

*FDA Center for Tobacco Products
Tobacco Products Scientific Advisory Committee (Open)*

March 2, 2011

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1 FOOD AND DRUG ADMINISTRATION
2 CENTER FOR TOBACCO PRODUCTS
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5 TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE
6 (TPSAC)
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8 Open Session
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10 WEDNESDAY, MARCH 2, 2011
11 10:30 a.m. to 3:00 p.m.
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14 9200 Corporate Boulevard
15 Rockville, Maryland
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20 This transcript has not been edited or corrected, but
21 appears as received from the commercial transcribing
22 service.

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1	C O N T E N T S		1	P R O C E E D I N G S	
2	AGENDA ITEM	PAGE	2	(10:31 a.m.)	
3	Call to Order		3	Call to Order	
4	Jonathan Samet, M.D., M.S.	11	4	DR. SAMET: Good morning. I think we'll go	
5	Conflict of Interest Statement		5	ahead and start the meeting. I'm Jon Samet, the	
6	Caryn Cohen, DFO	12	6	chair of the Tobacco Products Scientific Advisory	
7	Introduction of Committee Members	16	7	Committee. I want to welcome you and thank you for	
8	FDA Presentation: Menthol Report		8	joining us. I want to make a few statements, and	
9	David Ashley, Ph.D.	18	9	then we will introduce the committee.	
10	Building a Population Dynamics Model of the		10	For topics such as those being discussed at	
11	Consequences of Menthol Cigarettes for		11	today's meeting, there are often a variety of	
12	Smoking Prevalence and Disease Risks		12	opinions, some of which are quite strongly held.	
13	David Mendez, Ph.D.	23	13	Our goal is that today's meeting will be a fair and	
14	Discussion of Draft Chapter 3		14	open forum for discussion of these issues, and that	
15	Neal Berkowitz, M.D.	50	15	individuals can express their views without	
16	Discussion of Draft Chapter 6		16	interruption. Thus, as a general reminder,	
17	Jonathan Samet, M.D., M.S.	71	17	individuals will be allowed to speak into the	
18	Presentation: Rates of Users Switching		18	record only if recognized by the chair. We look	
19	to and from Menthol and Non-Menthol		19	forward to a productive meeting.	
20	Cigarettes: Answers to Follow-Up Questions		20	In the spirit of the Federal Advisory	
21	Eric Johnson, Ph.D.	81	21	Committee Act and the Government in the Sunshine	
22			22	Act, we ask that the advisory committee members	
		Page 10			Page 12
1	C O N T E N T S (continued)		1	take care that their conversations about the topics	
2	AGENDA ITEM	PAGE	2	at hand take place in the open forum of the	
3	Update of Chapter 4		3	meeting.	
4	Patricia Nez Henderson, M.P.H., M.D.	103	4	We are aware that members of the media are	
5	Update of Chapter 5		5	anxious to speak with the FDA about these	
6	Melanie Wakefield, Ph.D.	105	6	proceedings. However, FDA will refrain from	
7	Dorothy Hatsukami, Ph.D.	125	7	discussing the details of this meeting with the	
8	Open Public Hearing	132	8	media until its conclusion. Also, the committee is	
9	Update of Chapter 7		9	reminded to please refrain from discussing the	
10	Jonathan Samet, M.D., M.S.	164	10	meeting topics during breaks. Thank you.	
11	Menthol Report - Industry Perspective		11	Caryn?	
12	Daniel Heck, Ph.D., DABT	171	12	Conflict of Interest Statement	
13	Committee Discussion	178	13	MS. COHEN: The Food and Drug Administration	
14	Adjournment	183	14	is convening today's meeting of the Tobacco	
15			15	Products Scientific Advisory Committee under the	
16			16	authority of the Federal Advisory Committee Act of	
17			17	1972. With the exception of the industry	
18			18	representatives, all members and non-voting members	
19			19	are special government employees or regular federal	
20			20	employees from other agencies and are subject to	
21			21	federal conflict of interest laws and regulations.	
22			22	The following information on the status of	

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1 this committee's compliance with federal ethics and
2 conflict of interest laws, covered by, but not
3 limited to, those found at 18 U.S.C., Section 208
4 and Section 712 of the Food, Drug, and Cosmetic
5 Act, is being provided to participants in today's
6 meeting and to the public. FDA has determined that
7 the members of this committee are in compliance
8 with the federal ethics and conflict of interest
9 laws.

10 Under 18 U.S.C., Section 208, Congress has
11 authorized FDA to grant waivers to special
12 government employees and regular federal government
13 employees who have potential financial conflicts
14 when it is determined that the agency's need for a
15 particular individual's services outweighs his or
16 her potential financial conflicts of interest.

17 Under Section 712 of the FD&C Act, Congress
18 has authorized FDA to grant waivers to special
19 government employees and regular federal employees
20 with potential conflicts of interest, when
21 necessary, to afford the committee essential
22 expertise.

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1 Related to the discussion of today's
2 meeting, members of this committee have been
3 screened for potential financial conflicts of
4 interest of their own, as well as those imputed to
5 them, including those of their spouses or minor
6 children, and, for purposes of 18 U.S.C.
7 Section 208, their employers. These interests may
8 include investments, consulting, expert witness
9 testimony, contracts, grants, CRADAs, teaching,
10 speaking, writing, patents and royalties, and
11 primary employment.

12 Today's agenda involves receiving an update
13 on the Menthol Subcommittee and receiving and
14 discussing presentations regarding the data
15 requested by the committee on the March 30-31, 2010
16 meeting of the Tobacco Products Scientific Advisory
17 Committee. This is a particular matters meeting,
18 during which general issues will be discussed.

19 Based on the agenda for today's meeting and
20 all financial interests reported by the committee
21 members, no conflict of interest waivers have been
22 issued in connection with this meeting. To ensure

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1 transparency, we encourage all committee members to
2 disclose any public statements that they may have
3 made concerning the issues before the committee.

4 With respect to FDA's invited industry
5 representatives, we would like to disclose that
6 Drs. Daniel Heck and John Lauterbach and Mr. Arnold
7 Hamm are participating in this meeting as non-
8 voting industry representatives, acting on behalf
9 of the interests of the tobacco manufacturing
10 industry, the small tobacco manufacturing industry,
11 and tobacco growers, respectively. Their role at
12 this meeting is to represent these industries in
13 general and not any particular company. Dr. Heck
14 is employed by Lorillard Tobacco Company. Dr.
15 Lauterbach is employed by Lauterbach and
16 Associates, LLC. And Mr. Hamm is retired.

17 FDA encourages all other participants to
18 advise the committee of any financial relationships
19 that they may have with any firms at issue.

20 I'd like to remind everybody to please turn
21 off your cell phones completely if you have not
22 already done so. They interfere with the PA system

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1 in this room. I would also like to identify the
2 FDA press contacts. They are Jeffrey Ventura and
3 Tesfa Alexander. And if either or both of you are
4 here, could you please stand up?

5 Thank you very much.

6 Introduction of Committee Members

7 DR. SAMET: Thank you. Let me now ask the
8 committee to introduce themselves. Actually,
9 beginning -- let's see.

10 Mark, are you back on the phone?
11 DR. CLANTON: I am back online.
12 DR. SAMET: Why don't you go first?
13 DR. CLANTON: Dr. Mark Clanton, representing
14 pediatrics, oncology, public health. I work for
15 the American Cancer Society.

16 DR. SAMET: And let me just check. Are
17 there any other members on the phone?
18 [No response.]
19 DR. SAMET: I didn't think so.
20 Melanie?
21 DR. WAKEFIELD: Dr. Melanie Wakefield. I'm
22 from the Cancer Council Victoria in Melbourne,

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1 Australia, and a voting member of the committee.
2 DR. HATSUKAMI: I'm Dorothy Hatsukami from
3 the University of Minnesota.
4 DR. BENOWITZ: Neal Benowitz, University of
5 California San Francisco.
6 DR. NEZ HENDERSON: Patricia Nez Henderson,
7 Black Hills Center for American Indian Health.
8 DR. HENNINGFIELD: Jack Henningfield, Pinney
9 Associates in Bethesda and Johns Hopkins Medical
10 School in Baltimore.
11 MS. DELEEUEW: Karen DeLeeuw, Colorado
12 Department of Public Health and Environment.
13 DR. ASHLEY: David Ashley, FDA.
14 DR. DEYTON: Lawrence Deyton, FDA.
15 DR. MCAFEE: Tim McAfee, Center for Disease
16 Control.
17 DR. BACKINGER: Cathy Backinger from the
18 National Cancer Institute, representing the
19 National Institutes of Health.
20 MR. HAMM: Arnold Hamm, representing U.S.
21 tobacco growers.
22 DR. LAUTERBACH: John Lauterbach,

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1 Lauterbach & Associates, representing the small
2 business tobacco manufacturers.
3 DR. HECK: Dan Heck of the Lorillard Tobacco
4 Company, representing the tobacco manufacturers.
5 DR. SAMET: Thank you.
6 Before we get going, let me just point out
7 that while the agenda shows us going until 5:00, it
8 would appear that the majority of the committee
9 members have flights that will necessitate them
10 leaving by approximately 3:30. So while some of
11 you may be saddened by the shortening of the
12 meeting, so be it.
13 What that means, actually, is that after
14 lunch, we will just proceed straight through our
15 business, and I think we will have ample time to
16 discuss the matters on today's agenda.
17 So let me turn to David Ashley.
18 FDA Presentation – Menthol Report
19 DR. ASHLEY: I am going to give just a brief
20 introduction. For those of you don't know me, I'm
21 David Ashley. I'm director of the Office of
22 Science here at the Center for Tobacco Products.

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1 If you haven't heard this before, I'm
2 surprised, but I'm going to go ahead and say it
3 again. The charge to the TPSAC is to produce a
4 report and recommendations on the impact of the use
5 of menthol in cigarettes on public health,
6 including such use among children, African-
7 Americans, Hispanics, and other racial and ethnic
8 minorities. And that report is due March 23rd,
9 2011.
10 Next, I want to talk a little bit about what
11 to expect from the report. We have one more full
12 committee meeting scheduled right now for
13 March 17th and 18th, in just a couple of weeks.
14 The report itself is broken down into eight
15 chapters, and I'm not going to read this slide.
16 You all can look at that, and if you've got your
17 own handouts, you've got it in front of you.
18 From what I understand, there is a
19 possibility that some of these topics may actually
20 be shifted around. All the topics will be covered.
21 All the topics will be there. but just to make a
22 little bit more equality in some of the chapters,

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1 there may be just some movement of some of the
2 topics in those chapters, and that's still under
3 discussion.
4 The final report will be made available to
5 the public on FDA's website once it has been
6 reviewed for redaction of any commercial
7 confidential or trade secret information. And then
8 once that report is received, FDA will consider the
9 report and recommendations of the committee, as
10 well as other scientific evidence concerning
11 menthol cigarettes, and make a determination about
12 what actions, if any, are warranted.
13 There is no required deadline or timeline
14 for FDA to make such a determination, and any sale
15 or distribution restrictions or product standards
16 will be implemented through notice and comment rule
17 making.
18 Status of the information requested by
19 TPSAC. The model on the effect of menthol on
20 initiation and cessation is still in progress, and
21 David Mendez will be presenting on this later today
22 and giving us an update on that.

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1 Since the last meeting, FDA has responded to
2 some TPSAC requests. For example, some data from
3 the state of Massachusetts product analysis was
4 made available. FDA has also provided information
5 that was submitted by the public to the committee.
6 And other than public submissions to TPSAC, FDA
7 will not provide any additional data or information
8 for inclusion in the report because that deadline
9 is coming up very soon.

10 Then, a little bit, briefly on today's
11 meeting. The topics for today's meeting, first, we
12 had a very short closed session earlier this
13 morning, where we discussed commercial confidential
14 trade secret information from industry document
15 submissions. And then this is now the open
16 meeting, where there will be information from
17 industry document submissions on Topic 8, which can
18 be shared publicly; an update on the model of the
19 impact of menthol on initiation and cessation. We
20 will have public comments and a discussion of
21 drafts of chapters 3 and 6, and then updates on
22 chapters 4, 5, also chapter 7 and the industry

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1 perspective.

2 The questions posed to the committee for
3 this meeting today: What comments do the TPSAC
4 have regarding the proposed model that is
5 presented, and what feedback does TPSAC have
6 regarding draft chapters 3 through 7?

7 If there are any questions about this, I
8 will be glad to answer those?

9 DR. SAMET: Questions for David?

10 [No response.]

11 DR. SAMET: I might just note for the
12 record, in fact, that the drafts that are posted
13 are just that; they are drafts. So as the
14 committee has posted drafts, they are there for the
15 public to review and comment, but I think until our
16 report is final, I would just want to remind
17 everyone that these are, in fact, draft chapters.

18 Thank you, David.

19 DR. ASHLEY: Sure.

20 DR. SAMET: So I think, then, we'll go onto
21 the presentation by David Mendez, from the
22 University of Michigan. And, David, thank you for

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1 joining us again.

2 Presentation – David Mendez

3 DR. MENDEZ: Good morning. I am here to
4 present preliminary results from the model that I'm
5 building regarding the prevalence of menthol
6 smoking. And so I'd like to point out that these
7 results are totally preliminary at this point, and
8 any results and the work reported here is just my
9 own and does not reflect any of the opinions of the
10 FDA.

11 So this is the model, as we have been
12 discussing, that's a compartmental model in which
13 we have birth rate, and that keeps track of
14 initiation, both menthol and non-menthol, and keeps
15 track of former smokers. So the model divides the
16 population into menthol smokers, non-menthol
17 smokers, former smokers, and never smokers, and
18 keeps track of them from 2010 to 2050 from the ages
19 0 to 100. The former smokers are followed, not
20 just by the years, by age 0 to 100, but by years
21 quit, so every former smoker is followed up to 30
22 years of years quit.

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1 So this is the structure of the model that
2 we discussed before. And during the last meeting,
3 we were talking about the parameters that we needed
4 to populate the model. And these are the
5 parameters that I'm using in the presentation that
6 I'm going to share with you today. So we have, in
7 the data that are needed for the model so far, the
8 proportion of menthol initiation. That proportion
9 of menthol initiation, at the initiation, at age
10 18, what is the proportion of smokers that are
11 menthol smokers? And I have a central estimate of
12 40 percent.

13 Now, the proportion of menthol
14 experimentation is 45 percent. It's the proportion
15 of people that experiment, in between ages 12 to
16 17, that are smoking menthol. And we have a
17 central estimate of about .45.

18 The ratio of experimentation to becoming a
19 regular smoker -- that's at the ratio between
20 menthol and non-menthol -- we have an estimate of
21 1.61. That means that an experimenter with menthol
22 is 61 percent more likely to become a regular

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1 smoker than an experimenter of non-menthol.
2 The cessation ratio between menthol and non-
3 menthol, we have a central estimate of .95 and a
4 sensitivity between .9 and 1. That means the
5 central point estimate of .95 just implies that
6 there's a slightly lower cessation with menthol
7 smokers than with non-menthol smokers.
8 The mortality ratio, non-menthol to menthol,
9 we have a central estimate of 1, meaning that they
10 have the same mortality or health effects, but we
11 have sensitivity between .8 and 1.2. And switching
12 rate from menthol to non-menthol, from year to
13 year, I mean the annual switching rate, we have an
14 estimate of .6 percent for menthol to non-menthol,
15 and from non-menthol to menthol, .5 percent.
16 With that, I'm going to show you these are
17 the settings for the scenarios that I constructed
18 and I'm going to present today. So all these
19 scenarios, all of what I did is that you have these
20 central scenarios. So I present one output of the
21 model with the central scenarios, and then varying
22 each one of the sensitivity parameters that you

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1 see; at least on those tables, that are also
2 presented, keeping everything else constant.
3 The setting of the model is such that we
4 start -- the oldest scenarios, the current
5 conditions start and keep the initiation rates,
6 which is the prevalence of age 18 in this model of
7 21.8 percent. That's consistent with NHIS 2009.
8 Now, the counterfactuals, so we are going to
9 compare the model in a universe where there's no
10 menthol, and then that's the counterfactual. The
11 counterfactual uses an initiation rate which is
12 prevalent at age 18 of 17 percent. And I'm going
13 to show you how we ID'd that 17 percent, why that
14 17 percent comes about.
15 The counterfactuals assume that menthol
16 smoking does not exist. And if menthol did not
17 exist, then at 2010, we would have a different
18 prevalence than we have today, smoking prevalence.
19 But I have absolutely no basis to assume any
20 different prevalence. So I chose to start at the
21 same prevalence that we have in 2010.
22 So the scenario where there is no menthol is

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1 started with the same prevalence that we have in
2 2010 with menthol, except that we have a tiny
3 difference at age 18 because my initiation rate is
4 the prevalence at age 18. So to be consistent with
5 the model in the counterfactual, the prevalence at
6 age 18, we have to reflect the new initiation rate
7 of 17 percent. Everything else is going to be
8 exactly the same.
9 Then I'm going to present a comparison
10 between what would happen, with these scenarios, if
11 there is menthol and those parameters hold, and
12 what would happen if there is no menthol. And then
13 I'm going to track -- I'm going to start
14 accumulating initiation and death and prevalence
15 from 2010 to 2050. And I'm going to take the
16 difference between those scenarios and the
17 counterfactuals, and that's what I present as
18 excess cumulative differences. So when I talk
19 about excess cumulative death or excess cumulative
20 initiation, it's going to be the difference in
21 accumulation from 2010 to the specific year that we
22 are looking at between the scenario where there's

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1 menthol and the scenario where there is no menthol.
2 So this is the derivation of what would
3 happen with an initiation rate if we are in a
4 situation where there is no menthol. So if we
5 assume that there is no menthol -- so we have a
6 proportion of people that are experimenting, which
7 is 30 percent, and we kept that constant. But,
8 actually, that's not really in the computations.
9 The proportion of experimenters who smoke menthol
10 is 45 percent, and the proportion of experimenters
11 who smoke non-menthol right now is 55 percent.
12 I'm calling these yields, the yield from
13 experimenter to becoming a smoker. And we know
14 that we have the best estimate for the ratio of the
15 yield as 1.61. So given that the current
16 initiation rate is 21.8 percent, that 21.8 percent
17 came about with these computations. So we have a
18 proportion of experimenters that smoke menthol and
19 have a yield -- through the cites of the current
20 cohort and the proportion of experimenters that
21 smoke non-menthol, have a yield, and that combined
22 yield has produced the 21.8 percent.

1 So, with that, I figured out if we know that
2 the ratio from the yields is 1.61, I figured out
3 what the yield for non-menthol is. And then now
4 that we know what the yield from non-menthol is,
5 assuming that there's not going to be any menthol
6 and the same proportion of experimenters, now, all
7 the experimenters are going to experiment with non-
8 menthol, and they're going to have a lower yield to
9 become regular smokers. If we follow that
10 consistency of the approach, we found that the
11 initiation rate will be, in that specific scenario,
12 around 17 percent.

13 Now, with that, then I presented the
14 comparison of the scenarios with the central
15 parameters. What I call a scenario is the
16 situation where there's menthol and the
17 counterfactual situation where there is no menthol.
18 So I understand that, in the right column, in the
19 input, there is actually no menthol, but I just
20 want to make sure that I used the right parameters
21 to derive the conditions for non-menthol. That's
22 why there are some parameters listed on the right.

1 the counterfactual, so I just wanted to make sure
2 that the counterfactual matched exactly the
3 scenario that we're coming from.

