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RICO class actions: To win certification, the RICO claims must be driven by defendant-specific and not class-member specific evidence; otherwise, individualized issues predominate.

by Jay Bogan

Takeaway: RICO actions tend to be complex. RICO class actions add to the complexity, because class counsel must figure out a way to persuade a court that common issues predominate over individual ones. This is a challenge, because fraud-based RICO claims (the most common type of RICO claim) usually raise individualized issues of exposure to and reliance on an alleged scheme to defraud. These factors played out in *In re: Testosterone Replacement Therapy Products Liability Litigation*, MDL No. 2545, Case Nos. 14 C 1748, 14 C 8857, 2018 WL 3586182 (N.D. Ill., July 26, 2018), where the district court concluded that individualized issues predominated, because the evidence going to the key issues of exposure to and reliance on the alleged fraud – the evidence critical to a showing of RICO proximate cause – required class-member by class-member proof.

In that case – an MDL proceeding consolidated in federal court in the Northern District of Illinois – thousands of individuals asserted personal injury claims against a number of defendants, consisting of manufacturers, promoters, and sellers of testosterone replacement therapy (TRT) drugs. The individual plaintiffs claimed that use of TRT drugs caused serious personal injuries, such as "cardiovascular and venous thromboembolic injuries." *Id*. at *1. One of the plaintiffs in the MDL, however, was Medical Mutual of Ohio (MMO), a third-party payor (TPP) seeking to represent a class of TPPs. MMO claimed that the TPPs suffered financial harm as the result of the defendants' fraudulent marketing schemes, by reimbursing medically unnecessary or even harmful TRT prescriptions.

After various motions to dismiss were resolved, MMO's remaining claims consisted of one substantive RICO count (under 18 U.S.C. § 1962(c)), one RICO conspiracy count, and one count for negligent misrepresentation under Ohio law. MMO then moved to certify a nationwide class of TPPs and a subclass of Ohio TPPs.

In support of it RICO and negligent misrepresentation claims, MMO alleged that the Food and Drug Administration (FDA) only approved TRT drugs for the treatment of "classical hypogonadism," a relatively rare condition. Defendants, however, marketed the drugs for various "off-label" purposes, such as for erectile dysfunction, diabetes, AIDS, cancer, depression, and obesity. According to MMO, defendants' marketing scheme promoted the awareness of – and TRT drug prescriptions for – a disease that did not actually exist, called "Andropause" or "Low T."

Accordingly to MMO, there was “no competent medical evidence” showing that TRT drugs were appropriate to treat “Low T” or any other “off-label” condition or symptom. Indeed, TRT drugs posed safety risks, especially for older men (in 2014, the FDA published a drug safety communication announcing its investigation of cardiovascular risks to men posed by TRT drugs; in 2015, the FDA required label changes to TRT drugs). But the defendants’ marketing campaign nevertheless resulted in an “astronomical spike” in TRT drug prescriptions and sales, causing economic harm to TPPs such as MMO.

In support of its motion for class certification, MMO argued (among other things) that it was an adequate class representative and that common issues predominated over individualized issues. But the district court rejected these arguments.

In terms of MMO’s adequacy as a class representative, the district court ruled that “MMO is particularly vulnerable to defenses regarding its claims of reliance and injury.” *Id*. at *14. That was because “MMO did not implement a prior authorization requirement for topical TRTs until nearly four years after it alleges it first received notice of defendants’ alleged fraud.” *Id*. In contrast, defendants’ expert “presented evidence tending to suggest that at least some TPPs and PBMs [pharmacy benefit managers] monitored their formularies and prior authorization policies during the class period more vigilantly than MMO did.” *Id*. at *15. The district court further ruled that MMO engaged in “unconventional pharmacy management practices,” such as by not reviewing clinical information on an annual basis, and that such unconventional practices “could hinder [MMO’s] ability to prove crucial elements of its case such as receipt of and reliance on defendants’ alleged misrepresentations.” *Id*. Accordingly, the district court ruled that MMO could not adequately represent the TPP classes.

To assess whether individualized issues predominated over common ones, the district court identified both the individual and common issues presented by the evidence. The individualized issues included (1) TPP’s exposure to the alleged misrepresentations and (2) TPP’s reliance on the alleged misrepresentations.

Regarding exposure to the alleged misrepresentations, the district court analyzed the evidence, finding that there was no indication that “standardized” misrepresentations about TRT drugs were disseminated to the TPPs. While MMO suggested that declarations could be obtained from the putative class members about what misrepresentation were made to them, the court dismissed this suggestion, explaining: “sworn statements from class members regarding what they were told amounts to individualized, not common evidence.” *Id*. at *17. The court further rejected MMO’s reliance on select documents purporting to show common misrepresentations made to certain pharmacy benefit managers, ruling: “[h]aphazard evidence relevant only to certain PBMs, however, cannot serve as class-wide proof.” *Id*.

On the issue of reliance, the court observed that “[j]ust as MMO must prove that each of the thousands of putative class members received misrepresentations directly, MMO must also prove that each relied on the misrepresentations.” *Id*. at *18. Here, the court credited the evidence submitted by the class defendants “tending to show that TPPs’ formulary and utilization management decisions are complex and individualized.” *Id*. The court further found as “unpersuasive” authorities cited by MMO to the effect that RICO reliance may be presumed. The court concluded: “even assuming all TPPs received the same alleged misrepresentations, the question whether all TPPs based their formulary or utilization management decisions on the misrepresentations cannot be answered with common evidence.” *Id*. at *19.

The court did conclude that there were a number of common issues, because they all could be established through "defendant-specific" proof, as opposed to class-member specific proof. Those common issues included "whether (1) defendants' promotional materials were false and misleading; (2) defendants' alleged misrepresentations were material (for RICO purposes); (3) defendants knowingly or negligently made the alleged misrepresentations; and (4) defendants 'agree[d] to participate in an endeavor which, if completed, would constitute a violation of the substantive [RICO] statute.'" *Id*. at *20 (quoting *Goren v. New Vision Int'l, Inc.*, 156 F.3d 721, 732 (7th Cir. 1998)). In evaluating the common issues, the court noted (among other things) that "materiality for RICO purposes" could be established by common evidence "because the inquiry is an objective one." *Id*.

On balance, however, the individualized issues going to but-for and proximate causation for at least 10,000 TPP class members (exposure and reliance) predominated over the common issues. The court concluded: "Individualized issues are not just present in this case, but rather loom large." *Id*.