

**A Summary of the Statement by Jim Tozzi, Center for Regulatory Effectiveness  
before  
TPSAC August 30, 2010**

- 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.

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- 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.

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- 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.

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- 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.