4 The same thing is going to happen with the
5 menthol mortality multiplier. I put one there,
6 meaning that these mortality rates are the same.
7 So in the case where we are going to change the
8 mortality rates with menthol and non-menthol, then,
9 given the proportion of menthol and non-menthol,
10 the prevalence by age of menthol and non-menthol in
11 2010, then those mortality rates are going to
12 change by age for menthol and non-menthol. I want
13 to make sure that that's reflected in the
14 counterfactual when I change to the counterfactual.

15 DR. SAMET: David, can I interrupt you for
16 just a second, to make sure? Where you have, under
17 counterfactual, the 45 percent, you've replicated
18 that twice. Wouldn't that be -- in our
19 counterfactual would that be we don't have menthol?

20 DR. MENDEZ: We don't have menthol.

21 DR. SAMET: So you've actually carried over.
22 I just want to clarify for everyone.

1 For example, we have an initiation rate of
2 17 percent under the counterfactual. It's
3 proportional, and that was derived under the
4 assumption that there is a proportion of menthol
5 experimentation under the scenario that is menthol,
6 of 45 percent and the ratio of yield of 1.61. I
7 also have the overall cessation rates. That's the
8 one that was estimated previously there. Actually,
9 we have estimated it in a previous research
10 project.

11 What I want to say there -- we've listed
12 that in the counterfactual -- is that the cessation
13 rates will adjust -- for the non-menthol, have
14 adjusted appropriately to reflect that 95 percent.
15 So the idea is, in this scenario, in the actual
16 scenario, the overall cessation rates are the ones
17 listed. And those, because there's a proportion of
18 menthol and a proportion of non-menthol, then I
19 derive, on that scenario, the specific rates for
20 menthol -- the cessation rate for menthol and non-
21 menthol that match that ratio. And those specific
22 rates for non-menthol are the ones that are used in

1 DR. MENDEZ: Yes, yes. It's zero.

2 DR. SAMET: That would be zero, and where
3 you have experimentation -- initiation ratio,
4 menthol, the second 1.61, again, is just simply
5 replicated. They really don't belong there?

6 DR. MENDEZ: It's replicated.

7 DR. SAMET: I just wanted to make sure
8 everybody understands that.

9 DR. MENDEZ: Yes. That's why I used it. I
10 just wanted to clarify. It was for me to make sure
11 that I use the same parameters, too.

12 So then the model -- let's go to the right
13 side -- keeps track in every big compartment. The
14 compartments are many in this case because it's age
15 and years quit, et cetera. So I just aggregated,
16 by big compartments, the scenarios and the
17 counterfactual, and reported the prevalence from
18 2010 to 2050 under the scenario and the
19 counterfactual.

20 Also, I kept track -- the model keeps track
21 of the cumulative death from 2010 to 2050, and then
22 reports the difference of the cumulative deaths

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1 between the scenario and the counterfactual. So
2 there is some switching within the compartments, as
3 you can see. And I just posted that to make sure
4 the model was working correctly. And the flow is
5 conserved correctly.

6 The relevant point, the relevant columns are
7 the ones marked in yellow. So from 2010 to 2050,
8 that's the difference in cumulative death, and in
9 the second market, the last row, the total
10 difference in cumulative initiation. The
11 difference in cumulative initiation is going to be
12 – at age 18, the difference between that 21.8
13 percent and 17 percent. So you're going to see
14 that's very constant across scenarios because we
15 didn't change those parameters.

16 So now we have the sensitivity analysis of
17 the relevant parameters, or the parameters for
18 which I have sensitivity values. And the
19 proportion of menthol initiation drops to
20 35 percent. So if the prevalence or if the
21 proportion of menthol smokers at age 18 right now
22 is the 35 percent instead of 40 percent, we have a

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1 central estimate. These are the total number of
2 cumulative deaths. And if it is 45 percent, then
3 that would be the total number of cumulative
4 deaths, up to 319,596 in 50 years. If the
5 cessation ratio of menthol to non-menthol changes
6 to .9 instead of .95, that's going to be the
7 results of 322,392.

8 I checked that the results are consistent
9 with the changes in the parameters, so they are
10 representing -- the numbers are moving in the right
11 direction in all cases. If the cessation ratio,
12 menthol to non-menthol, is 1, then that means high
13 cessation. This is what we have. If the mortality
14 ratio, menthol to non-menthol, is .8, then in this
15 case, menthol is less harmful than non-menthol.

16 You see an interesting factor in the total
17 number of deaths. They will go up and
18 then -- first, in the counterfactual scenario,
19 there are more deaths than in the normal, in the
20 world with menthol. But this is not consistently
21 going up. It goes up and then the difference is an
22 inverted U-shape.

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1 There are two conflicting things in this
2 model. First, menthol is less harmful, but at the
3 same time the prevalence is dropping, so the
4 protective effect of menthol is becoming less and
5 less as we move forward. So actually, the model
6 was working. I was interested to see that non-
7 linearity was very well captured by the model. If
8 menthol is more harmful for regular cigarettes, the
9 non-menthol cigarettes, this is the scenario that
10 we are going to end up with. These are the results
11 of the model.

12 At the end, there's a summary of tables, a
13 summary of scenarios, just summarizing the results
14 of the model here, and the total cumulative deaths
15 and total -- the excess death, the difference
16 between the scenarios and the counterfactual in
17 both and the total excess number of initiators just
18 from 2010 to 2050. So that's the last volume.

19 So that's where I am right now, so I would
20 appreciate any comments and questions.

21 DR. SAMET: So thank you, David. And I
22 think there are a number of issues that we should

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1 talk about. One is beginning to fill in some of
2 the ranges on the parameters that are not included.
3 And I think as we complete our reviews of the
4 chapters over the next week or so, we should be
5 able to provide you with some ranges.

6 I just want to restate, and correct me if I
7 have this wrong, so that everybody is on the same
8 page as to what the "counterfactual" is,
9 remembering that the counterfactual, by the nature
10 of the word, is what does not exist.

11 So the comparison states the what does not
12 exist is the United States in 2010, as it would
13 have been had there never been menthol cigarettes,
14 based on the parameters that David has used to
15 develop the model.

16 DR. MENDEZ: Correct. And the only caveat
17 is that if we had never had menthol, the prevalence
18 in 2010 would have been different than what we have
19 now, but I don't have any basis to know what that
20 prevalence would be, so I chose to start at the
21 same prevalence that we have in 2010.

22 DR. SAMET: Then the projections are with

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1 the existence of menthol cigarettes versus this
2 comparison state, projected out over time, just to
3 be as clear as I can.
4 DR. MENDEZ: Yes.
5 DR. SAMET: Then I think, again, as I look
6 at the table of parameter estimates that you used,
7 I think there are some that we want to fill in.
8 Let me ask you a question. David reminded
9 us that the report is due March 23rd, and the
10 possibility of having a more focused model, perhaps
11 for African-Americans, do you think that's likely
12 or unlikely?
13 DR. MENDEZ: It depends on how soon you can
14 give me parameters for that. I can try. Right
15 now, the model is working correctly, as far as I
16 can tell. It's generating more than 200,000
17 numbers every time it runs. But there are a lot of
18 different checks of flow, of comparison of what
19 it's projecting for the total population of the
20 U.S.
21 So the issue is the model is extremely
22 segregated, so when you aggregate the model, you

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1 should produce numbers that are reasonable, that
2 have been published elsewhere. And the model is
3 all producing the same estimates, so I have those
4 checks done. So it's producing the same population
5 for the United States. It's producing the same
6 projected prevalence from other different models,
7 aggregate prevalence of smoking for all the
8 different models under this scenario. So there are
9 a lot of different checks that I've made to give me
10 some confidence that the model is working
11 correctly.
12 Now, the issue is, once the model is built,
13 running for different populations is
14 straightforward. It's time consuming, but
15 straightforward, so if I have the parameters, I
16 think we can have something.
17 DR. SAMET: Thank you and we will see if we
18 can develop those for you, I think, given our
19 charge to look at particular populations.
20 So let me ask, who has questions for David?
21 Dan?
22 DR. HECK: Yes. Thank you, Dr. Mendez. A

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1 question for you and perhaps for the committee to
2 ponder, if nothing else. We heard mention at the
3 prior meeting, the natural experiments we see
4 around the world, there are a number of countries
5 where menthol is essentially absent from the
6 market; Italy, Portugal, Austria, Argentina, Spain,
7 Greece. That is 1 percent or less of the market,
8 according to Nielsen data. In those countries, we
9 see youth smoking and adult smoking rates at least
10 as high, in fact, markedly higher than the U.S. If
11 the committee embraces this model as an accurate
12 prediction of this hypothetical situation, how can
13 that challenge be addressed, in terms of is the
14 model an accurate predictor, based on world
15 experience?
16 Not necessarily a question for you to answer
17 here, but I think we need to think about this as a
18 committee. It's a lot to absorb in one session.
19 DR. SAMET: Yes. My first response, then,
20 would be that the model itself is reflective of
21 what has happened in the United States, based on
22 the best parameters that we can develop from data

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1 that are available. So it is a United States-
2 attuned model, and we have not tried to build,
3 let's say, a model that would be at the population
4 level, using information across countries. And, in
5 fact, I would argue that that's probably extraneous
6 to our task.
7 I don't know if any other committee members
8 would like to comment here.
9 DR. WAKEFIELD: I think the situation in
10 other countries is that they have different policy
11 environments, which really does influence uptake
12 and cessation as well. So I think it's sensible to
13 stick with a model that very much reflects the
14 United States.
15 DR. SAMET: Arnold, did you have your hand
16 up before?
17 MR. HAMM: Yes, I did.
18 Dr. Mendez -- or maybe this is a question
19 for the committee -- is there any place in this
20 model that accounts for contraband and self-
21 mentholation?
22 DR. MENDEZ: No. The model is not

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1 reflecting what would happen if something happens
2 to menthol. The idea is if menthol had never
3 existed. The situation right now with menthol is
4 business as usual. The counterfactual is, menthol
5 never existed.
6 MR. HAMM: Okay.
7 DR. MENDEZ: So to answer your question, no,
8 but that's not what we're trying to compare.
9 DR. SAMET: John?
10 DR. LAUTERBACH: Yes. Dr. Mendez, what
11 concerns me here is the assumption that if menthol
12 didn't exist, the initiation rate would be less.
13 And then, you say this assumes that menthol never
14 existed as a cigarette or never was a cigarette
15 flavor; yet, what does the model say if menthol
16 stopped now?
17 DR. MENDEZ: I didn't do that. That's not
18 the experiment that I did. Again, the assumption
19 of the model is menthol didn't exist.
20 DR. SAMET: Neal?
21 DR. BENOWITZ: I just have a clarification
22 question. Can you go to the block diagram, the

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1 menthol cigarette prevalence model?
2 DR. MENDEZ: Sure.
3 DR. BENOWITZ: I'm just trying to figure out
4 where the number, the proportion of menthol
5 experimentation, comes into this model. I can see
6 the other parameters, where they sit. But where
7 does proportion of menthol experimentation sit in
8 the model?
9 DR. MENDEZ: So this part was done with
10 algebra. Right? So that's the portion of the
11 model that just computes the new initiation rate.
12 DR. BENOWITZ: Okay. Thank you.
13 DR. SAMET: There are others. Let's see.
14 Mark, do you have questions?
15 DR. CLANTON: No. Actually, the most recent
16 discussion answered most of my questions, so thank
17 you.
18 DR. SAMET: Dan?
19 DR. HECK: Just a very brief follow-on,
20 Mr. Chairman, to your comment and Dr. Wakefield's.
21 We have seen presented -- and I won't go and tell
22 them that again -- with regard to the U.S.

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1 situation, a couple times, the slides and graphic
2 data, from Nielsen or other sales data,
3 demonstrating, in the domestic U.S. situation, a
4 disconnect between no relation, in fact, an inverse
5 relationship between the popularity of menthol
6 cigarettes and youth smoking rate, for instance.
7 Granted, states in the U.S. do also vary, state by
8 state, by their tobacco control policies and such.
9 So just a cautionary note, the real
10 situation in the U.S. and around the world do
11 indicate some complexities that may not be
12 projected by the model.
13 DR. SAMET: I think it's fair to say that
14 it's hard to capture the real world in a model. I
15 agree.
16 Tim?
17 DR. MCAFEE: While I do appreciate this sort
18 of struggle with the focus on the counterfactual
19 model, which I think is one way to look at this, I
20 guess the one thing that I would posit around this
21 is that this is probably the most conservative way
22 to look at this situation, because the reality is

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1 that what would actually happen is not that we
2 would go back into the past and eliminate the
3 effects of whatever menthol would be. The reality
4 is that 40 to 45 percent of people would be faced
5 with the reality of not having menthol cigarettes
6 available. And you could discount that by some
7 smuggling function or something like that, but
8 that, clearly, there would be a disruptive impact
9 that would lead to some fraction of people making
10 quit attempts.
11 The small amount of evidence that we've had
12 given to us so far around that, being both what
13 smokers would prefer, around having menthol
14 removed, and then what their intents would be,
15 would suggest that this might be a significant
16 effect.
17 So, again, I would just assume that this is
18 -- assuming that the numbers were accurate, this
19 would be the most conservative estimate of what
20 would actually happen in the future.
21 DR. SAMET: Yes, Dan?
22 DR. HECK: Yes. Thank you, Dr. McAfee. I

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1 guess you're referring to the single telephone
2 survey that we heard presented partially at the
3 prior meeting. I would agree that that's a smaller
4 amount of evidence. And we have seen similar
5 surveys of smoker attitudes and opinions of
6 smokers, generally, some major proportion
7 expressing an intention to quit, for instance. I
8 don't recall an exact number.
9 So I would just -- as a cautionary note,
10 that a survey such as that, again, may not be an
11 accurate projection. It's a difficulty we all face
12 in trying to project the future of actual
13 behaviors.
14 DR. SAMET: Tim?
15 DR. MCAFEE: I completely agree with the
16 notion that you can't. But, clearly, I think it
17 was 50 percent of African-Americans and something
18 in the low 40s for all menthol users. And it's not
19 like we would actually expect that that many people
20 would end up quitting as a result of something like
21 this. But on the other hand, it's true that
22 something in the nature of 60 to 70 percent of

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1 smokers not only say they want to quit, but say
2 they intend to quit sometime in the next 6 to 12
3 months. But the reality is, they don't all, but
4 two-thirds of them actually do make a quit attempt
5 longer than 24 hours. And the probability that
6 they will quit is much higher if they express an
7 intention to quit than if they don't.
8 So although I completely agree that you have
9 to have some discount mechanism, which we've not
10 tried to model in this, I certainly think it would
11 be higher than zero. And everything else, from
12 what we know of the relationship of intention to
13 action, would suggest that we would create an
14 effect. I think you're right. It obviously would
15 not be 50 percent being successful.
16 DR. SAMET: Jack?
17 DR. HENNINGFIELD: Dr. Heck, what I'm
18 wondering about is are you concerned about the
19 accuracy of the model or are you challenging the
20 general prediction that taking menthol out would
21 substantially reduce smoking and mortality?
22 DR. SAMET: Just a reminder, before you do

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1 that, of what the counterfactual is. It's the
2 world as it would have existed, absent menthol,
3 compared to maintaining menthol as it is now.
4 DR. HENNINGFIELD: Yes.
5 DR. SAMET: So just to make sure that the
6 counterfactual is -- I think you alluded to a
7 different possibility.
8 DR. HENNINGFIELD: Yes. But that's what
9 we're using the model to try to I think help sort
10 out.
11 DR. SAMET: I think the model, at least from
12 my perspective, is to help us address our charge of
13 public health impact and try and have some
14 way -- not that I think we want numbers in ones,
15 twos, or threes, or something, but to have a
16 general sense of what public health impact might
17 be. I mean, I recognize that there are multiple
18 potential counterfactual scenarios, and perhaps
19 some others might be addressed in the future,
20 depending on policy needs. But I don't think,
21 between now and March 23rd, we're going to be
22 exploring too many different scenarios, Jack.

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1 DR. HENNINGFIELD: I agree, and I guess my
2 point is that we use this as a tool to help
3 predict. And, frankly, I'm not sure that it's
4 relevant how precise it is. And so picking around
5 the edges of the precision I think misses the
6 point. I think raising other countries completely
7 misses the point. We're using it to better
8 understand what has happened in the United States,
9 what may happen in the United States, in a country
10 where -- what is it -- around 18 percent of the
11 population smokes menthol cigarettes. And the
12 concerns of the companies that you represent is
13 that there would be a substantial decrease in the
14 market.
15 DR. HECK: To try to get your point, Jack, I
16 would not dispute the fact that the elimination of
17 any market segment -- call it 100-millimeter
18 cigarettes, call it light cigarettes or former
19 light cigarettes, call it cork-tip cigarettes, call
20 it hard-boxed cigarettes. Elimination,
21 statistically and modeled, of any market segment
22 would certainly be projected to have some influence

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1 on people's preference of smoking and their product
2 choice.
3 So I don't dispute that you can produce a
4 number projections with this. My only concern is
5 that for the real intent of this model, albeit more
6 rearward-looking than forward-looking, is the
7 effect of any dramatic action that FDA might choose
8 to take. That's the real reason we're asking this
9 question. So I don't dispute the fact that any
10 product segment becoming unavailable would have an
11 effect on smoking.
12 DR. SAMET: Just to remind us we're here to
13 talk about this particular model and the
14 presentation by David, I do think we, as a
15 committee, need to look further at the parameters
16 in the model. And I think with this further update
17 on the results, make sure we have a full
18 understanding of what the model is about.
19 Let me ask, are there other questions?
20 [No response.]
21 DR. SAMET: And I guess none from the phone.
22 DR. CLANTON: I'm here.

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1 DR. SAMET: Thanks, Mark.
2 DR. MENDEZ: Let me make, also, again, the
3 clarification that there is no assumptions in this
4 model. All the parameters that have been used have
5 come from somewhere, and they have been derived.
6 And they are available, publicly available. But
7 it's not something like what if this happens. The
8 parameters are real.
9 DR. SAMET: Good. Thank you very much,
10 David.
11 So I'm going to suggest that we move to some
12 of the materials that are listed as post-lunch,
13 probably the discussion of chapter 3, Neal, and
14 perhaps, chapter 6, and that we move onto those. I
15 think Neal's slated for 1:30, sort of the updated
16 discussion on chapter 3, which, of course, has been
17 posted. So I don't think you have any slides for
18 this, but I think we're just going to have a verbal
19 discussion of the evolution of this chapter, which
20 has been posted.
21 Chapter 3 - Neal Benowitz
22 DR. BENOWITZ: Thanks, Jon.

