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# Center for Regulatory Effectiveness States that the FDA Tobacco Advisory Committee is in Violation of the Federal Advisory Committee Act

WASHINGTON, Sept. 7 /PRNewswire-USNewswire/ -- The Center for Regulatory Effectiveness, a regulatory watchdog managed by former White House Office of Management and Budget regulatory officials, has issued a scathing report on FDA non-compliance with the Federal Advisory Committee Act (FACA).

Central to CRE's arguments is the fact that FDA is dominating the advisory committee by controlling the production of key studies. CRE has called these illegal actions to the attention of FDA a number of times but FDA continues to act outside the law because they conclude that since the product in question is tobacco that the normal rules of fair play do not apply.

On September 27 FDA is to announce a Menthol Subcommittee which will review scientific studies dealing with menthol. CRE has expressed the concern that FDA will continue to work outside the law regarding the operation of this subcommittee. More specifically, FDA will write the report and submit it to the Menthol subcommittee for an up or down vote as it did for the Constituents subcommittee --clearly using a group of outside scientists as a ruse for its preconceived views on the science.

HHS has an office dedicated to the enforcement of FACA, why has it not acted? Feel free to contact the Advisory Committee Oversight and Management Staff (ACOMS), FDA at 301-796-8220 or the Center for Tobacco Products 240-276-1717

CRE understands that elements of the tobacco industry were supportive of FDA regulation of its products; as the old saying goes: "you had better be sure what you wish for - you may get it".

TPSAC is going to review every major regulation dealing with the tobacco industry for years to come. It is essential that it begin its operations on a sound footing, meaning compliance with FACA and the Data Quality Act - the former a statutory mandate for fairness in its governance and the latter a statutory mandate to utilize sound science.

See related articles including FDA Week

See an entire Interactive Public Docket dedicated to the FDA Tobacco Advisory Committee.

Express your views here or at the end of this post.

For additional information, call the Center for Regulatory Effectiveness at 202.265.2383 or email Jim Tozzi at tozzi@therecre.com

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