UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

)

)

))

))

)

))

)

UNITED STATES OF AMERICA, Plaintiff, v. PHILIP MORRIS USA INC., f/k/a PHILIP MORRIS INC., *et al.*, Defendants.

Civil No. 99-CV-02496 (GK)

Next Scheduled Court Appearance: May 2, 2005

UNITED STATES' WRITTEN DIRECT EXAMINATION OF

TIMOTHY WYANT, Ph.D.

1 **Q:** Please state your name.

- 2 A: My name is Timothy Wyant.
- 3 Q: What is your professional expertise?
- 4 A: I am an expert in statistics and biostatistics.
- 5 Q: What is your educational background?
- 6 A: I received a B.A. in Mathematics from Oberlin College in 1970, and a Ph.D. in

7 Biostatistics from Johns Hopkins School of Hygiene and Public Health in 1979, which is

8 now called the Johns Hopkins Bloomberg School of Public Health.

9 Q: Doctor Wyant, what is biostatistics?

10 A: Biostatistics is a discipline that involves the application of statistical methods to

11 problems in public health, medicine, epidemiology, health economics, and health

12 administration.

13 Q: Doctor, what is your current position?

14 A: I am president of Decipher, a company that provides statistical consulting

15 services. Through this company, I provide independent statistical consulting services,

16 and I direct and manage statistical research and analysis projects. There are a number of

17 independent contractors and small businesses that routinely subcontract to Decipher to

18 assist with larger projects.

- 19 Q: How long have you run Decipher?
- 20 A: For approximately 17 years.
- 21 Q: What did you do before starting Decipher?
- 22 A: For eight years, I was Senior Statistician and Vice President of Econometric
- 23 Research, Inc., a consulting firm in Washington, D.C. Before I started working for

Econometric Research, I spent three years as a Mathematical Statistician with the United
 States Geological Survey in Reston, Virginia.

3 Q: Who hires you?

A: Corporations, government agencies, labor unions, and nonprofit trusts have all
retained me at various times. I also work for law firms, U.S. Attorneys' offices, and state
attorneys general doing analysis for litigation. I also work on scientific research projects
funded by government agencies.

8 Q: Doctor, what are some corporate projects that you have worked on?

9 A: I worked on analyses of drug dose regimens for the Amgen Corporation.

10 I prepared models and forecasts of ice field conditions near the Alaskan North

11 Slope for ARCO, as part of a project to develop design specifications for offshore oil

12 platforms and ice-breaking oil tankers.

13 I developed computer models that were used by insurance companies including

14 Nationwide, Allstate, Progressive, and AIG to help adjustors assess auto accident claims,

15 and to screen bills from medical providers who are treating accident victims.

16 For other corporations, I have developed forecasts of potential liability for

17 workplace exposures to asbestos, and of potential liability for defects in products such as

18 artificial hips and artificial knees.

- 19 Q: Doctor Wyant, what are some projects that you have undertaken for
- 20 government agencies?
- A: When I worked for the U.S. Geological Survey, I was one of the analysts who
 developed and implemented computer models used to forecast oil spill risks related to

1 sales of offshore oil drilling leases. I was also responsible for many analyses of flood 2 risks in U.S. rivers, and for analyses of the spread of air and water pollutants. 3 As a private contractor, I analyzed data on New York City's million plus annual 4 911 calls, and contributed to a plan that was adopted to overhaul the dispatch system and 5 improve response time. 6 For OSHA, I analyzed data on industrial respirators for the setting of performance 7 standards, and I have worked for the EEOC on employment discrimination issues. 8 **Q**: What are some projects that you have undertaken for nonprofit trusts? 9 A: I was responsible for the claims evaluation rules and procedures for the Dalkon 10 Shield Claimants Trust. This trust was responsible for settling or litigating claims for 11 injuries related to a defective contraceptive device. 12 I was also responsible for forecasting the total extent of future claims the Trust 13 would have to pay, to ensure that both past and future claimants would end up with 14 equivalent settlements from the fixed pot of money available. Using the rules, 15 procedures, and projections that I and my team developed, the Trust successfully 16 distributed about \$3 billion to over 200,000 claimants. 17 **Q**: Doctor, what other work have you undertaken for nonprofit trusts that 18 involve future predictions? 19 A: For a number of trusts that were set up to handle asbestos disease claims, I have 20 been responsible for forecasting the total number and types of compensable cancers that 21 will occur over the next 50 years. These forecasts have been used to establish payments 22 for current claims in a manner that would allow future claimants to be paid similar 23 amounts without exhausting the trust assets. I have also updated these forecasts

periodically to allow the trusts to track whether any modifications to existing payment
 levels were necessary.

3 **O**: Doctor Wyant, please give some examples of your litigation related projects. 4 A: I have testified on a number of occasions as an expert witness. My testimony has 5 typically involved presentation of the results of statistical analyses relevant to one or 6 more issues in a case. Typical subject areas in which I have done such analyses include 7 employment discrimination, disease from occupational exposures to asbestos, failure 8 rates of defective products, forecasts of natural gas demands, and health care costs due to 9 smoking cigarettes.

10 Q: Have any of these projects involved the forecasting of future cancers and 11 other chronic diseases?

12 A: Yes. In asbestos bankruptcies, statisticians typically forecast the total number and 13 type of compensable diseases that will occur in the future in order for a plan of 14 reorganization to set aside sufficient funds to pay future claimants. Given the ages at 15 which workers were exposed to asbestos in the workplace, their future life expectancies, 16 and the latency periods between exposure to asbestos and occurrence of disease, these 17 forecasts typically go out about 50 years. 18 Doctor, have you been qualified as an expert to testify about such forecasts? **Q**: 19 A: Yes. I have testified about my asbestos disease forecasts in both state court and in 20 federal bankruptcy courts. 21 **Q**: Were these forecasts similar to the ones you did for corporations regarding

- 22 their future asbestos liabilities?
- 23 A: Yes.

1	Q:	Doctor Wyant, have you testified on issues related to cigarette smoking?
2	A:	Yes. I testified in 1998 on behalf of the State of Minnesota and Blue Cross Blue
3	Shield	d of Minnesota with regard to the extent of the smoking attributable costs in both the
4	state 1	Medicaid program and in the Blue Cross Blue Shield health plan. My colleagues
5	and I	calculated that as of 1998, these programs had paid \$1.77 billion in smoking
6	attribu	atable costs to treat people with smoking attributable diseases. During closing
7	argun	nents after trial, the defendants settled with the State of Minnesota for \$6.1 billion,
8	and w	ith Blue Cross Blue Shield of Minnesota for \$469 million.
9	Q:	Have you been qualified as an expert in statistics and biostatistics in this and
10	other	cases?
11	A:	Yes, I have.
12	Q:	Doctor, turning to U.S. Exhibit 65258, is that a true and accurate copy of
13	your	curriculum vita updated to December 2003?
14	A:	Yes, it is.
15	Q:	Does it describe your publications?
16	A:	Yes. It lists government reports, conference presentations, and other articles and
17	report	as for which I was an author or co-author. The list includes a book chapter for
18	which	I was a co-author about the analysis that was performed in the Minnesota tobacco
19	case.	
20	Q:	Doctor Wyant, does your testimony in this case relate to statistical analyses
21	that y	ou have performed?
22	A:	Yes.

1	Q: Did you work with others in performing these statistical calculations?	
2	A: Yes. I worked with Jonathan Gruber, Ph.D., Leonard S. Miller, Ph.D. and Scott	L.
3	Zeger, Ph.D. Dr. Gruber is a professor in the Economics Department at MIT. Dr. Mille	er
4	was an economics professor in the School of Social Welfare at the University of	
5	California at Berkeley. He has recently retired, and is now an emeritus professor there.	
6	Dr. Zeger is professor and chair of the Department of Biostatistics at the Johns Hopkins	3
7	Bloomberg School of Public Health.	
8	For medical and scientific issues, we consulted with Dr. Jonathan M. Samet,	
9	M.D., M.S., the chair of the Department of Epidemiology at the Johns Hopkins	
10	Bloomberg School of Public Health. For selected economic and financial issues, we	
11	consulted with Dr. Franklin M. Fisher, professor of economics emeritus at the	
12	Massachusetts Institute of Technology.	
13	Q: What roles did these individuals play?	
14	A: Dr. Gruber estimated the size and characteristics of the Youth Addicted	
15	Population. This population consists of youth smokers during the period 1954-2000, ar	ıd
16	adults who became addicted as youths during that period.	
17	Dr. Miller, Dr. Zeger, and I collaborated on statistical analyses of that populatio	n.
18	The three of us co-authored expert reports submitted in this case, but I will be the only	
19	one of us testifying on these matters. Dr. Gruber also submitted expert reports in this	
20	case, for which he was the sole author.	
21	I worked with Dr. Gruber early on with regard to some aspects of his population	1
22	calculations. He subsequently described to me on a number of occasions his ultimate	
23	methods, approaches, and results. He transmitted the results of his work to Dr. Miller,	

1 Dr. Zeger, and me in the form of a number of computer files. The three of us relied on 2 Dr. Gruber's population calculations, and performed additional statistical analyses that 3 took as a starting point the population that Dr. Gruber estimated. 4 In the course of these analyses, Dr. Samet identified for us diseases and 5 conditions caused by smoking, and discussed with us characteristics of these diseases and 6 conditions that would be relevant to appropriate statistical modeling. Dr. Fisher provided 7 guidance and data for converting past and future health care dollars to their equivalent 8 values in a single reference year, 2001. 9 0: Doctor Wyant, you said that you worked with Dr. Gruber on some of his 10 calculations related to the Youth Addicted Population, is that correct? 11 A: Yes. He had the primary responsibility for these calculations, but in his initial 12 work on this task, I provided some assistance. 13 **Q**: Doctor, U.S. Exhibit 65967 contains emails exchanged between you and Dr. 14 Gruber. Do these emails bear on the work you did early on in assisting Dr. Gruber? 15 A: Yes, in general these emails relate to data, issues, or calculations that we were 16 addressing and considering. 17 **Q**: Doctor, what were you, Dr. Miller, and Dr. Zeger retained to do in this case? 18 A: Dr. Miller, Dr. Zeger, and I were retained to summarize the extent of the smoking

19 attributable adverse health effects due to smoking by the Youth Addicted Population.

Q: Doctor Wyant, before I ask you about the analyses that you, Dr. Miller, and
 Dr. Zeger performed with regard to smoking attributable adverse health effects,
 I'm going to ask a few questions about the Youth Addicted Population that was
 identified by Dr. Gruber. First of all, that population contained youth smokers, is
 that correct?

A: Yes. The computer files that we obtained from Dr. Gruber contained counts of
youth smokers in each year from 1954 to 2000. So, for example, we could see in these
files how many 15 year-olds in 1975 were smoking regularly, based on Dr. Gruber's
calculations.

10 Q: Did the Youth Addicted Population also include adults?

A: Yes. Dr. Gruber calculated how many youth smokers became addicted as youths
during 1954-2000, and he then tracked this subset of youth smokers into adulthood. So,
for example, in the computer files that we obtained from Dr. Gruber we could see how
many 30 year-old smokers there were in 2000 who had earlier become addicted as
youths, according to Dr. Gruber's calculations. To be included in the Youth Addicted
Population as an adult, a person had to have become addicted as a youth smoker
sometime during the period 1954-2000.

18 Q: Doctor, for how long did Dr. Gruber track the adult smokers who became 19 addicted as youths during 1954-2000?

A: He tracked and projected them through 2050. Prior to 2000, he estimated how
many of these adults there were each year by using nationally representative surveys
conducted by the National Center for Health Statistics. For each year from 2000 on, he

projected how many of these adults will still be present each year by applying standard
 mortality rates published by the Social Security Administration.

So in order to be in the Youth Addicted Population, a person had to have smoked
as a youth during 1954-2000. If a person became addicted as a youth during that period,
the Youth Addicted Population includes that person as an adult through 2050, but the
Youth Addicted Population acquires no new members after 2000.

7 Q: Doctor Wyant, why was entry into the Youth Addicted Population restricted
8 to the period 1954 to 2000?

9 A: My understanding is that this period is related to alleged wrongdoing by the10 defendants.

11 Q: Did Dr. Gruber calculate population counts for some alternative definitions 12 of the Youth Addicted Population?

A: Yes. All of his definitions included two basic groups: youth smokers, and adults
who became addicted as youths. But he looked at alternative definitions of "youth" and
"addiction."

Dr. Gruber calculated population counts first defining "youth" as under age 21, and then defining "youth" as under age 18. For each of these definitions of youth he calculated population counts using three different standards of youth addiction: (1) regular smoking as a youth, (2) smoking more than five cigarettes per day as a youth, and (3) smoking more than ten cigarettes per day as a youth. So we obtained six sets of population counts from Dr. Gruber – one for each

22 unique combination of "youth" – under 18 or under 21 – and standard of addiction –

smoked regularly, smoked more than five cigarettes a day, and smoked more than 10
 cigarettes a day.

3	Q:	For assessing the magnitude of adverse health effects due to smoking, do you
4	have	calculations for all six definitions of the Youth Addicted Population?
5	A:	Yes. I will present the results of all six calculations. But we focused on the
6	Yout	h Addicted Population that defined youth smoking as smoking under age 21, and
7	defin	ed youth addiction as smoking more than five cigarettes a day as a youth.
8		Unless I explicitly state otherwise, when I refer to "the Youth Addicted
9	Popu	lation," I mean this one.
10	Q:	Why did you focus on the threshold of more than five cigarettes a day?
11	A:	My understanding is that this choice had to do with expert opinions that were
12	expre	essed by Dr. Benowitz. Dr. Benowitz testified earlier in this case that smoking more
13	than	five cigarettes per day as a youth is a reasonable indicator of addiction that is fully
14	suppo	orted by medical and scientific findings.
15		Dr. Benowitz also testified that five cigarettes a day is a conservative addiction
16	stand	ard, and that an addiction standard as low as one cigarette a day would also be
17	reaso	nable.
18	Q:	Why did you focus on smoking before age 21?
19	A:	My understanding is that this is an age threshold that defendants use in their
20	publi	c marketing statements, asserting that they do not market to people under the age of
21	21.	

1	Q:	Doctor, as I understand it, the Youth Addicted Population consisted of two
2	group	os: youth smokers, and adults who became addicted as youth smokers. Did you
3	calcu	late the extent of smoking attributable adverse health effects in both of these
4	group	os?
5	A:	No. We calculated the extent of smoking attributable adverse health effects only
6	for the	e adults who became addicted as youths during the period 1954-2000.
7	Q:	Doctor Wyant, how many adults were in the Youth Addicted Population for
8	which	you will be presenting calculations to the Court?
9	A:	There were 57 million adults who became addicted as youth smokers during the
10	period	1 1954 to 2000, by the more than five cigarettes a day addiction standard.
11	Q:	Doctor, I'm now going to turn from the Youth Addicted Population itself to
12	your	calculations of adverse health effects due to smoking by members of that
13	popul	ation. What specific smoking attributable adverse health effects in the Youth
14	Addio	cted Population did you measure?
15	A:	We estimated the number of premature deaths, the number of years of life lost due
16	to pre	mature deaths, and for major diseases caused by smoking, the total number of
17	diseas	se treatment years, and the total health care costs associated with these disease
18	treatm	nent years.
19	Q:	Does U.S. Exhibit 17162 titled, "International Classification of Diseases,"
20	which	n was prepared by Dr. Jonathan M. Samet, M.D., M.S. identify these major
21	diseas	ses?
22	A:	Yes. When we began this work in 1999, Dr. Samet gave us this list of major
23	diseas	ses caused by smoking: atherosclerosis/aortic aneurysm, bladder cancer,

cerebrovascular disease, COPD, CHD, esophageal cancer, kidney cancer, laryngeal
 cancer, lung cancer, oral cancer, other arterial diseases, pancreatic cancer, and stomach
 cancer. Dr.Samet discussed other diseases and conditions as well, but these are the ones
 for which we calculated total disease treatment years and total health care costs.

5 Q: What role did lung cancer and the other major diseases play in your

6 calculation of premature deaths and years of life lost?

A: Analysts sometimes look at the overall adverse health effects of smoking, and
sometimes concentrate on adverse health effects associated with particular diseases or
conditions. Both approaches appear frequently in the peer reviewed scientific literature.

10 We calculated both kinds of measure. For deaths and years of life lost we focused 11 on the overall effects of active smoking, and for disease treatment years and health care 12 costs we focused on the major diseases.

We did not calculate deaths caused by secondhand smoke, either among adults or among infants or children. But for active smoking among adults, we looked at deaths due to all smoking attributable causes, not just deaths caused by the major diseases. The major diseases cause the majority of deaths, so they played an implicit role in our death calculations. But we did not apportion the deaths in the Youth Addicted Population to specific diseases or groups of diseases.

1 **O**: Doctor Wyant, based on your education, training, experience, expertise in the 2 science and application of biostatistics, discussions with Dr. Zeger, Dr. Miller, and 3 other experts, and your review of the published scientific literature on smoking 4 attributable adverse health effects in the United States, do you have an opinion to a 5 reasonable degree of certainty within your field about the smoking attributable 6 adverse health effects that will be experienced by the Youth Addicted Population? 7 A: Yes. 8 **O**: Does U.S. Exhibit 17406, titled "Adverse Health Effects of Smoking Among 9 the 57 Million Adults in the Youth Addicted Population" summarize your opinions? 10 A: Yes. The Youth Addicted Population comprises 57 million adults. We estimated 11 that, through the year 2050, smoking will cause 13.4 million of these adults to die 12 prematurely. We also calculated that because of their premature deaths, these 13.4 13 million persons will be deprived of a total of 173.5 million years of life. Dividing the 14 173.5 million years of life lost by the 13.4 million deaths yields an average of about 12.9 15 years of life lost for each smoking attributable premature death. 16 We estimated that, for smoking attributable occurrences of major diseases caused 17 by smoking, Youth Addicted Population members will on average receive medical 18 treatment in two different years before the end of 2050. This corresponds to a total of 19 107.6 million disease treatment years. Of course, some members will never be treated, 20 and others will be treated for many years, but the average -1.9 years -- is close to two 21 years apiece. The 107.6 million disease treatment years do not represent all years of 22 treatment for these diseases in the Youth Addicted Population, but only the excess 23 treatment years above and beyond what never smokers experience.

1 We calculated that through 2050, the smoking attributable health care costs for 2 treating people with the major diseases will total \$839.8 billion. Again, these are not the 3 total costs for all cases of treatment in the Youth Addicted Population, but just the costs 4 related to the excess cases of treatment above and beyond what never smokers 5 experience. Most of these smoking attributable health care costs will occur in the future. 6 The \$839.8 billion figure is the value in 2001 dollars of the costs that will eventually 7 accumulate over the whole period 1954-2050. 8 We could have extended all of these adverse health effect calculations beyond 9 2050. It is reasonable to expect that, given the current age range of the Youth Addicted 10 Population, members of this population will continue to experience adverse health effects 11 beyond this point. The year 2050 is a cutoff point that is generally consistent with cutoff 12 points that are used in other projections relied upon by courts, such as those for asbestos 13 disease. Going out to 2050 captures the majority of the expected adverse health effects in 14 the Youth Addicted Population. We calculated that by 2050 the magnitude of these 15 adverse health effects will be so large that any understatement due to limiting our 16 projection will not distort the basic picture. 17 **Q**: Dr. Wyant, are there other diseases and conditions that Dr. Samet identified 18 in his testimony to the Court that result in additional cases treated and health care 19 costs beyond what your calculations capture? 20 A: Yes.

First of all, as I said a short while ago, we focused on diseases and conditions due to active smoking. The 107.6 million disease treatment years and the \$839.8 billion in health care costs that I just described do not include any treatment years or costs

attributable to secondhand smoke. Dr. Samet testified that secondhand smoke causes
 lung cancer and coronary heart disease among adults. He also testified that among
 infants and children, maternal smoking or secondhand smoke cause SIDS, exacerbation
 of asthma, chronic respiratory symptoms, reduced lung function growth, middle ear
 disease, and acute respiratory illnesses.

6 Second, our disease cases and costs do not include any diseases cases or costs due 7 to conditions related to pregnancy and pregnancy outcomes. Dr. Samet testified that 8 maternal smoking causes 1) premature rupture of the membranes, placenta previa, and 9 placental abruption; 2) pre-term delivery and shortened gestation; and 3) fetal growth 10 restriction and low birth weight.

11 Third, Dr. Samet testified that smoking causes a number of specific diseases and 12 conditions that are not on the list of diseases that guided our calculations. These 13 additional diseases include cancer of the liver, cervical cancer, acute myeloid leukemia, 14 peptic ulcer, cataracts, low bone density, and reduced fertility. These diseases and 15 conditions would result in additional cases treated and health care costs beyond what our 16 calculations capture.

Finally, Dr. Samet testified that smoking causes general diminished health. Diminished health includes the general effect of cigarette smoking on a smoker's health status, the poorer general health status of smokers compared to non-smokers, and the general poorer respiratory health of the smoker, including respiratory symptoms and an increased risk for respiratory infections, pneumonia, influenza, and other respiratory diseases. The 107.6 million disease treatment years and the \$839.8 billion in health care costs that we calculated do not include the additional smoking attributable treatments or

costs among people in the Youth Addicted Population who do not have one of the major
 diseases, but suffer from diminished health.

3 Q: Doctor, have you made any estimates related to these additional diseases and 4 conditions in the Youth Addicted Population?

5 A: We made a calculation of health care costs associated with one manifestation of 6 diminished health, self-reported health status. Dr. Samet testified that self-reported 7 health status is one of several manifestations of diminished health. We calculated the 8 extent to which members of the Youth Addicted Population are likely to report a health 9 status of "fair" or "poor" through 2050, and the extent to which such people are likely to 10 experience elevated health care costs. Including smoking attributable costs related to fair 11 and poor health increased our cost estimate for major diseases by about 23%, to just over 12 \$1 trillion (or \$1,035 billion, to be more exact). As with the costs for treating people with 13 the major diseases, this \$1 trillion plus figure represents the value of the health care costs 14 in 2001 dollars.

Q: Doctor Wyant, with regard to your smoking attributable cost calculations of
about \$840 billion for major diseases, or more than \$1 trillion for major diseases
plus fair or poor health, what do you mean when you say that these figures are in
2001 dollars?

A: In fields such as economics, statistics, and finance, when an analyst wants to
summarize costs that occur over many years, the analyst commonly converts the costs to
their value in one reference year, such as 2001. Conversion is necessary because a
dollar in 2001 does not have the same value as a dollar in 1961, or a dollar in 2041. One
reason is inflation. The other reason has to do with the fact that it is more valuable to

1 have a dollar now than a dollar at some time in the future, even in a world with no2 inflation.

3 For example, if you buy a house today for \$100,000, and get a 30-year mortgage 4 with no down payment, your total mortgage payments over the years might add up to 5 \$300,000. But you wouldn't say that you just bought a \$300,000 house -- the value today 6 of your future stream of payments is \$100,000. The difference between the \$300,000 and 7 the \$100,000 relates both to anticipated future inflation, and the fact that you get the 8 \$100,000 today to buy a house to live in, and are willing to pay additional money in the 9 future for that benefit. Analysts typically express the notion that dollars now are worth 10 more than dollars in the future by referring to the "time value of money."

11 Sometimes, the term "in 2001 dollars" is used to indicate just one adjustment, for 12 inflation. In my testimony, I use the term to indicate adjustment for both inflation and the 13 time value of money. The phrase "conversion to present value as of 2001" is sometimes 14 used to refer to such composite adjustments. Conversion to present value is a common 15 practice in many legal situations. For example, if you injure someone in such a way that 16 they cannot work any longer, part of a damages calculation will typically involve 17 compensating the injured party for the loss of future income. Often this calculation is in 18 the form of a single payment that represents, as of the injury date, the present value of the 19 anticipated stream of future annual earnings.

Using standard formulas, different streams of payments over different time periods can be converted to present value as of a single reference year, to make valid comparisons that are easy to understand.