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1 I summarized chapter 3 at our last meeting,
2 and the draft of chapter 3 has been posted. Just
3 to summarize the overview, this chapter reviews
4 what menthol is and its chemistry and general
5 comments about the levels of menthol in different
6 cigarette tobacco and tobacco smoke; the
7 relationship between menthol and low-yield
8 cigarettes; and also mentions the question of
9 menthol analogs.
10 The second part discusses menthol's
11 mechanism of action, describes the various sensory
12 receptors that menthol acts upon, and makes a point
13 that menthol at different doses can produce a
14 smell, a cooling taste, and in high concentrations,
15 irritation and pain. And it discusses which
16 various receptors it works on. It works on several
17 of the sensory receptors. It can have both
18 stimulating and antagonistic effects at different
19 concentrations.
20 Another section relates to interactions with
21 menthol of nicotine. And it summarizes data
22 indicating that menthol has been shown to interact

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1 with the effects of nicotine in a couple ways.
2 Menthol pre-treatment, in several models, can
3 reduce the effects of nicotine, can reduce the
4 irritating effects of nicotine, and, therefore,
5 could, in theory, reduce the bitterness and
6 irritation of nicotine and smoke.
7 In other scenarios, where there are low
8 levels of nicotine, menthol can produce irritation,
9 and burning, and some of the impact that would
10 normally be associated with nicotine and basically
11 can make up for a low nicotine concentration. So
12 menthol really is modulating effects of nicotine as
13 part of the complex flavor of cigarettes, which is
14 a combination of the odor, the taste, and the
15 chemosensory impact.
16 The next section addresses menthol kinetics
17 and metabolism itself, and then metabolic
18 interactions with nicotine and tobacco-specific
19 nitrosamines. It's noted that menthol is excreted
20 primarily as menthol glucuronide in smokers.
21 Menthol levels themselves in blood seem to be
22 fairly low. Some calculations have been made here

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1 of what some estimated levels of menthol in the
2 smoke would be. And that's important because it's
3 these concentrations that would act on sensory
4 receptors. And we know that a certain percentage
5 of nicotine is metabolized in the lung. And so
6 these concentrations would also be present at the
7 enzyme level in the lungs, and, therefore, could
8 have effects even if the blood levels were too low.
9 The much higher concentrations present in the lungs
10 could, in fact, affect metabolism and deal with
11 some of those estimates.
12 The interactions with nicotine are
13 summarized. There are certainly some in-vitro
14 studies and one human study that suggests that
15 menthol has a small effect on nicotine metabolism.
16 There are other studies that don't find that,
17 looking at the nicotine metabolite ratio, which is
18 a problem because the effect of nicotine within
19 subjects studied was 10 percent, and the metabolite
20 ratio might not find an effect in a cross-sectional
21 study.
22 Then interactions with tobacco-specific

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1 nitrosamines, again, there are in-vitro data
2 showing that menthol can inhibit the
3 glucuronidation of the nitrosamine or carcinogen
4 NNAL. It could potentially increase its
5 carcinogenic potential. Some studies suggest that,
6 that may be happening in people smoking; others
7 don't find that effect. So there's mixed data.
8 The final section integrates the sensory
9 pharmacology with the effects of menthol in
10 cigarette smoke, and basically makes the point that
11 menthol can increase the smoothness and reduce the
12 harshness of smoke in some situations. In other
13 situations, when there's low nicotine, it can make
14 up for lower nicotine and contribute to the impact
15 and to the overall flavor and satisfaction from
16 cigarettes.
17 There is a new section that was entered,
18 that was added in response to comments at the last
19 meeting on genetic differences in taste. There
20 clearly are people who taste bitterness more than
21 others, and there are some genetic studies
22 identifying which genes are involved with that.

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1 There are data in smokers that smokers who
2 are more sensitive to bitter tastes are less likely
3 to smoke cigarettes, and certainly there is a
4 biological plausibility that menthol might, in
5 particular for such people, reduce bitterness and
6 enhance the tolerability of tobacco smoke.
7 The final section is evidence synthesis, and
8 the first one was, does menthol have cooling or
9 anesthetic properties that moderate the harshness
10 of tobacco smoke? And the evidence is sufficient
11 to conclude that menthol has such properties.
12 The second is, does nicotine make low-tar,
13 low-nicotine cigarettes more acceptable to smokers?
14 And the evidence is sufficient to conclude that
15 menthol does do that.
16 The third is, does menthol have an effect on
17 metabolism of nicotine or tobacco-specific
18 nitrosamines? And here, the evidence is sufficient
19 to conclude that it is at least as likely as not
20 that menthol inhibits nicotine metabolism and
21 possibly inhale metabolism of smokers. However,
22 it's not clear that these effects are translated

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1 into any effects on smoking behavior or toxicity.
2 The final section addresses whether it is
3 biologically plausible that menthol enhances the
4 addictiveness of cigarette smoking. And the
5 evidence is sufficient to conclude that it is
6 biologically plausible that menthol makes
7 cigarettes more addictive. And a number of
8 mechanisms are discussed here, including modulation
9 of nicotine effects; the importance of sensory
10 factors in nicotine addiction; and citing animal
11 studies where taste and smell enhance self-
12 administration; the fact that sensory experiences
13 contribute to conditioned aspects of smoking
14 behavior; and, again, citing basic psychology
15 studies.
16 The fact that stimuli associated with drug
17 intake, such as perhaps menthol, can evoke craving
18 that promotes presumption of self-administration of
19 the drug in a period of abstinence, certainly, the
20 question is raised about whether menthol is a
21 stimulus, and someone trying to quit smoking, it
22 could trigger relapse. And these mechanisms have

1 been described in animal studies.
2 That's basically the conclusions. Now, we
3 will be adding some additional studies on sensory
4 pharmacology, which have come up since this last
5 version, and I think that's basically it.

6 DR. SAMET: Thank you. Thank you, Neal.
7 And, of course, we have had an opportunity to
8 discuss this and the chapter's been posted and
9 available.

10 Are there questions or comments? John?

11 DR. LAUTERBACH: There are a variety of
12 menthol levels in cigarettes. And it seems that,
13 at least looking at cigarette sales of these
14 different brand styles, particularly the low-volume
15 sales of cigarettes with very high menthol levels
16 or deliveries that could be obtained through
17 smoking the cigarettes more intensively or
18 differently than on the various smoking
19 machines -- it would appear that if menthol was
20 increasing the addictiveness of tobacco, we see
21 quite a bit of a different distribution among the
22 sales of menthol styles with some of the ones that

1 the case of alcohol, the largest problem among
2 young people isn't with vodka; it's with beer and
3 lower concentrations. It doesn't take away from
4 the fact that alcohol is addictive. And we, again,
5 see the same thing with other drugs, opioids as
6 well, where there is a segment of the population
7 that goes for the highest strength opioids, like
8 intravenous heroin, in the broadest range of uses
9 for formulations that are not as powerful or
10 concentrated.

11 Actually, there's just a wealth of
12 experience with other drugs that is consistent with
13 these conclusions. The concept that you can
14 increase addictiveness by increasing the ease of
15 drug exposure is basic, whether you're trying to
16 establish addiction in animal models, as I did in
17 my own research, or in humans.

18 Crack cocaine, as Dr. Hatsukami and myself
19 and others have found, that form did not make the
20 molecule cocaine more addictive. It made it
21 easier, and more acceptable, and greatly increased
22 our nation's problem with cocaine.

1 are extremely unpopular now. If your hypothesis
2 were true, would be the ones that would be most
3 popular because those are the ones that would give
4 the smokers the most dose of menthol.

5 DR. BENOWITZ: On the literature that's
6 reviewed, it indicates that menthol does different
7 things at different levels, both of which could be
8 important. At lower levels, it really serves as a
9 cooling and soothing effect, reducing the harshness
10 of cigarettes. At higher levels, it's more on
11 impact and a taste.

12 So it seems clear that people smoke menthol
13 cigarettes for different reasons, and some reasons
14 are seen at low menthol levels and some reasons are
15 seen at high menthol levels. So I don't think that
16 this is as if a person were self-administering
17 menthol and trying to get higher doses. I think
18 they're getting different effects from menthol at
19 different levels of menthol.

20 DR. SAMET: Jack?

21 DR. HENNINGFIELD: Just to add to that, it's
22 consistent with other addictive drugs as well. In

1 So the idea that a substance can make it
2 easier to expose yourselves to dangerous levels is
3 not unique here. There are a lot of other examples
4 with other addictive drugs that are very consistent
5 here.

6 Finally, the importance of taste, smell,
7 other sensory stimuli, have been recognized as
8 important for other addictive drugs for more than a
9 half a century. And most recently, a lot of brain
10 imaging research is showing that stimuli associated
11 with drugs, be it cocaine, heroin, or cigarettes,
12 can trigger relapse, or cravings rather, and even
13 other withdrawal symptoms. So there's a lot of
14 evidence from the drug addiction literature as a
15 whole that is very consistent with what is very
16 succinctly presented in this section.

17 DR. SAMET: Let me ask a question. Are you
18 suggesting that this chapter should reinforce,
19 buttress, allude, to this larger literature?

20 DR. HENNINGFIELD: I think, right now, it
21 has -- I don't think it needs to be turned into a
22 surgeon general's report. I'm not sure. I don't

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1 recall if the ADA report, nicotine addiction
2 report, is referenced, but that reference alone
3 covers an awful lot of this territory, perhaps a
4 few more references.
5 But right now, I think it covers a lot of
6 the ground. I think the important thing is that,
7 to those of us that are familiar with the broader
8 addiction literature, this fits like a puzzle piece
9 very nicely. It's not an outlier.
10 DR. SAMET: Thanks. So perhaps, some
11 allusion is broader literature.
12 Dan?
13 DR. HECK: Yes. I have a number of comments
14 and issues with this first draft. I understand
15 it's a first draft. But just to try to follow on
16 to one of the later discussions here with regard to
17 the level of menthol and experimental studies
18 showing differential effects of cooling, and then
19 other effects at higher levels, do we have a clear
20 idea from the real cigarette tobacco smoke, the
21 real most relevant studies here, of what those
22 levels are and how they relate to those

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1 academically-determined levels for the local
2 anesthetic effect?
3 I think that'll be an important
4 consideration. It's a question not requiring an
5 answer, unless you know it off-hand. But I think I
6 see, in this chapter, a recitation of the familiar
7 and very interesting general pharmacology of
8 menthol. We understand quite a bit about that.
9 But I don't see a synthesis of those
10 observations, usually in menthol in isolation in
11 the animal studies or whatever, into a defensible
12 support for some of the conclusions drawn here.
13 There are some minor areas of fact that I've noted
14 throughout. I don't have to go through all those.
15 Synthetic menthol employed by the tobacco companies
16 is not a DL-racemic mix. It's 99 plus percent pure
17 L-menthol. That citation was attributed to a
18 Lorillard submission, but I reviewed that, and I
19 think it needs to be corrected to reflect that
20 L-menthol is a synthetic form used in tobacco
21 products.
22 Another question -- and I'm sorry I only had

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1 a day to read through this. I'm not quite sure
2 whether it was in this chapter or in chapter 6, the
3 statement that we've seen and heard in this forum
4 before, that 90 percent of cigarettes on the U.S.
5 market contain some menthol. I'd like to get that
6 corrected. That statement, as near as I can
7 determine, was delivered by Dr. Giovino in the
8 first menthol conference in a review presentation.
9 I've looked for the authoritative substantiation of
10 that and been unable to find it.
11 I think we've heard discussion already about
12 the low levels of menthol that are employed in some
13 proprietary top flavorings and things like that,
14 far below the taste threshold, or certainly the
15 pharmacological threshold, I think.
16 We've heard testimony from Altria, for
17 instance, who commands 50 percent of the market in
18 the U.S., that they do not employ menthol in their
19 non-menthol brand. So right there, you have a
20 sense that the statement that 90 percent of the
21 cigarettes have some menthol, it can't be true.
22 So I think we should not continue to cite

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1 that particular factoid, which in my own reading I
2 haven't been able to substantiate.
3 DR. SAMET: I would say, Dan, let me
4 interrupt, because you've already brought up
5 several points, and it might be better to be a
6 little --
7 DR. HECK: Yes.
8 DR. SAMET: -- consecutive here, perhaps.
9 I think on this 90 percent question, I know
10 that's mentioned. I think it's Giovino, a 1994
11 publication. And this is cited in chapter 1. And,
12 in fact, I went back and looked at it. And as I
13 recall, it does make mention -- I'd have to go
14 back -- to a paper on the development of analytic
15 methods for menthol. And that 90 percent may
16 relate to the particular cigarettes covered in that
17 analysis. I would have to refresh my memory. But
18 I think that is, in fact, where that particular
19 point could be traced back to.
20 I think this is a point where, if you can
21 guide us towards, perhaps, more authoritative
22 sources or updated sources, that would be helpful.

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1 I think on the first point, where you
2 started -- and I think Neal needs to respond here,
3 again. But is your suggestion, perhaps, that there
4 might be references that could be included on this
5 point that would be helpful in making chapter 3 run
6 deeper in the literature cited? In other words,
7 are you suggesting that we might have missed
8 something? I guess I heard the point, but now I'm
9 asking what next or what is missing?

10 DR. HECK: Yes. I apologize, Mr. Chairman,
11 for going on. I have quite a number of comments.
12 And some of these I think might be more efficiently
13 transmitted in a subsequent e-mail communication or
14 something. But I'm not aware of an authoritative
15 reference for what's really I think at issue here.
16 I saw the calculation presented of -- we're trying
17 to get at the local levels of menthol, at the
18 tissue-smoke interface. And I don't know that
19 that's a notable number. We've looked and tried to
20 develop a similar estimate ourselves, but it's a
21 difficult task.

22 On that topic, though, Neal, we saw an

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1 additional discussion in terms of the local level,
2 hypothesizing that local menthol may be
3 sufficiently high to inhibit lung, as opposed to
4 liver, metabolism of nicotine.

5 Do you have a ballpark estimate of what
6 percent of nicotine derived from smoking is, in
7 fact, locally metabolized in the lung as opposed to
8 the liver?

9 DR. BENOWITZ: There was one study,
10 basically, I think in dogs, estimating 10 percent.

11 DR. HECK: Yes. I think that was the only
12 study I was aware of, in an animal model as opposed
13 to humans. The other, I think a major concern I
14 have with regard to the metabolism question, is the
15 part on the reported effects of menthol on nicotine
16 metabolism and on NNAL metabolism.

17 I was a little surprised to see the relative
18 strength of the draft conclusion here on the
19 nicotine metabolism question because insofar as I'm
20 aware, a well-done study in 2004, a clinical study
21 of I think 14 smokers, did see this modest, maybe
22 10 percent, apparent effect on nicotine metabolism,

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1 developed not from the measured urinary deuterated
2 metabolites, which were no different, but from
3 apparently, a non-renal clearance.

4 That's the only paper I'm aware of that has
5 seen that effect in human smokers. And we have, in
6 the wake of that, a number of papers, including
7 Strausser 2007 to 2011; Ho, et al., 2009; Wang,
8 et al., 2010;, in the very large total exposure
9 study; Dr. Benowitz, a 2010 paper, not confirming
10 that observation. So I just would question whether
11 a single study, regardless of how well done,
12 outweighs very large subsequent studies in human
13 smokers that say that there's apparently no effect
14 in the actual smoking situation.

15 I think that same comment might be applied
16 to the NNAL metabolism assertion advanced by
17 Muscat, et al., in 2009. Oh, and by the way,
18 there's a misquote of the Richie paper on that
19 topic in here. Richie, et al., actually the same
20 group as Muscat, same subjects, and I think, same
21 urine samples, as a matter of fact, in 1997, had
22 come to the opposite conclusion, and that is that

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1 black race seemed to be associated with the lower
2 relative glucuronide NNAL as opposed to the
3 free -- in the later analysis by Muscat, et al., is
4 the only paper, I'm aware of, that has seen that.

5 And, again, we've seen discussion from the large
6 total exposure study and others, that this doesn't
7 seem to be a reality in the actual, real-life
8 smoking situation.

9 So I just would suggest these comments, and
10 more extensive ones, to suggest that the strength
11 of this draft conclusion might be reconsidered.

12 DR. SAMET: Neal, do you want to comment?

13 DR. BENOWITZ: Yes. I certainly think that
14 with the NNAL issue, the larger studies don't seem
15 to find an effect. There certainly is a biological
16 plausibility based on in-vitro studies. The
17 nicotine metabolism issue is more complicated. The
18 only way to do a definitive study to look for a
19 small effect is actually to give nicotine a measure
20 of metabolism explicitly, and my laboratory's the
21 only group that's done that.

22 When you look at the hydroxycotinine

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1 cotinine ratio, which is what the other groups have
2 looked at, that is a marker of oxidative
3 metabolism. But it's very variable, and it is all
4 cross-sectional studies, as compared to a within-
5 subject study. So the only gold standard study, it
6 is small, and that's its limitation, but the
7 highest quality study suggests that there's a small
8 effect.

9 Given that, I'm not sure that it matters.
10 The NNAL effect, I think we could probably argue
11 equipoise for that. But the bottom line for this
12 chapter, in any case, is that I don't think either
13 of these things plays much of a contribution in a
14 bottom-line assessment.

15 DR. HECK: I would agree with that synopsis,
16 but to the I guess supporting evidence for the NNAL
17 assertion, which I agree the evidence is modest; in
18 fact, that single study. But the in-vitro evidence
19 presented in that particular study was I think
20 quite limited in itself. It entailed a single vial
21 of human S9 from three Caucasian liver donors and a
22 two-hour incubation with, possibly, capacity-

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1 limiting levels of cofactors and levels of
2 substrate, and menthol hundreds of times, and
3 substrate millions of times, I recall, higher than
4 physiological. So a single in-vitro incubation
5 like that, I think doesn't provide a lot of
6 compelling support for the single paper, Muscat
7 asserting the NNAL effect.

8 Interestingly, too, I think that the Richie
9 paper, 1997, from the same Muscat group, did
10 actually -- it's buried in the human study. But
11 they did a rat experiment in that same paper,
12 looking at co-administration of NNK and menthol,
13 and found, actually, an increase in the
14 glucuronidation, glucuronidated NNAL excretion,
15 rather than a decrease. So I think there's at
16 least a small bit of in-vivo experimental evidence,
17 also contrary to the assertion.

18 DR. SAMET: Other comments on chapter 3?
19 Mark?

20 DR. CLANTON: No additional questions.
21 DR. SAMET: Thank you.
22 Anyone else?

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1 [No response.]
2 DR. SAMET: Neal, anything else further from
3 you?
4 DR. BENOWITZ: No.
5 Chapter 6 – Jonathan Samet
6 DR. SAMET: Then I'm going to suggest we go
7 to chapter 6, which is actually Neal and myself.
8 This is a chapter concerned with a variety of
9 evidence, relevant to the potential comparative
10 health risks of menthol cigarettes versus non-
11 menthol cigarettes.
12 It covers the studies of smoking topography,
13 biomarkers, selected toxicology, and epidemiology,
14 and reaches an overall conclusion that the -- I
15 think everybody can see the conclusion -- evidence
16 is insufficient to conclude that it's more likely
17 than not that menthol cigarettes inhale
18 more -- well, I'm sorry, that the risks are
19 different at the bottom line. The evidence is
20 insufficient to conclude that smokers of menthol
21 cigarettes face a different risk of tobacco-caused
22 diseases than smokers of non-menthol. And there's

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1 other conclusions related to the topography and the
2 biomarkers.
3 So, Neal, do you want to comment on the
4 first two sections?
5 DR. BENOWITZ: Yes. We talked about this
6 last meeting as well. And as Jon said, there are
7 four sections. The first two are sections that
8 really look at whether menthol cigarette smoking
9 results in exposure to more tobacco smoke.
10 So the first set are really topography
11 studies where puffing behavior and things like
12 nicotine boosts, or carbon monoxide boosts, are
13 examined after smoking a single cigarette, usually
14 in a laboratory, smoking a cigarette through a
15 cigarette holder with a recording device.
16 These are small studies, in general. Some
17 involve force smoking or standardized smoking,
18 rather than natural smoking conditions. There are
19 a number of studies that show different results.
20 But on balance, I think there is no consistent
21 effect of menthol cigarettes on smoking behavior in
22 these studies.

