?s
mission to investigate whether nicotine is an addictive comp
ound or whether
currently available conventional tobacco products are associ
ated with serious
risks to health. It is also not the committee?s mission to
recommend whether or
not tobacco harm reduction should be pursued in the United S
tates.

It is the committee?s mission to articulate a scientifi
c strategy for
assessing the safety and efficacy of long-term use of either
pharmacologic
products or modified tobacco products for tobacco harm reduc
tion, rather than
cessation. As such, we will provide a strategy for assessin
g whether the
product reduces exposure to harmful substances in tobacco, w
hether such
reduction is associated with reduced harm to health, and mea
ningful surrogate
markers of this health effect. The committee will also asse
ss the public health
impact of a tobacco harm reduction strategy -- for example,
the effects on
initiation and cessation due to changes in perception of ris
ks to health from
tobacco use.

A working group consisting of Drs. Crout, Hatsukami, Sh
ields, and Wallace
invites you to join them on Wednesday, 1 March 2000 in Washi
ngton DC to discuss
the task before the committee and to explore how you can bes
t provide meaningful
scientific information for the committee?s consideration.

The committee is interested in exploring data and plans
for future
research. We are interested in identifying markers of expos
ure to tobacco and
surrogate markers of disease associated with tobacco use. W
e are also
interested in clinical trial design issues for studying the
safety and efficacy
of tobacco harm reduction strategies. Finally, we must cons
ider ways to assess

the public health implications for tobacco initiation and cessation of a harm reduction strategy.

We would appreciate your input on these issues as well as receiving, for example, scientific articles that you think the committee should review. We would appreciate if you could identify relevant research efforts you are currently sponsoring internally or externally, and relevant company documents made public under the Master Settlement Agreement or by congressional action. We would like to discuss theoretical, novel approaches, and the means to assess them, to tobacco harm reduction that could be pursued by either the tobacco or pharmaceutical industries. We are interested in the lessons learned by the tobacco industry from previous attempts at developing products for harm reduction. The committee is NOT requesting that you provide proprietary information.

The working group prefers to receive written material prior to the March 1 meeting and would then like the opportunity to discuss these and other matters with you on March 1. Under Section 15 of the Federal Advisory Committee Act any printed material you provide must be disclosed publicly. This invitation to meet with the working group and solicitation of input is not an endorsement of the products of your company or positions you might take regarding the health effects of tobacco or nicotine. The committee views this meeting as one of many important steps of information-gathering that will lead to a fully-informed technical report responsive to the request of the FDA and that will be useful to the entire medical, scientific, and policy communities.

The committee meets as a whole on March 2-3, 2000. Portions of the full committee meeting will be open to the public for observation

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, and you are
invited to attend those sessions, in addition to meeting wit
h the working group
on March 1. The agenda for March 2-3 is not yet finalized.
Information about
the committee and its activities can be found at
www4.nationalacademies.org.edu/cp.nsf. Choose the ?view by
title? option and
search for Assessing the Science Base for Tobacco Harm Reduc
tion.

Please do not hesitate to contact me at any time. I wi
ll call you in a day
or two to discuss your willingness to meet with us.

Thank you,

Kathleen Stratton, Ph.D.
Study Director

A copy of this letter has been sent to your office thro
ugh Federal Express.