1 **O**: Doctor Wyant, you testified that you also calculated adverse health effects for 2 some alternative definitions of the Youth Addicted Population. Does U.S. Exhibit 3 17751, titled "Smoking Attributable Adverse Health Effects; Youth Addicted 4 Populations -- Smoked Before Age 21" summarize your opinions with regard to 5 other definitions? 6 A: Yes. The tables in this exhibit show our adverse health calculations for the 7 populations defined by youth smoking under the age of 21. The tables contain separate 8 calculations for each of the three addiction standards: smoked regularly as a youth, 9 smoked more than five cigarettes a day as a youth, and smoked more than 10 cigarettes a 10 day as a youth. The tables also give separate calculations of adverse health effects 11 occurring in different time periods, as well as the total adverse health effects through 12 2050. Does U.S. Exhibit 17750 titled "Smoking Attributable Adverse Health 13 0: 14 Effects; Youth Addicted Populations -- Smoked Before Age 18" summarize your 15 opinions with regard to additional definitions of the Youth Addicted Population for 16 youth smoking under the age of 18? 17 A: Yes. The tables in this exhibit are similar to the tables in U.S. Exhibit 17751, but 18 the tables in this exhibit show our adverse health calculations for the populations defined 19 by youth smoking under the age of 18. 20 **O**: Doctor Wyant, how many peer reviewed studies related to smoking 21 attributable adverse health effects have you reviewed in order to form your opinion 22 in this case? 23 A: More than two hundred.

1	Q:	Will you be identifying in your testimony some studies that you relied upon
2	in doing your calculations and forming your opinions?	
3	A:	Yes.
4	Q:	Doctor, are these studies reliable authorities in the published scientific
5	litera	ture?
6	A:	Yes.
7	Q:	Doctor, did you also review reports of the Surgeon General of the United
8	States on smoking and disease as part of your investigation in this case?	
9	A:	Yes, I did.
10	Q:	Turning to U.S. Trial Exhibit 63621, did you review this 1989 Surgeon
11	General's report as part of your investigation in this case?	
12	A:	Yes, I did.
13	Q:	Do the conclusions in that report form part of the basis of the opinions that
14	you h	old in this case?
15	A:	Yes.
16	Q:	Turning to U.S. Trial Exhibit 88847, did you review this 2004 Surgeon
17	General's report?	
18	A:	Yes. After we performed our calculations and arrived at our opinions in this case,
19	the 20	004 Surgeon General's report was issued and admitted into evidence. In the course
20	of my	testimony, I will cite some relevant passages to assist the Court in understanding
21	our ca	lculations.
22	Q:	Is that report a reliable authority in the published scientific literature?
23	A:	Yes.

1	Q: Doctor, have you prepared a series of exhibits that summarize the facts and
2	data in the literature that form the basis for your opinions, in an effort to
3	demonstrate that your opinions are the product of reliable principles and methods
4	and that you have applied those principles and methods reliably to this case?
5	A: Yes.
6	Q: Doctor Wyant, are there any central concepts that play a role in the
7	assessment of adverse health effects caused by smoking in the Youth Addicted
8	Population?
9	A: Four main ideas emerged when we reviewed other studies that calculate the
10	effects of smoking in populations similar to the Youth Addicted Population.
11	First, the scale of the health effects that have been caused by smoking in the
12	Youth Addicted Population is enormous, and the ultimate scale of the future health
13	effects that will be caused by smoking in the Youth Addicted Population will be
14	enormous as well. The Surgeon General identifies smoking as the leading preventable
15	cause of disease and death in the United States. Based on typical rates of disease and
16	death that are observed among smokers, smoking will cause tens of millions of cases of
17	disease and millions of deaths in the Youth Addicted Population.
18	Second, in the Youth Addicted Population, the majority of the adverse health
19	effects have yet to occur. There is a time lag between smoking initiation and the onset of
20	many of the ensuing adverse health effects. Even today, many members of the Youth
21	Addicted Population have not yet been smoking long enough to experience the full
22	impact.

1 Third, many peer reviewed studies have assessed the scale of smoking attributable 2 adverse health effects in various populations. When we studied the Youth Addicted 3 Population, we could draw on methods and data sources that were developed and relied 4 upon in these studies. 5 Fourth, smoking causes numerous adverse health effects that span a variety of 6 different diseases and medical conditions. These adverse health effects in turn have 7 numerous consequences, including health care costs, pain and suffering, diminished 8 workplace productivity, disability, and death. Analysts quantify these health effects and 9 their consequences in different ways, producing a variety of measures of the enormous 10 scale of the public health impact of smoking. Each measure yields a different insight 11 into the breadth and magnitude of the impact of smoking. But analysts do not regard any 12 one measure as capturing the entirety of this impact. For the Youth Addicted Population, 13 we calculated four frequently used measures: smoking attributable deaths, smoking 14 attributable years of life lost, disease treatment years for smoking attributable diseases, 15 and smoking attributable health care costs. 16 **O**: Turning to the first of these four concepts, Doctor, did you prepare exhibits 17 that describe the scale of smoking attributable adverse health effects in the U.S.? 18 A: Yes. 19 **O**: Doctor, please turn your attention to U.S. Exhibit 17552, titled "The Burden 20 of Smoking Attributable Mortality." What does this exhibit show?

A: This exhibit gives excerpts from the two Surgeon General's reports that I
mentioned earlier – the reports for 1989 and 2004. The reports are titled "Reducing the

23 Health Consequences of Smoking: 25 Years of Progress" and "The Health Consequences

of Smoking," respectively. Several of the excerpts shown in this exhibit talk about the
enormous scale of the adverse health impacts of smoking, both in terms of absolute
numbers and in terms of comparison to other causes of death and disease. In 1989, the
Surgeon General said, "Smoking is responsible for more than one of every six deaths in
the United States. Smoking remains the single most important preventable cause of death
in our society."

7 Twenty-five years later, in 2004, not much had changed with regard to the general 8 scale of adverse health effects. In the 2004 report, the Surgeon General said, "Smoking 9 remains the leading preventable cause of disease and death in the United States, resulting 10 in more than 440,000 premature deaths each year." As noted in this report, this 11 premature death calculation was essentially the same as, and gave essentially the same 12 result as, a calculation reported earlier in a 2002 study published in the journal Morbidity 13 and Mortality Weekly Report. The more recent calculation simply added two additional 14 diseases that are caused by smoking.

Q: Looking at the excerpts in this exhibit, the terms "responsible for," "caused
by," "resulting in," and "attributable" are all used. What is the significance of the
different terminologies?

A: None. As the excerpts indicate, in examining the burden imposed on the United States population by smoking, these terms just provide different ways of saying the same thing. In the context of the scientific work that is summarized in these Surgeon General excerpts, just as in our own calculation for the Youth Addicted Population, phrases such as "caused by smoking," "attributable to smoking," "due to smoking," "smoking related," and "smoking is responsible for" are essentially synonymous.

1	The word "attributable" has one connotation that distinguishes it from the other
2	words in some situations. In epidemiology, it is often the case that an analyst can
3	calculate how many people in a population got sick or died from some cause, but cannot
4	list the names of each individual who died. An analyst studying the deaths that are
5	caused by auto accidents in the United States in a year could not only say there were
6	45,000 deaths, but could also, with some additional work, list the individuals: John Doe
7	in Salt Lake City in January, Jane Doe in Miami in March, and so on. For causes of
8	death like smoking, analysts can calculate the number of United States deaths that are
9	caused by smoking at 440,000 per year by determining the excess rates at which smokers
10	get sick and die compared to never smokers. But there is no way to assemble a
11	comprehensive list of specific individuals killed by smoking.
12	Q: Doctor, in what population did the 440,000 annual deaths that are cited by
13	the Surgeon General occur?
14	A: These are the average number of smoking attributable deaths in the United States
15	in each calendar year from 1995 to 1999. Most of the deaths occurred among current and
16	former smokers. A small number of them occurred among never smokers due to
17	secondhand smoke – about 38,000 annually from lung cancer and CHD or to children
18	of smoking parents – about 1,000 annually. These death totals come from pages 860-861
19	of the 2004 Surgeon General's report, U.S. Trial Exhibit 88847.

1 Q: Doctor, what do the excerpts from the Surgeon General's reports in U.S.

2 Exhibit 17552 say about the scale of adverse health effects in the Youth Addicted
3 Population?

A: One excerpt from the 1989 Surgeon General's report that appears in this exhibit
says, "Smoking is responsible for more than one of every six deaths in the United States.
Smoking remains the single most important preventable cause of death in our society." If
smoking ends up killing 1/6 of the 57 million smokers in the Youth Addicted Population,
there will be 9.5 million smoking attributable premature deaths among members of that
population. But the ultimate count is likely to be substantially greater than that.

10 Q: Why is the total count of smoking attributable premature deaths in the

11 Youth Addicted Population likely to exceed 9.5 million by a substantial amount?

A: The figure of "one in six deaths caused by smoking" given by the Surgeon
General was for a population that included both smokers and never smokers. The Youth
Addicted Population contains only smokers. In a population that consists exclusively of
smokers, the fraction of people who will end up dying of causes attributable to smoking
is likely to be higher, all else equal, than in a population that contains a mix of smokers
and never smokers.

18 Q: Doctor, your own calculations showed 13.4 million deaths in the Youth 19 Addicted Population, is that correct?

A: Yes. Our actual calculations were much more detailed and extensive than the
simple "back of the envelope" calculation that I just described. We based our
calculations on authoritative published sources for vital statistics such as age-specific
death rates, and we took into account such things as the exact age and gender profile of

the Youth Addicted Population I will describe our actual calculation methods in more
 detail a bit later.

3 But "back of the envelope" calculations do suffice to establish the general scale of 4 smoking attributable mortality in the Youth Addicted Population. We know from 5 applying the Surgeon General's figure not only that the general scale of smoking 6 attributable deaths will likely be in the millions, but also that a figure somewhat higher 7 than 9.5 million deaths is reasonable. "Reasonable orders of magnitude" like this one 8 play an important role in statistics and other technical disciplines. They serve as useful 9 checks and benchmarks. If more formal and extensive calculations yield figures far 10 outside of the reasonable range, then analysts typically take great pains to understand the 11 source of the discrepancy and further validate their results.

In the present case, our detailed formal calculations yielded 13.4 million smoking
attributable deaths, a figure entirely consistent with the "back of the envelope" lower
bound estimate of 9.5 million deaths.

Q: What can you say about the general scale of smoking attributable adverse
health effects other than premature deaths?

A: Looking again at U.S. Exhibit 17552, the Surgeon General said in 2004 that "…
for every premature death caused each year by smoking, there were at least 20 smokers
living with a smoking-related disease." If we apply a ratio of 20 to 1 to the millions of
deaths we expect in the Youth Addicted Population, we get tens of millions of annual
instances of disease as the general scale of smoking attributable disease in the Youth
Addicted Population.

1	More specifically, applying the 20 to 1 ratio to the 13.4 million deaths that we
2	calculated yields 268 million "years lived with a smoking attributable disease" in the
3	Youth Addicted Population. What we actually calculated was something slightly
4	different, "disease treatment years," and our calculation yielded 107.6 million smoking
5	attributable disease treatment years. Our measure required people to actually see a doctor
6	or have some other medical encounter specifically related to their disease during a year.
7	The simpler measure using the 20 to 1 ratio only required that people be living with the
8	disease, whether or not they saw a doctor. One would expect our measure to come out
9	lower than the simpler measure for this reason. In addition, the simple 20 to 1 ratio
10	calculation included common cancers such as cervical cancer, which were not included in
11	our list of major diseases. So again, it is not surprising that our more narrowly focused
12	measure yielded a smaller number of disease years.
13	But in terms of the general scale of smoking attributable adverse health effects,
14	the two measures are in agreement. Whether we are talking about a reasonable back of
15	the envelope calculation of "living with disease" years, or a more exact calculation of
16	"disease treatment" years, the general scale of these measures for the Youth Addicted
17	Population is tens of millions of years.
18	Q: What can you say about the general scale of smoking attributable health care
19	costs in the Youth Addicted Population?
20	A: The 2004 Surgeon General's report also cited a study that said smoking
21	attributable health care costs were about \$75 billion a year during the period 1995-1999.
22	This is the period in which smoking attributable deaths were occurring at an estimated
23	rate of 440,000 per year, as I discussed earlier. This \$75 billion in annual costs was

spread over both the smokers dying and the smokers living with a smoking related
disease. The overall pattern in the U.S. in 1995-1999, according to the above figures,
was that for every smoking attributable death, about \$170,000 in smoking attributable
dollars was being spent. (This \$170,000 figure is just \$75 billion divided by 440,000
deaths.) If we apply a ratio of 170,000 to 1 to the millions of deaths we expect in the
Youth Addicted Population, we get hundreds of billions of dollars as the general scale of
smoking attributable health care costs in the Youth Addicted Population.

8 More specifically, multiplying our 13.4 million deaths by \$170,000 dollars per 9 death yields over \$2.3 trillion in smoking attributable health care costs for the Youth 10 Addicted Population. This figure is considerably larger than the \$839.8 billion that we 11 calculated using more detailed and exact methods than simply applying a ratio. In part 12 this is due to the fact that the \$839.8 billion is in 2001 dollars. If we converted the \$2.3 13 trillion to 2001 dollars, a considerably smaller number would result. In addition, just as 14 with disease treatment years, the \$2.3 trillion figure from the simpler ratio calculation 15 includes dollars related to smoking attributable diseases and conditions that are not on 16 our list of major diseases. So again, it is not surprising that our more narrowly focused 17 measure yields fewer dollars than the simpler and more general measure.

But in terms of the general scale of smoking attributable adverse health effects,
the two measures are in agreement. The general scale of smoking attributable health care
costs in the Youth Addicted Population will be in the hundreds of billions of dollars.

21 Q: Doctor, returning to U.S. Exhibit 17406, titled "Adverse Health Effects of

22 Smoking Among the 57 Million Adults in the Youth Addicted Population," what

1 does this exhibit show with regard to summarizing the general scale of smoking

2 attributable adverse health effects in the Youth Addicted Population?

3 A: This exhibit shows, based on our detailed calculations for the Youth Addicted 4 Population, 13.4 million smoking attributable deaths, 107.6 million smoking attributable 5 disease treatment years, and \$839.8 billion in smoking attributable health care costs. 6 These figures are generated by more exact calculations than were performed in the simple 7 extrapolations I was just discussing. But both the simple extrapolations and the more 8 exact calculations yield the same general scale of adverse health effects in the Youth 9 Addicted Population -- millions of deaths, tens of millions of disease treatment years, and 10 hundreds of billions of dollars in health care costs.

11 Q: Doctor, have you had occasion to investigate the scale of adverse health 12 effects for causes other than smoking?

13 A: Yes. In my career I have worked on a number of projects and testified in court 14 cases that involve other causes of disease and injury, such as medical devices, silicone 15 implants, asbestos exposure, automobile accidents, and chewing tobacco. The scale of 16 the adverse health effects in those other cases has generally been much smaller than the 17 scale of adverse health effects that smoking is likely to produce in the Youth Addicted 18 Population. In other disease-related projects I have worked on, it is not unusual for small 19 technical changes in the calculation methods, or changes in a minor underlying 20 assumption, to affect substantially the general magnitude of results from statistical 21 models. That is unlikely to be the case here. 22 As U.S. Exhibit 17406 shows, even if one were to cut our calculations in half,

23 there would still be millions of smoking attributable deaths, tens of millions of years of

1	life lost, tens of millions of smoking attributable annual cases of treatment, and hundreds
2	of billions of dollars in smoking attributable health care costs in the Youth Addicted
3	Population. Even if one were to cut our calculations by 3/4, the same statement would
4	apply. Smoking attributable adverse health effects in the Youth Addicted Population are
5	not the kind of phenomena in which legitimate dispute is between "some barely
6	discernible effects" versus "no effects at all." The scale of the numbers is such that
7	questions regarding the exact counts of deaths or dollars can generally be thought of as
8	debates over which of the two adjectives "enormous" or "colossal" better characterizes
9	the magnitude of the adverse health effects.
10	Q: Doctor Wyant, is it likely in your opinion that smoking attributable deaths or
11	the other adverse health measures you calculate will end up being half or one
12	quarter of what you estimate?
13	A: No. I used those fractions simply as examples with which to convey the
14	enormous scale of the projected adverse health effects.
15	Ultimately, as with any statistical projection, it is likely that the actual measures
16	of adverse health effects in the Youth Addicted Population will differ to some extent
17	from what we have projected. For example, one way that the actual measures could end
18	up lower than what we project is if future smoking reduction programs are successful in
19	further reducing the level of smoking. Our projections assume, consistent with what is
20	done in similar peer reviewed studies, that current patterns of smoking behavior will
21	persist into the future.
22	Analysts who calculate and publish measures of smoking attributable adverse
23	health effects often suggest that implementation of more comprehensive smoking

reduction programs could eventually reduce future adverse health effects. For the Youth Addicted Population, the immense scale of the projected adverse health effects in the absence of such programs means that even reductions on the order of 10% to 20% will translate to millions of premature deaths averted and tens of billions of health care dollars saved. But reductions of this magnitude will still leave the ultimate scale of adverse health effects at millions of deaths, tens of millions of disease treatment years, and hundreds of billions of dollars.

8 Working to limit the magnitude of decreases that smoking reduction programs can 9 achieve is the fact that the programs cannot go back in time and eliminate past smoking, 10 or smoking that is occurring today. To repeat what the Surgeon General said in 2004 11 with regard to smoking attributable deaths, "The burden of smoking attributable mortality 12 will remain at current levels for several decades."

In addition, total adverse health effects in the future could easily be larger than what we calculated, not smaller, especially if current smoking behavior patterns do persist into the future. We deliberately omitted important categories of disease and dollars from our calculations in order to be conservative.

I will discuss our projection calculations in more detail later on. The main point
here is, for reasons such as the ones I just mentioned, I regard it as unlikely that the future
adverse health effects will be one half or one quarter of what we have projected.

20 Q: Doctor, you mentioned four central concepts that play a role in the

21 assessment of smoking attributable adverse health effects in the Youth Addicted

22 **Population.** You just discussed the first one -- the enormous scale of the adverse

23 health effects in this population. What was the second one?

The second main idea was that in the Youth Addicted Population, the majority of 1 A: the adverse health effects have yet to occur. 2

3	Q: Doctor, please direct your attention to U.S. Exhibit 17551, titled "Adults in
4	the Youth Addicted Population – 2005." What does this exhibit show?
5	A: This exhibit shows the current age profile of the adults in the Youth Addicted
6	Population – that is, the age profile in 2005. The red bars show the number of adults at
7	each age. For example, there are about a million members who are 30 years old, more
8	than 1.5 million members who are 45 years old, and about 600,000 members who are 70
9	years old. The age range is 21 to 71. Adults were added to the Youth Addicted
10	Population only if they smoked more than five cigarettes a day as youths during the
11	period 1954 to 2000. As of 2005, the oldest members of the Youth Addicted Population
12	are people who smoked as 20 year-olds in 1954, and who are now 71 years old.
13	The table at the bottom of the exhibit shows that the Youth Addicted Population
14	in 2005 currently comprises 55.1 million adults. Their average age is 46.
15	The black bars extending downwards on the right side of the exhibit show how
16	many members at each age have died since 2000. For example, about 100,000 of the
17	people who smoked as 20 year-olds in 1954, and who would have been 71 in 2005, have
18	died.
19	Q: Doctor Wyant, how does the age profile of the Youth Addicted Population
20	relate to the idea that the majority of the smoking attributable adverse health effects

21 have yet to occur?

Dr. Samet testified earlier in this case that people typically smoke for 20 years or 22 A: more before the risk of diseases such as lung cancer, COPD, and CHD starts to increase 23

substantially. Most of these diseases occur at older ages, although they can occur as early
 as the 30s or 40s.

3	As U.S. Exhibit 17551 shows, the average age of adults in the Youth Addicted
4	Population is currently only 46. It also shows that millions of adults in this population
5	are still in their 20s and 30s. So as of today, a large segment of this population is simply
6	too young to have experienced the full effect of smoking attributable adverse health
7	effects. Most of these adverse health effects will occur in the future, as this population
8	ages.
9	Take smoking attributable deaths as an example. The last people included in the
10	Youth Addicted Population were added in 2000, so the Youth Addicted Population was
11	capped in size at that point. Overall, the Youth Addicted Population comprises 57
12	million adults. As of 2005, U.S. Exhibit 17551 shows that an estimated 55.1 million of
13	these adults are still alive. The exhibit shows this 55.1 million figure in the box at the
14	bottom of the exhibit.
15	So as of today, fewer than two million members of the Youth Addicted
16	Population have died, including deaths from all causes, not just deaths caused by
17	smoking. We would not generally expect any more deaths than this to have occurred,
18	given the general youthful character of this population. I testified earlier that we
19	calculated that smoking will kill 13.4 million people in the Youth Addicted Population.
20	Clearly, as of today in 2005, the great majority of these deaths have yet to occur.
21	Q: Have you prepared exhibits that illustrate how smoking attributable deaths
22	in the Youth Addicted Population distribute over time?

23 A: Yes.

1 Q: Please tell the Court what U.S. Exhibit 17407, titled "Deaths -- Youth

2 Addicted Population" shows?

3 A: This exhibit charts our estimates of the annual smoking attributable deaths in the 4 Youth Addicted Population from 2001 through 2050. In 2001, there are just over 5 100,000 such deaths. The number of deaths increases each year until 2028, where there 6 are about 340,000 deaths. From 2029 through 2050, the number of smoking attributable 7 premature deaths declines each year, reaching about 240,000 by the year 2050. The 8 death counts in this exhibit come from our detailed calculations for the Youth Addicted 9 Population, and I will be describing how those calculations were made. 10 If we step back from these year to year details, this exhibit shows the general 11 picture of how smoking attributable deaths distribute over time. Most of the deaths occur 12 in the future, with a peak about 23 years from now. This pattern is consistent with the 13 kinds of temporal patterns of disease occurrence that were already described by Dr. 14 Samet. 15 Doctor Wyant, please direct your attention once again to U.S. Exhibit 17552, **O**: titled "The Burden of Smoking Attributable Mortality." What does this exhibit 16 17 show that would be relevant to how smoking attributable deaths distribute over time? 18 19 A: This is the exhibit that contains excerpts from the 1989 and 2004 Surgeon 20 General's reports. In 2004, the Surgeon General said that smoking causes more than 21 440,000 deaths each year. This is a figure that is very similar to other estimates of annual 22 smoking attributable deaths that have been published in recent peer reviewed articles.

23	"Deaths Youth Addicted Population" which shows your calculations of how
22	Q: Doctor Wyant, please direct your attention back to U.S. Exhibit 17407, titled
21	population of all U.S. smokers.
20	deaths per year - the Youth Addicted Population will always be a subset of the
19	peaking at a number substantially higher than 190,000 deaths per year, but below 440,000
18	Similarly, an analyst would generally expect annual smoking attributable deaths
17	on the overall average for the entire time period 190,000 deaths per year.
16	totals in the near future that fall generally close to, and perhaps below, the lower bound
15	I just calculated, an analyst would generally expect annual smoking attributable death
14	maximum number of annual deaths to be occurring. So, based on the approximate figure
13	period 2001-2050. This population is currently too young – average age 46 – for the
12	Deaths in the Youth Addicted Population will not occur evenly across the time
11	approximate lower bound on the average number of smoking attributable deaths per year.
10	year from 2001 through 2050. When we do this arithmetic, we get roughly 190,000 as an
9	this figure by 50, we can also get an approximate lower bound on the average deaths per
8	attributable deaths in the Youth Addicted Population – 9.5 million deaths. If we divide
7	Surgeon General can be used to construct an approximate lower bound for total smoking
6	of the Youth Addicted Population? Earlier, I discussed how other statements of the
5	How many of these 440,000 deaths per year are likely to occur among members
4	per year for the U.S. as a whole during the coming years.
3	these statements, we would expect to see roughly 440,000 smoking attributable deaths
2	mortality will remain at current levels for several decades." In general terms, based on
1	In 2004, the Surgeon General also said, "The burden of smoking attributable

Written Direct: Timothy Wyant, Ph.D., US v. PM, 99-cv-02496(D.D.C.)(GK)

Page 34

deaths in the Youth Addicted Population will distribute over time. How do the
annual number of deaths from your more exact calculations compare with the
general ranges you just inferred from statements of the Surgeon General?
A: Looking at this exhibit, in the near future we calculated annual smoking
attributable deaths in the Youth Addicted Population at 150,000 to 200,000 deaths per
year. These figures fall near or below the 190,000 figure extrapolated from the Surgeon
General's statements, as expected.

8 Near the peak year of deaths in 2028, we calculated annual smoking attributable 9 deaths in the Youth Addicted Population at 300,000 to 340,000 per year. These figures 10 are substantially higher than the 190,000 figure extrapolated from the Surgeon General's 11 statements, but below the 440,000 deaths that are projected for the United States as a 12 whole – again, as expected.