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1 Now, one caveat for all of these studies is
2 that they generally involve heavy, regular smokers.
3 And the one question that still I think is not
4 fully resolved is what menthol does to people who
5 are smoking relatively few cigarettes per day,
6 where there might be a reason to get as much
7 nicotine per puff as possible. And none of these
8 studies have really addressed very light smokers.
9 The second section, or the biomarker
10 studies, are larger studies. These are, in
11 general, cross-sectional studies, and these looked
12 at biomarkers of nicotine exposure, either cotinine
13 levels or urine nicotine equivalents. They have
14 looked at nitrosamine exposure. They have looked
15 at polycyclic hydrocarbon and other tobacco toxins,
16 and some have been quite large. In general, there
17 is no consistent effect of menthol on exposure.
18 So from these two sets of studies, I think
19 we cannot conclude that menthol is associated with
20 inhalation of more smoke or that menthol is
21 associated with greater exposure to tobacco toxins.
22 DR. SAMET: Actually, why don't we do this

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1 in segments? Any comments on the elements of the
2 chapter that Neal just presented? Dan?
3 DR. HECK: Just a brief comment. I know
4 we've seen presentations by Dr. Sarkar of Altria of
5 this large study and the special analysis of the
6 10-or-less smokers requested by the committee. And
7 I realize this is not, I guess, published yet, but
8 I think with the data having been shared with FDA
9 and the committee, and the presentations that were
10 given, and, generally, the quality of the study,
11 and the papers that have been published, I would
12 hope that this section would give that as full a
13 consideration as possible because it's, in my mind,
14 probably the biggest and best study that has been
15 or ever will be done on that topic of biomarkers of
16 exposure.
17 DR. BENOWITZ: The Sarkar study is included
18 in the biomarker analysis.
19 DR. HECK: Yes. Again, I only had a day to
20 review this, but if the treatment is anything other
21 than fairly substantial, I think that the study is
22 probably worthy of -- there's a lot of information

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1 in there that I think will inform several of these
2 chapters, and I think it would be advantageous for
3 us to take advantage of that to the maximum extent
4 we can.
5 DR. BENOWITZ: Again, I should add also,
6 there are tables that have not been finalized yet,
7 that really summarize the studies. And so they
8 include more detail from the Sarkar and Wang
9 analysis. They're basically the same data set, in
10 terms that there I think they measured main
11 findings. So it will be expanded a little bit with
12 those tables.
13 DR. SAMET: Any other comments for Neal?
14 Yes, Jack?
15 DR. HENNINGFIELD: Part of the challenge of
16 a chapter like this is that you have to look in
17 isolation at the contribution of menthol to
18 disease, specifically, but how it is linked to the
19 population, the overall population impact of
20 menthol, which is clearly greatest in African-
21 Americans, where I think there's no question that
22 if menthol wasn't there, there would be some

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1 reduction. We don't know how great.
2 I guess the linkage, then, comes in the
3 final conclusions, the overall. But I think even
4 within the chapter, it would be useful to link the
5 evaluation of the disease consequences of menthol
6 to the overall population effects related to
7 addiction. And, again, crack cocaine was an
8 example where that greatly increased our nation's
9 population exposure to cocaine, even increasing the
10 risk of diseases like HIV/AIDS that weren't caused
11 by crack, but that contributed. So I think
12 someplace in this --
13 DR. SAMET: Yes. Actually, what you want is
14 at the end of chapter 2. And I don't think it
15 needs to be repeated there, but that's where we
16 discuss the idea of models and the very important
17 idea of the population attributable risk, describe
18 what leads to population burden from any exposure
19 in general, i.e., what you said, Jack, an increase
20 in the population involved, exposed, or the risks.
21 So we've set the stage there I think for
22 exactly what you're saying. So I don't think we

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1 need to allude back to that again in this chapter.
2 Dan?
3 DR. HECK: Just a quick general question,
4 maybe for the Chairman or the FDA. These redacted
5 sections that we see in some of these chapters, of
6 course, I'm curious what they are, and I understand
7 why they're redacted, I think, but it makes me
8 curious as to whether any of the conclusions that
9 are publicly available here were driven
10 significantly, in a game-changing way, by those
11 apparently confidential information.
12 DR. SAMET: I think, for one, obviously, the
13 commercial confidential information has been
14 redacted. Second, we are trying to make certain
15 that all of the information that, for the moment,
16 is said to be commercial confidential is, in fact,
17 commercial confidential. We're doing some checking
18 and I don't think -- so far, we've been trying to
19 review the totality of the evidence and supply FDA
20 with a report that covers the full scope of the
21 evidence. I'm not aware of anything that's -- I'll
22 use the word pivotal -- not revealed in the

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1 publicly available information.
2 DR. BENOWITZ: I would certainly add from my
3 perspective that the redacted information does not
4 influence the conclusions.
5 DR. SAMET: So before lunch, let me move on
6 to just the last segments of chapter 6. And,
7 again, this has been discussed before. I think
8 what is new in this version is a brief and I think
9 still rather selective review of some of the
10 relevant toxicological information. Working with
11 Neal, that's going to be augmented a bit. I think
12 there's some question about the relevance of some
13 of the fairly artificial systems, in which menthol
14 or smoke from menthol cigarettes has been assessed.
15 Perhaps, the more important other piece of
16 the chapter is the review of the epidemiological
17 information. Again, there will be a table
18 describing the principle studies. I actually think
19 we've discussed those studies at some length.
20 Probably, commenters have also reviewed those
21 studies. They're relatively limited in number in
22 the fact it's essentially only for lung cancer that

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1 we have estimates of relative risk for developing
2 this disease in menthol smokers versus non-menthol
3 smokers, with multiple studies, and we're aware
4 that there may be one additional study to cite.
5 I think those estimates have been discussed,
6 and the general conclusion from those -- and, again,
7 I will note that we're missing really sufficient
8 evidence on both heart disease and chronic
9 obstructive pulmonary disease through the major
10 outcomes, diseases caused by smoking. But the
11 overall conclusion, based on the evidence we had,
12 is the one I read, that we can't conclude that
13 there's a different risk in these diseases in
14 smokers of menthol versus non-menthol cigarettes.
15 So that is chapter 6. And let me ask if
16 there are any questions either on the components I
17 just covered or chapter 6 in total? Mark?
18 DR. CLANTON: No.
19 DR. SAMET: Okay. It's noon. It's
20 lunchtime. I'm going to suggest that we try to
21 reconvene at 12:45, given the constraints on the
22 schedule, so that we make certain to discuss

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1 everything as fully as possible. So with that,
2 let's all dash and find food.
3 A reminder to the committee not to discuss
4 any of the meeting topics over the lunch amongst
5 ourselves, with the press, or with any member of
6 the audience.
7 (Whereupon, at 12:03 p.m., a luncheon recess
8 was taken.)
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1 AFTERNOON SESSION
2 (12:51 p.m.)
3 DR. SAMET: We are reconvening the committee
4 meeting; if everybody could take their seats,
5 please.
6 Caryn?
7 MS. COHEN: If you are planning to speak
8 during the open public hearing and you haven't
9 already signed up, please go outside and sign up
10 just outside these doors here, and Tom Graham will
11 help you with that and give you your number. Thank
12 you.
13 DR. SAMET: Then we're going to proceed with
14 the presentation by Eric Johnson from RTI. Eric?
15 Thank you.
16 Presentation – Eric Johnson
17 DR. JOHNSON: Yes. Thank you. I presume
18 we'll do this like we did before. Right? So I'll
19 just tell you when I need to switch the slides?
20 MS. COHEN: Yes, please.
21 DR. JOHNSON: So the topic for this
22 afternoon that I'll be presenting is to follow up,

1 group, were provided for all smokers and for
2 current switchers from the Switching Book during
3 the January public TPSAC meeting. And I've
4 included those data here, and we'll review them
5 briefly.
6 We also reviewed all of the submitted
7 documents for additional stratified analyses by
8 age, as well as looking at length of time of
9 smoking current brand, the idea there being that if
10 you've been smoking for less than or equal to a
11 year, this is likely to include a significant
12 proportion of switchers.
13 So these are the data that were presented
14 from the Switching Book during our prior public
15 TPSAC meeting, and they come from a national sample
16 of smokers, approximately 34,000 smokers, who were
17 interviewed in 1991 regarding their smoking
18 behaviors.
19 This presented table breaks out those
20 current smokers into several demographic
21 categories, including our focus here by different
22 age groups, and looked at switching from non-

1 quick fast, in the closed session of the -- I think
2 it's February 10th meeting of the TPSAC. The
3 disclaimer here is that the analyses and
4 conclusions that are being presented in this
5 presentation are those of the authors and RTI's and
6 are not attributable to the FDA.
7 So, as I mentioned, the purpose is to
8 respond to two specific requests for additional
9 information following one of our prior meetings.
10 The first of these requests was to examine the data
11 available on analyses that might be stratified by
12 age, in terms of switching between menthol and non-
13 menthol cigarettes.
14 The second is to present data on switching
15 within menthol brands to the extent possible,
16 focusing on Kool as a benchmark for super high
17 menthol and, again, to the extent possible, examine
18 patterns of that within menthol-brand switching by
19 demographic, length of time of smoking, and other
20 characteristics.
21 So the first topic, switching stratified by
22 age, some of these data, rates on switching by age

1 menthol to either another non-menthol brand or a
2 menthol brand -- let's see, columns three and
3 four -- or switching from a menthol cigarette to a
4 non-menthol or to a different menthol cigarette, so
5 essentially, both cross-flavor and within-flavor
6 switching rates.
7 The numbers presented here, for example, if
8 we focus on the first row for an age group, 18 to
9 24 years of age, we would interpret these numbers
10 as 7.4 percent of this age group, who are smokers,
11 switched from a non-menthol cigarette to another
12 non-menthol brand of cigarette. Similarly, of the
13 18- to 24-year old smokers, 1 percent switched from
14 a non-menthol cigarette to a menthol cigarette and
15 so on.
16 So if we look across these age groups from
17 18 all the way down to 65 plus, we see a trend
18 toward a higher rate of switching within younger
19 age groups compared to older age groups, for three
20 of the four comparisons that we're looking at. So
21 switching from non-menthol to another non-menthol,
22 from non-menthol to a menthol, and also switching

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1 from a menthol to a non-menthol, there's some
2 indication of higher rates of switching for the
3 youngest age group of adults, 18 to 24.
4 Now, this table from the same data examines
5 the demographic characteristics of switchers, so
6 this is restricted to people who had changed their
7 brand of cigarette over that one-year interval.
8 [Pause.]
9 DR. SAMET: Eric, we're back.
10 DR. JOHNSON: Great. As I was saying, this
11 table presents data on the demographic
12 characteristics of switchers, so it's limited to
13 those who had switched brands of cigarettes in the
14 past year. And the percentages in columns 3
15 through 6 are among each of these categories, so
16 switched from non-menthol to non-menthol accounts
17 for 2,000 cigarette smokers. And of those,
18 16.6 percent are in the age range of 18 to 24; 26
19 are between 25 and 34 and so on.
20 So we, for most categories, did not tend to
21 see, looking just at those percentages, a higher
22 switching rate or a higher number of young adults

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1 among switchers, in contrast with the prior slide.
2 However, that appears to be largely due to the
3 representation of each age group in the number of
4 smokers overall. That is, if you look at the
5 second column, this is the percent of smokers
6 included in the sample by age group, and we can see
7 that the youngest age group, 18 to 24, accounts for
8 13.6 percent of all of the smokers.
9 So for at least a few of these categories,
10 it would appear that, relative to their
11 representation in the smoking sample overall, the
12 younger smokers do have higher rates of switching,
13 even within these data.
14 These data were identified as part of our
15 review and have not been presented before. And
16 they come from the Newport menthol category
17 analysis, which examined the cigarette tracking
18 study data from 1987 to 1989. In that sample, the
19 overall rate of switching in the past year was
20 3.5 percent. And what the study presented in terms
21 of an age breakdown or a stratified analysis is
22 really specifically looking at menthol to non-

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1 menthol switching, and particularly among Newport
2 smokers.
3 So we can see, from those data, the 18- to
4 24-year-olds represented about 13 percent of the
5 Newport smokers, but they represented about
6 31 percent of those that were switching from the
7 Newport to a competitive non-menthol cigarette.
8 These were the only age-stratified analyses that
9 were presented in that study.
10 So, overall, examining the rates of
11 switching among all smokers, by age group, suggests
12 higher rates of switching among the youngest
13 adults, 18 to 24, except for the pattern of
14 switching within menthol brands, where there did
15 not appear to be a higher rate. Eighteen to 24-
16 year-olds also may be disproportionately
17 represented among cross-flavor switchers relative
18 to the proportion of smokers they represent in the
19 smoking population overall.
20 Unfortunately, no additional or age-specific
21 information was found for the length-of-time
22 analysis, so we couldn't break down the smoking for

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1 less than or equal to one year across age groups in
2 any of the data that we reviewed.
3 So we're now changing to the second topic
4 that we needed to address for response to the
5 questions, and that was switching among menthol
6 brands. We reviewed the submitted Topic 8
7 documents for brand-level analyses that would allow
8 us to look at menthol brand switching. Four
9 documents provided useful data. Three of them were
10 reviewed here. One of them was reviewed this
11 morning as a commercial confidential document.
12 The available data in these documents
13 largely focused on Newport, Salem, and Kool brands
14 of cigarettes. The industry analysis of switching
15 generally did not distinguish between non-menthol
16 and menthol brands for those brands that had both.
17 So, for example, Virginia Slims were not further
18 broken down into menthol and non-menthol versions,
19 which just really limits our analysis here.
20 So the first of the three studies that we'll
21 review is again from the Switching Book. That was
22 that telephone survey of 34,000 current smokers.

1 And the data provided really show analyses of
2 switching to and away from selected brands over
3 time, as well as by source and destination of
4 brands, really as a percentage of brands of
5 switchers. So we'll review tables and figures for
6 each of these menthol brands in order, from Kool,
7 Newport, and finally Salem.

8 So this is a table from the Switching Book
9 report, and it tracks the overall rate of switching
10 to the Kool brand and away from the Kool brand over
11 time. So the second column is from the 1982 data,
12 and they track this rate of switching all the way
13 out to the 1991 data. And you can see in the third
14 row of the table that there is a trend toward a
15 decreasing percentage of switchers among the Kool
16 smokers. That's actually switchers to Kool, so the
17 folks that are switching into their brand as their
18 new preferred brand of cigarette is dropping over
19 time from 8.7 percent down to 2.6 percent.

20 In about the middle of the table, there is
21 the row for switching from Kools, so the out-
22 switchers or those that are being lost to a

1 switchers who had switched from another Kool
2 product to a current Kool brand. That accounts for
3 about .5, and then Newport accounts for about
4 .3 percent.

5 These are the out-switchers, the brands to
6 which Kool is losing smokers. And, again, this is
7 the 1991 data, so this is for the 8.2 percent of
8 Kool smokers who are switching away from Kool. In
9 the brand box under R.J. Reynolds, you see the
10 Salem data. It's .3 percent. Under Brown &
11 Williamson, switching to another Kool brand is
12 about .5 percent, and switching to Newport under
13 Lorillard is about 1.2 percent.

14 These are the same data or the same set of
15 analyses for Newport. So, again, the third row
16 shows us the percent of Newport smokers that had
17 switched to Newport. It also shows a falling trend
18 from 1982 to 1991 from approximately 11 percent
19 down to 5 percent. The switchers from Newport,
20 that is, the ones that they're losing, also shows
21 this lower trend, from about 11.6 percent down to
22 4.9 percent. But in contrast to the Kool data that

1 competitor brand. And, again, there's a downward
2 trend, from 15 percent to about 8 percent over this
3 time period from '82 to '91. It's interesting to
4 note that the percentage of Kool smokers who are
5 switching out or away from Kool in each of these
6 years is greater than the percentage of those
7 switching into the Kool brand of cigarettes.

8 Now, the prior slide was analysis of all
9 switching into and away from the Kool brand. The
10 report further breaks this down, looking at in-
11 switchers, those that are moving to the Kool brand,
12 and looking at the source of those switchers by
13 company in the first row of this figure and by
14 brand within company in the second row.

15 So you interpret this table -- this is from
16 the 1991 data -- that about .9 percent of the
17 overall 2.6 percent can be attributed to loss or
18 in-switching from Phillip Morris brands. Of
19 particular relevance for our question here, we have
20 to look at specific brands of Salem, which is a
21 menthol brand, and that accounts for about
22 .3 percent Kool, which they actually include

1 we had looked at just a few moments ago, the
2 relative balance between switchers to Newport --
3 the ones that they're gaining -- and switchers away
4 from Newport -- the ones that they're losing -- are
5 about the same, year to year, so they seem to be in
6 balance.

7 So breaking down the in-switchers by the
8 brand from which they came, again, if we look under
9 R.J. Reynolds, we find the Salem brand of
10 cigarette, and that accounts for about 1 percent of
11 the 5.1 percent; Kool, again about 1 percent under
12 Brown & Williamson; and an alternative Newport
13 brand, about .5 percent.

14 Out-switchers. So approximately .6 percent
15 of the Newport smokers are switching out to a Salem
16 brand of cigarette, .2 percent to a Kool brand, and
17 .5 percent to an alternative Newport brand of
18 cigarette.

19 Finally, the Salem data, our Salem series
20 here, as with the other two brands, we see a
21 falling trend in terms of the switching to Salem,
22 as well as switching away from Salem -- I'm sorry,

1 I misspoke -- switching to Salem, we see the
2 following trend, from about 12 percent to
3 3.8 percent over this time period. And in contrast
4 to the other two brands, the rate of switching away
5 from Salem holds relatively steady across time and
6 is increasingly larger than those switching to
7 Salem over this time period, again sort of
8 suggesting a loss of market share for Salem,
9 relative to the other brands.

10 So the in-switchers, where the current Salem
11 smokers are coming from, again, if we look under
12 R.J. Reynolds, an alternative Salem brand accounts
13 for about .7 of the 3.8 percent overall. For Kool
14 brand, it accounts for about .2, and Newport
15 accounts for about .5.

16 Where are the Salem smokers going when they
17 switch out to an alternative brand? In terms of
18 the menthol brands, under R.J. Reynolds, Salem
19 accounts for about .7 of that 10.2 percent; Kool
20 accounts for about .2; and Newport accounts for
21 about .8, so relatively small amounts of that
22 overall 10.2 percent are accounted for by those

1 conducted in 1996, of approximately 2,300 menthol
2 smokers, and these were divided across three
3 developmental areas, and they're described here as
4 high SDI, medium, and low. Unfortunately, SDI was
5 not defined in the document, and so it's a little
6 difficult to figure out what part of the marketing
7 segment the report focuses on. However, among
8 those included, we do know the eligibility
9 criteria. They had to smoke at least five
10 cigarettes a day and buy at least one menthol pack
11 out of their average of 10 packs purchased; so 1
12 out of every 10 had to be menthol in order to be
13 included in this study.

14 The information that they had, relative to
15 the question of switching within brands, menthol
16 brands, broke down into these two tables, the top
17 table looks at the percent of each of these brands
18 in the overall sample that switched in the past
19 five years. So, overall, within the sample,
20 approximately 27 percent of the smokers had
21 switched their brand, preferred brand of cigarette,
22 in the last five years. When you break that down,

1 other menthol brands.

