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<u>Second Circuit Rejects the Use of "Aggregate Proof" of Causation in a Putative</u> <u>Consumer Class Action</u>

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In <u>UFCW Local 1776 v. Eli Lilly & Co.</u>, No. 09-0222-CV, 2010 WL 3516183 (2d Cir. Sept. 10, 2010), the <u>United States Court of Appeals for the Second Circuit</u> reversed an order of the <u>United States District Court for the Eastern District of New York</u> certifying a class of third party payors ("TPPs") consisting of unions and insurers who underwrite the purchase of drugs prescribed by physicians in an action against pharmaceutical manufacturer Eli Lilly & Co. ("Lilly") alleging civil violations of the <u>Racketeer Influenced and Corrupt Organizations Act</u>, <u>18 U.S.C. §§ 1962</u>, <u>1964</u> ("RICO"). At the core of this decision is the Second Circuit's rejection of the use of "aggregate proof" of causation in the consumer class certification process.

In this case, the TPPs asserted, among other things, civil RICO violations based on Lilly's alleged misrepresentations about its drug Zyprexa®. Zyprexa® is a prescription medication that has been approved by the <u>United States Food & Drug Administration</u> for treatment of schizophrenia and bipolar disorder. However, Lilly actively promoted the use of Zyprexa® to treat less severe conditions, such as depression and anxiety, for which there is allegedly no evidence that Zyprexa® provides effective treatment. The TPPs alleged that Lilly engaged in mail and wire fraud by deliberately misrepresenting the drug's safety and efficacy to physicians, thereby conducting a racketeering enterprise in violation of RICO. A civil RICO claim requires a plaintiff to show (1) a substantive RICO violation; (2) injury to the plaintiff's business or property; and (3) that such injury was by reason of the substantive RICO violation.

Under the predominance requirement of <u>Federal Rule of Civil Procedure Rule 23(b)(3)</u>, the TPPs needed to show that substantial elements of their claim against Lilly may be established by generalized, rather than individualized, proof. To recover damages under RICO, a plaintiff must show (1) a substantive RICO violation; (2) injury to the plaintiff's business or property; and (3) that such injury was by reason of the substantive RICO violation. The TPPs theory of injury on class certification was that they had paid a higher price for Zyprexa® than they would have been charged absent these misrepresentations (the "loss-of-value" or "excess price" theory). The district court certified the TPPs class finding that the misrepresentations were "broadbased" and consequently that the requisite reliance could be proved by "aggregate proof." Lilly appealed the class certification order under Federal Rule 23(f).

The Second Circuit reversed, holding that the RICO claims could not be pursued by the TPPs as a class because a resolution of the issues was impossible to achieve through generalized proof as required by Rule 23(b)(3). In reversing the grant of class certification, the Second Circuit focused heavily on the issue of causation. It noted that to show injury by reason of a RICO violation, a plaintiff must demonstrate that the violation was the but-for *and* proximate cause of his or her injury. The Second Circuit concluded that the TPPs' "excess price" theory of injury was not susceptible to generalized proof with respect to either form of causation. The TPPs could not show but-for causation because doctors generally do not consider the price of a medication when prescribing pharmaceuticals. Thus, any reliance by doctors on Lilly's supposed misrepresentations could not be the but-for cause of the price that the TPPs ultimately paid for each prescription.

The Court cited its decision in *McLaughlin v. American Tobacco Co.*, 522 F.3d 215 (2d Cir. 2008), which dealt with alleged misrepresentations in the marketing of light cigarettes as healthier than full-flavored cigarettes. The putative plaintiff class in *McLaughlin* consisted of smokers who had bought the light cigarettes and had suffered the same ill health effects as if they had smoked the full-flavor ones. The Second Circuit held that reliance on a misrepresentation made as part of a nationwide marketing strategy "cannot be the subject of general proof." In arriving at this conclusion, the Court rejected application of a "fraud-on-the-market" presumption analogous to the presumption in securities fraud cases, explaining that the market for consumer goods is "anything but efficient" and that general reliance on public misrepresentations cannot be assumed when deciding whether to certify a class. Because prescribing doctors consider a number of factors, usually not including price, when prescribing a medication, the Court held that reliance upon Lilly's statements as to efficacy and side effects could not be presumed for each prescription and could therefore not be a but-for cause of the premium price paid by the TPPs.

The Second Circuit also rejected the TPPs' proximate cause theory. It held that, even assuming but-for causation, the causal chain between Lilly and the overpaying TPPs was unacceptably "attenuated" and could not be demonstrated by generalized proof. The TPPs' theory of liability "rested on the independent actions of third and even fourth parties" as physicians, pharmacy benefit managers and therapeutics committees all played a role in the chain between the Lilly and the TPPs. Assuming uniform reliance and behavior on the part of each of these assorted players would be assuming too much. The Court also stressed that the TPPs did not allege that they themselves had relied upon Lilly's misrepresentations, stating that "the only reliance that might show proximate causation with respect to price is reliance by the TPPs, not reliance by the doctors." The TPPs were in a position, after all, to negotiate the price paid for Zyprexa®. While most TPPs failed to negotiate Zyprexa®'s price, there is evidence that some did begin to request rebates as the side effects of Zyprexa® became more generally known. However, other TPPs, even after the alleged misrepresentations came to light, continued to pay full price. These varied responses, said the Second Circuit, made generalized proof of reliance by doctors inappropriate. Thus, proximate cause could not be shown through generalized proof. The Court remanded *Lilly* to the district court to reconsider a portion of its ruling denying Lilly's motion for summary judgment.

Further, the Second Circuit vacated the order denying Lilly's motion for summary judgment on

the merits. The TPPs' "excess price" theory was "too attenuated" to satisfy RICO's causation requirement. However, the TPPs' alternative theory (the "quantity effect" theory, which posited that improper promotion of off-label use for Zyprexa resulted in more off-label prescriptions for Zyprexa than would otherwise have been written) was "less attenuated" and, while it could not support class certification, this alternative theory could be viable for some individual TPPs or other purchasers. Because the District Court did not consider individual claims under the "quantity effect" theory, the case was remanded for possible further consideration of summary judgment.

The decision in *Lilly*, along with the decision in *McLaughlin*, demonstrates an unwillingness by the Second Circuit to allow "aggregate proof" of causation to facilitate class certification in consumer class actions. Further, although only mentioned explicitly in *McLaughlin* but not *Lilly*, both of these decisions demonstrate that the use of "aggregate proof" in class actions can distort the number of plaintiffs actually injured and/or the total amount of damages caused by the alleged wrongful conduct. This kind of disconnect offends the <u>Rules Enabling Act, 28 U.S.C. §</u> 2072(b), which provides that federal rules of procedure, such as Rule 23, cannot, be used to "abridge, enlarge, or modify any substantive right."