13 To repeat, these are just general "reasonableness checks." Extrapolating from one 14 or two overall rates reported by the Surgeon General does not substitute for the more 15 exact statistical calculations that we performed to address the specific characteristics of 16 the Youth Addicted Population. But reasonableness checks of this sort are among the 17 things that statisticians look at when they conduct their analyses.

18 Q: What causes the number of deaths to decline in the later years?

A: This happens mostly because the Youth Addicted Population begins to die off in
substantial numbers as its members age. As we go out towards 2050, there are simply
fewer and fewer people who could get sick – many have already died. The number of
annual deaths is guaranteed to drop to zero if we go out far enough, and the chart in U.S.
Exhibit 17407 shows that the annual death counts are dropping fairly rapidly by the time
 we hit the year 2050.

3 Q: Doctor, you have talked about two central concepts -- the enormous scale of
4 adverse health effects due to smoking, and the distribution over time of these
5 adverse health effects in the Youth Addicted Population. You mentioned four
6 central concepts in all. Can you explain the third one?

A: The third main idea was that many peer reviewed studies have assessed the scale
of smoking attributable adverse health effects in various populations. When we studied
the Youth Addicted Population, we could draw on methods and data sources that were
developed and relied upon in these studies.

11 It is not surprising that many studies have been conducted, given the enormous 12 scale of adverse health effects that are caused by smoking. In 1989, as the Court saw in 13 U.S. Exhibit 17552, the Surgeon General called smoking the most important preventable 14 cause of death in our society. In 2004, the Surgeon General was still calling smoking the 15 most important preventable cause of disease and death. Numerous researchers have 16 echoed this opinion. Given the magnitude of smoking related adverse health effects in 17 the United States and elsewhere, it is not surprising that there have been, and continue to 18 be, many published scientific studies on the consequences of smoking. Dr. Samet 19 referred to the more than 1,600 studies in the Surgeon General's database. 20 Studies often focus on a single narrow scientific question, and so not every 21 individual study leads immediately to a calculation of, for example, the total number of 22 smoking attributable premature deaths in the Youth Addicted Population. But there have 23 been numerous published studies that do calculate smoking attributable premature deaths

Page 36

1	and other measures of adverse health effects for populations that are similar to the Youth
2	Addicted Population. I just discussed, as just one example, the calculation of 440,000
3	smoking attributable deaths per year in the U.S. population from 1995-1999 that was
4	presented in the 2004 Surgeon General's report.
5	To a large extent, our task was simply to adopt and extend methods that were used
6	in these studies in order to calculate more precisely the total smoking attributable deaths
7	in the Youth Addicted Population. We were not doing something novel or
8	unprecedented, but in many respects just extending and adapting the work of others in an
9	appropriate manner.
10	Q: Doctor, in relying on other studies, you didn't just take, say, a percentage of
11	smokers dying from smoking attributable causes reported in some journal article,
12	and multiply times the number of people in the Youth Addicted Population, is that
12 13	and multiply times the number of people in the Youth Addicted Population, is that correct?
12 13 14	and multiply times the number of people in the Youth Addicted Population, is thatcorrect?A:No, although based on my general experience in conducting applied statistical
12 13 14 15	and multiply times the number of people in the Youth Addicted Population, is thatcorrect?A:No, although based on my general experience in conducting applied statisticalprojects, one could do what you suggest and get an answer that was adequate for many
12 13 14 15 16	and multiply times the number of people in the Youth Addicted Population, is thatcorrect?A:No, although based on my general experience in conducting applied statisticalprojects, one could do what you suggest and get an answer that was adequate for manypurposes. But we wanted to be more exact. One reason that just applying a simple
12 13 14 15 16 17	and multiply times the number of people in the Youth Addicted Population, is thatcorrect?A:No, although based on my general experience in conducting applied statisticalprojects, one could do what you suggest and get an answer that was adequate for manypurposes. But we wanted to be more exact. One reason that just applying a simplepercentage would be somewhat inexact is that the age and gender mix of the Youth
12 13 14 15 16 17 18	and multiply times the number of people in the Youth Addicted Population, is thatcorrect?A:No, although based on my general experience in conducting applied statisticalprojects, one could do what you suggest and get an answer that was adequate for manypurposes. But we wanted to be more exact. One reason that just applying a simplepercentage would be somewhat inexact is that the age and gender mix of the YouthAddicted Population is not exactly the same as the age and gender mix in, say, the
12 13 14 15 16 17 18 19	and multiply times the number of people in the Youth Addicted Population, is thatcorrect?A:No, although based on my general experience in conducting applied statisticalprojects, one could do what you suggest and get an answer that was adequate for manypurposes. But we wanted to be more exact. One reason that just applying a simplepercentage would be somewhat inexact is that the age and gender mix of the YouthAddicted Population is not exactly the same as the age and gender mix in, say, thepopulation of U.S. smokers in 1995-1999. As Dr. Samet testified, the relative risk of
12 13 14 15 16 17 18 19 20	and multiply times the number of people in the Youth Addicted Population, is thatcorrect?A:No, although based on my general experience in conducting applied statisticalprojects, one could do what you suggest and get an answer that was adequate for manypurposes. But we wanted to be more exact. One reason that just applying a simplepercentage would be somewhat inexact is that the age and gender mix of the YouthAddicted Population is not exactly the same as the age and gender mix in, say, thepopulation of U.S. smokers in 1995-1999. As Dr. Samet testified, the relative risk ofdeath for smokers compared to never smokers differs by age and gender. By adapting
12 13 14 15 16 17 18 19 20 21	and multiply times the number of people in the Youth Addicted Population, is thatcorrect?A: No, although based on my general experience in conducting applied statisticalprojects, one could do what you suggest and get an answer that was adequate for manypurposes. But we wanted to be more exact. One reason that just applying a simplepercentage would be somewhat inexact is that the age and gender mix of the YouthAddicted Population is not exactly the same as the age and gender mix in, say, thepopulation of U.S. smokers in 1995-1999. As Dr. Samet testified, the relative risk ofdeath for smokers compared to never smokers differs by age and gender. By adaptingand refining the methods used in other studies and then making a calculation specific to

profile of the Youth Addicted Population. This was the case not only for deaths, but also
 for the other adverse health effects that we measured.

3 Q: How substantial are the differences between the Youth Addicted Population 4 and the U.S. population?

5 A: Not very substantial, in terms of assessments of the general scale of smoking 6 attributable health effects, or in terms of applicability of previously developed statistical 7 methods. Calculating smoking attributable deaths for the Youth Addicted Population is 8 not like making that calculation for, say, Aleutian Islanders. As the citation from the 9 1989 Surgeon General's report in U.S. Exhibit 17552 indicates, the great majority – four 10 out of five as of that report -- of smokers in the U.S. start smoking under the age of 21. 11 And based on the smoker count calculations for the Youth Addicted Population, the great 12 majority -86% -- of adult smokers who smoked regularly under the age of 21 since 1954 13 smoked more than five cigarettes a day as youths.

14 The import of all of this is that when we calculated premature deaths and other 15 measures for the Youth Addicted Population, we were to a reasonable extent calculating 16 these measures for a group that is similar to U.S. smokers as a whole, and to subgroups of 17 U.S. smokers that have been the focus of other studies. To get more exact estimates 18 specific to the Youth Addicted Population, some careful extension and refinement of 19 previously used methods was warranted. But "extension" and "refinement" are the 20 appropriate terms. No wholesale overhauls or extraordinary revisions were needed, 21 because the Youth Addicted Population is not that dissimilar to other populations of 22 smokers that have been the subject of recent research.

Q: Doctor Wyant, you mentioned a fourth concept as playing a role in the
 assessment of smoking attributable adverse health effects, which involved the
 variety of adverse health effects caused by smoking. Please explain what you mean
 by that.

5 A: Smoking causes a wide variety of diseases and conditions. Dr. Samet and other 6 experts in this case have listed and described them at some length. In adults, these 7 diseases and conditions range across lung and other cancers, COPD, heart disease and 8 stroke, cataracts, respiratory difficulties, and nonspecific diminished health. Other 9 smoking caused diseases and conditions affect pregnant women, infants, and children. 10 These diseases and conditions impose a range of burdens on a population. They 11 can obviously cause extensive pain and suffering in the people who have them, and often 12 lead to premature death. These diseases and conditions also place a burden on the health 13 care system – in any given year, they require many doctor visits and hospital stays, and 14 these encounters in turn impose financial costs that are borne by the sick individuals and 15 their families, by medical providers when the sick individuals are indigent and uninsured, 16 by private health plans (and ultimately the subscribers to these plans), and by publicly 17 funded programs such as Medicaid and Medicare (and ultimately the taxpayers). These 18 diseases and conditions also impose an economic burden outside of the health care 19 system, in that sick people often cannot work. If they can work, they may work fewer

20 hours, or work less productively.

Diseases caused by smoking impose additional burdens, both emotional and financial, on the families of persons who have such diseases. Families face the emotional consequences of having a loved one ill and suffering, and the emotional consequences of

Written Direct: Timothy Wyant, Ph.D., US v. PM, 99-cv-02496(D.D.C.)(GK)

Page 39

having a loved one die prematurely. They devote time, effort, and expense to providing
care for a sick family member. They face the financial burdens that are imposed when a
wage-earner dies, or when a family member has to stop working to provide in-home
health care.

5

O:

Did you analyze all of these adverse health effects?

A: No. We focused on the subset of adverse health effects that I described earlier:
deaths, years of life lost, disease treatment years, and health care costs.

8 These health effects have impacts that are amenable to statistical summary. For 9 example, we calculated the total number of people in the Youth Addicted Population who 10 receive medical treatment for major smoking attributable diseases in any given year. 11 From statistical quantities like the number of smoking attributable disease treatment 12 years, the Court can indirectly make some qualitative inference about intangibles such as 13 the general scale of smoking attributable pain and suffering, and also about the general 14 economic burdens that are imposed by smoking in the Youth Addicted Population.

Q: Doctor, can you sum up in a concise way what these four central concepts say
about assessing smoking attributable adverse health effects in the Youth Addicted
Population?

A: The scale of the impact of smoking attributable adverse health effects will be
enormous. Most of this impact will occur in the future. Many studies of similar
populations confirm that the scale of impact will be enormous, and provide a guide to
methods that can be used to measure with reasonable accuracy the scale of impact in the
Youth Addicted Population. There are many adverse consequences of smoking, so it is

useful to calculate a number of different measures of the impacts, but no single statistical
 measure can capture the entirety.

3 Q: Doctor Wyant, turning to a specific adverse health effect, how did you

4 calculate premature deaths in the Youth Addicted Population?

5 A: We calculated a measure used in epidemiology called the "attributable fraction"6 and applied it to the Youth Addicted Population.

7 Q: Doctor, please direct your attention to U.S. Exhibit 17541 titled

8 "Measurements Used in Epidemiology – Example of Rates and Fractions from

9 Published Studies." What does this exhibit show?

A: This exhibit shows an example calculation for 66 year-old male current smokers.
The annual mortality rate for these current smokers is 3.5%, meaning that out of 1,000,
35 will die on average during the course of a year. The mortality rate for male never
smokers at this age is 1.4%, meaning that out of 1,000, 14 will die on average during the
course of a year.

15 The relative risk of death is one measure that is used in epidemiology. Dr. Samet 16 described it in his testimony. The relative risk is the ratio of the mortality rates – that is, 17 the current smoker rate divided by the never smoker rate. Or equivalently, the relative 18 risk is the number of smokers out of 1,000 dying during the course of a year divided by 19 the number of never smokers out of 1,000 dying during the course of a year. In the example, the relative risk is 2.5, which is 3.5% divided by 1.4%, or 35 divided by 14, 20 21 whichever way you want to think about it. This means that for male smokers at this age, 22 current smokers die at two and a half times the rate of never smokers.

1	Another measure described by Dr. Samet is the attributable risk. The attributable
2	risk is the difference of the mortality rates. In the example in U.S. Exhibit 17541, the
3	attributable risk is 3.5% minus 1.4%, or 2.1%. Or, if you prefer thinking in terms of
4	deaths per thousand, 35 minus 14 equals 21 per thousand.
5	The attributable risk is the excess mortality rate for smokers beyond what is
6	experienced by never smokers. In this example, an additional 2.1% of smokers die
7	during the course of a year above and beyond the 1.4% who would die if the never
8	smoker mortality rate applied. Or equivalently, an additional 21 smokers out of a
9	thousand die during the course of a year above and beyond the 14 "baseline" deaths that
10	would occur if the never smoker mortality rate applied.
11	A third measure that is used in epidemiology is the attributable fraction. The
12	attributable fraction is the attributable risk divided by the smoker mortality rate. In the
13	example, the attributable fraction is 21 per thousand divided by 35 per thousand, which is
14	.6, or in percentage terms, 60%. An attributable fraction of 60% means that 60% of the
15	total smoker deaths are attributable to smoking. The remaining 40% are the "baseline"
16	deaths that would occur if the smokers died at the never smoker mortality rate.
17	This example is a hypothetical, with mortality rates rounded for ease of
18	explication, but the numbers that are used are realistic to a reasonable degree of
19	approximation.
20	All of these measures are simply different ways of comparing the mortality rates
21	of smokers and never smokers, and expressing the extent to which the smokers die at
22	elevated rates compared to similar never smokers.

1	Q: Does U.S. Exhibit 17542 titled "Measurements Used in Epidemiology –
2	Example Calculation of Smoking Attributable Deaths" describe the calculation of
3	the number of smoking attributable deaths in the Youth Addicted Population?
4	A: Yes. It gives another example. Suppose there are 100,000 66 year-old male
5	current smokers in the Youth Addicted Population. We take this count and multiply by
6	the mortality rate of 3.5% from the previous exhibit to get the total number of deaths.
7	Then, we multiply this total number of deaths by the attributable fraction of .6, or 60%, to
8	get 2,100 smoking attributable deaths over the course of a single year.
9	The important point here is not the actual numbers, but the basic method. Once
10	an analyst has obtained an appropriate mortality rate and an appropriate attributable
11	fraction from published studies, he or she can apply them to different populations. So for
12	example, an analyst studying smoking attributable deaths in Virginia could apply the rate
13	and fraction in the exhibit to the count of 66 year-old male current smokers in Virginia to
14	estimate the annual number of smoking attributable deaths for Virginians in that age-
15	gender group. For "Virginia", one could substitute "Maryland", or "people born east of
16	the Mississippi," or "people who were teenagers in the 1950s."
17	In fact, the example in U.S. Exhibit 17542 is a realistic depiction of the actual
18	calculation for the Youth Addicted Population for the year 2000. We got the smoker
19	counts for this population from Dr. Gruber. Very roughly, 100,000 was the number of 66
20	year-old male current smokers in the Youth Addicted Population in 2000.
21	In U.S. Exhibit 17542, the figures that are specific to the Youth Addicted
22	Population are shaded in blue. The count of 66 year-old male current smokers is shaded
23	in blue – this is one subset of the smokers in the Youth Addicted Population. This count

appears on the on the left side of this exhibit. Then, to this count we apply the measures derived from published studies – the mortality rate and the attributable fraction – which are shaded in green. The previous exhibit, U.S. Exhibit 17541, described how these two measures are derived. The result of these calculations appears at the right -- the number of smoking attributable deaths during the year for this subgroup of the Youth Addicted Population. This total smoking attributable deaths figure is shaded in blue.

We used the computer to repeat this basic calculation for male and female
smokers of different ages, for different calendar years, and for former smokers as well as
current smokers. Once an analyst has the basic formula and appropriate inputs – the
smoker counts from Dr. Gruber and appropriate mortality rates -- it is straightforward to
repeat the calculation for each of the subgroups.

12

Q: Doctor, where did the mortality rates you used come from?

13 A: We obtained the appropriate mortality rates from the Social Security

Administration, or SSA. The SSA is charged with doing the actuarial work that assesses the current and future fiscal health of the Social Security program. The SSA accordingly pays a lot of attention to life expectancies and death rates, and many researchers rely on their figures.

We obtained the relative risks from two sources: Monograph 8 from the National Cancer Institute, and the 1989 Report of the Surgeon General. The figures in these publications were derived from a large national cancer study from the late 1980s, the Cancer Prevention Study II, or CPS-II. As Dr. Samet testified, this study is an authoritative source for relative risks.

23 Q: Were the mortality rates published in a form you could just copy and use?

A: Not quite. What is published is the overall mortality rate for the U.S., but with
 some simple algebra, an analyst can take relative risks for smokers and calculate the
 separate mortality rates for smokers and for never smokers.

4 Relative risks for former smokers are not published to the same level of age 5 specificity as are relative risks for current smokers. For both current and former smokers, 6 we could determine the relative risks for all ages combined. For current smokers, we 7 could determine relative risks by five-year age groups. If for all ages combined, the 8 excess risk for former smokers was, say, 50% of the excess risk for current smokers, we 9 applied this 50% figure to the excess risks for current smokers in each age group. This 10 method yielded estimates of age-specific relative risks for former smokers. We did these 11 calculations separately for men and for women.

12 The formula for calculating mortality rates from relative risks also requires the 13 number of smokers in a baseline year. We obtained these figures from the National 14 Health Interview Survey, or NHIS. The NHIS is the longest running, most commonly 15 used household survey of smoking behaviors in the United States.

16 Q: Doctor Wyant, how do your methods compare to methods that are typically
17 used in peer reviewed articles that look at deaths due to smoking?

A: We used methods that are essentially the same as those used in peer reviewed articles. There are minor variations in data and methods from article to article. I don't think you could find two articles in which the methods and data sources are identical in every single respect. But the essence of the attributable risk approach is the same in all the articles that I am aware of, and we took the same basic approach as used in those articles. The core notion is simple. Smokers die more frequently than similar never

Page 45

smokers. The excess number of deaths beyond what would have been the case if the
 smokers had died at the never smoker death rate are deemed smoking attributable.

3

Q: What happens in the future – say for 2010?

4 A: We projected what the age distribution of the Youth Addicted Population will 5 look like in 2010. So we calculated, as just one example, the number of 50 year-old male 6 current smokers in 2010. In essence, using a computer, we kept applying death rates and 7 smoking cessation rates to the Youth Addicted Population as it was in 2000, and 8 projected what the future will look like. The 40 year-old current smokers in 2000 9 become 50 year-old current smokers in 2010, appropriately diminished by deaths and 10 cessations that occur in the intervening years. Then, to get smoking attributable 11 premature deaths that occur in the year 2010 among the 50 year-old current smokers, we 12 repeated the attributable risk calculation that I described a few moments ago. 13 **Q**: Doctor, will all the 50 year-old current smokers in 2010 have been current

14 smokers in 2000 as well?

A: No. It's hard to quit for good. Some of the "former smokers" in 2000 will
resume smoking. Among the 50 year-old current smokers in 2010 there will be people
who had quit temporarily as 40 year-olds, and then resumed smoking.

18 Q: Doctor, do your calculations take temporary quitting into account?

19 A: Yes. Our cessation rates are "permanent" cessation rates. They focus on the

20 fraction of smokers who quit for good. Every year there is some movement back and

- 21 forth between current and former smokers, with some current smokers quitting
- 22 temporarily, and some former smokers resuming smoking. But on top of this back and

forth movement, there are some people who quit and never resume. Our cessation rates
 relate to this latter group.

3 Q: Where do your cessation rates come from?

4 A: For ages below age 65, we obtained cessation rates from Dr. Gruber. He 5 calculated them from the National Health Interview Survey. For ages above 65, we 6 calculated cessation rates from the Medicare Current Beneficiary Survey. This is a 7 survey of Medicare beneficiaries that is conducted each year by the federal government. 8 It is a data source that is frequently used by researchers studying the 65 and older 9 population. The survey asks about smoking, and typically people are surveyed for three 10 consecutive years. So a statistician can calculate the extent to which guit rates exceed 11 relapse rates from year to year, which in turn yields a permanent cessation rate. 12 **Q**: Doctor Wyant, did you give these cessation rates for ages above 65 to Dr.

13 Gruber to use in his own calculations regarding the size of the Youth Addicted

14 **Population**?

15 A: Yes.

16 Q: Is projecting a population into the future, as you do with the Youth Addicted
17 Population, a standard thing to do?

A: Yes. For example, it's in essence what the SSA does in making actuarial
calculations regarding the future solvency of Social Security and Medicare, although the
SSA routinely projects further in time than we do, going 75 years into the future.

21 Q: Doctor, please direct your attention once again to U.S. Exhibit 17406, titled

22 "Adverse Health Effects of Smoking Among the 57 Million Adults in the Youth

23 Addicted Population." Did you calculate the 13.4 million smoking attributable

1	deaths that are shown in this exhibit by applying to the Youth Addicted Population	
2	the m	ethods you've just described?
3	A:	Yes.
4	Q:	Does U.S. Exhibit 17406 also show the years of life lost that you calculated for
5	the Y	outh Addicted Population?
6	A:	Yes. We calculated that the 13.4 million smoking attributable deaths in the Youth
7	Addic	cted Population will result in 173.5 million years of life lost from 2001 through
8	2050.	
9	Q:	What do you mean by "years of life lost"?
10	A:	Smokers tend to die at younger ages than never smokers. At ages beyond 35,
11	smoke	er death rates are higher than never smoker death rates. Peer reviewed articles that
12	calcul	ate smoking attributable deaths refer to the excess deaths among smokers as
13	"prem	nature deaths." In a population in which such premature deaths occur, there are
14	some	years of life that the prematurely dying smokers would have experienced had they
15	achiev	ved the life expectancy of similar never smokers. The years of life these smokers
16	could	have expected to live, but didn't, are called "years of life lost."
17	Q:	Doctor, directing your attention to U.S. Exhibit 17430, titled "Measurement
18	Used	in Epidemiology – Years of Life Lost." What does this exhibit show?
19	A:	This exhibit illustrates the calculation of years of life lost. The mortality rates in
20	this ex	xhibit are exaggerated compared to the actual rates, for ease of explication. But the
21	essen	ce of the calculation method is accurately depicted.
22		The bottom half of the exhibit tracks 12 current smokers in 2000. The 12 smokers
23	collec	tively accumulate 12 "years lived" during 2000. That is, each of them is alive for

the whole year. Then four of them die. For convenience, let's assume that they die at
midnight on December 31st, so we don't have to deal with fractional years lived. So in
2001, eight surviving smokers live all year, and accumulate another eight "years lived."
Then four more die, leaving four survivors to live throughout 2002 and accumulate
another four "years lived." The total years lived by this group of current smokers is 12 +
8 + 4 = 24 years lived, as shown at the right side of the exhibit.

The top half of the exhibit tracks what would happen to our 12 smokers if they
experienced the mortality rates of similar never smokers. The 12 people accumulate 12
years lived in 2000, just like before. But the mortality rates for never smokers are lower,
so only two of the original 12 die at the end of 2000. So in 2001, there are 10 survivors
who accumulate 10 years lived. Two more die at the end of 2001, leaving eight survivors
who accumulate another eight years lived. The total years lived from 2000 through 2002
when we apply the never smoker mortality rates is 12 + 10 + 8 = 30.

The difference between the total years lived using never smoker mortality rates and the total years lived using current smoker mortality rates is 30 - 24 = 6 years of life lost. These are the additional years of life the smokers would expect to experience if they achieved the life expectancies of never smokers.

18 Q: Doctor Wyant, how does this example translate to the Youth Addicted 19 Population?

A: If we were to redo this exhibit with actual numbers – which would be hard to do and still have the exhibit be visually useful -- the counts of smokers at the left would come from Dr. Gruber. There would be a separate set of counts for each subgroup – and hence a separate exhibit – with subgroups defined by age, gender, and smoker category

1 (current or former). In each subgroup, of course, there are many more than 12 smokers. 2 Then the mortality rates derived from the scientific literature were used to go from one 3 year to the next – where the green arrows appear in the exhibit. The arithmetic is the 4 same – we calculate the total years lived at never smoker mortality rates, and then 5 subtract the total years lived at the smoker mortality rates, to get the years of life lost. 6 In doing the calculation for the Youth Addicted Population, we also dealt with 7 one additional phenomenon that is not shown in the exhibit. Each year some current 8 smokers quit and become former smokers. In our actual calculations, this just meant that 9 for the quitters, a former smoker mortality rate was then used instead of a current smoker

10 mortality rate. But the basic logic did not change.