2 So from the Switching Book, overall during
3 this period, it looks like Kool and Salem saw
4 greater out-switching than in-switching, suggesting
5 reducing market share, while Newport saw a relative
6 balance in terms of both gains and losses. Within
7 brands, if we take those figures that were all in
8 terms of the portion of the percent that they
9 account for, we can see that for Kool, about
10 23 percent of the switchers came from Newport or
11 Salem, while about 18 percent of the out-switchers
12 went to these brands.

13 For Newport, about 40 percent of the
14 switchers came from either Kool or Salem, while
15 16 percent of switchers went to these alternative
16 menthol brands. And, finally, for Salem, about 18
17 percent of the switchers came from either Kool or
18 Newport, while 10 percent of the out-switchers went
19 to these brands.

20 So this is the second of the studies that
21 provided some useful data, looking within menthol
22 brand smoking. It was a telephone survey that was

1 they looked at Newport, Kool, and Salem as the
2 menthol brands, and about 16 percent of the current
3 Newport smokers had switched to Newport in the past
4 five years. Only about 7 percent of the current
5 Kool smokers had switched to the brand within the
6 last five years, and about 18 percent of the Salem
7 smokers had.

8 The other piece of data that was available
9 looked at the percent of brands that had been
10 smoked among current Newport smokers, so further
11 breaking down the 243 current Newport smokers in
12 the sample by the percentage that came from
13 different prior brands. And so, approximately
14 37 percent of current Newport smokers came from
15 Kool, 4 from Salem, 28 percent from Marlboro
16 menthol, and 15 percent from other Newport brands.

17 This is another one of the studies that we
18 reviewed that provided some data on within menthol
19 brand switching. It was, again, another household
20 survey. This particular study had no dates, so we
21 don't know when it was conducted, but it was among
22 smokers, 21 years of age and older. There are

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1 about 3,000 participants. And they analyzed the
2 two sets of relevant information, the length of
3 time smoking their current brand, less than or
4 equal to one year. This is the table available,
5 among the LoFi or low-tar smokers, which was about
6 1,000 of the 3,000 subjects in the study. And
7 within each of these brands, approximately 2.7
8 percent of the Kool smokers had been smoking Kool
9 for less than or equal to one year; 7.4 percent of
10 Salem smokers, and 7.1 percent of the Newport
11 smokers had been smoking that brand for less than
12 one year.

13 The second piece of relevant data was to
14 look at the percentage or percent of brands among
15 all switchers to or in this category. And among
16 all switchers, a fairly large proportion were
17 Newport smokers at 35 percent, Salem smokers 17.6,
18 and Kool smokers, 5.9 percent. But, again, this is
19 a relatively small number of people that
20 contributed to this particular analysis, 34.

21 This is the last study that provides some
22 data within menthol brand switching, and it was

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1 focused on characterizing Kool and Newport
2 switchers. The data were derived from the 1992
3 cigarette tracking survey. And so for the Kool
4 brand, of the 154 Kool smokers, 33 switched to
5 another brand in the past year; 67 percent moved to
6 a discount brand. So it did not distinguish
7 between menthol and non-menthol, but some sense of
8 where they were going. And in terms of demographic
9 characteristics, about 63 percent of the switchers
10 were female, 70 percent were white, and only
11 4 percent were in the younger age range of 18 to 24
12 years of age.

13 Newport smokers, approximately 23 of the
14 184, switched to another brand. Of those that are
15 switching, 31 percent moved to Marlboro and
16 39 percent moved to these discount brands. Again,
17 this is not distinguished between menthol and non-
18 menthol. However, among switchers, 60 percent were
19 female, again, 85 percent were white, and in
20 contrast with Kool switchers, 38 percent were of a
21 relatively young age of 18 to 24.

22 So, in summary, across the data sources, it

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1 appears that switching among menthol brands favors
2 increasing market share by Newport, with reductions
3 in Salem and Kool. There's some inconsistent
4 evidence of differences, really, between switching
5 brands and gender, looking across all of these
6 studies.

7 We have a small of data that is stratified
8 by race, and ethnicity, or age. From those data,
9 it would suggest that the majority of menthol brand
10 switchers were white, and that the age
11 characteristics of switchers really differ by
12 brand, with younger smokers constituting a larger
13 proportion of switchers for Newport as opposed to
14 Kool.

15 One important limitation of these analyses
16 were that the data did not distinguish between
17 menthol and non-menthol flavors within brands; so
18 for the most part, distinguished between Marlboro
19 and Marlboro menthol, or between varieties of
20 Benson & Hedges, was not available in the data.
21 And so we couldn't track that kind of menthol-to-
22 menthol brand switching.

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1 I believe that was my last slide. Any
2 questions?

3 DR. SAMET: Thank you, Eric.

4 Questions? It was a very comprehensive
5 review of some data we have been looking for. I
6 guess, probably particularly, perhaps, Dorothy or
7 Melanie, if you have questions, there's a lot to
8 digest here.

9 DR. CLANTON: And Jon, Mark.

10 DR. SAMET: And Mark. Mark, if you have a
11 question, go ahead.

12 DR. CLANTON: I do. Very nice report. In
13 fact, we have been looking for a lot of this data
14 around switching. I think some of it's fairly
15 predictable when it comes to menthol. But my
16 question actually for Jon, is, is it your intention
17 to maybe use some of these data, switching data, to
18 either populate more precisely the model, or is
19 this generally going to be used as background
20 information in your report?

21 DR. SAMET: There is an estimate, now, of
22 switching in the model. These data might be used

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1 to refine those estimates or give balance, or I
2 guess potentially make them more age-specific,
3 which would be another possibility, or if a model
4 is developed for African-Americans, then I think
5 these data would be useful. Also, I think there's
6 this question of what are the patterns of switching
7 at younger ages is relevant to trying to understand
8 the importance of early use and patterns of
9 menthol.

10 DR. JOHNSON: No. I would say that, in
11 particular, since we are searching for data that
12 would drive the model's assumptions for African-
13 Americans, it might be really good to think about
14 including some of this, relative to African-
15 Americans.

16 DR. SAMET: Melanie?

17 DR. WAKEFIELD: Yes. I suppose just a
18 limitation of these data, as I understand it, it
19 doesn't include people aged under 18. And some of
20 this data kind of reinforces how important getting
21 kids to smoke a brand before the age of 18 is
22 incredibly important, because after that time,

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1 switching isn't really that common. So that is
2 something that I take away from these data.

3 DR. SAMET: Dan?

4 DR. HECK: I might offer a slightly
5 different takeaway. I think these data do
6 substantiate what has been presented in the marking
7 presentations, and that is that adult smokers are
8 the primary target of the marketing activities that
9 these sorts of market research or switching
10 research speak to.

11 DR. SAMET: Other questions for Eric,
12 comments?

13 [No response.]

14 DR. SAMET: Okay. Thank you, Eric.

15 DR. JOHNSON: Sure. Thank you.

16 DR. SAMET: So just to move on, then, we
17 have discussed chapters 3 and 6 before lunch, so I
18 think we have the public comment period at 2:00.
19 So we have, I think, time to proceed, at least
20 through chapter 4, and perhaps get started on the
21 two components of what is at the moment being
22 called chapter 5.

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1 Just one second. Caryn's going to make an
2 announcement.

3 MS. COHEN: Just one more reminder. If
4 you're planning to speak during the open public
5 hearing, please sign in immediately. You can just
6 walk out these doors right here, and somebody will
7 help you sign in and get your assignment number.
8 Thank you.

9 DR. SAMET: So let me ask, then, Karen and
10 Patricia, I'm not sure how you want to do this, but
11 just give an update on chapter 4.

12 Chapter 4 – Patricia Nez Henderson

13 DR. NEZ HENDERSON: Chapter 4 is looking at
14 the patterns of menthol cigarette smoking. Other
15 than, I guess, just to give an update, actually, we
16 are near completion of writing this chapter. We've
17 added a section to the introduction that will
18 address the history, and Karen's done a really good
19 job in getting some sources to talk about that.

20 We've taken your suggestions and
21 incorporated a box which provides definitions of
22 all the national surveys that we have used, in

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1 terms of their definitions for a menthol cigarette,
2 as well as just a lot more clarification on some of
3 the graphs and the figures.

4 So it's coming along really well, but this
5 chapter just provides an overall picture of what
6 the patterns of smoking is at the national level,
7 and sets the stage for both the subsequent chapters
8 after this.

9 DR. SAMET: Good. Karen, any additions?
10 [Dr. DeLeeuw indicates no.]

11 DR. SAMET: Let's see, comments from the
12 committee. So, as I said, this is really a chapter
13 that's descriptive, setting the stage, and
14 describing current patterns of menthol cigarette
15 smoking, using various national surveys --

16 DR. NEZ HENDERSON: That is correct.

17 DR. SAMET: -- with a bit of historical
18 introduction, sort of describing trends over time.
19 And I know this one has not been posted yet, so
20 this will be before our next meeting for comment.
21 But, as noted, it's pretty straightforward.

22 I don't know if anybody wants to comment

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1 further here.
2 [No response.]
3 DR. SAMET: Let's go onto what we're calling
4 chapter 5. These are likely to become two separate
5 chapters. They're both fairly substantial in
6 length and in the materials that they cover, one
7 having to do with marketing, which Melanie will
8 discuss, and the other having to do with
9 initiation, dependence, and cessation, which
10 Dorothy will discuss. And I think we have not
11 discussed marketing yet today, so this is, really,
12 our first discussion and airing of the approach,
13 and then the evidence that's been identified.
14 Melanie, please?
15 Chapter 5 – Melanie Wakefield
16 DR. WAKEFIELD: So you'll recall that the
17 last time we presented this chapter, Dorothy really
18 took the lead on it. And we did have a little bit
19 to say on what would be in the marketing section,
20 but it was still very much in development.
21 Since then, quite a lot of work's been done
22 on the chapter, and we have refined some of the

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1 questions that we propose to ask, and we also, as a
2 result of some discussion, have placed some of the
3 pieces that would have been in the marketing
4 section into the initiation, dependence, and
5 cessation section. And some pieces have gone to
6 chapter 3 as well, I think, in relation to sensory
7 experience. So it has kind of evolved.
8 The last time I talked about this section of
9 the chapter, I indicated there would be -- I think
10 it's roughly 85 references. And so that number has
11 kind of varied, as we've apportioned different
12 references here and there throughout the report, so
13 a bit of a moveable feast, really.
14 So at the moment, the chapter is really, I
15 think, focusing on -- starts out by looking at what
16 is menthol marketing, how are menthol cigarettes
17 marketed, and how is that similar or different to
18 the marketing of non-menthol cigarettes. And the
19 way that we've approached that is really to look at
20 the marketing framework, which is used in the
21 marketing of many products known as the four Ps,
22 which is product, place, price, and promotion. And

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1 in some of those, different models, packaging is
2 included as a fifth P as well, and we do that here.
3 So in this chapter, we first I think really
4 put focus on the fact that, in many respects, the
5 marketing of menthol is used as similar kinds of
6 strategies to the marketing of non-menthol
7 cigarettes, in terms of -- we have some description
8 of the product itself, which kind of gives an
9 overview of some of the brands.
10 We give an overview of the price of menthol
11 cigarettes and non-menthol product. We've used
12 material from industry submissions, from retail
13 scanner data, and from some of the point-of-sale
14 audit studies that have been done with store
15 audits, empirical studies, and also data from
16 population surveys.
17 These data do I think seem to be fairly
18 consistent in showing that the price paid for
19 menthol cigarettes is slightly higher than for non-
20 menthol cigarettes, and that seems to be consistent
21 across the different data sources that are used.
22 So as a category difference, that is a difference

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1 between menthol and non-menthol cigarettes.
2 That might mean that people who smoke
3 menthol cigarettes value their cigarettes more.
4 They're prepared to pay more for them. We looked
5 at use of price promotions, and quite a lot of data
6 and information was presented on that from various
7 sources.
8 The scanner data I think show that in
9 relation to convenience stores, which is the outlet
10 where most smokers would buy their cigarettes, the
11 use of price promotions does tend to be higher for
12 menthol cigarettes than non-menthol cigarettes.
13 And so that's interesting to note.
14 It also, I think from some survey data,
15 shows that people are more likely to use price
16 promotions to buy menthol cigarettes, and that is
17 particularly the case amongst African-Americans.
18 So the fact that people have to pay a little bit
19 more for menthol cigarettes, they're more
20 expensive, does seem as though they're going to try
21 and use price promotions more often to try and
22 achieve a lower price out there to get them.

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1 They're pretty motivated to do that.
2 In relation to promotion, which is the third
3 P, we describe the different types of promotions
4 that are out there. We used and cite the FTC data,
5 and there's some confidential data that's being
6 provided to populate that section. There is
7 information available on use of advertising in
8 magazines and so forth, different sorts of avenues
9 for promoting menthol cigarettes that we describe.
10 We also draw on some analyses of
11 commercially available data in relation to
12 advertising expenditures for magazines in the U.S.
13 for menthol and non-menthol. Those data do seem to
14 suggest a greater pattern of expenditure to promote
15 menthol relative to non-menthol brands.
16 In relation to place, we look at the issue
17 of where menthol cigarettes are sold, so
18 predominantly, at the point of sale, the proportion
19 of marketing expenditure is allocated to retail and
20 price promotions. So there's a concentration, if
21 you like, of marketing at the point of sale in
22 retail outlets, and that's similar for non-menthol

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1 cigarettes as well.
2 In relation to packaging, we go into some of
3 the literature, which has examined how branding and
4 labeling influence consumers' expectations of what
5 the products might be like, and also influences
6 their sensory experience of the way in which they
7 do actually experience the products when they
8 consume it.
9 We draw on some tobacco industry document
10 reviews in relation to packaging. And some of
11 these studies that we described in the tobacco
12 industry documents are studies that give smokers
13 the same cigarettes to smoke, but they're branded
14 differently or labeled differently. And we find
15 that under those circumstances, people's experience
16 of the cigarettes will vary according to how
17 they're branded or labeled. And in the tobacco
18 industry documents, there are some of those studies
19 that have been conducted with menthol cigarettes,
20 and the results seem very similar.
21 We tried to, I guess -- prior to going into
22 the next question, which is really about what kind

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1 of health reassurance messages were used in menthol
2 marketing, we talk a little bit first about the
3 issue of explicit and implicit health messages, the
4 difference between the two. And so explicit health
5 messages are those that overtly make a health
6 claim, and so that might be a cigarette to soothe
7 the sore throat, we would describe as an explicit
8 health claim; if you use this product, this will
9 happen.
10 An implicit health claim might be a
11 cigarette as fresh as a mountain stream, and that's
12 a claim that's kind of more descriptive. It uses a
13 lot of imagery. And by associating the product
14 with something that's sort of fresh, and the great
15 outdoors, and healthy, and natural, it kind of
16 connotes healthiness. So it's a less direct way of
17 making a link between a product and a health
18 benefit.
19 We note that the use of these kind of
20 implicit messages serves to imbue the relationship
21 between the product and the outcome with some
22 degree of ambiguity. It's quite hard for consumers

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1 to challenge or discount that claim.
2 We talk about the early use of marketing
3 messages that explicitly promoted menthol
4 cigarettes to soothe a sore throat or clear a
5 blocked nose, and they do fall into the category of
6 explicit health claims. And we give lots of
7 examples of those that are drawn from the industry
8 documents and other kind of historical records.
9 We then move into describing some of the
10 more implicit health claims, and some of the rich
11 advertising industry imagery that has been used
12 over time, lots of use of water and ice and
13 springtime and those sorts of things as being
14 implicit health claims.
15 We also contextualize some of this with some
16 literature from the broader field, looking at how
17 branding and labeling influence the sensory
18 experience of using products other than smoking, so
19 the use of branding and labeling in influencing
20 consumers' perceptions and experiences of beverages
21 and also foods.
22 So in this area, we've drawn on some of the

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1 literature reviews from this field, which suggests
2 that I think sensory experience is quite
3 manipulatable, by branding and by labeling.
4 Consumers don't like to think that their experience
5 is going to be changed by these kind of things, but
6 time and time again, there are studies that
7 actually do find that sensory experience is quite
8 manipulatable.
9 So some examples are, just in the food area,
10 studies that show that you can change consumers'
11 experience and appraisal and liking of foods by
12 simply calling a product a succulent Italian
13 seafood filet instead of a seafood filet. It's the
14 same product, but if you actually use the more
15 descriptive language at the cafeteria, the people
16 who go ahead and buy that product will experience
17 it and rate it as more succulent and a whole lot of
18 other different adjectives. And they'll like it
19 more.
20 Also, this applies to children, some
21 interesting studies that have been done with
22 McDonald's branding, looking at having young

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1 children taste hamburgers and whether or not they
2 were labeled with the McDonald's label or not. And
3 the hamburgers that were labeled with McDonald's
4 were appraised as tasting better. So there's quite
5 a depth of literature in this area, too, which we
6 think really kind of feeds into the importance of
7 branding and labeling on consumer sensory
8 experience.
9 Moving on, in relation to the claims,
10 medicinal claims, and health claims, and taste
11 sensation, I have covered that a little bit
12 already. We go into looking at what other messages
13 were conveyed to potential consumers by marketing
14 as well.
15 There are a couple of other areas that have
16 been highlighted in branding. One of them is
17 youthfulness and sociability. Some of the
18 literature calls this the idea of highlighting
19 silliness and fun and very young activities, a
20 sense of great enjoyment; so some of the brands,
21 especially Newport, have a hook around that kind of
22 branding.

