PATIENT SAFETY BLOG

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Tobacco Industry Manipulates Study Results

In the latest edition of “will they ever learn,” tobacco industry studies conclude that additives such as menthol do not make cigarettes more toxic.

Except, of course, they do.

As reported on MedPage Today, more objective researchers—who had to sue for access to the industry studies in question—concluded that the smoke of cigarettes with flavor and other additives was significantly more toxic and higher in total particulate matter than cigarettes made of plain tobacco.

Industry players reported their study results as neutral, thanks to changes they made to adjust away significance, the researchers wrote in the December issue of PLoS Medicine. But from a solid-science perspective, the industry’s protocols were wanting, and their results reporting was … selective.

"These findings show that the tobacco industry scientific research on the use of cigarette additives cannot be taken at face value," the PLoS editors concluded.

Such is the long history of big tobacco. Remember how it manipulated the scientific results on secondhand smoke?

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Manufacturers tinker with tobacco, adding ingredients to make smoke less irritating to the respiratory system or to make it taste better. Additives can affect bioavailability—the amount of drug that is absorbed from a given dose—and entice people to start smoking. And they can make it more difficult to stop.

In 2009, the FDA prohibited flavor additives except for menthol, despite concluding that "it is 'biologically plausible' that adding menthol to cigarettes makes them more addictive and harder to quit and that companies that sell menthol cigarettes target minorities and kids with their advertising."

Long before 2009, Philip Morris anticipated regulation of tobacco by the FDA, and embarked on research to influence any proposed regulation. The result was four "Project MIX" papers published in 2002. Big surprise: They concluded that there was no evidence of substantial toxicity from different combinations of 333 additives found in commercially available cigarettes.

The PloS researchers took issue not with how the data were collected, but how they were analyzed and interpreted.

The 51 constituents of smoke from the test and control cigarettes were subjectively chosen; missing from the analysis was certain carcinogenic compounds. And although levels of ammonia were assessed, those data weren't published either.

Originally, the studies were supposed to analyze the additives on a per-cigarette basis. But the published paper fudged the biological importance of this result by "normalizing" the toxin results by total particulate matter (TPM).

Such an adjustment showed that only 5 of 31 toxins increased with the additives; 15 showed decreases. But people smoke whole cigarettes. For a whole cigarette, 31 of 51 chemicals increased with at least one of the additive groups.

Other problems with the industry-manipulated report include the use of only nine rats per group, a short exposure period and equally insufficient follow-up period. That means researchers would be unlikely to observe side effects that take longer to present. And screening tests were used exclusively instead of more sensitive dose-response measures. That means you can't determine changes in potential harm with additives.

Without the ability to see tobacco industry study protocols and the raw data, as well as what it chooses to publish, the FDA is ill-equipped to make decisions about the complete danger of its products.

Sadly, consumers and patient advocates long ago learned that you can't underestimate the venality of the tobacco industry.

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