11 Q: What mortality rates did you use for the years of life lost calculation?

A: We used the same mortality rates that we used in calculating the 13.4 million
smoking attributable deaths. I described the sources for these death rates a little earlier.
We also used the same smoking cessation rates that we used in the death calculations.

15 Q: Doctor Wyant, is calculating "years of life lost" a standard thing to do?

16 A: Yes. In published studies that calculate how many premature deaths are due to 17 some specific cause, a "years of life lost" calculation is frequently made. Sometimes the 18 alternative phrase "years of potential life lost" is used, but with either wording the 19 calculation is essentially as I just described it.

20 Q: What does the measure "years of life lost" show the Court if the Court is

- 21 already aware of the number of "premature deaths?"
- A: Calculating "years of life lost" is one way of summarizing the extent to which a cause of death tends to affect younger people, as opposed to the elderly. For

1 example, the calculation for the Youth Addicted Population might have shown only 13 2 million years of life lost, to go with the approximately 13 million premature deaths. A 3 statistician would usually interpret such a pattern as saying, "smoking affects mostly the 4 elderly" -- in overly simplified terms, killing lots of 90 year-olds who would likely have 5 died at 91. Such a pattern of deaths would be devastating to 90 year-olds and their 6 friends and families. But the overall impact on the Youth Addicted Population would 7 nonetheless be quite different than if 30 year-olds bore the brunt of the deaths. 8 In actuality, causes of death typically affect a mixture of young and old, and 9 calculating years of life lost provides a measure of how early, on average, the deaths tend 10 to occur. Our calculation for the Youth Addicted Population yielded 173.5 million years 11 of life lost. Dividing the173.5 million years of life lost by the 13.4 million premature 12 deaths yields an average of 12.9 years of life lost for each smoking attributable death. 13 This is a figure that is consistent with what we know about the impact of smoking based 14 on many published studies – smoking does cause deaths among the elderly, but also 15 causes many deaths among younger people, starting in their thirties and forties. So while 16 some premature deaths in the Youth Addicted Population will occur among the elderly, 17 and result in only a year or less of life lost, others will occur among younger people, and 18 result in thirty or more years of life lost. By our calculation, to repeat, the overall average 19 comes out at 12.9 years of life lost for every premature death. 20 **O**: Doctor Wyant, turning your attention to U.S. Exhibit 18239 titled "U.S. 21 **Smoking Attributable Deaths and Years of Life Lost – Selected Peer Reviewed**

22 Literature and U.S. Experts," is this an exhibit that you prepared to compare your

calculations of premature deaths and years of life lost to those found in the peer 2 reviewed literature? 3 A: Yes. 4 Doctor, what does this exhibit show with regard to these calculations? **O**: 5 A: The table in this exhibit compares the results of two calculations from the peer 6 reviewed literature of smoking attributable premature deaths, and of smoking attributable 7 years of life lost. The calculations were made for different populations and different time 8 periods, although there is a lot of overlap from one calculation to the next. They were 9 made by a number of different analysts, at different times. 10 Our calculations for the Youth Addicted Population – the same ones I have been 11 discussing – appear on the second line of the table, in red. The first and third lines, in 12 black, give the results of similar calculations done in the two peer reviewed studies, by 13 two other sets of experts. The calculations address both the percentage of smokers who 14 die of causes that are attributable to their smoking, and the average years of life lost for 15 each such premature death. 16 The first row summarizes results that were published in Morbidity and Mortality 17 Weekly Report in 1996. The third row summarizes results published in another article in 18 this same scientific journal in 2002. 19 **Q**: How do the different calculations compare?

1

20 A: One place the Court can see how they compare is the right-most column. A 21 moment ago, I described our calculation of 12.9 years of life lost in the Youth Addicted 22 Population, on average, for each smoking attributable premature death.

The column at the right hand side of this exhibit shows the corresponding
calculation for each of the three studies. The Youth Addicted Population figure, 12.9
years lost per smoking attributable death, appears in the second row, in red. The other
figures range from 12.0 years lost per death to 13.7 years lost per death. So our figure is
in the middle of this range.

6 The other place that the Court can see how the different calculations compare is in 7 the second column from the right. This column gives the number of smokers dying of a 8 smoking attributable cause, expressed as a percent of the total number of smokers. This 9 figure cannot be calculated from what was presented in the 2002 article. The figure from 10 the 1996 study is 32%, somewhat higher than our 24% figure for the Youth Addicted 11 Population. In other words, the published study estimates that the percentage of smokers 12 who will die smoking attributable deaths will be even higher than what we estimate for 13 the Youth Addicted Population, but will be in the same general range as what we 14 estimate.

15 Q: Doctor Wyant, what are the different populations addressed in the

16 calculations shown in U.S. Exhibit 18239?

A: The exhibit describes the different populations. The Morbidity and Mortality
Weekly Report study from 1996 focused on people in the United States who were under
age 18 in 1995, and projected forward in time to get the total smoking attributable deaths
in this group over their lifetimes. We focused on the Youth Addicted Population in 2000.
This population included smokers age 12 to 66 in 2000. We projected forward in time
through 2050. The Morbidity and Mortality Weekly Report study from 2002 focused on

the average annual deaths for the population of all U.S. smokers during the period 1995 1999.

Were these other populations similar to the Youth Addicted Population?

A: Yes. They are obviously not identical, to the Youth Addicted Population or to
each other, but they are generally similar to the Youth Addicted Population. In fact, they
both overlap with the Youth Addicted Population.

7 Q: Doctor, if I understand you, one of the comparison studies in U.S. Exhibit

8 18239 project forward in time to calculate future deaths and years of life lost, like

9 you did with the Youth Addicted Population, is that correct?

3

Q:

A: Yes. The figures I have been citing for the Youth Addicted Population are based
on a projection through 2050. The Morbidity and Mortality study from 1996 projects
over the lifetime of a group that includes newborns in 1995. So if most members of this
group die by age 100, the Morbidity and Mortality study projects through 2095,
approximately.

15 Doctor, you've discussed a number of details related to this exhibit. Can you **O**: 16 briefly summarize how this exhibit supports your overall conclusions and opinions? A: 17 Yes. Even focusing just on mortality, there is more than one way to summarize 18 the impact of smoking attributable adverse health effects. With mortality, it is useful to 19 look at both the number of deaths, and how early they occur in life, which is expressed as 20 years of life lost. The usefulness of different measures of impact was one of the four 21 main ideas I discussed earlier. All three studies in this exhibit look at both total smoking 22 attributable premature deaths, and also at years of life lost, although one of them does not 23 provide enough information to calculate the percent of smokers dying prematurely for

reasons attributable to smoking. Or put differently, all three studies look at both the total number of premature deaths, and also at how early in life the deaths tend to occur. So the studies summarized in this exhibit support my opinions that (1) multiple measures of the impact of smoking are useful, and (2) smoking attributable deaths and years of life lost are standard measures.

6 Second, one of the articles in the exhibit projects forward in time to calculate total 7 smoking attributable premature deaths for its populations of smokers. This is what we do 8 as well for the Youth Addicted Population, in order to address the temporal patterns that 9 link smoking to disease. So this exhibit confirms that for a current population that 10 includes younger smokers, most of the smoking attributable mortality effects have yet to 11 occur. This is the second of the four main ideas that I discussed at the beginning of my 12 testimony. A statistician has to look to the future to fully assess the ultimate impact of 13 smoking in any current population. The exhibit also shows that it is reasonable and 14 generally accepted to project forward 50 years or more.

Third, another of the main ideas that I discussed at the beginning of my testimony was the existence of numerous studies that address smoking attributable adverse health effects, from which methods can be adapted to measure the impact of adverse health effects in the Youth Addicted Population. This exhibit summarizes two such studies. There are other similar studies that could have been added to the exhibit as well. The studies in this exhibit represent current scientific thinking -- one of them was published in 2002.

Fourth, the remaining main idea that I discussed earlier was that the scale of
smoking attributable adverse health effects is enormous. This exhibit provides another

1	confirmation of that fact. It shows that roughly a quarter to a third of smokers die
2	prematurely for reasons attributable to their smoking, and lose roughly 13 years of life for
3	every premature death, on average. If you apply the percentages and averages from any
4	of these studies to the 57 million people in the Youth Addicted Population, you get
5	millions of smoking attributable premature deaths, and tens of millions of years of life
6	lost, which is what we have calculated to be the general scale of the mortality impacts.
7	Fifth, this exhibit shows that the results of our calculations for the Youth Addicted
8	Population are consistent with the published calculations of other experts for similar
9	populations. Our estimated percentages of smoking attributable premature deaths, and of
10	smoking attributable years of life lost, are in the middle of or just below the figures that
11	have been reported by other experts. If anything, these comparisons suggest that our
12	calculations may understate the ultimate consequences of smoking in the Youth Addicted
13	Population with regard to mortality.
14	Sixth, this exhibit gives a reasonable and appropriate summary of the level of
15	uncertainty associated with estimates of mortality effects for populations like the Youth
16	Addicted Population. The estimated percentage of smoking attributable deaths ranges
17	from 24% to 32%. The estimated years of life lost per premature death ranges from 12.0
18	years to 13.7 years.
19	Q: Doctor, are there other aspects of these studies that support your conclusions
20	and opinions?
21	A: Yes. The methods used in these studies to calculate and project smoking
22	attributable deaths and smoking attributable years of life lost are similar to the methods
23	we used. The methods are not identical across the studies – it would be highly unusual if

Page 56

that were the case. The fact that different investigators separately choosing their own
 methods and data sources come to similar conclusions also reinforces the validity of the
 results.

But setting aside minor technical differences, the essential approaches in these studies are the same as in ours. Both of the other studies in the exhibit used the method of attributable risk. They both relied on relative risks derived from the CPS-II studies from the late 1980s. And the one that projected forward in time used smoking cessation rates that were calculated from recent government surveys. All of these statements are true of our analysis as well.

Q: Doctor Wyant, are there any other noteworthy similarities between the peer
reviewed study that projected smoking attributable deaths and years of life lost
forward in time, and your analysis that projected these mortality effects for the
Youth Addicted Population?

14 A: They both make the assumption that current patterns of smoking behavior will 15 persist into the future. It is not news that humans cannot perfectly predict the future. But 16 statistical projections are made all the time, and relied on in many circumstances. The 17 existence of this published projection of smoking attributable deaths is just one 18 confirmation of that fact. Absolute perfection is not required for usefulness or reliability. 19 It is true that some things are generally harder to project reliably than others. In 20 my opinion, smoking attributable deaths can be projected as or more reliably than other 21 phenomena for which projections are commonly made and relied on. There are millions 22 of people in the Youth Addicted Population. Overall death rates have been reasonably 23 stable for many years, so we have a good idea how long people alive today will live.

Written Direct: Timothy Wyant, Ph.D., US v. PM, 99-cv-02496(D.D.C.)(GK)

Page 57

Smoking habits can change in the future. But the Youth Addicted Population has already taken on a very substantial "toxic load" from past smoking. Based on Dr. Samet's testimony about the nature of smoking attributable diseases such as COPD, some of its members are already irreversibly ill. And the Youth Addicted Population continues to add significantly to its toxic load every day, based on current smoking levels.

6 These are substantial demographic forces. Projecting smoking attributable deaths 7 is, in some sense, like projecting how long it will take a long, fully loaded freight train 8 moving at 60 miles an hour to come to a complete stop. The answers to that question will 9 vary somewhat, according to factors such as whether the train is on an uphill grade and 10 whether the tracks are wet. But regardless of what is assumed about factors like these, it 11 takes miles for such a train to stop from the moment the brakes are first applied. About 12 the only thing that could bring the train's progress to a complete halt within a few feet is 13 a collision with a similar size train traveling at 60 miles an hour, on the same track, and in 14 the opposite direction.

15 From a biostatistical or demographic standpoint, considering ways in which all 16 future smoking attributable deaths in the Youth Addicted Population might be eliminated 17 forces an analyst to contemplate extreme and highly unlikely scenarios. These extreme 18 scenarios might include cataclysmic events that killed everyone tomorrow, or the sudden 19 emergence of miraculous medical advances like simultaneous cures for cancer, COPD, 20 and heart disease. (And while such hypothetical cures might reduce future smoking 21 attributable deaths, they could also increase future smoking attributable health care costs, 22 as the cures may not be cheap.)

1	The assumed persistence of current and recent smoking patterns as a basis for
2	future projections in the 1996 peer reviewed study attests to the reasonableness of such an
3	approach in our analysis of the Youth Addicted Population. There is no compelling
4	evidence that would definitively favor any other scenario. However, as I have said,
5	analysts who publish estimates of smoking attributable deaths often suggest that
6	implementation of more comprehensive programs to discourage initiation and encourage
7	cessation could materially reduce future smoking attributable deaths, although could not
8	eliminate them entirely.
9	Q: Doctor Wyant, what do you mean in the title of U.S. Exhibit 18239 by the
10	phrase "Selected Peer Reviewed Literature?"
10 11	phrase "Selected Peer Reviewed Literature?"A:I selected representative peer reviewed studies that we looked at when we were
10 11 12	phrase "Selected Peer Reviewed Literature?"A:I selected representative peer reviewed studies that we looked at when we wereperforming our calculations for the Youth Addicted Population. There are other peer
10 11 12 13	phrase "Selected Peer Reviewed Literature?"A:I selected representative peer reviewed studies that we looked at when we wereperforming our calculations for the Youth Addicted Population. There are other peerreviewed studies that we looked at that are similar to the 2002 study published in
10 11 12 13 14	phrase "Selected Peer Reviewed Literature?"A:I selected representative peer reviewed studies that we looked at when we wereperforming our calculations for the Youth Addicted Population. There are other peerreviewed studies that we looked at that are similar to the 2002 study published inMorbidity and Mortality Weekly Report. There have also been more recently published
 10 11 12 13 14 15 	phrase "Selected Peer Reviewed Literature?"A:I selected representative peer reviewed studies that we looked at when we wereperforming our calculations for the Youth Addicted Population. There are other peerreviewed studies that we looked at that are similar to the 2002 study published inMorbidity and Mortality Weekly Report. There have also been more recently publishedstudies that calculate and project smoking attributable deaths. But based on my general
 10 11 12 13 14 15 16 	phrase "Selected Peer Reviewed Literature?"A:I selected representative peer reviewed studies that we looked at when we wereperforming our calculations for the Youth Addicted Population. There are other peerreviewed studies that we looked at that are similar to the 2002 study published inMorbidity and Mortality Weekly Report. There have also been more recently publishedstudies that calculate and project smoking attributable deaths. But based on my generalexperience with, and review of, the scientific literature in this regard, the articles
 10 11 12 13 14 15 16 17 	phrase "Selected Peer Reviewed Literature?"A:I selected representative peer reviewed studies that we looked at when we wereperforming our calculations for the Youth Addicted Population. There are other peerreviewed studies that we looked at that are similar to the 2002 study published inMorbidity and Mortality Weekly Report. There have also been more recently publishedstudies that calculate and project smoking attributable deaths. But based on my generalexperience with, and review of, the scientific literature in this regard, the articlessummarized in this exhibit provide a reasonable and representative picture of what is

Q: Doctor Wyant, in the part of U.S. Exhibit 18239 that summarizes your own
 calculations, the percentage of people dying prematurely due to smoking, and of the
 years of life lost per premature death, are for the Youth Addicted Population
 defined as "smoked more than five cigarettes a day under the age of 21," is that
 correct?

6 A: Yes.

7 Q: Doctor, did you get similar results when you looked at other definitions of the
8 Youth Addicted Population?

9 A: Yes. Whether we changed the definition to "under the age of 18," to "smoked
10 regularly," or to "smoked more than 10 cigarettes a day," the results for the percentage of
11 smokers dying prematurely due to smoking, and for the average years of life lost per
12 premature death, were similar. The percentage of population members dying prematurely
13 because of smoking was always between 23% and 25% across the different definitions.
14 The average years of life lost per smoking attributable premature death was always
15 between 12.9 and 13.1 years.

16 Q: Please turn your attention to U.S. Exhibit 18238 titled "Annual Smoking

17 Attributable Deaths in the United States – Selected U.S. Studies." What does this

18 chart say regarding trends in smoking attributable mortality?

19 A: This chart shows the course of smoking attributable mortality in the United States

20 from 1984 through 1999. Each of the five colored circles in the chart represents an

- 21 annual estimate from either a peer reviewed article in an American scientific journal or
- 22 from a Surgeon General's report. The color indicates the source yellow for the Journal

of the American Medical Association (JAMA), red for Morbidity and Mortality Weekly
 Report, and green for the Surgeon General's report.

3 The solid black line connects these estimates, and shows that the estimates of 4 annual smoking attributable mortality have stayed between 400,000 and 450,000 deaths 5 per year from 1985 through 1997. In the most recent peer reviewed study, the 6 calculations were for the average annual number of smoking attributable deaths for the 7 years 1995-1999. In the chart, I show the annual average from this study in the symbol 8 that appears at the midpoint year, 1997. 9 The chart shows no substantial trend since 1985. There is a slight rise in the line 10 as it goes from 1985 to 1997, but this slight rise generally corresponds to the inclusion in 11 the more recent studies of deaths due to secondhand smoke. 12 **Q**: Doctor, how does the chart in this exhibit support your opinions and conclusions? 13 14 A: It confirms that there have been numerous published studies that estimate total 15 smoking attributable deaths in the U.S. It confirms that the scale of smoking attributable 16 deaths in the U.S. is enormous, with annual deaths consistently estimated to exceed 17 400,000 deaths per year. It supports the conclusion that, as the Surgeon General said in 18 2004, and consistent with our calculations for the Youth Addicted Population, the burden 19 of smoking attributable mortality will likely remain at current levels for several decades. 20 It indicates that our projection that annual smoking attributable deaths in the Youth Addicted Population will climb to about 340,000 deaths per year is reasonable. By 2028, 21 22 the year of peak smoking attributable mortality in the Youth Addicted Population 23 according to our calculations, people in the Youth Addicted Population will comprise the

Page 61

1 majority of U.S. smokers in the age ranges at which smoking attributable deaths tend to
2 occur.

In addition, the investigators in these published studies used methods similar to
ours – they applied attributable risks to counts of current and former smokers in the U.S.
population, and relied on estimates of relative risk that were derived from the American
Cancer Society's CPS-II studies from the late 1980s.

7 Q: Doctor, in the title of U.S. Exhibit 18238 what do you mean by the phrase, 8 "Selected U.S. Studies?"

9 A; The chart focuses on a set of peer reviewed studies that we looked at during the 10 time period in which we were performing our calculations for the Youth Addicted 11 Population. These studies in turn cite other similar studies that were done in prior and 12 intervening years. These other studies, as is clear from the descriptions of them that 13 appear in the studies included in the chart, gave mortality estimates consistent with the 14 estimates that the chart depicts.

In addition, more recent studies of a similar nature have been published, and there have been multinational studies that apply slightly different methods to estimating annual mortality in the United States and other countries as well. These latter studies have been cited in publications such as the 2001 Surgeon General's report.

But based on my general experience with, and review of, the scientific literature related to annual smoking attributable mortality estimates, the articles summarized in this exhibit provide a reasonable and representative picture of what has been reported in other studies as well.

1 **O**: Besides comparing your results with those from similar studies, have you 2 made any other calculations that would measure the uncertainty in your 3 calculations of smoking attributable deaths in the Youth Addicted Population? 4 A: Yes. We looked at what would happen if we were to define the Youth Addicted 5 Population differently. The Youth Addicted Population, as I have been using the term, is 6 defined using a youth smoking threshold of more than five cigarettes smoked a day. We 7 increased the size of the Youth Addicted Population by lowering the smoking threshold 8 to just regular smoking as a youth, regardless of the number of cigarettes a day. We 9 calculated that, through 2050, 15.6 million smoking attributable deaths will occur in this 10 expanded population. We also shrank the Youth Addicted Population by raising the 11 smoking threshold to more than 10 cigarettes a day. Making this change yielded a 12 calculation of 9.4 million premature deaths through 2050. 13 **Q**: Doctor, directing your attention to U.S. Exhibit 17410 titled "Deaths – Youth 14 Addicted Population: Different Smoking Thresholds." What does this exhibit show 15 the Court? 16 A: This exhibit summarizes the three different estimates I just mentioned, and shows 17 how the deaths distribute over time. The table at the bottom of the exhibit shows the 15.6 18 million, 13.4 million, and 9.4 million smoking attributable deaths that are associated 19 respectively with the three different addiction standards: regular smoking, smoking more 20 than five cigarettes a day, and smoking more than ten cigarettes a day. 21 The vertical black bars show how the smoking attributable deaths distribute over 22 time during the period 2001 to 2050 - rising to a peak in 2028, and then declining. The 23 chart is similar to U.S. Exhibit 17407. This previous exhibit used vertical black bars to

1 show the number of smoking attributable deaths each year for the Youth Addicted 2 Population. The bars in U.S. Exhibit 17410 show the number of smoking attributable 3 deaths each year for the larger population that includes all adults who smoked regularly 4 as youths. 5 The red lines show the heights of the bars for each of the three definitions of the 6 Youth Addicted Population, all of which define "youth" as under age 21. The top red 7 line, as indicated by the labels at the right of the chart, shows the annual smoking 8 attributable deaths using a "smoked regularly" definition. The middle red line shows the 9 annual smoking attributable deaths using the more than five cigarettes a day definition. 10 The lowest red line shows the annual smoking attributable deaths using the more than ten 11 cigarettes a day definition. 12 The trends for all three scenarios are similar. The number of annual smoking 13 attributable deaths increases each year from 2001 through 2028, and then declines each 14 year through 2050. 15 Except for the different addiction standards, are the definitions of the **Q**: 16 populations represented by three sets of bars the same? 17 A: Yes. In all three cases, we looked at the people who met the smoking threshold as 18 a youth during the time period 1954-2000, and defined "youth" as "under the age of 21." 19 **O**: Did you do any other investigation of the effects of different population 20 definitions? 21 Yes. We looked at what happens if you change the definition of "youth" to A: 22 "under the age of 18." We calculated that, for adults who became addicted under the age 23 of 18 during the period 1954 to 2000, there will be 9.9 million, 8.0 million, and 4.5

million smoking attributable deaths associated respectively with the three addiction
standards: regular smoking, smoking more than five cigarettes a day, and smoking more
than ten cigarettes a day.

4 Q: Looking again at U.S. Exhibit 17410 titled "Deaths - Youth Addicted
5 Population: Different Smoking Thresholds," what does this exhibit indicate about
6 the period after 2050?

7 A: The Court can see from the heights of the bars in the chart that while the number 8 of annual deaths is declining in the years just prior to 2050, there will continue to be 9 deaths in the years after 2050. The heights are not dropping to zero abruptly, but are 10 declining gradually. According to our calculations, smoking attributable deaths in the 11 year 2050 will still be occurring at a rate of more than 240,000 per year in the Youth 12 Addicted Population. Some of the members of the Youth Addicted Population will be as 13 young as 62 in the year 2050. From that fact alone, we would anticipate many more 14 smoking attributable deaths after 2050.

The fact that in our estimates we stopped accumulating deaths as of 2050 means that our projection of 13.4 million total smoking attributable deaths is conservative. A calculation using a 2050 cutoff tends to understate the ultimate total smoking attributable deaths in the Youth Addicted Population, since it is likely that smoking attributable deaths in this population will persist well beyond that point.

20 Q: Doctor, did you also calculate years of life lost for other youth smoking
21 thresholds?

22 A: Yes. When we changed the smoking threshold to just daily smoking as youths,

the smoking attributable years of life lost increased from 173.5 million to 200.5 million.

When we applied a more restrictive threshold of smoking more than 10 cigarettes a day
 as youths, the smoking attributable years of life lost dropped to 121.9 million.

Just as with total deaths, we also looked at what would happen if we changed the definition of "youth" from below age 21 to below age 18. Making this change yielded calculations of 128.0 million, 103.9 million, and 59.3 million smoking attributable years of life lost associated with the different addiction standards: regular smoking, more than five cigarettes a day, and more than ten cigarettes a day.

8 **Q**: Doctor Wyant, you just discussed two measures of adverse health effects --9 smoking attributable deaths and smoking attributable years of life lost -- for six 10 alternative definitions of the Youth Addicted Populations. Have you collected all of 11 the various adverse health effect estimates for all six of the alternative definitions of 12 the Youth Addicted Population and summarized them in a one set of exhibits? 13 A: Yes. U.S. Exhibit 17751 contains comprehensive tables of the different adverse 14 health estimates for adults who smoked under the age of 21, including all the estimates of 15 smoking attributable deaths I just discussed. This exhibit also breaks down these 16 estimates by time period.