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1 Also, another type of message that is being
2 promoted is group identity and in-group belonging.
3 And that's particularly the case for youth, I
4 suppose, and in relation to African-Americans as
5 well. And we cover quite a lot of literature in
6 that area from industry documents and from some
7 empirical studies as well. So just in relation to
8 the youth area, some of the empirical studies show
9 that in ads for menthol cigarettes, the models are
10 perceived to be significantly younger than in ads
11 for non-menthol cigarettes.
12 We then come onto a section which is related
13 to who the target populations are for menthol
14 marketing. And we cover the literature in that
15 area in relation to youth, in relation to women,
16 and in relation to African-Americans, and then for
17 other race and ethnic groups. And that literature
18 that we use in this section has quite a lot of
19 evidence that comes from the tobacco industry
20 documents, which are a rich source of information
21 about what consumers think about the products that
22 they use. There is also a number of empirical

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1 studies that we cite as well.
2 In relation to African-Americans, there is
3 quite a large number of empirical studies for that
4 area. In the African-American population subgroup,
5 there are quite a lot of empirical studies in that
6 area. So I think, brought together, some of this
7 targeted marketing area in the literature that we
8 cover, really I think does give good evidence for
9 the notion that menthol marketing has been targeted
10 at certain population subgroups.
11 I think looking at the overall area of
12 tobacco marketing, which has been summarized
13 extensively in Monograph 19, published a couple of
14 years ago by the National Cancer Institute,
15 targeted marketing is a basic strategy of
16 marketing, identifying target groups, and then
17 making sure that your marketing is tailored to
18 and reaches your target audiences is a fundamental
19 aspect of marketing.
20 What's different about menthol marketing is
21 that it has very much been targeted to African-
22 Americans. That isn't so much the case with non-

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1 menthol marketing. And menthol marketing has also
2 been targeted to other race and ethnic groups. We
3 see a bit of evidence in relation to Hispanic
4 groups and also in relation to youth.
5 Then, finally, we come to looking at
6 consumer perceptions, consumer beliefs about harm
7 and whether those beliefs are implicit or explicit.
8 Again, there's a lot of information from the
9 tobacco industry documents that we draw on, again,
10 lots of information from consumers about why they
11 use menthol cigarettes and how they make their way
12 to smoking menthol cigarettes. And there are a
13 number of different empirical studies as well,
14 seven or eight I think we have here, that have been
15 summarized.
16 Overall, the tobacco industry document
17 reviews and one of the more qualitative empirical
18 studies are consistent in finding that consumers do
19 have mistaken beliefs about the benefits of smoking
20 menthol cigarettes. Those beliefs are generally
21 not explicit. There are a couple of studies
22 published recently that ask directly whether people

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1 think menthol cigarettes are less harmful or not,
2 and those studies do not find that people have
3 explicit beliefs that menthol is harmful.
4 But underneath that, there does seem to
5 be -- if you dig a bit deeper, there certainly does
6 seem to be this enduring, persisting, implicit
7 beliefs below the surface that menthol cigarettes
8 do maybe confer some kind of health benefit,
9 certainly in relation to being easier to use when
10 you have a cold or a sore throat, but potentially
11 just less harmful across the board. But, again,
12 those beliefs are not quite difficult to identify
13 unless you probe around and do some more
14 qualitative research. And that's where some of
15 that seems to come to light, in both the more open
16 kind of methods that are used in qualitative
17 research, open-ended question methods in
18 qualitative research, and also in the more data
19 questioning that goes on in consumer research.
20 DR. SAMET: Thank you, Melanie. As you can
21 see, there's a great deal of material available
22 that has been reviewed, and a fairly extensive

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1 draft, that as it moves through its next stage,
2 we'll be able to post.
3 Having heard a lot, are there questions or
4 comments for Melanie? Tim?
5 DR. MCAFEE: Well, this is really
6 fascinating, and thank you for your in-depth look
7 at this. I guess the thing I'm curious about, and
8 I assume we'll hear this when you get to the
9 conclusions, is it's essentially kind of the
10 same -- it's kind of the counterfactual equivalent
11 in the marketing universe, if you think you will
12 have been able to glean enough information from
13 this review to answer, basically, the question that
14 we ultimately asked, does the marketing of menthol
15 cigarettes increase the prevalence smoking beyond
16 the anticipated prevalence if such cigarettes were
17 not available, and is there something kind of
18 intrinsic to the nature of the way that menthol is
19 being marketed specifically, that if menthol were
20 not available as a product, there wouldn't just be
21 substitute of phenomenon going on?
22 DR. WAKEFIELD: I don't think, at this

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1 point, I'm going to answer that specific
2 overarching question, but I'll just make some
3 observations I think. I think it's true to say
4 that there is no one single image of a menthol
5 smoker. I mean, consistent with branding, people
6 smoke different menthol cigarettes, according to
7 the brand image that they wish to reflect. There
8 are some aspects of the product that flow through
9 and deliver for them, that are consistent with the
10 brand image. So there's no one kind of menthol
11 smoker.
12 Having said that, I am quite struck by the
13 fact that you get category differences between
14 menthol smokers and non-menthol smokers when you're
15 looking at some of the other outcomes with
16 Dorothy's section, and I think that's quite
17 significant.
18 So I think the other thing to say is that we
19 kind of look for biological plausibility in making
20 a decision about causation. And I think it's
21 important to look for plausibility in relation to
22 how might marketing influence population behavior.

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1 It's very much I think the fact that we have a
2 context for what we know about tobacco marketing
3 through the huge amount of work that was done for
4 Monograph 19. So we know that there's causal
5 evidence that tobacco marketing is related to
6 increased uptake, high smoking prevalence in the
7 population.
8 The question here is, what about menthol
9 marketing? And I think in reflecting on the
10 similarities and differences between menthol
11 marketing and non-menthol marketing, in general,
12 they're similar, but there are some differences.
13 One of the differences is that there have
14 been messages that have been transmitted about
15 menthol cigarettes which have to do with the
16 soothingness of the product, the refreshing nature
17 of the product. So there's implicit kind of
18 health-related messages, which follow through with
19 the delivery of the sensation that one gets. And
20 that's different, too, to non-menthol cigarettes.
21 DR. SAMET: Dan, do you have a question?
22 DR. HECK: I do have a question, but as you

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1 were speaking, I was noticing the implicit health
2 claim on my water bottle here, which features a
3 blue sky, and an elk, and some trees. My question
4 is this. You did mention, earlier in your
5 comments, that menthol cigarettes on average are
6 more costly than non-menthol in your analysis or
7 some analysis. Then you also mentioned that price
8 promotion is more aggressive in the menthol
9 segment.
10 Do you or will the report chapter have a
11 perspective on -- do those effects neutralize each
12 other, so in effect, the price is about the same?
13 DR. WAKEFIELD: It's hard to tell. We
14 didn't get that answer when we asked in the July
15 meeting.
16 DR. SAMET: Although I will note, Dan, that
17 my Diet Coke bottle says "The Heart Truth" on it.
18 Jack?
19 DR. HENNINGFIELD: Two things. One is that
20 the factors that we're looking at include African-
21 American and minority targeting, and that seems to
22 be a pretty strong conclusion. The other thing, on

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1 the health claims, or the implicit health claims, I
2 wonder if you can tie that into the Monitoring the
3 Future survey data. And one of the most persistent
4 findings, in roughly four decades, of Monitoring
5 the Future's survey data is the inverse
6 relationship between drug use and health concerns,
7 across every drug category. And it's remarkable.
8 We've got four decades of data, whether it's
9 opioids, prescription drugs. When fears go down,
10 drug use tends to come up. Marijuana use is
11 tending to come up right now. When fears go up,
12 drug use goes down.
13 It's amazing, and it would be interesting to
14 maybe take a look at that, those data, and maybe
15 pull it in, because it's a huge body of data, that
16 what you're saying, the extent to which there is a
17 perception that menthol is reducing concerns, that
18 fits into a very large body of data. If you need
19 help looking at those data, I'd be happy to help.
20 DR. SAMET: Were there other comments,
21 questions?
22 DR. CLANTON: Jon, this is Mark.

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1 DR. SAMET: Yes, Mark?
2 DR. CLANTON: Melanie, I realize that you
3 and Dorothy looked through just an enormous vast
4 quantity of papers in order to write chapter 5, but
5 I want to ask another counterfactual question. And
6 I realize you may not be able to answer it, but I
7 do want to ask it.
8 In a counterfactual world where menthol
9 never existed, is there anything in the marketing
10 data that would imply that marketing non-menthol
11 cigarettes, in a counterfactual world, to African-
12 Americans would somehow be different than marketing
13 menthol cigarettes in the current world to African-
14 Americans?
15 Is there anything you're able to glean that
16 might help us understand how there might be
17 fundamental differences in marketing tobacco in
18 general to African-Americans versus the way menthol
19 cigarettes are currently marketed to that group?
20 DR. WAKEFIELD: Good question. I think I
21 might take that on notice.
22 DR. CLANTON: Thank you.

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1 DR. SAMET: I am going to suggest, Dorothy,
2 that we go to your chapter, your component of
3 chapter 5, I think what will become a separate
4 chapter given the length of the two contributions.
5 And you've talked about this before, so I think
6 there's really not more to an updating – thinking
7 about this component and where it can go. And I
8 think everyone has seen that there's a lengthy
9 piece on marketing and then also a lengthy piece on
10 another very important part of the story that we
11 probably intend to separate.
12 Chapter 5 – Dorothy Hatsukami
13 DR. HATSUKAMI: So this part of the chapter,
14 which will now be a new chapter, is on initiation,
15 dependence, and cessation. And in the last
16 presentation, I gave or identified the number of
17 articles for each of the questions that we were
18 trying to address. Since that time, we have added
19 some new articles, and added information from the
20 presentations that we had at the last meeting.
21 What I'd like to do today is just provide a
22 preliminary evidence synthesis. So I just wanted

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1 to stress that these are just preliminary at this
2 point in time and they are perhaps potentially
3 bound to be modified.
4 So in the area of initiation, this is the
5 evidence synthesis. We believe that the evidence
6 is sufficient to conclude that a higher prevalence
7 of menthol cigarette use is observed among a
8 younger population of smokers compared to an older
9 population, with the exception of African-
10 Americans, where you observe high rates among both
11 the younger population, or the youth, and adults.
12 Additionally, within a population of youth,
13 a higher rate of menthol cigarette use is observed
14 among the younger, compared to the older population
15 of youth. We believe that the evidence is
16 sufficient to conclude that there is an increasing
17 trend towards a higher rate of menthol cigarette
18 smoking among adolescent cigarette smokers,
19 complemented with a decreasing trend of non-menthol
20 cigarette smoking, even among adolescents who smoke
21 less than 100 cigarettes per day -- oh, I'm sorry;
22 less than 100 cigarettes in a lifetime. That would

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1 be an excessive amount of cigarettes, to be sure.
2 Although the prevalence of smoking is
3 declining, the rate of decline for prevalence of
4 menthol cigarette smoking is less than the rate of
5 decline in the prevalence of non-menthol cigarette
6 smoking. There's evidence to suggest that less
7 established smokers are more likely to smoke
8 menthol cigarettes than more established smokers
9 when examining the duration of use.
10 Although most studies showed that the age
11 initiation was similar between menthol and non-
12 menthol smokers, the one Adolescent -- there was
13 only one -- Adolescent National Survey showed
14 menthol smokers experienced an earlier age of
15 initiation. This finding was observed even when
16 controlling for age, race, and gender.
17 The evidence is sufficient to conclude,
18 based on the concordant findings of several
19 internal tobacco industry documents studies, that
20 tobacco companies were aware of the appeal of
21 menthol cigarettes to younger inexperienced
22 smokers, or initiates, because these cigarettes are

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1 easier to smoke. And chapter 3 indicates
2 biological plausibility of increased appeal of
3 menthol cigarettes because of their physiological
4 effects.
5 So that's on initiation. In the area of
6 addiction, in terms of looking at the likelihood of
7 becoming addicted, that particular question, to
8 date, only one unpublished secondary analysis has
9 addressed this issue. In a sample of adolescent
10 students who were assessed across different regions
11 in the U.S., this evidence indicates that menthol
12 cigarettes are associated with increased transition
13 to greater or established smoking, and possibly
14 dependence.
15 With regards to whether menthol cigarettes
16 increases degree of addiction to smokers, or to the
17 smoker, among adults, there is little evidence to
18 support the conclusion that menthol cigarettes
19 increase addiction to smoking, based on the mixed
20 results on differences between menthol and non-
21 menthol for pharmacokinetics of nicotine,
22 cigarettes per day, exposure to nicotine in general

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1 and per cigarette, although little is known -- and
2 this is something that Dr. Benowitz had talked
3 about -- about the differences in those who smoke
4 less than 10 cigarettes per day, or those who are
5 in the early stages of smoking acquisition and
6 subjective measures of dependence.
7 However, among youth, there is sufficient
8 evidence to indicate that those who smoke menthol
9 tend to be more dependent than those who smoke non-
10 menthol cigarettes, as reflected by the amount of
11 cigarettes smoked and dependence in several
12 dependence measures. Thus, this population seems
13 to be particularly vulnerable to the effects of
14 menthol in smoking.
15 In terms of the area of cessation, there is
16 sufficient evidence, based on national surveys and
17 clinical studies, to show that non-white smokers of
18 menthol cigarettes compared to non-menthol
19 cigarette smokers experience more difficulty with
20 cessation. The population that seems to be
21 particularly vulnerable is the African-American
22 population. The results also show that menthol

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1 cigarette smoking may lead to less responsiveness
2 to medication. This is an area that requires
3 further exploration. Unfortunately, there are no
4 studies that have been conducted among adolescent
5 smokers.
6 Then, finally, menthol cigarettes are
7 marketed towards and smoked more by a population of
8 smokers that are at the highest risk for poor
9 cessation outcomes. They include the African-
10 Americans and the young.
11 So that's basically where we are at this
12 point in time.
13 DR. SAMET: And leading up to those
14 conclusions, there's a substantial body of evidence
15 it has reviewed.
16 DR. HATSUKAMI: Yes.
17 DR. SAMET: And I think that the draft
18 chapter is probably roughly 50 plus pages at this
19 point.
20 DR. HATSUKAMI: Yes.
21 DR. SAMET: So, again, recognizing you've
22 heard some conclusions, and this one also has not

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1 yet been --
2 DR. HATSUKAMI: Right.
3 DR. SAMET: -- the chapter's not yet been
4 posted, are there questions or comments? Dan?
5 DR. HECK: Just kind of a broad comment for
6 the committee, for us to ponder, the
7 difficulty -- well, one of the charges we have is
8 to integrate things like these survey data of youth
9 and others, documenting this relative increase in
10 the popularity or preference for menthol cigarettes
11 in recent years.
12 Integrate that into an overall judgment of
13 population harm in the face of the decreasing
14 prevalence of smoking, both among youth and among
15 adults, and expressed another way, the sales of
16 menthol are going down. So this is going to have
17 to be -- this is going to be one of the challenges
18 for us, to try to integrate each of these areas
19 into an overall judgment of net effect on public
20 health.
21 DR. SAMET: Thank you. Fair statement, the
22 real world is messy.

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1 Let's see. Mark, are you on?
2 DR. CLANTON: I am on.
3 DR. SAMET: Yes. Do you have any comments
4 or questions? I just didn't want to forget you.
5 DR. CLANTON: I have no comments or
6 questions.
7 DR. SAMET: Anyone else?
8 [No response.]
9 DR. SAMET: And I'll comment briefly, Dan,
10 on some of the thinking about chapter 7, Dan, just
11 coming back to that point and the challenge that we
12 face.
13 [No response.]
14 Open Public Hearing
15 DR. SAMET: Then what we'll do is we will
16 move to the public comment period, and then we'll
17 return, and I will just give a quick update on the
18 final chapter, which I guess will become chapter 8
19 now and talk about that, and then we'll hear from
20 Dan. But first we'll move to the open public
21 hearing.
22 Let me give the remarks for that.

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1 Both the Food and Drug Administration, the FDA, and
2 the public believe in a transparent process for
3 information gathering and decision making. To
4 ensure such transparency at the open public hearing
5 session of the advisory committee meeting, FDA
6 believes it is important to understand the context
7 of an individual's presentation.

8 For this reason, FDA encourages you, the
9 open public hearing speaker, at the beginning of
10 your written or oral statement, to advise the
11 committee of any financial relationship that you
12 may have with a sponsor, its product, and, if
13 known, its direct competitors.

14 For example, this financial information may
15 include the sponsor's payment of your travel,
16 lodging, or other expenses in connection with your
17 attendance at the meeting. Likewise, FDA
18 encourages you, at the beginning of your statement,
19 to advise the committee if you do not have any such
20 financial relationships.

21 If you choose not to address this issue of
22 financial relationships at the beginning of your

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1 statement, it will not preclude you from speaking.
2 The FDA and this committee place great importance
3 in the open public hearing process. The insights
4 and comments provided can help the agency and this
5 committee in their consideration of the issues
6 before them.

7 That said, in many instances and for many
8 topics, there will be a variety of opinions. One
9 of our goals today is for this open public hearing
10 to be conducted in a fair and open way, where every
11 participant is listened to carefully and treated
12 with dignity, courtesy, and respect. Therefore,
13 please speak only when recognized by the chair.
14 Thank you for your cooperation.

15 Then, a reminder to the speakers, you have
16 eight minutes for your presentations. And I think,
17 if I see how things are set, you will get a warning
18 at two minutes, probably an orange light.

19 So let's begin with our first speaker, David
20 Levy from the Pacific Institute for Research and
21 Evaluation, and I guess Legacy. David?

22 DR. LEVY: Thank you for the opportunity to

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1 present here. Support has been provided to me by
2 the American Legacy Foundation, and that's
3 specifically to model the effect of a menthol ban.
4 In addition, in my general modeling efforts, I have
5 been funded through the National Cancer Institute.

6 What I specifically do through my modeling
7 efforts is model the effect of a specific policy,
8 that is, a ban on menthol cigarettes, and look at
9 the effects of that ban on smoking prevalence and
10 smoking-attributable deaths. I'm using a model
11 that has been validated and used quite extensively.
12 We've developed models for about 35 countries now
13 and validated for quite a few of those, as well as
14 for quite a few number of states.

15 The results I'm going to be presenting today
16 are forthcoming in the American Journal of Public
17 Health, and that article has been made available to
18 the committee, although it is embargoed. And I'm
19 using the standard structure that I've used in my
20 past work. And it's, in structure, very similar to
21 the model that was presented earlier by David
22 Mendez; that is, it's a dynamic model, one that

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1 looks at effects over time, and the population
2 moves through times, aging through and allowing for
3 births and deaths. Then overlaid on that's a
4 smoking model, which distinguishes never, current,
5 and former smokers, and allows for quitting and
6 relapse.

7 What this model does as specific to menthol
8 is distinguishes, both in current and former
9 smokers, menthol and non-menthol use, as well as a
10 group called no usual preference. And this is
11 based on the 2003 CPS-TUS data, which, to my
12 knowledge, is the largest dataset, and for the year
13 2003, provides extensive information on menthol
14 versus non-menthol cigarettes.

15 I use standard kinds of methods in
16 developing estimates of smoking-attributable
17 deaths. And another thing my model does is,
18 through the period 2003 to 2010, allows for the
19 effects of policies, and then from 2010 onwards,
20 assumes policies, other than the menthol ban, stay
21 constant at their 2010 level.

22 This model involves the quitting process

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1 quite extensively, allowing for when an individual
2 quits, the potential for relapse, and how that
3 tendency to relapse varies with the number of years
4 since the smoker has quit. So you have people
5 running through smoking, quitting, going back to
6 smoking, and so on.
7 What I do is I look at a menthol ban with a
8 very specific structure, which I'll describe in a
9 minute. But we start the ban in 2011, and we look
10 and we assume that the ban stays in effect. In the
11 model, there are several important assumptions that
12 are made. We look at smoking initiation through
13 age 24. After age 24, we allow for cessation and
14 relapse. We also look at the effects of policies
15 through 2010. And another important assumption
16 that we make is that the relative mortality risks
17 are the same for menthol and non-menthol smokers.
18 We also assume that the mortality risks are the
19 same for African-Americans and others, and we do
20 have a separate model for African-Americans.
21 Now, in developing the specific scenarios
22 which we examine, we did a fairly extensive review

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1 of the literature, but there are several important
2 pieces of evidence that we use. One is a study
3 that I did with John Tauras, Frank Chaloupka, and
4 others, which looks at switching in reaction to
5 price and other policy changes between menthol and
6 non-menthol. And in that, we found that menthol
7 smokers are less likely to switch than non-menthol
8 smokers.
9 Another study that was done looked at
10 cessation rates and found that cessation is lower
11 among menthol than non-menthol. And as described
12 earlier, there is also evidence on initiation. I'm
13 running a bit short on time. The other bit of
14 evidence you've seen here is the evidence regarding
15 what menthol smokers say they'll do in light of a
16 ban, suggesting that a large number of them would
17 quit.
18 We look at three different scenarios.
19 They're at 10, at 20, and at --
20 DR. SAMET: I'm just going to suggest, why
21 don't you move to your results quickly so we can
22 see them?

