior to or at the onset of the litigation (instead of years later) and make a frank determination regarding the merits of the suit. All parties, and society as a whole, benefit from limiting litigation to meritorious claims. In particular, permitting only meritorious actions to proceed would lower prescription prices for the public, since the cost of frivolous litigation costs would no longer be passed along to the consumer.

Despite the obvious need for affidavit-of-merit laws in pharmaceutical and medical device cases, based on policy concerns identical to those in professional negligence cases, there has as yet been no groundswell to universally enact such legislation. Illinois, for example, did at one time have this type of legislation in effect, which applied broadly to all products liability actions. The Illinois statute required an attorney certification to be filed simultaneously with the initial pleading identifying the specific defect in the product and stating that the specific product defect caused the injury at issue. See 735 Ill. Comp. Stat. Ann. 5/2-623. In 1997, however, the Supreme Court of Illinois found other parts of the Illinois Civil Justice Reform Act of 1995 (of which the affidavit-of-merit statute was a part) unconstitutional on the grounds that parts of the statute unrelated to the affidavit-of-merit provisions constituted “special legislation” and violated the equal protection clause of the state constitution. See generally Best v. Taylor Mach. Works, 689 N.E.2d 1077 (Ill. 1997).

What’s Standing in the Way?

There are several possible explanations for the lack of affidavit-of-merit statutes applicable to drug and medical devices. First, the differences between the elements of a professional negligence case and a products liability action might arguably make affidavit of merit requirements in products liability actions more difficult to satisfy. In professional negligence cases, an affidavit of merit traditionally addresses only the breach of the standard of care: There is no requirement that there be an initial demonstration that the breach of standard of care was the cause of the plaintiff’s injury. Conversely, in order to have any true impact on reducing frivolous litigation, an initial expert pleading in a products liability case would necessarily focus on the issue of causation, which is a much more complex and subjective finding to make.
Although such a concern has merit, an identical argument can be made at the expert discovery phase of the litigation. Thus, this argument is not unique to preliminary expert pleadings and doesn’t justify disregarding an affidavit of merit requirement in products liability cases. A compromise position might be a requirement of an affidavit of merit certifying only as to product defect, not as to causation. This compromise, although it may have some effect, is not as critical as the causation requirement, which would effectively eliminate lawsuits brought by plaintiffs that are not even injured.

Additionally, it can be argued that affidavit-of-merit statutes are unconstitutional violations of the equal protection clause in that the statutory standards would treat drug and medical device plaintiffs differently from plaintiffs in other litigations. At least in the medical malpractice context, however, even the Illinois Supreme Court has found that affidavit-of-merit statutes are not unconstitutional on equal protection grounds because such statutes are rationally related to a legitimate governmental interest in reducing frivolous actions and, therefore, do not violate equal protection principles. See DeLuna v. St. Elizabeth’s Hosp., 588 N.E.2d 1139, 1146 (Ill. 1992).

WHY WE NEED AN AFFIDAVIT OF MERIT REQUIREMENT

Just last year, The New York Times reported that mass tort litigation against drug and medical device companies was at an all time high with no end in sight. See generally Berenson, A: Trial Lawyers Are Now Focusing on Lawsuits Against Drug Makers, N.Y. Times, May 18, 2003, at 1. An undeniable force driving mass tort litigation is the desire to amass as many cases as possible with little regard for the merits of the individual cases. As the In re: Phenylpropanolamine (PPA) Litigation, MDL No. 1407, has illustrated, once plaintiffs are forced to prove causation and are unable to do so, the mass tort momentum is halted. Since the In re Phenylpropanolamine court’s ruling a year ago that plaintiffs’ experts had failed to demonstrate a causal link between cardiac injuries, as well as seizures and psychoses occurring more than 3 days after ingestion of PPA-containing products, several hundred cases have been dismissed either voluntarily or on the merits in connection with related summary judgment motions. See generally, www.wawd.uscourts.gov/wawd/mlnl.nsf/main/page.

Lack of causation is often the glaring weakness in drug and medical device actions. Thus, it would only make sense that any key tort reform measure in the drug and medical device context would be aimed at a prima facie showing of causation at the inception of the litigation. Affidavits of merit in complex products liability cases, such as drug and medical device litigations, would serve to greatly reduce frivolous litigation. Such a requirement in the drug and medical device context would force plaintiffs to spend time thinking through the merits of their cases at the case’s inception to explore whether or not there is a causal link. The result would be that only arguably meritorious cases would proceed to litigation. Given that litigation costs often drive up the price of prescriptions, a decrease in frivolous drug and medical device litigation would greatly benefit the public.

This article is reprinted with permission from the September 2004 edition of the LJN-PHARMACEUTICAL & MEDICAL DEVICES LAW BULLETIN © 2004 ALM Properties, Inc. All rights reserved. Further duplication without permission is prohibited.