THE DEBATE CONTINUES

Out of Context: Out of Trust

In the interest of accurate public information and patient safety, I am responding to the carefully-worded release to *FindLaw/Legal News* (April 16, 2009) by The Containment Technologies Group, Inc., which clearly implies that the recent dismissal of their ill-fated Defamation claim against the American Journal of Health-System Pharmacy (AJHP), myself, and my co-authors was merely a legal technicality, rather than the unqualified failure articulated by Chief Judge David F. Hamilton, 7th U. S. District Court.

HISTORY: On March 15, 2007, Marghi R. McKeon, William T. Weiss, and I joined in the publication of an objective study in the AJHP entitled "Potential for Airborne Contamination in Turbulent and Unidirectional-Airflow Compounding Aseptic Isolators." The outcomes of our study were highly unfavorable to the turbulent airflow MIC4 compounding aseptic isolator (CAI) CTG produces, as compared to four, other CAI's incorporating unidirectional airflow technology.

This study was systematically based on realistic, scientifically-sound testing protocols derived from actual sterile compounding challenges; relevant tests encompassing those challenges; and reasonable conclusions drawn from the test results. The study was extensively reviewed and recommended for publication by four expert peer-reviewers, and by the Director, Division of Manufacturing and Product Quality, FDA.

PEER REVIEW OUTCOMES: In Judge Hamilton's words: "The responses from the peer reviewers were **powerful and positive**." (Emphasis added) p. 29[1]. "The four reviewers all acknowledged the significance of the manuscript. Reviewer 1 called it 'a critically needed article to educate pharmacists and technicians on the performance attributes of isolators.' Reviewer 2 wrote that the article 'should be a very high priority paper for publication.' Reviewer 3 wrote that the article 'covers a very important topic and I believe is critically important work . . . This needs to get out to the pharmacy community.' Reviewer 4 wrote that the article 'is a badly needed piece of information'" p. 9.

CTG's INARGUABLE POSITION: Notably, to any extent that our test protocols might have been considered inconclusive, it was a result of CTG's absolute refusal to provide an MIC4 unit for testing; to otherwise cooperate in the study, or allow any in-depth analysis. Amazingly, having refused to provide its unit or protocols for evaluation, CTG then claimed that the study was: a) invalid because of our failure to use the CTG protocols, and b) motivated by malice. In the decision, His Honor's admonishment underscored the manifest absurdity inherent in CTG's argument in the following excerpts:

"In effect, Containment Tech argues that any testing done without its permission is invalid and cannot be published without the risk of litigation. And Containment Tech refused to provide those protocols to the authors! It could not first refuse to provide the protocols and then sue because the researchers did not use them . . . **To hold otherwise would give parties with a financial interest a stranglehold on scientific study.**" [emphasis added] p. 31.

It was also noteworthy to Justice Hamilton that CTG was given yet a second opportunity to review and contest the study results, in strict confidence, after the initial draft was accepted by AJHP, and prior to publication. Again, the Judge emphasized that:

"Even more damaging to Containment Tech's claim is the authors' attempt to receive feedback after the initial draft was accepted for publication. At that point, all plaintiffs' Rahe had to do was guarantee confidentiality. Containment Tech then would have been free to comment on the study as it deemed necessary p. 35. Crucially, Containment Tech refused even to review the article or to highlight the alleged deficiencies it now sets out before the court." [Emphasis added] p. 32.

OUT OF CONTEXT: By parsing portions of the Judge's statements in its *FindLaw* release, CTG hinted that the Court inferred and acknowledged bad science or flawed methods and conclusions on our part. In fact, quite the opposite is true: The Court emphasized that the fundamental legal pre-condition for our summary judgment required the Court to essentially theorize all factual issues in CTG's favor. However, this was not a true factual conclusion, but a only legal process, requiring the Court to "view all the evidence in the record in the light most favorable to CTG [sic]". For our request for summary judgment to be granted, the Court needed to conclude that "no rational fact-finder could decide in favor of (CTG)." p. 18.

OUT OF TRUST: The Court fulfilled this pre-condition, but did not in any manner arrive at the factual conclusion implied by CTG in its release. To the contrary: The Court only *theorized* that even *if* the publication had been based on "Bad, but honest science ...[7]", it still would not be actionable as defamation. Moreover, to ensure that no reasonable onlooker would come to the perverse conclusion implicit in the release by CTG, the Court hastened to add the following footnote to that statement, omitted by CTG in the release:

"[7]**The Court is not suggesting the science was actually bad or that the conclusions were false**. For the purposes of summary judgment, however, the court (in viewing all the evidence in the light most favorable to CTG) must assume that the methods and conclusions were flawed, as plaintiff's expert witness Madsen testified." [Emphasis added] p. 34.