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1 DR. LEVY: Okay. One of the things we look
2 at what would happen in the absence of a ban -- and
3 we do find that the percentage of menthol would
4 increase slowly over time. Now, in terms of the
5 ban itself, we see that the way we model it,
6 there's a fairly immediate effect of the ban, as we
7 find with most policies. And you see the three
8 scenarios, the 10-percent, 20-percent, and 30-
9 percent reduction, which maintains itself over
10 time.
11 Now, when we did the modeling for African-
12 Americans, we find larger effects because of the
13 fact that a much larger percentage of African-
14 Americans smoke menthol than non-menthol
15 cigarettes. And, finally, and I think most
16 importantly, is the number of lives saved. And
17 what we find is with a 10-percent reduction -- that
18 is, 10 percent of those who smoke menthol quit in
19 the face of a ban -- we find that by the year 2050,
20 over 300,000 lives are saved. With a 20-percent
21 change, we find almost 500,000 lives changed. And
22 with 30 percent, we find over 600,000 lives are

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1 saved.
2 DR. SAMET: David, if you could just wrap
3 up, say, in the next 30 seconds.
4 DR. LEVY: I guess the other important point
5 I'd like to make is that disproportionately,
6 African-Americans are affected, and you see that
7 nearly a third of the lives saved are among
8 African-Americans, even though they're a much
9 smaller percent of the population. Thank you.
10 DR. SAMET: Thank you. And we do have the
11 publication to read, and this provides I guess a
12 counterpart to the modeling that the other David,
13 Mendez is carrying out. Addressing another I think
14 perhaps can raise the ban question as another
15 scenario to consider.
16 So are there clarifying questions for David
17 around this work? Yes, Cathy?
18 DR. BACKINGER: Just a quick clarifying
19 question. You talked about cessation and relapse.
20 How did you calculate that for menthol smokers?
21 Was it the same for menthol and non-menthol or was
22 there a difference, for cessation and relapse over

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1 time?
2 DR. LEVY: As I mentioned, we had done a
3 separate study of cessation rates. And we used the
4 cessation rates, actual cessation rates in 2003,
5 which were very similar to those found in 2006, of
6 menthol smokers versus non-menthol smokers. We
7 also distinguished by age and by gender, so we used
8 very finely-tuned measures based on this previous
9 study that we had done.
10 DR. SAMET: Dan?
11 DR. HECK: Just a quick question, perhaps to
12 FDA. Was this manuscript provided to the FDA or to
13 the committee, provided to the industry
14 representatives, members of the subcommittee, or
15 the committee?
16 MS. COHEN: It's in your packet.
17 DR. HECK: Okay. Thank you.
18 DR. SAMET: Mark? Just did not forget you.
19 DR. CLANTON: No. That was very
20 interesting, and I'll look forward to reviewing the
21 publication, period.
22 DR. SAMET: Okay. Good.

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1 Thank you, David.
2 DR. LEVY: Thank you.
3 DR. SAMET: Our next presenter is Jane Lewis
4 from Altria Client Services.
5 DR. LEWIS: Good afternoon. I am Dr. Jane
6 Lewis. I am the senior vice-president of the
7 Tobacco Regulatory and Health Sciences Group at
8 Altria Client Services, and I'm speaking today on
9 behalf of Phillip Morris USA. And I appreciate the
10 opportunity to make comments to the committee.
11 The Family Smoking Prevention and Tobacco
12 Control Act established menthol as one of FDA's and
13 this committee's first regulatory considerations.
14 Specifically, the committee was tasked with
15 developing for FDA a report and recommendation on
16 the impact of the use of menthol in cigarettes on
17 public health. This committee has attempted, over
18 the course of the last 12 months, to establish and
19 implement a framework to review and assess the
20 relevant science and other factors that must be
21 considered in developing its recommendation.
22 We appreciate and acknowledge the

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1 complexities of tobacco science, but the question
2 at hand is straightforward. Are menthol cigarettes
3 more harmful than non-menthol cigarettes? We
4 continue to believe, given the extent of the
5 available scientific information, that the answer
6 to this question is no. We remain committed to
7 providing the FDA information that supports its
8 stated goal of a science- and evidence-based
9 decision-making process.
10 Specific to menthol, we have provided
11 numerous scientific and other related documents to
12 support the process, including two written
13 submissions in March and June of 2010, which
14 provided a detailed analysis of the then-available
15 science; presentations delivered to this advisory
16 committee in July of 2010 to address requested
17 topic areas such as biomarkers.
18 In August of 2010, we responded to the
19 agency's document collection request on menthol.
20 We provided over 3,600 internal documents
21 responsive to the request, as well as other
22 menthol-related information. In August of 2010, we

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1 also voluntarily provided the agency the underlying
2 data from our total exposure study. Lastly, in
3 December of 2010, we provided the agency an in-
4 depth analysis of the potential of countervailing
5 effects of a ban on menthol cigarettes.
6 As we have previously conveyed to the agency
7 in these submissions and presentations, our
8 analysis of the relevant science in comparing
9 menthol to non-menthol cigarettes leads us to the
10 following evidence-based conclusions.
11 In non-clinical testing, menthol cigarettes
12 do not result in increased toxicity compared to
13 non-menthol cigarettes. In clinical testing,
14 smoking menthol cigarettes as compared to non-
15 menthol cigarettes, produces no consistent effect
16 on human puffing and inhalation behavior. Further,
17 the most robust studies show there is no effect on
18 biomarkers that estimate average daily exposure or
19 biomarkers of potential harm.
20 Overall, the weight of the scientific
21 evidence indicates that menthol does not change the
22 inherent health risk of cigarette smoking. For

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1 disease risk, evidence from epidemiological studies
2 suggests no effects of menthol.
3 As it relates to the impact of menthol on
4 smoking initiation, the research is limited.
5 Initiation is a complex issue where future research
6 may be needed. For example, there might be an
7 opportunity to incorporate additional questions
8 into future national government surveys.
9 Nonetheless, the limited available evidence
10 suggests there is no unique effect. Menthol does
11 not increase dependence, based on widely-accepted
12 measurement methods. And, finally, cessation
13 outcomes do not support a conclusion that there is
14 an effect due to menthol.
15 During the course of the last 12 months, the
16 body of science related to menthol has continued to
17 grow. In order to fully integrate the recent
18 science with what we had previously provided to the
19 agency, Phillip Morris USA intends to submit its
20 own perspective on menthol to the agency by
21 March 23rd, 2011.
22 In sum, there is no science- or evidence-

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1 based reason that would support a TPSAC
2 recommendation to ban menthol cigarettes, or
3 otherwise impose additional restrictions. It is
4 also important to remember, however, that the Act
5 requires the agency to consider other factors in
6 addition to the science, including the
7 countervailing effects of any potential regulatory
8 action such as a ban on menthol cigarettes.
9 As we outlined in our December 2010
10 submission, a ban on menthol cigarettes is certain
11 to trigger a series of lasting and severe
12 unintended consequences and other countervailing
13 effects that would be detrimental to public health
14 and society.
15 Further, during the February 10 TPSAC
16 meeting, one of our company experts provided
17 additional information regarding anticipated
18 outcomes in the illicit cigarette trade that would
19 likely result from a ban. Neither the TPSAC nor
20 the agency should discount the seriousness of these
21 potential countervailing effects.
22 We encourage you to fully review and weigh

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1 the unintended consequences of any menthol-specific
2 regulatory action as you undertake your
3 deliberations of menthol. From the perspective of
4 an impact on public health, is it clear that the
5 available science, in conjunction with potential
6 unintended consequences, does not support a ban of
7 menthol cigarettes.
8 Many aspects of the Act, which the agency
9 has already begun to implement, are intended to
10 address, among other things, youth initiation and
11 use of tobacco. The agency has indicated that they
12 believe these actions will discourage non-users,
13 including kids, from trying cigarettes, and without
14 the countervailing effects of a ban. Actions such
15 as these should be given sufficient time to be
16 fully implemented. Thank you, and I'd be glad to
17 answer any questions you have.
18 DR. SAMET: Thank you. And, actually, you
19 reminded me that it's now been almost a year.
20 Let's see. Questions or comments? Mark,
21 again, not to forget you.
22 DR. CLANTON: Thank you for not forgetting,

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1 but no questions here.
2 DR. SAMET: Thank you for your presentation.
3 Our next presenter is Jim Tozzi from the
4 Center for Regulatory Effectiveness.
5 MR. TOZZI: Good afternoon, members of the
6 committee, Mr. Chairman. I'm Jim Tozzi. I'm with
7 the Center for Regulatory Effectiveness. As you've
8 heard many times, we're regulatory watchdogs. We
9 get grants from all industries, including the
10 tobacco industry, and we look at agencies to see if
11 they comply with the good government statutes,
12 which translates into how regulators are regulated.
13 What I want to do in the few minutes that's
14 given to me is summarize what we think the work of
15 this committee has been to date. I'm particularly
16 interested in the public participating in this, and
17 we have a number of websites that the public looks
18 at. And for the first time, we're going to
19 actually put these remarks on our website today and
20 solicit public comment. And you'll be able to see
21 all those that either agree or disagree with my
22 comments.

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1 Now, who in particular in the public are we
2 interested in addressing this? First, the parents
3 of youth who are going to purchase counterfeit
4 cigarettes, which have been proven to have toxic
5 effects in an order of magnitude greater than legal
6 cigarettes, should be more active in this
7 proceeding.
8 African-Americans should also care. They're
9 going to be forced to commit crimes by buying
10 illegal cigarettes. Third, the non-smoking public
11 should also care. Why? Because they're going to
12 fuel terrorist activities through the purchase of
13 illegal cigarettes, which will also be subject to
14 increasing violent actions by drug cartels in the
15 United States.
16 In our view, three issues dominate this
17 proceeding. One, do menthol cigarettes increase
18 mortality morbidity relative to legal cigarettes?
19 Two, do menthol in cigarettes make it easier to
20 start smoking or more difficult to stop? And
21 third, what's the effect on the black market?
22 With respect to morbidity and mortality,

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1 TPSAC has been presented with a wide range of
2 studies, the hard science dealing with these two
3 topics. The overwhelming weight of the evidence
4 suggests there is no increase in morbidity or
5 mortality, relative to non-menthol effects, and
6 kudos to the committee for stating this, at least
7 in my opinion, in your draft report.
8 On initiation/cessation, the data on that,
9 the soft science, is mixed, although we think it's
10 tending towards no effect. The problem with these
11 studies, as you all know, is that the underlying
12 studies were not focused on initiation/cessation,
13 and they were the subject of subsequent reviews,
14 which were trying to fit a new study design into
15 old study objectives.
16 CRE examined a number of the studies that
17 you're relying on, not all of them. We think we've
18 demonstrated, and it's subject to public comment,
19 that a number of them, not all of them, were not
20 compliant with the Data Quality Act, which means by
21 federal statute, the agency can't use them. We
22 filed a petition with the agency on these, and

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1 under the act they will have to respond sometime,
2 and I know they're pretty busy people, so that may
3 be a while.
4 On initiation/cessation, if you look at all
5 the data, we call your attention to two extremely
6 powerful statistical studies that we would like to
7 quote. And both of them -- I didn't think I made
8 that good of a point, but thank you -- the two that
9 we would like to comment on, which we think have
10 particular statistical power, and they've been
11 quoted accurately -- one of the parts I think
12 Dr. Benowitz stated -- Dr. Hyland of Roswell Park
13 and Dr. Muscat, under contract for the Public
14 Health Service, concluded these data indicate that
15 mentholated cigarettes do not exhibit greater signs
16 of nicotine dependence as measured by the
17 likelihood of future cessation, time to first
18 cigarette in the morning, or the number of
19 cigarettes smoked per day. That was a 20,000-
20 sample study and that was subject to those results.
21 Dr. Muscat concluded cigarette mentholation
22 was not associated with continued smoking. The

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1 findings suggest that menthol does not increase the
2 addictive properties of tobacco and nicotine. So,
3 based on that, I think this is mixed at best,
4 tending towards no effect.
5 Finally, on contraband, the expert on
6 contraband, your fellow or sister, whatever way you
7 would use it, federal agency is ATF. And it's
8 difficult for me to understand why this committee
9 is not addressing that issue. Maybe I'll learn
10 after one of you leave, and I can watch when you
11 write memoirs in a journal, and I'll find out.
12 But we're not leaving it up to that. We
13 wrote to the general counsel of your agency and
14 asked them, does the fact that the statute says
15 study the public health effects of contraband mean
16 that? We think it does. And it'll be interesting
17 if the general counsel answers our letter,
18 subsequent to the issuance of your report and what
19 that person's answer will be.
20 But this is what ATF said about contraband.
21 Cigarette smuggling profits fund terrorism and
22 other deadly groups, criminal groups. Counterfeit

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1 cigarettes pose health standards over and above
2 those of genuine cigarettes. Illegal cigarette
3 trafficking makes it easier for children to smoke.
4 In particular, they went on to say the
5 traffic of contraband cigarettes is a worldwide
6 problem. Billions of dollars of tax revenue are
7 lost by all levels of government throughout the
8 world. Much of the illicit profit is gained by
9 organized crime and terrorist groups. Then they go
10 onto say that trafficking and counterfeiting
11 contraband products poses a serious health risk –
12 and that's your bag, right -- to society. There
13 are no standards for production of counterfeit
14 tobacco. This allows things for biological and
15 chemical contaminations.
16 So what I'm saying, that is not CRE's
17 statement. That is a statement in the federal
18 register, a determination of fact that was
19 presented by a federal agency. So I beg of you to
20 look at what your fellow agencies are saying about
21 this issue. It's not an issue that I made up; it's
22 that they're saying the public health effects of

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1 contraband is a big issue.
2 So where does this all lead me? There has
3 been a storm of data on this proceeding, and if you
4 look through this big storm, I see one tree
5 standing. That tree has a sign coming down, "Too
6 early; cannot base on science to ban menthol."
7 Thank you.
8 DR. SAMET: Thank you. I would just point
9 out that you've not yet heard about what will be in
10 chapter 7 on contraband. That's something we will
11 come to when I provide a general description of
12 chapter 7.
13 Are there questions or comments?
14 MR. TOZZI: Mr. Chairman, would you yield
15 your time for a comment on that?
16 DR. SAMET: No.
17 MR. TOZZI: No? I thought so.
18 DR. SAMET: But are there questions or
19 comments?
20 [No response.]
21 DR. SAMET: Mark?
22 DR. CLANTON: None here.

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1 DR. SAMET: Thank you. Thank you for being
2 there.
3 Okay. Thank you. And I think our final
4 speaker is Niger Innis from the Congress of Racial
5 Equality.
6 MR. INNIS: Thank you, Mr. Chairman. Thank
7 you to the committee. I'm Niger Innis, the
8 national spokesman for the Congress of Racial
9 Equality, one of our country's oldest human rights
10 and civil rights organizations. CORE has no
11 financial relationship with tobacco interests, pro-
12 tobacco interests, anti-tobacco interests, none of
13 the above. My accountant would say unfortunately.
14 For the last several weeks, the world has
15 been captivated by the revolution occurring
16 throughout the Middle East and northern Africa.
17 From Tunisia to Yemen, from Iran to Libya, diverse
18 people from varying countries are fighting for
19 liberty, fighting against their governments for
20 treating them like children that need a
21 paternalistic government to control their lives
22 because, somehow, the divine hand of government

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1 knows what's best for them. It's interesting that
2 in the waning days of Mubarak's regime in Egypt, he
3 actually referred to the revolting masses as his
4 children.
5 How ironic that we are here today, in the
6 freest country on earth, 5,000 miles away,
7 discussing the criminalization of a particular type
8 of legal product that has been partaken in by
9 millions of Americans every day, including the
10 Speaker of the House, who happens to be a
11 Republican, and the President of the United States,
12 that happens to be a Democrat.
13 I should say I have never, nor will I ever
14 smoke a menthol or non-menthol cigarette. And I
15 personally think that it is a nasty habit and it's
16 caused me to lose a couple of relationships. But I
17 think it's exponentially more offensive to my
18 sensibilities as a free man to suggest that we
19 ought to criminalize a particular type of legal
20 product because a particular community tends to
21 like it.
22 Your study is highly significant and

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1 symbolic for the African-American community for the
2 simple reason that menthol cigarettes are, indeed,
3 popular with blacks. It's no secret that menthol
4 cigarettes provide a taste and flavor that is
5 preferred by many African-Americans. Some even
6 call it, in my community, the black man's
7 cigarette. But is that reason enough to ban
8 menthol? Of course not. Because if that was the
9 case, I suggest that TPSAC should just consider and
10 recommend that all black people just be banned from
11 smoking, period. Now, this is silly, and we know
12 it's silly because it would clearly be
13 discriminatory, even if well intended.

14 If the government is not going to ban all
15 cigarettes, then the obvious question is, why
16 should it selectively ban those cigarettes that
17 African-Americans tend to prefer? To do so would
18 be benign paternalism.

19 In contrast to the absence of hard
20 scientific evidence against menthol being any more
21 addictive than non-menthol cigarettes, there are
22 significant indications that a ban on menthol would

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1 boomerang and create a bad situation in our
2 community.

3 It is CORE's hope that the advisory panel
4 will fulfill its requirement of considering the
5 unintended consequences of a ban on menthol
6 cigarettes. Any recommendation must be grounded in
7 a real-world understanding of the devastating
8 impact that illegal counterfeiting, smuggling,
9 distribution, and consumption of cigarettes has on
10 our lives and on our streets.

11 Just last weekend, I had a conversation at
12 my barbershop with a black woman and a white woman
13 who both, actually, smoked menthol cigarettes. I
14 told them I was coming down here to provide
15 testimony because there's a move afoot to ban
16 menthol cigarettes. And they told me this, and
17 this is a quote from them. "If that happens, I
18 will sell the cigarettes right here at triple the
19 price and make a fortune in this community." And
20 the other hairstylist responded, "I'll be your
21 first customer."

22 If smokers were a captive population and

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1 tobacco products a captive industry, you might be
2 able to make a case that banning menthol could
3 work. But because there would be a strong demand
4 fed by many alternative sources of cigarettes,
5 banning menthol would be a self-defeating and
6 indeed a very harmful step for my community. It
7 would drive more smokers to the unlicensed
8 unregulated side of the street, and more troubling,
9 it would give underage access to kids, making it
10 easy for them to smoke unregulated cigarettes. And
11 we have to ask ourselves, is that really what we
12 want to do?

13 If menthol is banned, history shows that a
14 large underground market would be created, and many
15 questions should follow. They involve questions of
16 how effective contraband tobacco enforcement has
17 been to date and the costs of additional law
18 enforcement. These are all questions that the
19 committee should have asked already and should have
20 addressed, but it has not, to the best of my
21 knowledge at this point, and I suspect will not.

22 I follow your deliberations with great

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1 interest, and your committee -- at this point I
2 fear the report has already been written, yet it
3 appears to me that so far you have not studied
4 these critical issues to the degree necessary and
5 to the extent that the United States Congress
6 requires.

7 Despite persistent concerns expressed months
8 ago by CORE, the National Black Chamber of
9 Commerce, various African-American law enforcement
10 groups, and others, it's alarming that TPSAC has
11 not sought out the advice of independent experts
12 who can testify about illicit tobacco markets,
13 worldwide trade and contraband cigarettes, how
14 blacks are affected by contraband markets, or the
15 toxic ingredients, like mercury, often found in
16 unregulated cigarettes.

