OCTOBER 31, 2024

# E.D.N.Y. deals blow to plaintiffs' claims – including mislabeling, false advertising and RICO claims – in multidistrict litigation concerning nasal decongestant phenylephrine

by James F. Bogan III

**Takeaway**: When it comes to mislabeling and related claims, and especially when human safety is not implicated, express preemption under the federal Food, Drug and Cosmetic Act (FDCA) remains a powerful tool in the hands of manufacturers and retailers of over the counter (OTC) drugs. In multidistrict litigation consolidated in the Eastern District of New York, Judge Cogan recently eviscerated the New York state claims alleged by the plaintiffs in a consolidated class action complaint. Judge Cogan also easily dispensed with the federal civil RICO claims alleged by those non-direct purchaser plaintiffs.

Since 1985, phenylephrine (PE) has been approved by the Food and Drug Administration (FDA) as a "safe and effective" nasal decongestant. More recent studies, however, questioned PE's efficacy. In 2023, the FDA's Nonprescription Drug Advisory Committee (NDAC) concluded that the scientific data did not show that PE was effective as a nasal decongestant. Nevertheless, a number of companies continued to manufacture, market, and sell PE OTC cough and cold medications.

Of course, litigation ensued. Various plaintiffs filed over 100 cases that were eventually consolidated in multidistrict litigation before the Eastern District of New York, alleging that the defendants knew PE was an ineffective decongestant but nevertheless continued to manufacture, market, and sell PE nasal decongestant products to consumers. *See In re: Oral Phenylephrine Marketing and Sales Practices Lit.*, 23-md-3089-BMC, 2024 WL 4606818 (E.D.N.Y. Oct. 29, 2024).

Under the direction of the MDL court, the plaintiffs filed an "Initial Streamlined Consolidated New York Bellwether Class Action" complaint, asserting various claims under New York law (including consumer protection and false advertising statutes, New York's U.C.C., and New York common law). They also alleged a federal civil RICO claim, based on alleged predicate acts of mail and wire fraud. As the district court noted, "[t]he parties agreed that plaintiffs would file this streamlined complaint, and defendants would move to dismiss it, to test claims and defenses common across the consolidated cases." *Id.* at *1. In their motion to dismiss, the defendants argued, among other things, that (1) plaintiffs' claims were preempted by the FDCA, and (2) plaintiffs did not have standing to assert a civil RICO claim. Judge Cogan granted the motion and dismissed the streamlined complaint.

The district court evaluated the legal framework of preemption, including the express preemption employed by the FDCA in the area of OTC drug labeling, as well as more specific federal OTC drug regulations. The court then proceeded to evaluate plaintiffs' mislabeling claims.

According to the district court, the PE labels were clearly not misleading: "whether a drug is 'effective' is

a term of art under the FDCA, and the statute empowers the FDA, not manufacturers, to make that determination. So, even taking plaintiffs' allegations as true, nothing on the labels was false or misleading – unless and until the FDA amends the monograph in response to the NDAC's findings, it is not misleading to state that PE is an effective nasal decongestant." *Id*. at *5 (citation omitted).

Further, nothing in the regulatory scheme "suggests that manufacturers have a freestanding duty to update their indications [of use on their product labels] in response to new scientific information." *Id*. at *4. In fact, if manufacturers did modify their labels in response to new scientific information, they would be transgressing what the FDA has promulgated they could disclose about PE on their product labels.

The district court's preemption analysis drew an important distinction between human safety-focused state law, on the one hand, and efficacy-focused state law, on the other. Plaintiffs' claims were efficacy-focused. They alleged "that defendants misled consumers by labelling their PE products as nasal decongestants despite knowing that PE was *no more than a placebo*, …" *Id*. at *3 (emphasis added). There was no allegation that PE was dangerous to human health. If human safety had been at issue, the FDA's regulatory scheme would have excepted state product liability claims from express preemption. But "whether a drug is effective remains within the exclusive purview of the FDA." *Id*. at *6. Accordingly, the court dismissed the mislabeling claims on the ground that they were expressly preempted by the FDCA.

The district court easily disposed of plaintiffs' remaining claims – for false advertising, false concealment and express warranty – on the same basis: because the defendants would have had to alter their product labels to escape liability on the remaining claims, those state law claims were likewise expressly preempted by the FDCA.

As for the federal RICO claim, Judge Cogan first had a thing to say about federal RICO claims generally: "Courts have described civil RICO as an unusually potent weapon – the litigation equivalent of a thermonuclear device. . . . The 'mere assertion of a RICO claim has an almost inevitable stigmatizing effect on those named as defendants,' yet 'plaintiffs wielding RICO almost always miss the mark.' Plaintiffs here are no exception." *Id*. at *7 (citations omitted).

He then found an easy way to jettison the RICO claim: because the plaintiffs were indirect purchasers of the PE products, they lacked standing to prosecute their civil RICO claims, under the direct-purchaser rule that applies both to antitrust and civil RICO claims.