U.S. Exhibit 17750 has similar tables for adults who smoked under the age of 18.
Q: Doctor Wyant, you testified earlier that ignoring what happens after 2050, as
you did, would tend to make your projections understated, relative to the likely
ultimate totals for the Youth Addicted Population. Are there other factors that
would tend to make your smoking attributable death projections understated as
measures of the total effects of smoking by members of this group?

1 A: Yes. So far, I have been talking about smoking attributable adverse health effects 2 that affect the Youth Addicted Population directly – that is, the extent to which adults in 3 this population die because they themselves smoked. But when adults in the Youth 4 Addicted Population smoke, their smoking also affects the health of other individuals 5 outside of the Youth Addicted Population. Smoking by adults in the Youth Addicted 6 Population will cause deaths from secondhand smoke. Women in the Youth Addicted 7 Population who smoke during pregnancy will cause some deaths to occur among their 8 newborn infants. Members of the Youth Addicted Population who become parents and 9 continue to smoke will also cause some deaths to occur among their infant children. 10 Dr. Samet testified about smoking causing these kinds of deaths. They are often 11 included in published smoking attributable death totals. For example, I discussed earlier 12 that among the 440,000 annual smoking attributable deaths in the United States that are 13 reported in the 2004 Surgeon General's report, there are deaths among never smokers due 14 to secondhand smoke – about 38,000 annually from lung cancer and CHD -- and to 15 children of smoking parents – about 1,000 annually. These death totals come from pages 16 860-861 of the 2004 Surgeon General's report, U.S. Trial Exhibit 88847. The 13.4 17 million smoking attributable deaths that we calculated for the Youth Addicted Population 18 did not include deaths in these categories. 19 **O**: Turning briefly to specific aspects of your calculations, how detailed were the 20 mortality rates that you used? 21 As I said earlier, we used overall U.S. mortality rates from the Social Security A: 22 Administration (SSA), and used relative risks from the 1989 Surgeon General's report 23 and from Monograph 8, a publication of the National Cancer Institute. The relative risks,

1	as Dr. Samet described in his testimony, measure the extent to which the mortality rates
2	for current and former smokers exceed the mortality rates for never smokers, and can
3	therefore be used to translate overall mortality rates into separate mortality rates for
4	current smokers, former smokers, and never smokers.
5	We used mortality rates from the SSA that differ by age, by gender, and by the
6	year of death. The "year of death" distinction relates to the fact that the SSA, in its
7	projected mortality rates for the future, adjusts for increasing life expectancies. The
8	relative risks from the Surgeon General and the National Cancer Institute vary by age,
9	gender, and whether or not a person is a current or a former smoker.
10	These relative risks from the Surgeon General and the National Cancer Institute
11	are what Dr. Samet referred to in his testimony as "age-adjusted" relative risks. The
12	mortality rates that we derived from them, which also vary by age as well as by gender,
13	year, and current/former smoker status, would typically be called "age-adjusted"
14	mortality rates.
15	Q: Are other kinds of adjustments ever used in epidemiology?
16	A: Yes, although not, as a rule, in calculations of smoking attributable deaths. Dr.
17	Samet described what are called "fully-adjusted" relative risks. Fully-adjusted relative
18	risks might be used if it were necessary to take into account other differences between
19	smokers and never smokers besides age and gender. As a group, smokers differ from
20	never smokers with regard to a number of factors. In theory, ignoring these additional
21	factors could result in simple age-adjusted calculations of smoking attributable deaths
22	either understating or overstating the actual totals. As Dr. Samet testified, the term
23	"potential confounders" is used in epidemiology to refer to such factors.

1	Analysts have looked repeatedly at whether age-adjusted relative risks and age-
2	adjusted mortality rates such as the ones that we used in analyzing the Youth Addicted
3	Population, that the Surgeon General has used in many reports, and that many other
4	analysts have used in peer reviewed studies might be "confounding" some smoking
5	attributable deaths with deaths attributable to other factors, or vice versa. But over and
6	over again, peer reviewed studies have concluded that age-adjusted mortality rates are
7	reliable for calculating smoking attributable deaths and other measures of adverse health
8	effects such as heart attacks.
9	One example that Dr. Samet cited related to a major longitudinal study of the
10	effects of smoking, the Nurses Health Study. He prepared an exhibit summarizing the
11	results of this study U.S. Exhibit 17131, titled, "Nurses Health Study." With regard to
12	this study, Dr. Samet testified that adjustment for confounders other than age had no
13	impact on the relative risk of smoking.
14	Q: Doctor, did you prepare additional exhibits that address the reliability of
15	age-adjusted relative risks and mortality rates?
16	A: Yes.
17	Q: What does U.S. Exhibit 18240 titled "Age-adjusted Mortality Rates in
18	Selected Peer Reviewed Literature" show?
19	A: This exhibit gives excerpts from a peer reviewed journal article and two Surgeon
20	General's reports that summarize findings with regard to the use of age-adjusted
21	mortality rates. Back in 1989, the Surgeon General's report said that " numerous
22	attempts to control statistically for confounding and stratifying variables have not
23	materially altered the estimated relative risks for cigarette-related diseases."

1 The other sources were published more recently, but come to the same 2 conclusion. In the article in the Journal of the American Medical Association (JAMA) 3 published in 2000, the authors conclude that estimates of the number of deaths caused by 4 smoking are not substantially altered by adjustments other than for age and gender. The 5 2001 Surgeon General's report said that "In most studies [of risk of death due to 6 smoking], risk estimates were not adjusted for potential confounders other than age. 7 However, studies in which adjustment was made for other factors found little evidence 8 that the estimates of risk associated with smoking were substantially different after 9 adjustment."

10 Q: What is your general conclusion from articles like these?

11 A: Using age-adjusted mortality rates, as we did, is a reliable way to calculate 12 smoking attributable deaths. Adjusting for factors other than age and gender is not 13 necessary. In addition, these articles provide another example illustrating one of the 14 general points that I made early on. The links between smoking and adverse health 15 effects have been the subject of frequent and repeated study. Decisions such as the one to 16 use age-adjusted mortality rates in premature death calculations are not new and untested, 17 but supported by substantial published work, including a number of recent, peer reviewed 18 articles.

Dr. Samet referred to the practice of adjusting for gender, age, and sometimes other potential confounders as ensuring that comparisons of smokers to never smokers are comparing "like to like." Of course, at some level it is impossible to exactly compare "like to like." Any two groups of people differ to some extent. But the import of the peer reviewed articles like the ones I have just been discussing is that in mortality

calculations like ours, comparing smokers to never smokers of the same age and gender
 is to a reasonable and sufficient degree comparing like to like.

3 Q: Does the fact that you don't adjust for factors such as obesity mean that you 4 don't think such factors can cause diseases such as CHD?

5 A: Of course not. But just because another factor besides smoking can cause a 6 disease does not mean that the factor somehow makes smoking healthy, or confers some 7 sort of immunity to the effects of smoking. Dr. Samet referred in his discussion of the 8 Nurses' Health Study to factors like obesity as "potential" confounding factors when the 9 goal is to measure the link between smoking and CHD. "Potential" is an appropriate -10 and commonly used – adjective in such situations. In the peer reviewed articles I have 11 just been citing, adjustments for such factors in actuality made no practical difference. 12 **Q**: Doctor, before we leave the topic of smoking attributable mortality, please 13 direct your attention once more to U.S. Exhibit 18238 titled "Annual Smoking 14 Attributable Deaths in the United States – Selected U.S. Studies." This chart, as I 15 understood it, shows estimates of annual U.S. deaths due to smoking that appeared 16 in five different published studies, is that correct?

A: Yes. Page two of this exhibit shows the sources. Four of the studies were
published in peer reviewed journals. The fifth was part of the 1989 Surgeon General's
report. The most recent of the five studies was published in 2002.
1 **O**: Doctor Wyant, confidence intervals have been the subject of other testimony 2 in this case. Did the studies summarized in U.S. Exhibit 18238 calculate confidence 3 intervals around their estimates of the number of annual smoking attributable 4 deaths? 5 No. A: 6 **O**: Doctor, is it surprising that published articles like these do not calculate 7 confidence intervals? 8 A: No. In the field of biostatistics, the contrary is the case -- it would be unusual to 9 find confidence intervals in articles like these. 10 Confidence intervals play an important role in statistics and biostatistics, but not a 11 ubiquitous one. These are disciplines with many subareas that encompass both 12 theoretical research and practical applications. It is beyond the scope of my testimony to 13 talk about all of these subareas. But very briefly, one subarea in which confidence 14 intervals are common is in what I might call "basic" scientific studies or national surveys. 15 Much of scientific knowledge is built up from small, narrowly focused studies If we 16 restrict our attention to the studies of this sort that are conducted with reasonable care, the 17 reliability of the results typically depends on the sample size – how many study 18 participants or survey respondents there are – and the extent of the difference between the 19 groups being compared – to what extent does the treatment group fare better than the 20 control group, for example. Other factors can play a role as well, but for purposes of 21 explication, sample size and extent of difference suffice. 22 Because other researchers and applied practitioners will be reading the results of 23 these studies, and trying to decide whether, or to what extent, they should adjust their

thinking based on the study outcomes, the authors of the studies will typically calculate a
confidence interval in summarizing their results. A confidence interval takes into
account the combined effects of sample size and extent of difference, and translates them
into a single unified expression of reliability that is compact, standard, and commonly
understood.

6 Q: What kind of studies would not typically calculate confidence intervals, in 7 your experience?

8 One type of study in which the authors will often not calculate a confidence А 9 interval is a summary study, in which the results of basic studies in a number of different 10 areas are combined to determine the best assessment of our state of knowledge about 11 some situation or phenomenon of importance. For example, a study that estimates annual 12 smoking attributable deaths might combine results from (1) current health surveys to 13 determine smoking prevalence among adults, (2) studies that estimate how likely adult 14 smokers are to live with never smokers, (3) studies that estimate how likely it is that 15 pregnant women smoke, (4) studies that estimate how likely it is that parents of newborns 16 smoke, (5) studies that estimate relative risks of active smoking by adults, by disease, (6) 17 studies that estimate relative risks of secondhand smoke among adults, by disease, (7) 18 studies that estimate relative risks of maternal smoking as related to perinatal deaths, (8) 19 studies that estimate relative risk of maternal and parental smoking as related to infant 20 deaths, (9) estimates from vital statistics records of deaths by disease, and (10) studies 21 that estimate annual deaths in fires caused by smoking. It is often the case that 22 statisticians will disagree on the most appropriate method for calculating a confidence 23 interval in such situations. And often, such an interval is not very helpful – the

Written Direct: Timothy Wyant, Ph.D., US v. PM, 99-cv-02496(D.D.C.)(GK)

statistician's "best assessment" is still his or her "best assessment," with or without a
 confidence interval.

Another type of study in which the authors will often not calculate a confidence interval is a long-term projection study. The extent to which future events will deviate from long-term projections is typically influenced by which of a number of alternative assumptions will apply most forcefully in the years to come. It is often not clear how to build such alternative assumptions into a single confidence interval, or that doing so is within a statistician's expertise.

9 Q: Doctor Wyant, how do these general categories of statistical studies relate to
10 the smoking attributable death studies summarized in Exhibit 18238?

A: The studies in this exhibit are summary studies – they incorporate results from
basic studies on a number of related topics, like the ones that appear in the sample list I
just gave. That is why it is not surprising that these published, peer reviewed studies do
not give confidence intervals for their results.

Q: Can you give another example in which studies in your two categories are
relied on, and yet confidence intervals are not typically calculated?

17 A: Yes. When companies that are defendants in asbestos disease suits declare

18 bankruptcy, the bankruptcy courts often rely on projections of the number and value of

19 asbestos disease claims over the next 50 years in order to arrive at a plan of

20 reorganization. Statistical experts commonly calculate such projections from a variety of

- 21 basic studies on such topics as the number of exposed workers, the relative risks and
- 22 latency periods of exposure-related cancers, future mortality rates, and the value of
- 23 historic settlements. These studies fall into both of my categories they are

simultaneously summary studies and long term projections – and it is often the case that
they do not come with confidence intervals.

3 0: Doctor, in the kinds of summary studies and long-term projections that you 4 have been discussing, are there standard ways of assessing reliability and 5 uncertainty that do not involve a confidence interval? 6 A: Yes. First, an analyst can compare his or her results to the results of other 7 analysts who have done similar studies, but who made different decisions about, for 8 example, the basic studies or surveys on which to rely. Second, an analyst can calculate 9 alternative projections by varying some basic assumptions, and compare the results of 10 these different projections. I present both types of assessment in my testimony. 11 12 As one example of the first type of assessment, in U.S. Exhibit 18239, I compared 13 our estimate of years of life lost per smoking attributable premature death in the Youth 14 Addicted Population to estimates published by two other sets of analysts for similar 15 populations. The three estimates ranged from 12.0 to 13.7 years, with our estimate in the 16 middle of the range. 17 As one example of the second type of assessment, I compared our estimate of the 18 number of smokers in the Youth Addicted Population who will die prematurely because 19 of smoking to similar estimates that we calculated under alternative assumptions 20 regarding the standard of addiction. The projections ranged from 9.4 million smoking 21 attributable deaths to 15.6 million smoking attributable deaths, with our basic projection 22 for the Youth Addicted Population -- defined using the more than five cigarettes a day 23 addiction standard – at 13.4 million.

Written Direct: Timothy Wyant, Ph.D., US v. PM, 99-cv-02496(D.D.C.)(GK)

Page 75

1 **O**: Doctor Wyant, I'm now moving on to another of the measures of smoking 2 attributable adverse health effects that you have mentioned. You testified earlier 3 that in addition to estimating the smoking attributable deaths and years of life lost 4 in the Youth Addicted Population, you also estimated the smoking attributable 5 disease treatment years, is that correct? 6 Yes. A: 7 0: Doctor Wyant, please direct your attention again to U.S. Exhibit 17406, titled 8 "Adverse Health Effects of Smoking Among the 57 Million Adults in the Youth 9 Addicted Population." You testified that this exhibit gives your estimates for 10 disease treatment years, is that correct? Yes. We calculated that in the Youth Addicted Population from 1954 through 11 A: 12 2050, there will be 107.6 million smoking attributable disease treatment years for major 13 diseases. This amounts to almost two additional treatment years per adult, on average. 14 **Q**: How are disease treatment years defined? 15 Suppose a person goes to the doctor twice for COPD in 2000, not at all in 2001, A: 16 and once in 2002. This is counted as two disease treatment years – the person is treated 17 in the calendar years 2000 and 2002. 18 To clarify, by major diseases you are still referring to the diseases listed in **Q**: 19 U.S. Exhibit 17162 titled, "International Classification of Diseases," that was 20 prepared by Dr. Samet?

21 A: Yes.

Q: Doctor, what does U.S. Exhibit 17415, titled "Disease Treatment Years for Lung Cancer, COPD, CHD, Stroke ... Contributors to the Analysis" show?

A: Several experts contributed to our analysis of disease treatment years for the
major diseases. This exhibit lists those contributors. As I testified earlier, Dr. Gruber
provided us with the counts of smokers in the Youth Addicted Population.

I also testified earlier that Dr. Samet gave us a list of major diseases caused by
smoking. As U.S. Exhibit 17162 showed, this list includes lung cancer, COPD, CHD,
and stroke, as well as a number of other cancers and arterial diseases. In addition to
providing us with this list of diseases, Dr. Samet also discussed with us various
characteristics of smoking attributable diseases that might bear on the choice of
appropriate statistical models and calculation methods. He testified earlier in this case
about these discussions.

After obtaining the list of diseases, and the population counts for the Youth
Addicted Population, Dr. Zeger, Dr. Miller, and I worked together on measuring the
extent of smoking attributable adverse health effects in the Youth Addicted Population.
Dr. Miller worked primarily on the health care costs measure. For the disease treatment
years measure, Dr. Zeger was responsible for calculating the treatment rates for the major
diseases, and the likelihood that an annual case of treatment is smoking attributable.
I was primarily responsible for applying the rates calculated by Dr. Zeger to Dr.

- 20 Gruber's population counts, and thereby calculating the total disease treatment years in
- 21 the Youth Addicted Population.

Q: We talked earlier about Dr. Samet. What is Dr. Gruber's background and
 expertise?

A: Dr. Jonathan Gruber is currently a Professor of Economics at the Massachusetts
Institute of Technology, or MIT. Dr. Gruber received his undergraduate degree in
economics from MIT in 1987, and his Ph.D. in economics from Harvard University in
1992.

Dr. Gruber is also a Research Associate at the National Bureau of Economic Research (NBER), which is the leading academic economic research institution in the country not affiliated with a particular university. Since 1996, he has directed the NBER's Program on Children, which focuses on the economics of issues pertaining to children. He has served as a co-editor of three major journals in the field of economics, and is currently the Associate Editor of the *Journal of Health Economics*, the leading field journal in health economics.

14 In 2004, Dr. Gruber was appointed a Member of the Institute of Medicine. He 15 was appointed a Member of the National Academy of Social Insurance in 1996. In 2003, 16 he received the Richard Musgrave Prize for the best paper in the National Tax Journal. 17 In 1995, he received the American Public Health Association's Kenneth Arrow Award for 18 the Outstanding Health Economics Paper of 1994. In 1995, he was one of only 15 19 scientists nationwide to receive the National Science Foundation's Presidential Faculty 20 Fellowship, and in the same year received the Sloan Foundation Research Fellowship. In 21 1994, he received the FIRST Award from the National Institute of Aging. 22 Dr. Gruber has authored or co-authored 46 peer reviewed journal articles, and 30

articles in other venues, including three edited volumes.

Q: Doctor Wyant, do you know if Dr. Gruber has done research and published on issues related to tobacco?

3 A: Yes, Dr. Gruber has done both. Tobacco-related work has been and continues to
4 be a major focus of his work.

5 From 1997 to 1998, Dr. Gruber was Deputy Assistant Secretary for Economic 6 Policy at the United States Treasury Department. In that position, he worked with an 7 interagency task force on proposed legislation to comprehensively regulate youth 8 smoking in the United States. This legislation was subsequently known as the McCain 9 Bill. Dr. Gruber's primary responsibility for this task force was to develop financial 10 mechanisms to encourage the tobacco industry to reduce youth smoking. In addition to 11 his work with the task force, Dr. Gruber also participated in an assessment of the original 12 agreement signed between the tobacco industry and the states' attorneys general in April, 13 1997.

14Dr. Gruber has written numerous articles on the economics of smoking and health15that have been published in peer reviewed journals. Articles he has authored or co-16authored include "Is Addiction 'Rational'? Theory and Evidence" in the *Quarterly*17Journal of Economics in 2001, "The Economic Impacts of the Tobacco Settlement" in18the Journal of Policy Analysis and Management in 2002, and "Youth Smoking in the191990s: Why Did it Rise and What are the Long Run Implications" in the American20Economic Review in 2001.

Dr. Gruber also edited a volume titled *Risky Behavior Among Youth: An Economic Analysis*, which was published in 2001. He contributed a chapter to that
volume titled *Youth Smoking in the U.S.: Evidence and Implications*.

Written Direct: Timothy Wyant, Ph.D., US v. PM, 99-cv-02496(D.D.C.)(GK)

Q: Doctor Wyant, directing your attention to U.S. Exhibit 78532, is this Doctor
 Gruber's curriculum vita?
 A: Yes. It is current as of December 2003.

Q: Doctor Wyant, you testified that you relied upon Dr. Gruber's calculation of
the size and characteristics of the Youth Addicted Population in calculating all of
your measures of adverse health effects, is that correct?

7 A: Yes.

8 Q: Doctor, those measures would include your calculations of the 13.4 million 9 smoking attributable deaths and 173.5 million years of life lost that you discussed a 10 little earlier, as well as your calculation of the 107.6 million disease treatment years, 11 is that also correct?

12 A: Yes.

Q: Doctor, before I ask you to describe how you calculated the 107.6 million
disease treatment years, I'm going to ask you some questions about how Dr. Gruber
calculated the Youth Addicted Population. First of all, what did Dr. Gruber
provide you?

A: He provided us with computer files that contained counts of people in the Youth
Addicted Population. As I testified earlier, the Youth Addicted Population consists of
both youth smokers and adults who became addicted as youth smokers during the period
1954 to 2000. I have been focusing my remarks on a Youth Addicted Population defined
as people who smoked more than five cigarettes a day under the age of 21 during that
time period.

1	Dr. Gruber gave us four computer files for this population. The four files
2	contained counts of male current smokers, male former smokers, female current smokers,
3	and female former smokers, respectively. Each file showed, for each calendar year from
4	1954 to 2050, the number of smokers at each age. Earlier, in U.S. Exhibit 17542, I gave
5	an example of how we calculated smoking attributable deaths for 66 year-old male
6	current smokers in the year 2000. In that example, the number of people in that
7	particular group of smokers would have come from one of the "cells" in Dr. Gruber's
8	computer file for current male smokers – the cell for 66 year-olds in the year 2000.
9	Q: You testified previously about calculating adverse health effects for
10	alternative definitions of the Youth Addicted Population. Did Dr. Gruber provide
10 11	alternative definitions of the Youth Addicted Population. Did Dr. Gruber provide you with similar computer files for those definitions?
10 11 12	alternative definitions of the Youth Addicted Population. Did Dr. Gruber provideyou with similar computer files for those definitions?A:Yes. As I testified earlier, he looked at two different definitions of "youth
10 11 12 13	alternative definitions of the Youth Addicted Population. Did Dr. Gruber provideyou with similar computer files for those definitions?A:Yes. As I testified earlier, he looked at two different definitions of "youthsmoking" – smoking before the age of 18, and smoking before the age of 21 – and three
10 11 12 13 14	alternative definitions of the Youth Addicted Population. Did Dr. Gruber provideyou with similar computer files for those definitions?A: Yes. As I testified earlier, he looked at two different definitions of "youthsmoking" – smoking before the age of 18, and smoking before the age of 21 – and threedifferent standards of addiction – smoked regularly as a youth, smoked more than five
 10 11 12 13 14 15 	alternative definitions of the Youth Addicted Population. Did Dr. Gruber provideyou with similar computer files for those definitions?A: Yes. As I testified earlier, he looked at two different definitions of "youthsmoking" – smoking before the age of 18, and smoking before the age of 21 – and threedifferent standards of addiction – smoked regularly as a youth, smoked more than fivecigarettes a day as a youth, and smoked more than 10 cigarettes a day as a youth. That
 10 11 12 13 14 15 16 	alternative definitions of the Youth Addicted Population. Did Dr. Gruber provideyou with similar computer files for those definitions?A:Yes. As I testified earlier, he looked at two different definitions of "youthsmoking" – smoking before the age of 18, and smoking before the age of 21 – and threedifferent standards of addiction – smoked regularly as a youth, smoked more than fivecigarettes a day as a youth, and smoked more than 10 cigarettes a day as a youth. Thatmakes six definitions – two youth smoking definitions times three standards of addiction.
 10 11 12 13 14 15 16 17 	alternative definitions of the Youth Addicted Population. Did Dr. Gruber provideyou with similar computer files for those definitions?A:Yes. As I testified earlier, he looked at two different definitions of "youthsmoking" – smoking before the age of 18, and smoking before the age of 21 – and threedifferent standards of addiction – smoked regularly as a youth, smoked more than fivecigarettes a day as a youth, and smoked more than 10 cigarettes a day as a youth. Thatmakes six definitions – two youth smoking definitions times three standards of addiction.For each of these six definitions, Dr. Gruber provided us with four computer files

1	Q: Doctor Wyant, please direct your attention once more to U.S. Exhibit 17410
2	titled "Deaths – Youth Addicted Population: Different Smoking Thresholds." What
3	does this exhibit show the Court about the size of the different Youth Addicted
4	Populations?
5	A: This is the exhibit that also shows, for the "under age 21" definition of "youth
6	smoking," the annual smoking attributable deaths projected for each of the three
7	addiction standards. I discussed this exhibit earlier, focusing on the number of deaths.
8	The table at the bottom of the exhibit provides some information on the size of the
9	different Youth Addicted Populations.
10	Each definition of the Youth Addicted Population included both youth smokers
11	and adults who became addicted as youths. We restricted our calculations of smoking
12	attributable adverse health effects to the latter group the adults in the Youth Addicted
13	Populations who became addicted as youths.
14	The table at the bottom of U.S. Exhibit 17410 shows how many adults became
15	addicted before the age of 21 under the different addiction standards. There were 67
16	million, 57 million, and 39 million such adults, corresponding respectively to the
17	addiction standards of smoked regularly as a youth, smoked more than five cigarettes a
18	day as a youth, and smoked more than 10 cigarettes a day as a youth.
19	Q: Doctor, what are the corresponding counts for adults who became addicted
20	as youths when "youth" is defined as under the age of 18?
21	A: There were 43 million, 33 million, and 19 million adults who became addicted as
22	youths, corresponding respectively to the addiction standards of smoked regularly as a

youth, smoked more than five cigarettes a day as a youth, and smoked more than 10
 cigarettes a day as a youth.