Then, to the extent that the Court addressed the merits of Madsen, the plaintiff's expert witness, Justice Hamilton had this to say:

"Four separate peer reviewers found the authors' methods appropriate and their conclusions valid. Additionally, Weiss consulted three co-workers at the Mayo Clinic who supported publication. Weiss Decl. Three peer reviewers found their alcohol drying time study appropriate. The article has been published in a widely read journal and had received (as of the time of depositions) no negative feedback. Madsen's affidavit shows at most that others in the field can disagree with the conclusions, but Containment Tech would be better served to turn those findings into a rebuttal piece and let the scientific community make its own determination on the merits." p. 31.

PUNITIVE MEASURES FOR AN UNJUSTIFIED LAWSUIT: Also, in its release, CTG implies that Indiana's Anti-SLAPP statute provided some form of technical escape from the otherwise normal consequences of our publication. However, Judge Hamilton decried that disguised assertion as well, stating: "Substantively, the Act does not replace the Indiana common law of defamation but provides simply that the (defendants) must establish that the (alleged defamatory statement) was lawful." p. 17. In other words, to the extent that the statute alters the common law, it was to place an additional legal burden on us, the defendants. The Anti-SLAPP statute is also a statutory defense that provides the financial relief of attorney's fees to the victorious parties in an unjustified defamation suit; in this case, the AJHP, myself, and my colleagues. In the Judge's opinion, this clearly was such a suit.

THE COURT'S MANDATE: The torturous progress of this litigation to our ultimate vindication must not be undermined by the parsed, and, therefore, misleading response of CTG. The Court clearly reinforced the significance of our shared interest in robust discussion and open debate without the specter of expensive and frivolous litigation. As Justice Hamilton's final pronouncement so aptly stated: "Quite simply, this battle should take place in the pages of the ASHP journal and similar publications, not in a court." p. 40. I therefore encourage and invite CTG to heed this mandate and engage in a more productive dialogue than one it has so inappropriately positioned in our legal system.

In his decision, Judge Hamilton's grave and unmistakable pronouncement was that "**Containment Tech must live with the consequences of this study**." (Emphasis added.) p. 31. If CTG intends to continue to argue the merits of its product, it should do so within the pages of this esteemed journal, and it should rely solely on scientific argument and successfully peer-reviewed studies, rather than a misdirected attempt to manipulate the clear conclusion of The Chief Justice's well-considered decision—The decision that neither I, my colleagues, nor the AJHP have done anything other than to produce clear, credible evidence of our scientifically defensible, but unfavorable opinion of CTG's product.

Gregory F. Peters
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1 Page numbers refer to the decision of Justice Hamilton, signed March 26, 2009, U. S. Federal Court File No. 1:07-cv-0997-DFH-TAB. The unabridged, 42-page decision is available directly from the Court's internet facility, at:
http://www.insd.uscourts.gov/Opinions/AQ9970O2.pdf

Containment Technologies Group Announces Results of Legal Action

INDIANAPOLIS, April 16 /PRNewswire/ — Containment Technologies Group, Inc. received a ruling from a federal judge in a lawsuit against The American Society of Health-System Pharmacists, Gregory F. Peters, Marghi R. McKeon and William T. Weiss relating to an article entitled Potential for Airborne Contamination in Turbulent and Unidirectional-Airflow Compounding Aseptic Isolators, which was published in March 15, 2007 issue of the American Journal of Health-System Pharmacy. The court ruled that, under Indiana law, defamation actions based on speech about matters of public concern require proof of "actual malice" - either knowledge of actual falsity or reckless indifference to truth or falsity. The court acknowledged that "whether or not Peters did legitimate work, ASHP is protected under an actual malice standard..."

The court ruled in favor of the defendants based on the Indiana Anti-SLAPP statute and concluded that individuals are free to express opinion under the First Amendment right of free speech. The court also noted that "Bad but honest science is not actionable as defamation" and "for purposes of summary judgment, however, the court must assume that the methods and conclusions were flawed..."

Containment Technologies Group, Inc., filed the lawsuit on June 22, 2007, is disappointed in the ruling, and is reviewing its options, which include appealing the decision to the 7th Circuit Court of Appeals.

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