17 CORE hopes that TPSAC did not put on
18 blinders months ago to reach a preconceived
19 decision and to pursue a pasha-like paternalistic
20 goal and agenda. CORE is urging the FDA, in the
21 strongest terms, not to jump to preconceived
22 conclusions that menthol cigarettes should be

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1 banned simply because they are popular with blacks.
2 Government's efforts to demonize menthol-flavored
3 cigarettes will simply add yet another government-
4 imposed prohibition on a legal activity, and,
5 hence, another government restriction on the
6 people's ability to exercise their liberty, and
7 this being done in the freest, or what is currently
8 the freest country on earth.
9 The role of government should be to educate
10 citizens by providing accurate information. I
11 support rigorous and early education about the
12 dangers of smoking in our schools. CORE would
13 support maximizing the social media revolution to
14 directly alert children and parents about the
15 dangers and hazards of smoking menthol and non-
16 menthol cigarettes. I would urge all cigarette
17 companies, menthol and non-menthol alike, to
18 contribute or expand their contribution to said
19 efforts to educate the public. These are things
20 that government should and can do.
21 Governments should not attempt to control
22 the lives of adults and tell them what they can and

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1 cannot do, whether it involves alcohol, fast food,
2 sweets, or in this case, cigarettes. That's what
3 freedom and liberty are ultimately about. If in
4 the convenience in our American luxury, we've
5 forgotten what liberty is, all we have to do
6 tonight is turn on CNN and watch people who are
7 dying for it. Thank you.
8 DR. SAMET: Thank you. Because this is a
9 public meeting, I just feel like I need to make
10 several clarifications about TPSAC's role. And
11 first, sitting here on March 2nd, I wish that our
12 report were done and ready for March 23rd, but I
13 can assure you, we face a very busy three weeks
14 ahead, and we are sitting here, gaining further
15 input into our report because we are still in
16 progress.
17 If you were to look carefully at the Act,
18 you will find that TPSAC's charge with regard to
19 the report does not mention a ban; it mentions
20 public health impact and other information that is
21 to be provided to FDA as guidance. Any policy
22 actions that might follow lie with the FDA and not

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1 TPSAC.
2 So I want to be very explicit about what our
3 role is. We are fully cognizant of the provisions
4 that suggest that, included within our scope of
5 activity is assessment of countervailing effects,
6 one of which could be contraband and of
7 consequences. We will comment on that. We would
8 not be, I think if a ban were undertaken or some
9 other measure of restricted access to menthol-
10 containing cigarettes, the sole source of guidance
11 or expertise that FDA might turn to. And I think
12 under the Act, in fact, the charge is to the
13 Secretary to consider such measures.
14 So I want to be very specific, because I
15 appreciate what you are saying, and I also want to
16 define what is within the boundaries of the charge
17 given to us for the report to be submitted on
18 March 23rd, and what might lie more broadly within
19 the purview of FDA.
20 So let me ask, are there other questions or
21 comments for this presentation?
22 [No response.]

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1 DR. SAMET: And, Mark, do you have any
2 comments?
3 DR. CLANTON: Mr. Chairman, given your
4 clarifications, I have no additional questions or
5 comments.
6 DR. SAMET: Anyone else?
7 [No response.]
8 DR. SAMET: Okay. Thank you.
9 MR. INNIS: Thank you, Mr. Chairman.
10 Chapter 7 – Jonathan Samet
11 DR. SAMET: Then the open public hearing
12 portion of this meeting has now concluded, and we
13 will no longer take comments from the audience.
14 And thank you all for your comments. We'll now
15 turn our attention to address the task at hand, the
16 careful consideration of the data before the
17 committee, as well as the public comments.
18 Let's see. By my watch, we have roughly 45
19 minutes left. We've I think pretty much left
20 behind the discussions of two pieces of chapter 5,
21 unless there's anything else. I think we've had an
22 opportunity to discuss those.

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1 I will say that there will be a concluding
2 chapter, chapter 8, and I think at this point,
3 there's been enough discussion of that chapter to
4 have a general sense of what goes into it. And,
5 clearly, part of our task over the next three weeks
6 is to bring that chapter to a close.
7 If you will, think back to chapter 1, which
8 describes, essentially, the charge to us, and in
9 chapter 2, how we're going to go about doing our
10 business. There seven questions related to
11 individual smokers and two related to population-
12 level consequences of the availability of menthol
13 cigarettes. We intend to provide answers to those
14 questions that will be put in the conclusory
15 language that we have described in the report,
16 which, you remember, is based around this idea of
17 equipoise.
18 The support for whatever our answers may be
19 will be drawn from the prior chapters that set out
20 the evidence, and that will be chapters 4, 5, 6,
21 and 7, I think, in the renumbered version. And we
22 will refer specifically and directly to the key

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1 information that will lead decision making in one
2 direction or another.
3 We intend I think to provide some overall
4 conclusions and recommendations, as we have been
5 asked to do in the Act. And then also, it is here
6 that we will consider these so-called
7 countervailing consequences, including the question
8 of contraband.
9 This is TPSAC's look at the contraband
10 issue, and we recognize that there are others who
11 may choose to be looking at this in the future. We
12 have heard from certainly a number of experts and
13 various groups, offering their opinion about the
14 potential for contraband, and we are looking at
15 that information carefully.
16 We may also have some recommendations for
17 areas where further data-gathering or further
18 research might be of benefit for decision making.
19 We don't see our task as setting out an academic
20 research agenda on menthol in cigarettes. There
21 are indeed many scientific questions that could be
22 explored, and many intriguing ideas have been

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1 voiced around this table over the last year. But
2 if we see key items that might be important to
3 answer questions that FDA might need answered, we
4 will put those there.
5 So this is just sort of a broad overview of
6 the working outline of chapter 7, and I'm certain
7 we will get at least a preliminary draft made
8 available before our next meeting. So I don't know
9 whether there are questions or comments on my
10 somewhat cursory overview, but I think that's sort
11 of what we can do right now.
12 So let me ask. Tim?
13 DR. MCAFEE: I guess this is sort of a
14 procedural question. I'm becoming a little
15 anxious, realizing how close we are getting to the
16 due date. It's essentially what you see happening
17 between now and the end, particularly around these
18 remaining chapters for which we've heard summaries
19 of but haven't seen drafts, and some of which are
20 still in play.
21 Do you have thoughts about how you may
22 communicate with the committee, et cetera, between

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1 now and when we meet? I'm just worried about being
2 exposed to a chapter five minutes before we have to
3 say, yes, this looks good.
4 DR. SAMET: I am looking to Caryn to see
5 whether she wants me to answer that. So if you're
6 becoming anxious about the time --
7 [Laughter.]
8 DR. SAMET: -- you don't have any sympathy.
9 I think the answer to the question is, obviously,
10 we're going to post these as soon as we feel they
11 are ready. I mean, there's an awful lot of work
12 that's been done. These are lengthy documents with
13 extensive referencing and tables. For one, we want
14 to have them in good shape when they are posted.
15 We want to make certain that we've eliminated
16 errors. We're working on that.
17 I would think that chapter 4 is coming
18 relatively close to being finished. That's a more
19 descriptive chapter, and would likely be, I think,
20 available rather soon I think. And Karen and
21 Patricia are nodding their heads yes.
22 Now, the chapters 5a and 5b or 6 and 7,

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1 there's a lot of writing, still things to pull
2 together, and I'm going to suggest that probably
3 they might become available, possibly around
4 roughly the mid-point between now and our next
5 meeting or somewhere around 10 days from now,
6 perhaps. They're not a quick read. So we'll try
7 and get them out there so that everyone has an
8 opportunity to review them with sufficient time.
9 I actually do see that the final concluding
10 chapter -- and actually I want to come back because
11 I did miss one thing when I presented it to
12 you -- will be a little bit more of a just-in-time
13 product. We will also -- in terms of the question
14 of public health impact, I think our conclusions
15 will be both qualitative and perhaps quasi-
16 quantitative, drawing on the modeling work done by
17 David Mendez. We'll take a close look at the
18 modeling work that David Levy presented, for its
19 utility for making some of these same kind of
20 judgments about the approximate magnitude of any
21 public health burden that might be associated with
22 menthol cigarettes. So that will be in chapter 7

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1 as well.
2 So Tim, any other questions about this?
3 DR. MCAFEE: Would it be helpful to the
4 process if we had a feedback mechanism, other than
5 bringing our points up, or would you rather not?
6 We'll do it in the public setting once you arrive,
7 which is fine. I just want to confer.
8 DR. SAMET: Yes. I think that's what we
9 will be doing.
10 Yes, Cathy?
11 DR. BACKINGER: Also, a question of
12 clarification, because the Act talks about a report
13 and recommendation. And I certainly understand and
14 appreciate the distinction that it's a report to
15 FDA, and FDA then makes a decision about how to
16 move forward. But will there be recommendations in
17 the report?
18 DR. SAMET: We've been asked to make
19 recommendations, so there will be --
20 DR. BACKINGER: I've seen it. We've had the
21 conclusions or the synthesis statements in the
22 chapters we've seen to date.

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1 DR. SAMET: Yes. No. There will be
2 recommendations as we have been requested to do,
3 and as we said, this chapter 7 is in evolution.
4 Anything else on this chapter and what I
5 guess is the end game, in a sense? We have taken
6 some solace that no matter what, March 23rd will be
7 here.
8 Mark, anything you want to add?
9 DR. CLANTON: Nothing here.
10 DR. SAMET: Thank you. Then I guess the
11 next agenda item is to hear from you, Dan, on the
12 report that you're involved in developing.
13 Menthol Report – Industry Perspective
14 DR. HECK: I share all the concerns about
15 the rapidly approaching date that have been
16 mentioned just now. As I stated before, our
17 intention was to have the industry perspective
18 report done as early as possible, but it's getting
19 closer and closer to that date now, where we're
20 working feverishly on that.
21 The reported writing is largely complete.
22 There's some minor phrasing and things being added

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1 still, but I get the impression, just as a
2 snapshot, that the status of that report is in a
3 similar stage, if not maybe slightly ahead of the
4 committee's work. But then again I haven't seen
5 all of the committee's work, so we're kind of on
6 the same timetable.
7 The intention is to provide this report to
8 the FDA as requested, and as we heard from Altria,
9 some industry stakeholders may choose to
10 communicate to FDA their perspectives. Otherwise,
11 our intention, very shortly now, is to circulate
12 the draft report among the industry stakeholders,
13 probably through their representatives or directly,
14 to give them input. And they will be given an
15 opportunity to sign onto and join in on that
16 report, or again, comment to FDA as they deem fit.
17 The content of the report, in terms of the
18 issues, I think is essentially identical to those
19 we've been discussing for the last year. The
20 organization is somewhat different, but not
21 entirely dissimilar.
22 We have a chapter 1, which I
will overview briefly, the statutory charge and

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1 approach and not unlike chapters 1 and 2 of the
2 voting members' report.
3 The report will lay out its process of being
4 both inclusive and incorporating rigorous
5 scientific procedures and evaluating the best
6 available data on the topics at hand. The FDA, of
7 course, is held to a similar process, to consider
8 all available and verifiable data impacting the
9 question at hand. And the evaluation of the data
10 will follow objective standards and will not
11 discount studies funded by the industry, if those
12 are otherwise scientifically sound and rigorous,
13 because, in fact, an example, the total exposure
14 study, I think some of those best and biggest
15 studies have been funded by industry interests.
16 Studies that -- again, this is chapter 1,
17 our kind of philosophy. Certainly studies that
18 provide rigorous statistical precision and
19 experimental design with measurable outcomes will
20 be given emphasis. A greater weight will be given
21 to those studies, as lesser or no weight, as
22 appropriate, will be given to things like secondary

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1 analyses, unpublished staff opinion papers. And
2 industry document reviews is another area that
3 won't be heavily emphasized, because we've found
4 historically that these papers often contain a lot
5 of inaccuracies and misrepresentations, so we won't
6 be relying heavily on those, that sort of
7 literature.
8 Chapter 2 is, I think, analogous to
9 chapter 4 of the voting members' report,
10 summarizing the demographic data of smokers of
11 menthol cigarettes. We'll give attention to the
12 statutory charge to address impacts on adolescents
13 and minority populations.
14 Chapter 3 of the industry perspectives
15 report is I think analogous to the major chapter 6,
16 that we've seen the draft of. We'll have the
17 review of the scientific evidence relating to the
18 major biomedical disciplines; epidemiology,
19 biomarkers, smoking topography, toxicology, and
20 smoke chemistry. I think we haven't heard a lot
21 about smoke chemistry in regard to the voting
22 members' report.

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1 Frankly, there isn't as much on that topic
2 as we'd like, but what we do have available will be
3 included and reviewed there. The chapter will also
4 assess disease risk in subgroups, such as by sex or
5 minority populations, where the research data do
6 allow you to do that.
7 Chapter 4 will be a review of the scientific
8 evidence on smoking initiation with regard to
9 menthol, and that evaluation will include both the
10 scientific literature available, as well as the
11 national survey data that we've discussed.
12 Chapter 5 will be an appraisal of the effect
13 of menthol, or potential effect, on cessation and
14 dependence. As you know, these topics are kind of
15 intertwined. Our original perspective was to have
16 these as separate chapters, but they're kind of
17 coming together. So I kind of think that that will
18 be a freestanding chapter, appropriately melding
19 the data available on those topics, including the
20 national survey study data.
21 Chapter 6 will talk about several of the
22 hypotheses that we've seen speculated, or offered,

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1 or discussed here at the TPSAC table. Some of
2 these may well be woven into other chapters. They
3 would include things like whether smokers perceive
4 menthol to be less harmful, whether a person
5 experimenting with smoking would find menthol
6 cigarettes less harsh or more easy to smoke. And
7 this chapter will also address some industry
8 marketing practices or at least some of the
9 anecdotal discussion of those that we've heard at
10 the table.
11 Chapter 7 will address the unintended
12 consequences or countervailing effects, a topic
13 we've heard about from the public speakers and that
14 has been commented upon in written form by the
15 industry stakeholders. I think the essence of
16 these comments on the countervailing effects
17 required in Section 907(b)(2) is found in the
18 written comments submitted to date, and some of the
19 spoken comments. So I think that chapter will be
20 kind of a synopsis of that topic.
21 Chapter 8 will be the industry's conclusions
22 regarding menthol cigarettes. And, by the way,

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1 each of these chapters I've itemized will have
2 chapter conclusions and an appropriate little
3 summary up front, an executive summary of sorts.
4 And this final chapter 8 will synthesize those
5 individual topical conclusions, based on their
6 degree of certainty with which we can
7 scientifically reach those, and maybe try to
8 identify any areas that require any further work,
9 maybe to flesh out a scientifically defensible
10 advisory opinion to FDA.
11 So that's a very quick summary of the
12 report. Again, our intention was to have this
13 process farther along by now, but it is, indeed, a
14 monumental task. I don't think the industry's
15 perspective report is going to greatly exceed, in
16 length, the voting members' report as such that we
17 can project that now. I think it may be slightly
18 longer, but not truly encyclopedic.
19 DR. SAMET: Thank you. Actually, it's not a
20 length contest.
21 [Laughter.]
22 DR. HECK: We win. Yes.

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1 Committee Discussion
2 DR. SAMET: Dan, let me ask you just a
3 couple questions. I mean, the way you're
4 constructing this, are you going to be able to
5 share drafts? I guess your comment about smoke
6 chemistry, for example, and you know we've seen
7 some issues about menthol in particulate matter,
8 for example.
9 Are there drafts that you might be able to
10 share in advance that you feel would be helpful,
11 having seen the development of the report by the
12 voting members? So that's the first question to
13 you.
14 DR. HECK: I guess, as I stated before, that
15 was the intent. But the way we're getting close to
16 this time deadline, I think the report will be
17 provided to the FDA, who asked for it, as soon as
18 possible, on or before that deadline. But that
19 deadline is approaching quickly, so I don't
20 anticipate the report being available in draft or
21 final form, much before the deadline.
22 We certainly have to circulate our draft

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1 among the representative parties to give them an
2 opportunity to comment. I'm hoping there won't be
3 extensive comments.
4 To your second question about the chemistry,
5 for instance, frankly, there's not a lot of
6 chemistry. There is scattered chemistry available
7 in various industry studies that are available on
8 the document websites, but the main chemistry
9 information we have I think was included in the
10 2010 review paper as an appendix, that data having
11 previously been unpublished, but was published in
12 that fashion, but set aside is an appendix to
13 clarify that it was not reviewed, published
14 literature.
15 I did see in the information packet a 2002
16 industry white paper. The chemistry information in
17 that paper is identical. It is the same as in the
18 2010 review paper's appendix, so there's
19 nothing -- I'm not recalling anything unique in
20 that.
21 DR. SAMET: Good. Probably just as a
22 follow-up, I think recently, for example, both you

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1 and John sent some helpful references. And if as
2 you compile references -- I mean, perhaps short of
3 a draft -- if you see something that you think is
4 critical or useful, and you sent it on, we could
5 share it and see if there is something --
6 DR. HECK: Yes. I am glad you mentioned
7 that because, of course, as soon as I sent that
8 little packet of PDFs, I found another one that was
9 just as good. But as I understood it, the date for
10 getting things in for consideration had passed. I
11 know just this very week, on Monday, I saw a new
12 paper on nicotine and tobacco research regarding
13 adolescent smoking in Native American populations
14 with some menthol data contained. And somehow,
15 very kind of late breaking would be --
16 DR. SAMET: Yes. Apparently, Caryn has just
17 whispered in my ear that that would be for public
18 submissions, but you could share references. As a
19 member of TPSAC, you could share references with
20 us. So, again, if you see something --
21 DR. HECK: Yes, yes. And by the same token,
22 if you're aware of anything that I might not have

1 seen or had access to at this late date, I would be
2 pleased to try to consider that.
3 DR. SAMET: At some point, there will be a
4 central database of references assembled, and then
5 we can certainly share that when it's -- and that
6 shouldn't be too far off, I hope. It can't be too
7 far off.
8 DR. HECK: I'll take a special look at the
9 smoke chemistry, but, as I'm recalling, there isn't
10 a whole lot published, surprisingly, given the
11 prominence of the topic. I had called the
12 attention of the group to the Technical Journal of
13 the Tobacco and Smoke Sciences, the Beitrage
14 Journal, we call it. Most of what's published,
15 that's unfortunately not to date been indexed on
16 PubMed or anything, so it's hard to find unless you
17 know where to look. There is an effort on the part
18 of the journal to get listed on PubMed, but it's
19 just underway now.
20 DR. SAMET: Are there other questions for
21 Dan? Comments? Yes, Cathy?
22 DR. BACKINGER: Just a quick question.

1 for a long time, though.
2 If nothing else, let me just ask before we
3 finish up, if there's anything else. I do think,
4 though, I have to have some discussion about the
5 March 17th/18th meeting, to just get organized on
6 that, but that will happen over the next week or
7 so, I think.
8 DR. DEYTON: It will have to.
9 Adjournment
10 DR. SAMET: It will have to. Yes, yes.
11 Let me thank everyone for a lot of hard
12 work, the public for your input. We are all
13 looking forward to March 23rd. Thanks, and see you
14 in a couple of weeks.
15 (Whereupon, at 3:09 p.m., the open session
16 was adjourned.)
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1 Given the modeling data that David Mendez
2 presented, and then David Levy, is the industry
3 report going to comment or analyze or do anything
4 with those data? Just curious.
5 DR. HECK: I only saw the model presented
6 for the first time when the public did at the last
7 meeting and with some more information this time.
8 My initial sense of that model is that what we
9 really lack is input numbers that we can plug in
10 with confidence. You can choose one survey or
11 another to do that.
12 But no. There have been some models
13 developed in the industry for kind of related
14 topics, things like harm reduction, or smoker's
15 products (unclear), that kind of thing, not
16 specific for the menthol question because the
17 menthol questions didn't arise until fairly
18 recently.
19 DR. SAMET: Any other questions for Dan?
20 Mark?
21 [No response.]
22 DR. SAMET: Maybe Mark is gone. He hung in

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