3 Q: What data did Doctor Gruber use to calculate the number of smokers in the 4 Youth Addicted Population?

A: He used The National Health Interview Survey, or NHIS. The NHIS is an annual
survey of a sample of U.S. households conducted by the National Center for Health
Statistics, a division of the Centers for Disease Control. The Centers for Disease Control
are commonly referred to as the CDC.

9 The NHIS is the longest running, most commonly used household survey of 10 smoking behaviors in the United States. The NHIS has many years of smoking 11 information available. It has very large sample sizes – each of the recent surveys covers 12 about 40,000 households containing about 100,000 individuals -- and it is nationally 13 representative. Based on my experience as a statistician, the NHIS is a widely used and 14 commonly relied upon survey in public health and biostatistics applications, and it is 15 frequently relied upon in studies of smoking. Based on discussions I had with Dr. 16 Gruber, I also understand that in the field of economics, the NHIS is commonly 17 understood to be the best source of data related to smoking prevalence. It is often used as 18 a data source for studies in peer reviewed journal articles. The sample sizes are large 19 enough to yield reliable estimates of smoking in the U.S. population, and of 20 subpopulations such as the Youth Addicted Population. There were 19 NHIS surveys from 1970 to 1999 that collected information on 21 22 smoking. Dr. Gruber focused on ten of them – the "core" surveys -- in calculating the

23 size of the Youth Addicted Population. All of the 19 surveys had information on the

number of current and former smokers by age and gender. The ten core surveys had
additional information on ages of initiation and cessation. From these surveys, Dr.
Gruber could estimate, for example, not only how many smokers there were in the United
States during each year from 1954 to 2000, but also how these smokers were distributed
by age and gender. Within age and gender categories, he could estimate how many
began smoking before age 21, and how many began smoking at or above age 21.

Q: How did Dr. Gruber calculate these counts for the years in which there was no NHIS survey that asked about smoking?

9 A: He used a method called "backcasting." For example, using the 1980 NHIS 10 survey Dr. Gruber could estimate the number of current smokers in the United States who 11 were 50 years old in 1980. For years prior to 1980, he could work backwards from this 12 estimate. In the previous year, 1979, these smokers would have been 49 years old. So 13 Dr. Gruber, still using the 1980 NHIS survey, could also estimate how many 49 year-olds in 1979 were current smokers, and similarly how many 48 year-olds in 1978 were current 14 15 smokers, and so on all the way back to the different ages of initiation that were reported 16 by 50 year-olds in the 1980 survey. He just had to apply a mortality adjustment to 17 account for the additional smokers who would have been 50 years old in 1980, but who 18 died in some year prior to 1980.

19

20

He applied mortality adjustments based on the mortality rates obtained from the Social Security Administration. I described these rates earlier in my testimony.

Q: Doctor Wyant, did Dr. Gruber make any other adjustments in calculating his backcasts?

A:. Yes. First of all, in any given year Dr. Gruber had up to ten different backcasts,
from the ten different NHIS core surveys, with which to calculate the number of smokers
in different categories. So he averaged the backcast estimates available for any given
year.

7 In addition, for the core survey years, he also had the contemporaneous surveys 8 themselves. For example, in 1997, he had estimates of smoker counts derived from the 9 1997 core survey. He also had backcasts to 1997 from the 1998 and 1999 core surveys. 10 Overall, Dr. Gruber found that backcast estimates yielded higher current smoker 11 counts in core survey years, on average, than the corresponding counts derived from the 12 contemporaneous surveys themselves. So he applied a "backcast adjustment" that 13 reduced the counts of current smokers in backcast estimates to match, on average, the 14 counts from contemporaneous surveys. This adjustment typically reduced the backcast 15 counts of current smokers by about 15% from their initial values. 16 **O**: Doctor, is it necessarily the case that counts from the contemporaneous 17 surveys should take precedence over counts from the backcast estimates? 18 A: No. I understand that from his extensive experience as a researcher in tobacco 19 issues, Dr. Gruber considers it well known that contemporaneous surveys tend to underestimate the incidence of smoking. My understanding from my discussions with Dr. 20 21 Gruber is that he considers both backcast estimates and contemporaneous estimates to be 22 valid estimates of smoker counts. I understand that he adjusted his estimates to more

closely reflect the lower counts from the contemporaneous surveys.

Q: Did Dr. Gruber identify other reasons why backcast estimates might differ from contemporaneous survey estimates?

3 A: Yes. One reason is temporary quitting. Smokers often quit smoking, and then 4 relapse. The backcast estimates are based on when survey respondents say they started 5 smoking, and when (or if) they say they stopped. The backcasts assume continuous 6 smoking from initiation to final cessation, or, for continuing smokers, from initiation to 7 the backcast survey year. The backcasts do not take into account periods of temporary 8 quitting. Their disregard for temporary quitting would tend to make the backcast 9 estimates higher than the contemporaneous survey estimates. 10 There are ways to adjust backcasts to take into account temporary quitting. But 11 Dr. Gruber took the more conservative route of simply adjusting the backcasts to produce 12 current smoker counts at the lower levels exhibited in contemporaneous surveys. 13 **Q**: Doctor Wyant, how important were Dr. Gruber's backcasts in your use of his 14 population counts to calculate adverse health effects? 15 A: The backcasting part of Dr. Gruber's work was not very important, in our context. 16 His backcasting affected only population counts prior to 1999. All of the smoking 17 attributable premature deaths that we calculated occurred after 1999, so his backcasts did 18 not affect our mortality measures at all. And the great majority of the smoking 19 attributable disease treatment years and associated excess health care costs that we 20 calculated occurred after 1999 as well. So while Dr. Gruber's work in making full and

21 appropriate use of the available data through his backcasts played a useful role in making

22 our analysis a more careful one, the numerical impact of his choice of backcasting

23 methods on our cost and treatment measures was minor.

1 Q: Doctor Wyant, what additional steps were involved in Dr. Gruber's

2 calculation of the Youth Addicted Population?

3	A: The estimates I just described yield counts of the total smokers in the U.S. who
4	started before age 18, or before age 21. The next step was to reduce the counts of adult
5	smokers in these two categories by the percentage of youth smokers who smoked more
6	than five cigarettes a day, or by the percentage of youth smokers who smoked more than
7	ten cigarettes a day, in order to generate the other definitions of the Youth Addicted
8	Population. Dr. Gruber made these reductions based on additional NHIS data on youth
9	smoking intensity.
10	So, for example, if only 85% of twenty year-old regular smokers smoked more
11	than five cigarettes a day, he reduced the estimated number of adults in the corresponding
12	Youth Addicted Population by 15%.
13	Q: Doctor, what was the most recent NHIS survey that Dr. Gruber used?
14	A: The most recent survey he used was conducted in 1999.
15	Q: How did he calculate population counts after that year?
16	A: He used mortality rates to calculate how many of the youth addicted smokers
17	estimated from the 1999 survey would be alive in each year up to 2050. He used
18	cessation rates to calculate how many of them would still be current smokers in each year
19	up to 2050. I described this process earlier in my testimony, when I talked about how
20	premature deaths and years of life lost are calculated.

Q: Did Dr. Gruber take steps that would tend to make his population counts conservative?

3 A: Yes. The manner in which he applied his addiction standards would tend to make 4 his counts conservative. I understand that Dr. Gruber's experience as a tobacco 5 researcher has led him to conclude that youth smokers who smoke more cigarettes a day 6 tend to continue smoking further into adulthood than youth smokers who smoke fewer 7 cigarettes a day. So the more than five cigarettes a day population should contain a 8 greater proportion of current smokers at adult ages compared to the regular smoker 9 population, and the more than ten cigarettes a day population should contain a greater 10 proportion of current smokers at adult ages than either the regular smoker or the more 11 than five cigarettes a day population. 12 But Dr. Gruber's calculations simply assumed that the populations under all three

13 addiction standards would have cessation rates equal to the regular smoker cessation 14 rates. Had he taken additional steps to calculate the higher number of continuing 15 smokers that would likely have been present in the more than five cigarettes a day 16 population, for example, then our smoking attributable death calculation would likely 17 have yielded more than the 13.4 million deaths that we actually calculated.

18 Q: Did Dr. Gruber perform any checks on his population calculations?

A: Yes. Of course, just carrying out his calculations using different addiction
standards is one form of check. It shows the numerical effects of making different
assumptions about what constitutes addiction.

He also made a number of technical checks. For example, he examined a number of different methods for calculating the backcast correction, to make sure that he was not missing some pattern in how backcasts change over the years that would affect how
different surveys should be used.

3 He made another very substantial check, which was to repeat his calculations 4 using a different data source. He calculated the Youth Addicted Population using the 5 Current Population Survey Tobacco Use Supplement, or CPS-TUS, instead of the NHIS. 6 The CPS-TUS is another large nationally representative survey that is often used by 7 tobacco researchers. Dr. Gruber obtained very similar results when he switched to this 8 survey. For example, when he calculated the share of United States cigarettes smoked by 9 the Youth Addicted Population, he got a figure from the CPS-TUS based population that 10 was only 5% higher than the corresponding figure from the NHIS based population. Doctor Wyant, did you yourself perform an independent check of Dr. 11 **O**: 12 **Gruber's population counts?** 13 A: Yes. 14 **O**: Please describe this check. 15 A: David M. Burns, M.D., is an expert who testified in this case. He has done 16 research in a number of tobacco related areas. One of the analyses that he and his 17 colleagues conducted is published in the National Cancer Institute's Monograph 8, in the 18 chapter titled "Cigarette Smoking Behavior in the United States." (Burns, D., L. Lee et 19 al., "Cigarette Smoking Behavior in the United States," Monograph 8: Changes in 20 Cigarette-Related Disease Risks and Their Implication for Prevention and Control, 21 National Institutes of Health, National Cancer Institute, 1997, pages 13-112.) In this 22 chapter, he and his colleagues describe a calculation that was very similar to what Dr. 23 Gruber did in calculating the size and characteristics of the Youth Addicted Population.

Page 89

1	Dr. Burns and his colleagues took NHIS surveys, and calculated the prevalence of
2	smoking in the United States, by age and gender, from 1900 to 1988. (By prevalence, I
3	mean the percentage of people who smoked.) They calculated the prevalence of both
4	current smoking and ever smoking. Like Dr. Gruber, Dr. Burns and his colleagues used
5	NHIS surveys, filled in years in which there were no surveys by exploiting information
6	from the surveys on ages of initiation and cessation, and made a mortality adjustment.
7	Their methods were not identical to Dr. Gruber's, but were similar in terms of basic
8	approach and data sources.
9	I applied their prevalence estimates to U.S. population data through 1988 to
10	convert these estimates into counts of smokers. From 1988 to 1999, I estimated smoker
11	counts from NHIS surveys. But I did not do backcasting. Instead, I estimated trend
12	curves over time for smoker counts at each age, using standard statistical formulas for
13	doing trend analysis, and used those trend curves to estimate smoker counts for each year
14	from 1989 to1999. To get smoker counts after 1999, I projected into the future using
15	mortality rates.
16	Using this population, I calculated total smoking attributable health care costs that
17	were within 3% of the total that we calculated using Dr. Gruber's calculation of the
18	Youth Addicted Population.
19	Q: Did you consider using your population counts instead of Dr. Gruber's?
20	A: No. In my opinion, Dr. Gruber did a much more thorough and detailed job of
21	calculating and checking the Youth Addicted Population than I did. I made my
22	calculation only as additional check. In the field of applied statistics, independent checks
23	of this sort are often not available. But when they are, and they yield results as close as

Page 90

this one did to the results obtained using Dr. Gruber's numbers, analysts usually interpret
such a replication of results as providing strong additional support for the reasonableness
and reliability of the basic methods being used.

Doctor Wyant, do you know if Dr. Gruber made any causal analysis of the

4 5 **Q**:

impact of defendants' conduct on youth smoking?

A: My understanding from my discussions with Dr. Gruber is that he did not do such
an analysis, he was not asked to do so, and he understood that this issue involved a wide
range of conduct that was being addressed by other experts.

9 Q: Doctor, please direct your attention once again to U.S. Exhibit 17415, titled

10 "Disease Treatment Years for Lung Cancer, COPD, CHD, Stroke ... – Contributors

11 to the Analysis." Before I switched to asking you about Dr. Gruber's work in

12 calculating the Youth Addicted Population, you were describing the roles different

13 people who are identified in this exhibit played in contributing to your calculation of

14 disease treatment years. What roles remain to be described?

15 A: I just described Dr. Gruber's role in calculating the counts of smokers in the

16 Youth Addicted Population. Earlier in my testimony, I described Dr. Samet's role in

17 identifying and describing the major diseases caused by smoking.

18 The next contributor listed in this exhibit is Dr. Zeger. Dr. Zeger was responsible 19 for calculating the treatment rates for the major diseases, and the likelihood that an 20 annual case of treatment is smoking attributable.

21 Q: What is Dr. Zeger's background and expertise?

His full name is Scott L. Zeger. Dr. Zeger is a biostatistician. He is Professor and
Chair of Biostatistics at Johns Hopkins Bloomberg School of Public Health in Baltimore,

Maryland. He received his B.A. in Biology at the University of Pennsylvania in 1974 and
 his Ph.D. in Statistics from Princeton University in 1982.

3 Dr. Zeger is a Fellow of the American Statistical Association, a Fellow of the 4 American Association for the Advancement of Science, and Co-Editor of the Oxford 5 Press journal *Biostatistics*. He was awarded the 1987 Snedecor Award (with co-author 6 Dr. Kung-Yee Liang) for best paper in biometry. 7 The American Public Health Association recognized Dr. Zeger in 1991 with the 8 Spiegelman Award for contributions to health statistics. Recently, Science Watch 9 identified Dr. Zeger as one of the top 25 most cited mathematical scientists of the past 10 decade. His research focuses on the design and analysis of data from biomedical studies. 11 He has made many contributions to studies of smoking and health, and to studies of 12 environmental health. 13 **Q**: Doctor Wyant, do you know if Dr. Zeger has authored peer reviewed articles 14 related to the adverse health effects of smoking? 15 Yes, he has. He was a co-author of a recent article that described the A: 16 development and application of methods for calculating smoking attributable cases of 17 treatment. In this article, he and his co-authors described the results of applying the 18 methods to the U.S. population. Applying similar methods to the Youth Addicted 19 Population yielded the 107.6 million smoking attributable disease treatment years I have

20 been discussing.

Written Direct: Timothy Wyant, Ph.D., US v. PM, 99-cv-02496(D.D.C.)(GK)

Q: Has Doctor Zeger authored other publications on smoking attributable adverse health effects?

3	A: Yes. He was the lead author of a chapter in a book published by Springer in
4	2000. Dr. Samet and I were co-authors, as was Dr. Leonard S. Miller. Dr. Miller also
5	worked with Dr. Zeger and me in the present case, as a contributor to measuring the
6	smoking attributable health care costs in the Youth Addicted Population.
7	The book chapter describes our estimates of smoking attributable health care costs
8	for the Minnesota Medicaid Program and for Blue Cross Blue Shield of Minnesota. Dr.
9	Zeger and I testified in the case that was brought by these health plans against the tobacco
10	companies in 1998. Dr. Miller worked with us in that case as well.
11	The full citation is Zeger, S.L, T. Wyant, et al., "Statistical Testimony on
12	Damages in Minnesota v. Tobacco Industry," Statistical Science in the Courtroom, J.L.
13	Gastwirth ed., Springer-Verlag, New York, 2000, pages 303-320.
14	Q: Doctor Wyant, directing your attention to U.S. Exhibit 78545, is this Doctor
15	Zeger's curriculum vita?
16	A: Yes. It is current as of December 2003. Among other things, it lists the more
17	than 20 peer reviewed journal articles for which Dr. Zeger was the lead author, and the
18	more than 90 peer reviewed journal articles for which he was a co-author.
19	Q: Doctor, what does U.S. Exhibit 17416 titled "Disease Cases and Their
20	Medical Costs Attributable to Smoking: An Analysis of the National Medical
21	Expenditure Survey" show?
22	A: This exhibit gives excerpts from the article that Dr. Zeger co-authored in 2003. In
23	the study that is summarized in this article, he and his colleagues estimated the number of

1 smoking attributable cases of treatment in the United States for the major diseases that 2 are caused by smoking. In that study they focused on the same major diseases that we 3 addressed in our analysis of cases treated in the Youth Addicted Population. Those 4 diseases are listed in U.S. Exhibit 17162, which was prepared by Dr. Samet. As I noted 5 earlier, Dr. Zeger and the other authors of the "Disease Cases" article calculated smoking 6 attributable cases of treatment using essentially the same methods that we used for the 7 Youth Addicted Population. 8 What does U.S. Exhibit 17548 titled "Measurements Used in Epidemiology --**Q**: 9 **Example Calculations' show the Court?**

A: Earlier, I described how several common measures in epidemiology are
calculated. One of them was the attributable fraction. This exhibit shows how
attributable fractions are applied in an analysis of a population such as the Youth
Addicted Population.

14 The first line repeats from U.S. Exhibit 17542, an exhibit that I discussed 15 previously. U.S. Exhibit 17542 illustrated the application of the attributable fraction of 16 deaths to get the number of smoking attributable deaths. An analyst multiplies the 17 number of smokers times the mortality rate to get the number of deaths. The analyst then 18 multiplies the number of deaths by the attributable fraction to get the number of smoking 19 attributable deaths.

The second line shows a similar application, but for cases of treatment instead of deaths. This line is laid out like the previous one. Instead of a mortality rate, we use a treatment rate. The number of smokers times the treatment rate gives the total number of cases. Then we use the attributable fraction of cases treated instead of the attributable fraction of deaths. Applying this attributable fraction to the number of cases treated
 yields the total number of smoking attributable cases treated.

2

The essence of the calculation is the same, whether we are talking about smoking attributable deaths or smoking attributable cases of treatment. The difference for our analysis of the Youth Addicted Population is in the sources of the occurrence rates and of the attributable fractions. For deaths, we relied on figures from published sources such as the 1989 Surgeon General's report. For cases of treatment, we relied on figures that were calculated by Dr. Zeger from the National Medical Expenditure Survey.

9

Q: Doctor Wyant, how do cases treated relate to disease treatment years?

10 A: The calculations in U.S. Exhibit 17548 yield annual totals. So if they are carried 11 out for one calendar year, they yield the total number of people who are being treated in 12 that year for one or more of the major diseases. This total is typically called the "number 13 of cases" or the "number of cases of treatment" or the "number of disease cases" for the 14 year.

15 If the calculations are then carried out for the next calendar year, another set of 16 cases of treatment results. If we add the two annual totals together, we get what we call 17 the number of disease treatment years. The number of disease treatment years in this 18 latter example would be the number of people treated just in year one, plus the number of 19 people treated just in year two, plus two times the number of people treated in both years. We use the phrase "disease treatment years" to emphasize that we are adding up every 20 21 instance in which an individual is treated during a calendar year, so one individual can 22 contribute more than one treatment year to the total. The terms "disease treatment years" 23 and "annual cases of disease" really mean the same thing, but the latter phrase is

Written Direct: Timothy Wyant, Ph.D., US v. PM, 99-cv-02496(D.D.C.)(GK)

sometimes interpreted as being a count of unique individuals. We use the phrase "disease
 treatment years" to avoid confusion of this sort.

3 Q: Returning to U.S. Exhibit 17416 titled "Diseases Cases and Their Medical
4 Costs Attributable to Smoking: An Analysis of the National Medical Expenditure
5 Survey," does this exhibit talk about the use of attributable fractions?

A: Yes. This is the exhibit that gives excerpts from the 2003 article by Dr. Zeger and
his colleagues in the Journal of Econometrics. According to the first excerpt, "The
population attributable fraction is commonly used in epidemiology to describe the
proportion of disease that is due to a particular causal factor. In this paper, we estimate
... the fraction of cases of a particular group of diseases that is attributable to smoking
(SAF)."

12 Q: Doctor, please direct your attention to U.S. Exhibit 17544 titled "Male

13 Treatment Rates by Age for Lung Cancer / COPD." what does this exhibit show?

A: This exhibit illustrates how Dr. Zeger and his colleagues calculated treatment
rates and attributable fractions from the National Medical Expenditure Survey. I testified
earlier that all of the standard epidemiology measures that we used in analyzing adverse
health effects in the Youth Addicted Population involve comparing the occurrence rates
for smokers with the occurrence rates for similar never smokers.

19 The National Medical Expenditure Survey tracked more than 30,000 people for a 20 year, and recorded all of their medical encounters. The survey also collected information 21 on smoking status. So it is possible to calculate the number of smokers and never 22 smokers that were treated for one of the major diseases in the course of a year. Once you 23 have these counts, you can calculate the treatment rates.

1	In this exhibit, the upper black line shows the treatment rates for male pack-a-day
2	smokers for ages 40 to 94. At age 70, for example, about five percent of such smokers
3	get treated for diseases such as lung cancer and COPD during the course of a year.
4	Smoking a pack of cigarettes a day is a fairly typical rate of smoking for continuing
5	smokers.
6	The lower black line shows the treatment rates for male never smokers.
7	Continuing with the age 70 example, about one percent of 70 year-old male never
8	smokers get treated for one of these diseases.
9	Epidemiologic measures such as the attributable fraction can be calculated from
10	the treatment rates for smokers and never smokers, as I described earlier. Attributable
11	fractions reflect the extent to which smoker treatment rates exceed the never smoker
12	treatment rates. The red zone in U.S. Exhibit 17544 shows the extent to which the
13	smoker rate exceeds the never smoker rates at different ages.
14	In Dr. Zeger's analysis, he developed attributable fraction formulas for different
15	numbers of cigarettes per day, and for different ages of smoking initiation and cessation,
16	as well as for different ages and genders.
17	Q: Doctor Wyant, what do you mean when you say "diseases such as lung
18	cancer and COPD?"
19	A: If we look again at U.S. Exhibit 17162, which shows the list of major diseases
20	that were identified by Dr. Samet, we can see that he divided the diseases into two
21	groups. The diseases with high relative risk are lung cancer, COPD, and laryngeal
22	cancer. These three diseases make up one group, and the remaining diseases make up a
23	group that has somewhat lower relative risk. We calculated smoking attributable cases of

1	treatment separately for the two groups, which we designated the Lung cancer/COPD
2	group and the CHD/Stroke group. Dividing the major diseases in this fashion adheres to
3	the structure that was laid out by Dr. Samet. The total of 107.6 million smoking
4	attributable disease treatment years in the Youth Addicted Population is the total for all
5	the major diseases combined. We do not double count – if a person is treated for, say,
6	COPD and CHD and atherosclerosis all during the course of one calendar year, this
7	counts as one annual case of treatment, or one disease treatment year.
8	Q: Earlier, Doctor, you discussed the issue of potential confounding factors. Did
9	Dr. Zeger's analysis of cases address this issue?
10	A: Yes, it did. Dr. Samet testified in this case about potential confounding factors, as
11	I discussed earlier in my testimony. As Dr. Samet put it, these are factors that are mixed
12	up with smoking. Analysts try to compare smoker rates to rates for reasonably similar
13	never smokers, in order to isolate the effect of smoking. Dr. Samet referred to this
14	strategy as "comparing like to like."
15	As Dr. Samet testified, one way to compare like to like is to create "piles" of
16	people that are similar with regard to potential confounding factors, and compare smoker
17	and never smoker rates within each pile. Another way to account for potential
18	confounders, as Dr. Samet also testified, is to use multivariate models.
19	Dr. Zeger used the latter method of multivariate models in his analysis of the
20	National Medical Expenditure Survey. In his peer reviewed journal article, he and his
21	colleagues referred to "generalized additive models" and "smoothing splines." These are
22	the statistical terms of art that describe the kinds of multivariate models that he used in
23	both his peer reviewed study and in analyzing adverse health effects in the Youth

Written Direct: Timothy Wyant, Ph.D., US v. PM, 99-cv-02496(D.D.C.)(GK)

Addicted Population. The essential notions are (1) these are multivariate models of the sort that Doctor Samet described to the Court, (2) these particular types of multivariate models are commonly used in biostatistics for these kinds of applications, (3) the essential purpose of the models is to calculate the extent to which smoker disease rates exceed never smoker disease rates, and (4) the models simultaneously adjust for a number of potential confounders in order to compare "like to like" in a reasonable manner.

