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Oversize Drug Packaging Suits Are A 'Waste' For Plaintiffs

Law360, New York (March 10, 2016, 10:48 AM ET) --
This year, congressional scrutiny — and bouts of public outrage — have been aimed squarely at the pricing practices of some in the pharmaceutical industry. Never wont to let public attention go unexploited, the plaintiff's bar has seized on these concerns to launch salvo after salvo of litigation, claiming everything from deceptive pricing tactics to patent manipulation to antitrust violations. Often, these attacks have been propped up by unsupported science and misleading expert opinion.


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A new study published on March 1, 2016, in the peer-reviewed British Medical Journal (BMJ) will do little to quell outrage and return regulator focus back to sound science. The study, "Overspending Driven by Oversized Single Dose Vials of Cancer Drugs," purports to find that infused prescription drug manufacturers are improperly packaging larger quantities of drugs than are needed into each vial, leading to higher than necessary patient costs and waste.[1] The study reports that "waste" allegedly occurs when oncology drugs are sold in "single dose packages" and dosing is based on patients' weight or body size.[2] Because an individual patient's body size may not exactly match the amount of drug included in the vial, there may be some leftover medicine, which may be discarded.[3] Examining sales data for 20 of the top-selling cancer drugs, the authors estimate that more than $1.8 billion of drug company revenue comes from the quantity of these drugs that ultimately goes unused.[4] They claim another $1 billion in markups is added by doctors and hospitals on this unused portion.[5]

The authors allege that this "waste" makes it possible for prescription drug companies to "artificially increase the amount of drug they sell per treated patient."[6] Although the study focused on cancer drugs, the authors state that they believe the problem of mismatched single-dose vials and doses "is not unique" to cancer therapy, but also affects pricing of other high-cost medications for treatment of illnesses such as asthma and rheumatoid arthritis.[7] The authors recommend that regulators explore requiring drug manufacturers to "provide drugs in a reasonable set of size options to ensure the amount of wasted drug is low" or to require manufacturers "to refund the cost of leftover drugs."[8] They also recommend that policy makers "revisit the current U.S. Food and Drug Administration guidance on the appropriate packaging of infused drugs in single dose vials."[9] The news media has been quick to seize on this report, with

articles appearing in The New York Times and The Washington Post, among others.

An Obvious Problem With This Analysis

Despite its sweeping conclusions, the study relies on a flawed premise. To determine “waste,” the authors calculated what percentage of the single-use vial is administered on average to each patient and what percentage is discarded.[10] The authors then looked at the estimated annual sales data for each of these drugs and “apportioned” a percentage of those sales to the “wasted” drugs — essentially just multiplying annual sales revenue by an estimate of the average percentage of unused drugs.[11] The study fails, however, to provide any support for the authors’ implicit suggestion that pricing of prescription drugs is linear to dosing — i.e., that decreasing the dosing volume by a certain percentage would result in a proportional cost savings to patients.

Setting aside other potential methodological shortcomings, the study’s reliance on this unsupported assumption renders its results questionable. There is no requirement that pharmaceutical manufacturers price their products in exact proportion to the volume in the bottle. And there are various important reasons that manufacturers offer some extra volume of medication in their dosing options. Moreover, in setting prices for their products, drug manufacturers take into account all of the expenditures that go into bringing products to market, not just the marginal cost of producing another milliliter of medicine. For example, inherent in bringing a prescription medicine to market are vast research, development and regulatory expenditures. Recent economic studies have conservatively estimated that the fully capitalized cost of bringing a new medicine to market is approximately $800 million.[12]

Regulatory Hurdles Mandate Preemption

What’s more, the study ignores the difficult regulatory hurdles and significant costs involved in such a change. It is for exactly this reason that a court dismissed a putative class action raising similar claims of deception through “drug waste.” Thompson v. Allergan USA Inc., 993 F. Supp. 2d 1007, 1014 (E.D. Mo. 2014).

In Thompson, the plaintiff brought a consumer fraud class action alleging that the pharmaceutical manufacturer was engaging in "overfilling" by putting more than a single dose of medication in single-use vials.[13] The class claimed it was paying too much because it was being forced to buy more medicine than needed for treatment.[14] The court dismissed the case, finding that the FDA approved the drug exactly as it was being sold, in a single-use vial with an approved volume of medicine. The court noted that the FDA had found that the additional unadministered volume of the drug helped ensure proper dosing and promoted “product stability.”[15] And a dosage change would be a "major change" to the product that required prior FDA approval.[16] The court held, "[I]f defendants were unable, under federal law, to independently lower the volume in each vial of [their drug] to be in compliance with the state duties alleged by the plaintiff, the plaintiff’s state claims would be preempted. ... The court concludes that reducing the amount of medicine in each ... vial is a major change requiring prior FDA approval.”[17] The result: the plaintiff’s claims were preempted based on the U.S. Supreme Court’s decisions in PLIVA Inc. v. Mensing, 131 S. Ct. 2567 (2011) and Mutual Pharmaceutical Co. v. Bartlett, 133 S. Ct. 2466 (2013).[18]

The court in Thompson recognized that “waste” may not always be what it seems. The FDA gives careful thought and consideration to the drugs it approves and regulates. Unused product may be there for a variety of reasons — promoting product stability, aiding efficient dosing or even assisting in simplifying

hospital inventory complexity. Moreover, drug packaging is a complex area in which patient safety is always the primary concern. The FDA may require expensive clinical trials before approving the varying doses suggested in the article, eliminating any purported cost savings. And the design and regulatory considerations associated with these issues will continue to fall to FDA and prescription drug manufacturers — and not those who seek to exploit the issue in the popular press, basing their attacks on faulty assumptions.

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DISCLAIMER: Shook Hardy & Bacon LLP represented Allergan in the Thompson litigation.

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[1] Peter B. Bach, et al., Overspending Driven by Oversized Single Dose Vials of Cancer Drugs, BMJ 2016;352:i788.

[2] Id.

[3] Id.

[4] Id. at *1-2.

[5] Id. at *2.

[6] Id. at *1.

[7] Id. at *2

[8] Id. at *2-3

[9] Id.

[10] Id.

[11] Id.

[12] See DiMasi, Joseph A., Ronald W. Hansen, and Henry G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," Journal of Health Economics (2003), 22:151-185.

[13] Thompson, 993 F. Supp. at 1009.

[14] Id. at 1009-10.

[15] Id. at 1010.

[16] Id. at 1013-14.

[17] Id.

[18] Id.

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