## The Noose Tightens Around TPP Economic Loss Claims

Yesterday, the Eleventh Circuit affirmed dismissal – for failure to state a claim – of TPP economic loss claims in the Trasylol litigation. <u>See Southeast Laborers Health & Welfare Fund v. Bayer Corp.</u>, No. 10-13196, \_\_\_\_\_ Fed. Appx. \_\_\_\_, <u>slip op.</u> (11th Cir. Oct. 24, 2011). That's good news for our clients and bad news indeed for peddlers of bogus TPP claims.

The reason the TPP lost is quite simple. The TPP had a lot of theories, but no facts – specifically "no facts indicating how it would have independently evaluated Trasylol's medical appropriateness" aside from leaving the decisions to prescribing physicians (which the TPP disclaimed) or to the FDA (any attempt to challenge FDA approval was a preempted "fraud on the FDA" claim) or to the market (which without more, is barred under New Jersey law). <u>Slip op.</u> at 15.

The TPP tried New Jersey consumer protection law, the federal RICO statute, and New Jersey law of warranty – and lost on all three. <u>Strike three, you're out</u>.

The court spent most of its analysis on the New Jersey consumer protection claim, and largely applied the same conclusions to the remaining two claims. As to that claim, the court held:

(1) There's no presumption of reliance applicable to a New Jersey consumer protection claim. <u>Slip op.</u> at 9-10. New Jersey rejected fraud on the market <u>several years ago</u>. <u>Id.</u> at 10-11.

(2) Consumer fraud claims can't be based upon allegations "that absent the [defendant's] allegedly fraudulent conduct, a medication would not have been on the market." <u>Slip op.</u> at 12. That's a form of fraud on the FDA, and it's been preempted since <u>Buckman Co. v. Plaintiffs' Legal Committee</u>, 531 U.S. 341 (2001):

"A theory of causation relying solely on an allegation that the medication in question would not have been on the market absent the alleged fraudulent conduct is no more than a state law "fraud on the FDA" theory, a theory that has been specifically rejected by the Supreme Court."

## Slip op. at 13 (citing Buckman).

(3) A "medical necessity" claim must be accompanied by some allegations that the TPP actually would have conducted an separate review of such necessity"

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"On the facts alleged, the only causal nexus between the revelation of Trasylol's true risk profile and [plaintiff's] determination not to pay for Trasylol is merely a repackaged form of indirect causation – relying either on the FDA's approval decisions for Trasylol or a market capable of efficiently digesting the truth and relaying it to [plaintiff] in the form of a market price. Contrary to [plaintiff's] suggestion, either theory of causation is far from direct, and foreclosed by the relevant case law."

<u>Slip op.</u> at 15.

(4) There's no presumption of causation either. <u>Slip op.</u> at 17. It's almost pathetic how much TPP plaintiffs seek to displace real evidence with supposed "presumptions" (that don't exist).

The analysis of the RICO claim was failure to plead causation reprised, only this time phrased in terms of the indirectness analysis of our good friend, <u>Holmes v. Security Investor Protection Corp.</u>, 503 U.S. 258 (1992). <u>Slip op.</u> at 19-20.

The implied warranty claim saw the rejection of yet another unsupported presumption claim – this time with a holding that drugs were not "per se unmerchantable" simply because they are allegedly harmful. <u>Slip op.</u> at 22. The court saw it as something of a cheeky argument since no specific harm to anyone is alleged (why all TPP claims are bogus):

"[Plaintiff] does not allege that Trasylol failed to [work] or that it or any of its members were physically harmed by Trasylol. Moreover, Southeast has failed to identify any case law to support its theory that the potential of a drug to cause harmful side effects, in the abstract, renders a drug per se unmerchantable, even as to plaintiffs that did not suffer the side effects. Thus, the complaint does not allege that Trasylol is unfit for the ordinary purpose for which it was sold."

<u>Slip op.</u> at 23 (emphasis added). It is a good idea – if making an argument predicated on injury – that injury at least be alleged.

Anyway, we're running out of ways to say the TPP economic loss claims are meritless. So we'll leave it at that – they are.

Thanks to our friends at <u>Sidley</u> for sending this opinion along.