8 One advantage of multivariate models such as the ones that were used by Dr. 9 Zeger is that they produce attributable fraction formulas not just for "the group of current 10 smokers age 35 to 64", but for any age, any duration of smoking, and any number of 11 That is why in U.S. Exhibit 17544, which compares the treatment rates packs per day. 12 for continuing pack-a-day smokers and for never smokers, the rates at different ages are 13 expressed as curves. As the Court can see, by tracing along the curves in this exhibit, it is 14 possible to determine the treatment rates for smokers and for never smokers at any age. 15 Earlier in my testimony, I used the curves in this manner to identify the treatment rates 16 for 70 year-olds.

With the use of multivariate models, a statistician is not required to group people
into, say, just three age groups as was the case in some of the studies discussed by Dr.
Samet that used the "pile" method to compare like to like. Dr. Zeger's multivariate
models produce curves that yield estimates for any age.

Multivariate models also allow analysts to adjust simultaneously for a number of
 potential confounding factors, as Dr. Samet described in his testimony. Looking again at
 U.S. Exhibit 17544, the potential confounders (in addition to age and gender) for which

Dr. Zeger adjusted his attributable fractions are listed at the bottom: income level, seat
belt use, education, geographic region, marital status, and race. When treatment rates for
smokers and never smokers are compared, as was done in this exhibit, the comparisons
are for people who are identical with respect to these potential confounders.

5 Q: What was the effect of adjusting for potential confounding factors?

6 A: Dr. Zeger and his colleagues summarized their findings in their peer reviewed 7 article. In U.S. Exhibit 17416, the exhibit that gives excerpts from that article, the 8 following excerpt appears at the bottom of the exhibit: "The additional potential 9 confounders, including poverty status, marital status, and education, showed little 10 association with the log odds in either disease group [the two groups being Lung 11 Cancer/COPD and CHD/Stroke]. This is consistent with previous investigations ..." 12 In other words, once Dr. Zeger and his colleagues took age and gender into 13 account, for practical purposes they were comparing like to like. The differences 14 between the treatment rates for smokers, and the treatment rates for never smokers of the 15 same age and gender, were due almost entirely to the fact that one group smoked or used 16 to smoke, and the other did not.

As the article excerpt says, this finding is consistent with what other studies have reported. In one example I cited earlier, Dr. Samet in his testimony in this case looked at the Nurses' Health Study, which investigated smoking-related heart attacks. In that study, he noted that age-adjusted relative risks were essentially the same as fully adjusted relative risks. That is, the adjustment for potential confounders other than age had no impact on the relative risk of smoking for heart attacks.

1	Earlier in my own testimony, I discussed U.S. Exhibit 18240, which lists a
2	number of peer reviewed articles that came to similar conclusions. These articles
3	concluded, along with the Surgeon General, that when calculating smoking attributable
4	deaths, adjusting for age and gender is reasonable and sufficient.
5	Q: Doctor Wyant, is the National Medical Expenditure Survey a reliable data
6	source for this kind of analysis?
7	A: Yes. Many peer reviewed studies similar to the one conducted by Dr. Zeger rely
8	on this government survey.
9	Q: Doctor, please direct your attention to U.S. Exhibit 17546, titled "Using the
10	National Medical Expenditure Survey to Estimate the Smoking Attributable Health
11	Care Costs in the Peer Reviewed Literature." What does this exhibit show the
12	court?
13	A: This exhibit gives quotes from four recently published peer reviewed articles that
14	rely on the National Medical Expenditure Survey, or NMES. In a 2001 article in Chest
15	that estimated the cost of treating COPD in the United States, the authors noted that
16	"the 1987 NMES was designed to provide extensive information on health
17	expenditures The inclusion of economic data in the NMES is a significant advantage
18	over other population-based national medical surveys." In a 1999 article in Social
19	Science & Medicine that estimated smoking attributable health care costs in the U.S., the
20	authors said that " NMES is uniquely appropriate to the task of estimating the impact
21	of smoking on medical care costs."
22	In a 2002 article in the American Journal of Public Health that also estimated
23	smoking attributable health care costs in the U.S., the authors said that NMES provided

Page 101

"...the most comprehensive data available..." for this task. And Dr. Zeger and his
 colleagues, in their peer reviewed article that I discussed earlier, concluded that "...
 NMES is still the best source of information for this kind of study."

Q: Doctor, please direct your attention once again to U.S. Exhibit 17544 titled
"Male Treatment Rates by Age for Lung Cancer / COPD ." You described earlier
how this exhibit illustrates the extent to which treatment rates for current smokers
exceed those for never smokers, based on Dr. Zeger's calculations using NMES.

8 What else can be gleaned from this exhibit?

9 A: Towards the beginning of my testimony, I discussed four main ideas that emerge 10 from studies of smoking attributable adverse health effects. One of these concepts was 11 that most of the adverse effects of smoking in populations like the Youth Addicted 12 Population have yet to occur. I discussed the fact that currently, the average age of the 13 Youth Addicted Population members is only 46. I noted that smokers at this age are 14 typically too young to have experienced the full adverse effects of smoking.

This exhibit sheds some additional light on this issue. The Court can see in the chart that at age 46, although there is a noticeable elevated treatment rate for smokers compared to never smokers, the treatment rates are miniscule compared to what they will become at older ages. At age 46, less than one percent of the smokers are being treated for diseases such as lung cancer and COPD during the course of a calendar year.

20 Q: Are there any other points you would like the Court to understand with

- 21 regard to U.S. Exhibit 17544?
- 22 A: There are two additional points.

First, some analysts describe the adverse effects of smoking in terms of
"premature aging." This chart suggests why that description arises. For diseases such as
lung cancer and COPD, continuing smokers such as those that are represented in this
exhibit experience rates of disease that are similar to the rates that are experienced by
never smokers who are much older.
The Court can see from the chart that never smokers do get diseases such as lung
cancer and COPD, and that their disease rates increase with age. But as just one example
that can be drawn from the chart, continuing smokers at age 50 are already experiencing
levels of disease that never smokers do not experience until around age 70.
The second point I would make with regard to this chart is that it could be
somewhat misleading with regard to the ages at which most smoking attributable diseases
occur. The chart shows that disease rates for smokers are very high at older ages. At age
90, for example, the annual treatment rate exceeds 20%.
However, most smoking attributable cases of treatment occur well before age 90.
The reason is simple. People that continue to smoke a pack of cigarettes a day
throughout their lives, and experience the elevated risks of disease that are reflected in
the chart at ages 50-80, seldom live to age 90.
Q: Doctor, does U.S. Exhibit 17744, titled "Male Treatment Rates by Age for
Lung Cancer / COPD – Cases Between Age 50 and Age 85" illustrate this
phenomenon?
A: Yes. As the bracketed region shows, about 95% of the smoking attributable cases
of treatment for male continuing smokers occur between the ages of 50 and 85. Younger

than 50, there are lots of smokers still alive, but the disease rates are low. After age 85,
the disease rates are high, but not many smokers are left.

This kind of "peaking" of disease occurrence between ages 50 and 85 explains why our projected annual smoking attributable adverse health effects in the Youth Addicted Population will increase in the coming decades, peak about 15 to 25 years from now, and then decline. U.S. Exhibit 17407 and U.S. Exhibit 17410 illustrated these kinds of trends for deaths. By 2050, only about 17 million members of the Youth Addicted Population will still be alive, and their average age will be 78.

9 Q: Doctor Wyant, turning from the high ages to the low ages, the chart in U.S.

10 Exhibit 17744 begins at age 40, is that correct?

11 A: Yes. Doctor Samet suggested that we restrict our calculation of smoking 12 attributable cases of disease in the Youth Addicted Population to people who are being 13 treated for the major diseases at age 40 or above. Although smoking can cause major 14 diseases to occur before age 40, it does so infrequently. One way an analyst can avoid 15 possible intermingling of smoking with other factors, in addition to adjusting for potential 16 confounders, is to apply a minimum age threshold for calculating disease rates. Dr. 17 Zeger used a minimum age threshold of 40 both in his calculations related to adverse 18 health effects in the Youth Addicted Population, and in his peer reviewed article from 19 2003 on smoking attributable disease cases and health care costs in the United States as a

20 whole.

1 **O**: What did Dr. Zeger do with people in the National Medical Expenditure 2 Survey who were over age 40, and being treated for one of the major diseases caused 3 by smoking, but who reported that they had first been diagnosed under age 40? 4 A: Doctor Samet instructed us to apply this minimum age threshold to the dates of 5 treatment, not the dates of first diagnosis. He recommended that ICD-9 codes from his 6 list of the major smoking related diseases should not be considered as caused by smoking 7 unless the person with that ICD-9 code had reached age 40. So Dr. Zeger did not look at 8 the date a survey respondent said that he or she was first diagnosed. He looked at 9 whether or not the respondent had any medical encounters at age 40 or above that, on the 10 basis of ICD-9 codes, were specifically related to one of the major diseases caused by 11 smoking.

12 This is also how Dr. Zeger applied the age threshold in his peer reviewed journal 13 article. Applying an age threshold in this manner is consistent with what is done in many 14 peer reviewed mortality studies, including a number of studies that are referenced in my 15 demonstrative exhibits. Such studies typically look at smoking attributable deaths that 16 occur at age 35 and higher. They apply this minimum age threshold of 35 to the outcome 17 measure – death. They do not look back in time and try to screen out deaths for 18 decedents who had received an initial diagnosis of a smoking related disease before they reached the age of 35. 19

20 Q: You and your colleagues had a number of discussions with Dr. Samet and 21 other medical experts on the aspects of diseases caused by smoking that might be 22 relevant to your statistical models, is that correct?

23 A: Yes.

1 Q: Doctor Wyant, is the manner in which you applied your minimum age

2 threshold consistent with what you learned from these discussions about the

3 characteristics of the major diseases caused by smoking?

A: Yes. Ignoring survey respondents who report a first diagnosis before age 40
would suggest, for example, that if a person smoked two packs a day beginning at age 15,
had a heart attack at age 35, continued to smoke two packs a day until age 45, and then
had another heart attack, that smoking could have played no role in causing the second
heart attack. Such an assertion does not conform to my understanding – as gleaned from
the typical interactions that a biostatistician has with medical experts – of how smoking
works.

11 Q: Doctor, how important is your use of an age 40 threshold?

A: It contributes to making our analysis a more careful one, but the effect on final
counts of disease treatment years is minor. As U.S. Exhibit 17744 shows, the occurrence
rates of the major diseases that are caused by smoking are quite low at ages close to 40.
In addition, because major diseases that are caused by smoking do occur before age 40,
excluding such occurrences from our analysis would tend to make our final estimates of
disease treatment years understated.

18 Q: Doctor, did your calculation methods carry any other safeguards against 19 overstating smoking attributable cases of disease?

A: Yes. We did not attempt to count everyone living with a smoking attributable disease during a given calendar year. We restricted our calculation of disease cases to people who actually had medical encounters during the calendar year, to begin with, and then we further required that at least one of these encounters be coded as specifically

1	related to one of the major diseases that are caused by smoking. We did not, for example,
2	automatically record a disease year for a person in every calendar year subsequent to an
3	initial diagnosis of emphysema. This was true even if during a post-diagnosis calendar
4	year the person had numerous medical encounters for pneumonia and other respiratory
5	difficulties. Unless at least one of the encounter records specifically indicated COPD or
6	another one of the major diseases as a reason for the encounter, we did not count the
7	person as a disease case for that year. Other studies in the peer reviewed literature take a
8	more inclusive approach to counting disease years. I cited one such study earlier in my
9	testimony. That study calculated an annual prevalence of smoking attributable disease
10	that was substantially higher than what we calculated for the Youth Addicted Population.
11	Q: Doctor, you have described the roles of Dr. Zeger and others in the
12	calculation of the 107.6 million disease treatment years in the Youth Addicted
12 13	calculation of the 107.6 million disease treatment years in the Youth Addicted Population. What was your primary responsibility in this effort?
12 13 14	calculation of the 107.6 million disease treatment years in the Youth AddictedPopulation. What was your primary responsibility in this effort?A: I received counts of current and former smokers in the Youth Addicted
12 13 14 15	 calculation of the 107.6 million disease treatment years in the Youth Addicted Population. What was your primary responsibility in this effort? A: I received counts of current and former smokers in the Youth Addicted Population, by age, gender, and year from Dr. Gruber. From Dr. Zeger, I obtained
12 13 14 15 16	calculation of the 107.6 million disease treatment years in the Youth AddictedPopulation. What was your primary responsibility in this effort?A:I received counts of current and former smokers in the Youth AddictedPopulation, by age, gender, and year from Dr. Gruber. From Dr. Zeger, I obtainedaverage treatment rates and attributable fractions for current and former smokers, by age
12 13 14 15 16 17	calculation of the 107.6 million disease treatment years in the Youth AddictedPopulation. What was your primary responsibility in this effort?A:I received counts of current and former smokers in the Youth AddictedPopulation, by age, gender, and year from Dr. Gruber. From Dr. Zeger, I obtainedaverage treatment rates and attributable fractions for current and former smokers, by ageand gender. For each age, gender, and year, I multiplied counts of smokers times
12 13 14 15 16 17 18	calculation of the 107.6 million disease treatment years in the Youth AddictedPopulation. What was your primary responsibility in this effort?A:I received counts of current and former smokers in the Youth AddictedPopulation, by age, gender, and year from Dr. Gruber. From Dr. Zeger, I obtainedaverage treatment rates and attributable fractions for current and former smokers, by ageand gender. For each age, gender, and year, I multiplied counts of smokers timestreatment rates to get total cases treated. I then multiplied the total cases treated by the
12 13 14 15 16 17 18 19	 calculation of the 107.6 million disease treatment years in the Youth Addicted Population. What was your primary responsibility in this effort? A: I received counts of current and former smokers in the Youth Addicted Population, by age, gender, and year from Dr. Gruber. From Dr. Zeger, I obtained average treatment rates and attributable fractions for current and former smokers, by age and gender. For each age, gender, and year, I multiplied counts of smokers times treatment rates to get total cases treated. I then multiplied the total cases treated by the attributable fractions to get the number of smoking attributable cases of treatment in each
 12 13 14 15 16 17 18 19 20 	 calculation of the 107.6 million disease treatment years in the Youth Addicted Population. What was your primary responsibility in this effort? A: I received counts of current and former smokers in the Youth Addicted Population, by age, gender, and year from Dr. Gruber. From Dr. Zeger, I obtained average treatment rates and attributable fractions for current and former smokers, by age and gender. For each age, gender, and year, I multiplied counts of smokers times treatment rates to get total cases treated. I then multiplied the total cases treated by the attributable fractions to get the number of smoking attributable cases of treatment in each year from 1954 to 2050. I then added up these annual cases over all the years to get the
 12 13 14 15 16 17 18 19 20 21 	 calculation of the 107.6 million disease treatment years in the Youth Addicted Population. What was your primary responsibility in this effort? A: I received counts of current and former smokers in the Youth Addicted Population, by age, gender, and year from Dr. Gruber. From Dr. Zeger, I obtained average treatment rates and attributable fractions for current and former smokers, by age and gender. For each age, gender, and year, I multiplied counts of smokers times treatment rates to get total cases treated. I then multiplied the total cases treated by the attributable fractions to get the number of smoking attributable cases of treatment in each year from 1954 to 2050. I then added up these annual cases over all the years to get the total smoking attributable disease treatment years. In other words, I just repeatedly
 12 13 14 15 16 17 18 19 20 21 22 	 calculation of the 107.6 million disease treatment years in the Youth Addicted Population. What was your primary responsibility in this effort? A: I received counts of current and former smokers in the Youth Addicted Population, by age, gender, and year from Dr. Gruber. From Dr. Zeger, I obtained average treatment rates and attributable fractions for current and former smokers, by age and gender. For each age, gender, and year, I multiplied counts of smokers times treatment rates to get total cases treated. I then multiplied the total cases treated by the attributable fractions to get the number of smoking attributable cases of treatment in each year from 1954 to 2050. I then added up these annual cases over all the years to get the total smoking attributable disease treatment years. In other words, I just repeatedly applied the formula shown in U.S. Exhibit 17548 titled "Measurements Used in
1 **O**: Did you calculate smoking attributable cases of treatment for other 2 definitions of the Youth Addicted Population, as you did for smoking attributable deaths? 3 4 A: Yes. As I testified earlier, for the Youth Addicted Population, in which adults 5 become members only if they smoked more than five cigarettes a day as youths, we 6 calculated 107.6 million smoking attributable disease treatment years through 2050. 7 When we relaxed the threshold to daily smoking as youths, and thereby included a 8 larger number of adults, we calculated 124.7 million smoking attributable disease 9 treatment years. When we increased the threshold to more than 10 cigarettes a day as 10 youths, and thereby included a smaller number of adults, we calculated 74.6 million 11 smoking attributable disease treatment years. 12 In addition, just as we did for smoking attributable deaths, we looked at disease 13 treatment years for the different addiction standards, but restricting the calculations to 14 adults who smoked before the age of 18, instead before the age of 21. For this group, we 15 calculated 79.3 million, 63.6 million, and 36.5 million disease treatment years 16 respectively for the addiction standards smoked regularly before age 18, smoked more 17 than five cigarettes a day before age 18, and smoked more than 10 cigarettes a day before 18 age 18. 19 **Q**: What would have happened if you had projected out further than 2050? 20 A: We would have accumulated additional smoking attributable disease treatment

21 years, just as we would have accumulated additional smoking attributable deaths if we22 had projected further.

Q: Did your calculations capture all smoking attributable disease treatment years?

3 A: No. As I stated earlier, Dr. Samet testified that smoking causes a number of 4 specific diseases and conditions that are not on our list of major diseases. These include 5 cancer of the liver, cervical cancer, acute myeloid leukemia, peptic ulcer, cataracts, low 6 bone density, and reduced fertility. These diseases and conditions would result in 7 additional disease treatment years and health care costs beyond what our calculations 8 captured. In addition, our calculations did not include disease treatment years that stem 9 from exposure to secondhand smoke. 10 **O**: Doctor, I am now going to move on from disease treatment years to another 11 adverse health effect. You testified earlier that in addition to estimating the 12 smoking attributable deaths, years of life lost, and annual cases of treatment for the 13 major diseases, you also estimated the smoking attributable health care costs 14 associated with treating people with major disease. Is that correct? 15 A: Yes. 16 Returning again to U.S. Exhibit 17406, titled "Adverse Health Effects of **O**: 17 Smoking Among the 57 Million Adults in the Youth Addicted Population," you 18 testified that this exhibit gives your estimated smoking attributable health care 19 costs, is that correct? 20 A: Yes. We calculated that in the Youth Addicted Population, for people with one of 21 the major diseases there will be \$839.8 billion in smoking attributable health care costs

22 through 2050.

1 **O**: Doctor, please direct your attention to U.S. Exhibit 17545, titled "Health 2 Care Costs for Lung Cancer, COPD, CHD, Stroke ... Contributors to the Analysis." 3 What does this exhibit show? 4 A: As with other measures of adverse health effects, calculating smoking attributable 5 health care costs was a collaborative effort. This exhibit lists people who contributed to 6 that effort. 7 The actual cost calculation was done collaboratively by Dr. Zeger, Dr. Miller, and 8 me. As with cases treated, we first obtained counts of smokers in the Youth Addicted 9 Population from Dr. Gruber, and the list of major diseases from Dr. Samet. 10 Dr. Zeger's primary responsibility was to calculate the smoking attributable 11 fraction of expenditures, or SAFE, from the National Medical Expenditure Survey. For 12 health care dollars, this measure is analogous to the attributable fraction measure that I 13 discussed for disease treatment years and for premature deaths. The SAFE represents the 14 fraction of total health care costs among smokers of a given age or gender that is smoking 15 attributable. 16 Dr. Miller's primary responsibilities were (1) to calculate the average health care 17 costs for smokers and never smokers, by age and gender, (2) to calculate the rate at which 18 these average expenditures increased from 1954 to 2000, and (3) to project the future rate of increase in these average costs through 2050. 19 20 My primary responsibility was to put these pieces together and calculate the total 21 smoking attributable health care costs for the Youth Addicted Population.

2	obtain	ed from Dr. Franklin M. Fisher. This yielded the \$839.8 billion in smoking
3	attribu	table health care costs.
4	Q:	What is Dr. Miller's background and expertise?
5	A:	His full name is Leonard S. Miller.
6		He received a Ph.D. in 1967 in economics from the University of California at
7	Berkel	ley. He served on the faculty of the School of Social Welfare at the University of
8	Califo	rnia at Berkeley from 1971 to 2003, becoming a full professor in 1985. He retired
9	as a fu	ll-time faculty member in 2003, but maintains a continuing relationship with the
10	depart	ment as an emeritus professor.
11		He has written or co-authored 54 articles, 2 books, and 23 monographs and book

I then converted these costs into 2001 dollars by applying discount rates that I

1

chapters in the field of health economics, and on economic analyses of education and
welfare. He has been studying and writing about different aspects of health care costs
since 1985. With regard to smoking attributable health care costs in particular, he has coauthored seven peer reviewed articles that estimate these costs in different populations.
He has also co-authored two monographs and a book chapter on smoking attributable
health care costs.

As I mentioned earlier, Dr. Miller worked with Dr. Zeger and me in estimating health care costs in the lawsuit brought by State of Minnesota and Blue Cross Blue Shield of Minnesota against the tobacco companies, which was settled during trial in 1998. Dr. Miller also served as a consultant to the state attorneys general when they crafted the Master Settlement Agreement that resolved state litigations against the tobacco industry.

1 His calculations were used to determine how to apportion the industry payments among 2 the individual states.

3 **O**: Doctor Wyant, directing your attention to U.S. Exhibit 78537, is this Doctor 4 Millers's curriculum vita?

5 A: Yes. It is current as of December 2003. It lists the articles, books, and

6 monographs I just mentioned, including more than 25 articles in peer reviewed scientific 7 journals on which Dr. Miller was a co-author and more than 15 articles in peer reviewed 8 scientific journals on which Dr. Miller was the lead author.

9 0:

What is Dr. Fisher's background and expertise?

10 His full name is Franklin M. Fisher. Until June 30, 2004, he was the Jane A:

11 Berkowitz Carlton and Dennis William Carlton professor of economics at the

12 Massachusetts Institute of Technology, or MIT, until June 30, 2004. On that date he

13 retired from MIT. He is now a professor of economics emeritus.

14 He received a B.A. summa cum laude in economics from Harvard in 1956, an

15 M.A. in economics from Harvard in 1957, and a Ph.D. in economics from Harvard in

16 1960. He was a professor at MIT from 1960 to 2004, and a full professor from 1965 to

17 2004. Before MIT he was an assistant professor of economics at the University of

18 Chicago. He has also taught as a visiting professor at Harvard, Oxford, the London

19 School of Economics, Hebrew University, and several other institutions.

20 He is a former president of the Econometric Society, and a Fellow of that society 21 and of the American Academy of Arts and Sciences. He has received a number of 22 awards and honors, and is the author or co-author of over 15 books and well over 100 23 peer reviewed articles.

Q: Doctor Wyant, directing your attention to U.S. Exhibit 78531, is this Doctor Fisher's curriculum vita?

