Like it or not, TPSAC is governed by the FACA statute.

Why does Congress mandate that “advisory” committees work and govern pursuant to the FACA statute?

We ask this question because it is not unusual for Congress to mandate FACA committees and agencies to oppose them.

Why?—because if FACA is adhered to both in spirit and to the letter of the law, it makes it difficult for agencies to railroad preconceived ideas into a rulemaking.

CRE concludes that TPSAC is violating the FACA statute.

We have outlined our concerns in considerable detail in correspondence to the FDA.

Why is CRE concerned? -- because we want FDA to take the necessary actions to come into compliance with FACA prior to announcing the menthol subcommittee.

What are the more serious violations of FACA by the FDA?

Balance

“Balance” means different things to different people.
There are, however, two elements of “balance” that I would like to address.

--- Federal Employees as Members

--- Scientific Background of Members

Federal Employees as Members

The TPSAC constituents subcommittee has nearly one federal employee on the committee for each non-federal employee.

Why is CRE concerned?—because where you sit is often where you stand

If the Secretary wants federal input she can request federal agency views without appointing them to an “advisory” committee, often viewed as a disinterested group of subject experts.

Is CRE concerned about the 50% level of feds? What about 25% or 10%.

CRE’s concern is why are there any federal employees on the constituents subcommittee?

I have been on FACA committee(s) for nearly two decades and I have never served with a federal employee.

EPA’s Science Advisory Board is similar to TPSAC in that it is a standing committee, formed in 1978, to provide scientific advice to the agency.

The SAB has six subcommittees, neither the parent committee or any of its six subcommittees have any federal employees.
What about the State Department’s Advisory Committee on International Economic Policy?

Some 60 members, not one federal employee

There should be no federal employees on TPSAC or its subcommittees

- nessuno
- ninguno
- aucun

Any language you say it in, it is “none”.

Now allow me to address another component of balance, scientific disciplines.

CRE sees the science issues related to menthol as:

1. Hard Science—toxicological studies dealing with well defined endpoints such as cancer.

2. Soft science—studies dealing with initiation and cessation.

In our view, the hard science issues are resolved, for example menthol does not cause cancer.

Regarding initiation and cessation, we have reviewed nearly fifty percent of the studies identified by FDA.
If you compare the robustness of the initiation/cessation studies with those in the hard science, in our opinion, there is no comparison; the toxicological studies win by a landslide.

This is not imply that the initiation/cessation studies are useless, but instead they are pointers and not determinative.

Accordingly, we recommend that the menthol subcommittee include a number of mathematical statisticians who have no prior experience in public health issues to review the initiation/cessation studies.