3 A: Yes. It is current as of December 2003.

4 Doctor, turning once more to U.S. Exhibit 17548, titled "Measurements Used 0: 5 in Epidemiology -- Example Calculations," what does this exhibit show? 6 A: This exhibit shows that the basic logic of the health care costs calculation 7 parallels the logic of other calculations that I have already described. In this exhibit, 8 there are three rows in which the text is colored red. The first two of these rows revisit 9 the logic used to calculate smoking attributable deaths and smoking attributable cases 10 treated, respectively. 11 I have not previously discussed the third row in this exhibit. This is the row that 12 focuses on health care costs. The flow of calculations for health care costs follows the 13 same pattern that the Court saw for deaths and cases treated. 14 We start with the number of smokers in the Youth Addicted Population. We then 15 multiply by the average annual health care costs per smoker. The product of this 16 multiplication is the total health care costs for smokers during a calendar year. Then, we 17 multiply the total health care costs by the attributable fraction of health care costs. This last multiplication yields the subset of the total health care costs that is attributable to 18 19 smoking. 20 **O**: Doctor Wyant, looking at the exhibit as a whole, what does the first column 21 show? 22 A: The first column is always the number of smokers in the Youth Addicted

23 Population. These are the counts we obtained from Dr. Gruber.

1	As I said previously, Doctor Gruber provided counts broken down by age, gender,
2	calendar year, and whether the smokers are current smokers or former smokers. The
3	health care costs logic that is shown in this exhibit was applied over and over again, for
4	each unique combination of age, gender, calendar year, and smoking status, just as was
5	the case for deaths and cases treated. As we applied the basic calculation logic to
6	different groups of smokers, the individual components of the calculation were modified
7	as appropriate to reflect the specific group that was being addressed. In other words,
8	when we were addressing 66 year-old male current smokers in Dr. Gruber's counts, we
9	used average costs for 66 year-old male current smokers, smoking attributable fractions
10	for 66 year-old male current smokers, and so on.
11	We restricted these cost calculations to the adults in the Youth Addicted
12	Population who had become addicted as youths.
13	Q: Doctor, moving to the right, please describe the second column.
14	A: The second column is always a rate or an average. So moving down the rows, we
15	see the death rate, the treatment rate, and the average health care costs. Mathematically,
16	a rate and an average are really the same. The death rate, for example, is the total number
17	of deaths divided by the total number of smokers. Similarly, "average health care costs"
18	is the total number of dollars divided by the total number of smokers.
19	These rates and averages are used to determine how many deaths, cases of
20	treatment, or health care dollars there are in total for each group of smokers supplied
21	from Dr. Gruber.

1	I already described how we calculated death and treatment rates. Dr. Miller
2	calculated the average annual health care costs that appear in the third row of U.S.
3	Exhibit 17548.
4	Q: Doctor Wyant, what does the word "annual" signify with regard to health
5	care costs in this exhibit?
6	A: We did all of our adverse health effect calculations separately for each calendar
7	year. Health care costs are no exception. The term "average annual health care costs"
8	refers to the average costs per smoker in a calendar year.
9	Health care costs have increased over time, and are projected to increase in the
10	future as well. Dr. Miller took increasing health care costs into account when he
11	calculated the average costs per person in each calendar year.
12	As an example, take 66 year-old male current smokers, which is a group we have
13	used as an example in several of these exhibits. I will round Dr. Miller's calculations for
14	this group to the nearest \$100, for ease of exposition. For 1990, he calculated the average
15	annual health care costs for smokers in this group at \$4,000 per person. For 2000, he
16	calculated these costs at \$6,500 per person, and for 2010 at \$10,300 per person.
17	Q: Doctor, how did Dr. Miller go about determining average health care costs
18	over time?
19	A: Doctor Miller analyzed data from a number of sources. For past trends, there is a
20	long historic record that is tracked by the Consumer Price Index, which has a medical
21	care component. In addition, the government has periodically conducted surveys such as
22	the National Medical Expenditure Survey that provide substantial detail on how average
23	costs vary by age, gender, and smoking status. Dr. Miller used these sources to calculate

average health care costs historically and to determine a long-term cost trend with which
 to project future costs. There are widely used statistical methods to make such
 calculations. They are referred to as "time series" methods. Dr. Miller applied those
 methods here.

5 Q: Is projecting health care costs into the future a standard thing to do in health
6 economics?

A: Yes. For example, the Centers for Medicare and Medicaid Services (CMS), the government agency that administers the Medicare and Medicaid programs, has both short-term and long-term forecasting groups that routinely project health care costs up to 75 years in the future, in order to assess the solvency of these programs. Actuarial and accounting firms make similar projections, and organizations such as health insurers and employers who provide health benefits rely on such projections in planning their future operating budgets and benefits packages.

14 Somewhat similar projections are often made in court cases involving permanent 15 disability, where part of the damages is often the expected lifetime medical costs of the 16 injured party.

17 Q: Doctor Wyant, are sources such as those used by Doctor Miller commonly 18 relied upon in such projections?

A: Yes. I have already described the National Medical Expenditure Survey, and how
it is a standard source for calculating such quantities as average health care costs by age,
gender, and smoking status. The Consumer Price Index and its medical components are
frequently relied upon to determine trends and project them into the future. In addition,
Dr. Miller used the National Health Accounts to adjust and check his calculations. The

National Health Accounts are the government's official data source for annual aggregate
 health care spending in the United States.

However, every analyst faces choices among a number of sources that can be used
in making projections. Dr. Miller chose to project forward from the 1987 National
Medical Expenditure Survey, because more recent surveys have been more limited in
scope. Checking his projected costs against recent costs reported in the National Health
Accounts indicates that his costs are currently low by 8-9%.

8 In addition, his projected rate of cost growth for future years – which he based on 9 extrapolated trends in the Medical Consumer Price Index -- is lower than rates projected 10 by other forecasters. As a result, Dr. Miller described his projections as "lower bound" 11 estimates that understate current health care costs, and are likely to understate future 12 health care costs as well.

Q: Doctor, earlier you described in general terms the conversion of health care
costs to 2001 dollars. Just to be clear, did you apply such a conversion to all of the
health care costs that you calculated using Dr. Miller's averages?

16 A: Yes. As I noted earlier, it is hard to assess and compare streams of costs that 17 extend over many years. Commonly, these costs are converted to value as of a reference 18 year, and we converted them to 2001 dollars. In the example I discussed just a moment 19 ago for 66 year-old current smokers, the unconverted average dollars calculated by Dr. 20 Miller were \$4,000 for 1990, \$6,500 for 2000, and \$10,300 for 2010. Converted to 2001 dollars, which are the dollars we used in calculating and presenting total smoking 21 22 attributable health care costs for the Youth Addicted Population, these figures become 23 \$7,200, \$6,900, and \$4,400.

1 Most of the health care costs for the Youth Addicted Population will occur in the 2 future. The conversion to 2001 dollars reduces future costs substantially from their 3 nominal amounts in the years in which they are projected to occur, and the further you go 4 into the future, the greater the reduction.

5 Q: Doctor, can you briefly describe the calculations that reduced the future costs
6 to 2001 dollars?

7 A: Conversion to 2001 dollars involves the application of what are called "discount 8 rates." As I said earlier, we obtained discount rates from Dr. Fisher. Discounting future 9 dollars involves a calculation that is basically a compound interest calculation in reverse. 10 For example, take a savings account with a 5% interest rate, compounded annually. The 11 value of the account next year is 1.05 times the value this year. The value the following 12 year is again 1.05 times greater, or 1.05 times 1.05 times the value this year. Discounting 13 an amount of money two years in the future, assuming a 5% discount rate, involves 14 dividing that future amount by a quantity equal to 1.05 times 1.05. 15 In our conversion to 2001 dollars, we estimated the proportion of health care costs 16 in the Youth Addicted Population that will be paid by various payers – private health 17 insurers, smokers and their families out of pocket, the federal government through 18 Medicare, and state governments through Medicaid and other state health programs. For 19 each of these payers, Dr. Fisher provided discount rates that basically reflect the different 20 interest rates these payers would have to pay to borrow money. For example, for the out 21 of pocket costs, Dr. Fisher used average credit card interest rates, and for the insurers, the

22 average private cost of capital for insurers.

Q: Doctor Wyant, is it your understanding that these are standard ways to proceed in converting to present value as of 2001?

A: Yes, with one qualification. There are a number of discount rates that experts typically use to reduce future dollars to 2001 dollars. I understand that Dr. Fisher consistently chose rates that, among the future discount rates that are commonly used, would be among the most conservative. That is, from the commonly used future discount rates that would be appropriate, he chose rates that would yield among the lowest total smoking attributable health care costs in the Youth Addicted Population after converting to 2001 dollars.

10 Q: Doctor Wyant, health care costs prior to 2001 were also converted to 2001 11 dollars in your calculations, is that correct?

12 A: Yes. This calculation was less important in the sense that the great majority of the smoking attributable health care costs for the Youth Addicted Population will occur in 13 14 the future. The conversion of pre-2000 costs involved increasing pre-2001 health care 15 costs according to appropriate annual interest rates for each of the payers. Dr. Fisher 16 again provided interest rates appropriate to this task. I understand that, from the 17 commonly used interest rates that would be appropriate, he again chose rates that would 18 yield among the lowest total smoking attributable health care costs after converting to 19 2001 dollars.

1 Q: Doctor, directing your attention again to U.S. Exhibit 17548 titled

2 "Measurements Used in Epidemiology -- Example Calculations," the average annual

3 health care costs per smoker that you have been describing are the average costs

4 referenced in the third row, second column, is that correct?

A: Yes. To make sure we stay oriented here, each row focuses on one of the
measures of smoking attributable adverse health effects. The third row focuses on health
care costs. The second column, as I have described, shows the annual rates or averages
used in calculating the different measures. For the health care costs – the subject of the
third row -- the second column does refer to the average annual health care costs per
smoker that I have been discussing, which were calculated by Dr. Miller.

11 Q: Please describe the third column of this exhibit.

12 A: Not all the deaths, cases of treatment for major diseases, or health care costs that 13 occur among smokers are attributable to their smoking. As I described earlier, we 14 calculate an epidemiologic measure called the "attributable fraction" to calculate the 15 excess portion of deaths, cases of treatment, or health care costs that are caused by 16 smoking. The third column in the exhibit shows how the attributable fractions of deaths, 17 cases of treatment, and health care costs enter into the calculations of the respective 18 adverse health effect measures for the Youth Addicted Population. I described earlier our sources for the attributable fractions for deaths and for 19 20 cases of treatment. Dr. Zeger calculated our attributable fractions for health care costs, 21 using the National Medical Expenditure Survey. He described the basic method that he 22 used in his peer reviewed article that is excerpted in U.S. Exhibit 17416 titled "Diseases 23 Cases and Their Medical Costs: An Analysis of the National Medical Expenditure

Survey." I referred to this exhibit earlier in my testimony, because it also relates to Dr.
 Zeger's calculations regarding the 107.6 million smoking attributable disease treatment
 years.

4 In the peer reviewed article referenced in U.S. Exhibit 17416, Dr. Zeger at times 5 uses the expression "smoking attributable fraction of expenditures," abbreviated as 6 SAFE. The SAFE is synonymous with "the smoking attributable fraction of health care 7 costs" or "the attributable fraction of health care costs," which are the phrases I typically 8 use. In fact, in this exhibit the Court can see that Dr. Zeger and his colleagues also used 9 more than one form of expression -- the term "costs" attributable to smoking appears in the title, and the term "expenditures" attributable to smoking appears in the quote from 10 11 page 139.

12 Q: How did Dr. Zeger go about calculating the smoking attributable fraction of 13 health care costs?

A: First, he focused on major diseases that are caused by smoking. By "major
diseases," I continue to mean the major diseases on the list provided by Dr. Samet, which
I described earlier in the context of smoking attributable cases of treatment in the Youth
Addicted Population. The \$839.8 billion smoking attributable health cost figure for the
Youth Addicted Population represents only those costs that are associated with people
being treated for one of the major diseases caused by smoking.

Dr. Samet, in his earlier testimony in this case, discussed many additional diseases and conditions that are caused by smoking that are not on the "major disease" list. As the second quote in U.S. Exhibit 17416 from Dr. Zeger's peer reviewed 2003 article notes, focusing on the major diseases yields cost estimates that are lower than what have been reported elsewhere in the peer reviewed literature. "Our approach is
 conservative because we have focused only upon the major diseases caused by smoking
"

4 Second, Dr. Zeger calculated the smoking attributable fraction of cases of 5 treatment for major disease, as I have already described in my testimony. He also, based 6 on people participating in the National Medical Expenditure Survey, estimated the 7 number of smokers in the United States who were being treated for one of the major 8 diseases, and how many of these cases were smoking attributable. That is, as I have 9 described, he calculated the number of excess cases occurring among the smokers by comparing them to similar never smokers. 10 What remained was to calculate the excess annual cost that is associated with 11 12 being treated for one of the major diseases above and beyond the baseline average cost of

people without the disease, but otherwise similar to those being treated. Once Dr. Zeger had reliable estimates of both the number of smoking attributable cases, and also how expensive it was to be a case, he could determine for groups of smokers of any age or gender both their total health care costs, and the portion of those costs attributable to the excess cases of treatment among the smokers.

18 Q: Doctor Wyant, turning your attention to U.S. Exhibit 17547, titled

19 "Measurements Used in Epidemiology – Example Calculations: Excess Cost

20 Attributable to Disease," can you describe what this exhibit shows?

21 A: This exhibit shows via a simplified hypothetical example how Dr. Zeger

22 calculated the fraction of health care costs that are attributable to having one of the major

23 diseases. At the top, the Court can see a group of people who were being treated for a

major disease during the year of the National Medical Expenditure Survey. The health
care costs for these people averaged \$15,000 apiece for the year. In the next line, the
Court can see a group of similar people who were not treated for a major disease during
the year of the survey. The health care costs for these people averaged \$700 apiece for
the survey year.

In the next lines, the Court can see that the relative costs for people being treated
are 21.4 times higher than the costs for people without the disease, and that on average
the costs that are attributable to being treated for the disease were \$14,300 per person -\$15,000 minus \$700. In the final line, we see the attributable fraction of costs -- \$14,300
divided by \$15,000, or 95%.

Each of these calculations is analogous to calculations we saw in previous exhibits that demonstrated the calculation of attributable risk. Instead of "relative risk" we have "relative cost," instead of "attributable risk" we have "attributable cost," and so on. The calculations in the previous exhibits estimated the extent to which smoking elevates the risk of being treated for a disease. Here, similar calculations estimate the extent to which being treated for a disease elevates the annual health care costs.

17

Q: In what way is this example simplified?

A: Well, the numbers are hypothetical, and chosen for ease of exposition. But more importantly, the actual average costs that we calculated were done at a much greater level of detail, just as I described earlier for the calculations of treatment rates. Dr. Zeger used multivariate statistical methods of the sort that were briefly described by Dr. Samet in his earlier testimony in this case. Using these methods, Dr. Zeger could calculate expected costs for unique combinations of characteristics such as age, gender, smoking status, household income level, marital status, and education. The methods allowed Dr.Zeger to compare "like to like" in a sophisticated manner. He could isolate the extent to which costs were higher due to treatment for a major disease by comparing the costs for treated people with the costs for untreated people who were otherwise similar to the treated people with respect to age, gender, smoking status, income level, and so on.

6 In recent years, increased computer power has allowed the expanded use of 7 computer intensive multivariate methods in statistics that do not require as many 8 simplifying assumptions as some of the earlier multivariate methods. Dr. Zeger and his 9 colleagues applied such computer intensive methods, which are described in the field of 10 statistics by phrases such as "semi-parametric K x (1:10) matching." The expansion of 11 such phrases into a detailed schematic diagram of exact computational steps is not 12 necessary to understand the essence of what was accomplished. Dr. Zeger and his 13 colleagues used sophisticated procedures that address some possible shortcomings in 14 methods that were used in other peer reviewed studies of smoking attributable health care 15 costs. But at the end of the day, Dr. Zeger and his colleagues obtained results for major 16 diseases that were very close to results obtained using multivariate methods commonly 17 seen in the peer reviewed health cost literature. To the extent there were differences, the 18 methods used by Dr. Zeger and his co-authors yielded smoking attributable fractions that 19 were lower than would have been the case had they limited themselves to earlier 20 methods. As they stated on pages 147 and 148 of their peer reviewed article from 2003, 21 "... the estimated SAFEs using our matching algorithm are conservative relative to the 22 estimates using the [earlier] log-normal model ... Our statistical methods are 23 complementary to those used by previous investigators."

Q: Doctor, please direct your attention once again to U.S. Exhibit 17548 titled
 "Measurements Used in Epidemiology -- Example Calculations." Where do Dr.
 Zeger's calculations that you just described appear on this chart?
 A: The last line of the chart, as I said earlier, summarizes the basic flow of

calculations for smoking attributable health care costs. The last component at the right is
the smoking attributable fraction of health care costs. Dr. Zeger's calculations relate to
that component.

8 Earlier when I talked about smoking attributable cases of treatment, I described 9 how Dr. Gruber categorized the Youth Addicted Population in any given year according 10 to "current" and "former" smoking status – a level of categorization that is frequently 11 relied upon in Surgeon General's reports and other scientific publications. Dr. Zeger 12 carried out calculations at a more detailed level – his formulas, for example, could be 13 used to generate estimates of smoking attributable fractions not just for former smokers, 14 but for former smokers who smoked a pack a day but quit five years ago, smoked two 15 packs a day and quit ten years ago, and so on. But once you have the ability to make 16 detail-level calculations, it is relatively straightforward to consolidate them. Using the 17 National Medical Expenditure Survey, Dr.Zeger could apply his detail-level formulas to 18 all 66 year-old female former smokers in the survey, for example, and generate a 19 consolidated smoking attributable fraction of health care costs applicable to this group. 20 It is those smoking attributable fractions of health care costs - by age, gender, and current/former smoking status - that comprise this final calculation component in U.S. 21 22 Exhibit 17548.

Q: Did you make additional calculations to assess the reliability of your health care cost calculations?

A: We made several such calculations. I mentioned earlier in my testimony that in addition to the major diseases, there are other smoking-caused diseases and conditions that Dr. Samet identified in his testimony to the Court. These additional diseases and conditions lead to additional health care costs beyond the \$839.8 billion for major diseases.

8 I listed these additional diseases and conditions earlier. One of them was the 9 condition Dr. Samet referred to as general diminished health due to smoking. He listed 10 several ways in which diminished health manifests itself, one of which was that smokers 11 are more likely to report that they are in poor health.

12 The National Medical Expenditure Survey asked participants to describe their health as "poor," "fair," "good," or "excellent". Using methods similar to those we used 13 14 for major diseases, we calculated the extent to which smokers are more likely than 15 similar never smokers to report that they are in fair or poor health, and the extent to 16 which people reporting fair or poor health status tend to have elevated annual health care 17 costs. Just as with the major diseases, we then consolidated for each age, gender and 18 smoking status combination both the elevated costs that are associated with excess cases 19 of fair or poor health among the smokers, and the total costs among the smokers. 20 Dividing these smoking attributable fair-poor health costs by the total costs yielded the 21 smoking attributable fraction of health care costs due to fair-poor health. 22 We multiplied this smoking attributable fraction times the total costs in the Youth 23 Addicted Population to get the additional smoking attributable health care costs related to fair-poor health. When we combine the smoking attributable health care costs from this calculation with those from the major diseases, we obtained a total (in 2001 dollars) of \$1,035 billion for the Youth Addicted Population. Or in other words, we calculated just over a trillion dollars in smoking attributable health care costs for the Youth Addicted Population that were due to the combination of major diseases and fair-poor health.

6 Q: Are there likely to be other sources of smoking attributable health care costs 7 in addition to the major diseases and fair-poor health?

8 A: Yes. The elevated rate at which smokers report fair-poor health is just one 9 manifestation of diminished health. Dr. Samet mentioned several others, such as 10 respiratory problems and increased risk of respiratory infections. He also mentioned 11 other diseases and conditions besides the major diseases and diminished health. Smoking 12 causes cataracts, for example. It is expensive to treat cataracts, but they are treatable. It 13 is questionable whether just because people have cataracts, or have just been successfully 14 treated for cataracts, they will consider themselves to be in poor health Nothing in our 15 calculations would capture the costs of excess cataract surgeries among smokers who 16 consider their health to be good or excellent.

Dr. Samet also described other conditions that would be caused by smoking in the Youth Addicted Population, but would occur among people outside that population. For example, infants and newborns born to members of the Youth Addicted Population will incur costs that are attributable to maternal smoking or secondhand parental smoke. Dr. Samet also testified that smoking during pregnancy and other parental smoking causes premature birth, SIDs, and childhood asthma. Our calculations address only adults in the Youth Addicted Population, but not their children, and would not include such costs.

Q: For major diseases and fair poor health, did you capture all the smoking attributable dollars?

A: No. We did not capture nursing home costs. Smoking causes adverse health
effects such as strokes that often result in smokers being placed in nursing homes. Dr.
Samet discussed this phenomenon in his testimony. Strokes are on our list of major
diseases.

Peer reviewed studies on smoking attributable health care costs often includenursing home fees.

9 Q: Doctor Wyant, what other calculations did you make to assess the reliability 10 of your health care cost calculations?

11 A good way to assess the reliability of any calculation method is to apply that A: 12 method to some standard population, and then compare the results of applying that 13 method with the results that have been obtained by other investigators. A number of 14 analysts have calculated the smoking attributable percentage of health care costs for the 15 United States as a whole, and published these results in peer reviewed articles. We 16 applied our methods to that population, in order to make such a comparison. 17 **Q**: Doctor Wyant, turning your attention to page 1 of U.S. Exhibit 17738, titled 18 "U.S. Health Care Costs in the Peer Reviewed Literature", what does that exhibit 19 show? 20 A: The chart in this exhibit shows six published estimates of the percentage of U.S. 21 health care costs that is attributable to smoking. Each estimate is represented by a circle

22 on the chart. The vertical scale at the left, which is labeled "Smoking Attributable

Fraction," shows the percentages. Using this scale, the Court can see that the estimates
 range from 4.6% to 11.8%.

3 Each of the circles has a letter and a color code indicating the peer reviewed 4 journal in which the particular estimate was published. The six articles were published in 5 five different journals. The journal names appear at the bottom of the chart – The 6 American Journal of Public Health, Morbidity and Mortality Weekly Report, The Journal 7 of Econometrics, Public Health Reports, and Social Science & Medicine. The journal 8 that contained two of the articles was Morbidity and Mortality Weekly Report, a 9 publication of the Centers for Disease Prevention and Control – the CDC. That journal 10 published articles with smoking attributable cost percentages for the United States in 11 1994 and in 2002.

12 The circle at the far right represents the estimate that was published by Dr. Zeger 13 and his colleagues in their 2003 Journal of Econometrics article. That article contains the 14 lowest estimate among the six articles -- that 4.6% of U.S. health care costs are 15 attributable to smoking. But it is not surprising that the methods that were used in that 16 article yield a very conservative estimate. As I discussed earlier, that article, which used 17 calculation methods almost identical to those we used for the Youth Addicted Population, 18 addressed only the costs that were associated with being treated for one of the major 19 diseases caused by smoking. I described how those costs comprise only a subset of total 20 smoking attributable costs.

I discussed this article before. It was summarized in U.S. Exhibit 17416. In the words of one of the quotes that appear in that exhibit, "It is not surprising that this value [4.6%] is slightly lower than the 6-8% range of estimates previously reported (Miller et

Written Direct: Timothy Wyant, Ph.D., US v. PM, 99-cv-02496(D.D.C.)(GK)

Page 129

al. 1998). Our approach is conservative because we have focused only upon the major
 disease caused by smoking and have only considered the effects of smoking on costs that
 are mediated through diseases."

Returning attention to other estimates of the smoking attributable percentage of
U.S. health care cost estimates in the peer reviewed literature, page 1 of U.S. Exhibit
17738, there is a green zone that runs through the middle of the exhibit. It shows that the
middle four of the six estimates fall in the range of 6-9%. As the quote at the right hand
side of the chart indicates, the 2004 Surgeon General's report on page 871 summarized
the published literature as saying that "... costs attributable to smoking comprise 6 to 9%
of the total national health care budget."

Q: Doctor, please direct your attention to another exhibit, U.S. Exhibit 17539
titled "U.S. Health Care Cost Ranges in the Peer Reviewed Literature." What does
that exhibit show?

A: As we saw in the previous exhibit, different estimation methods yield slightly different estimates of the percentage of U.S. health care costs that are attributable to smoking. Periodically, the Surgeon General or other investigators review the published literature and summarize the results of various studies by reporting a range within which the smoking attributable portion of U.S. costs is likely to lie.

19 This exhibit gives three such reported ranges, in the form of quotes from the 20 sources. The first is from the 2004 Surgeon General's report, which says that,

21 "Generally, however, it appears that direct costs attributable to smoking comprise 6 to

22 9% of the total national health care budget. Cost estimates have tended to increase over

23 time, reflecting improvements in methodology, increases in medical expenditures for

smoking-related diseases because of inflation and/or technology, and expansion of the list
of diseases caused by smoking." This is an expanded version of the quote associated
with the "green zone" of estimates in the previous exhibit.

4 The second quote in the exhibit is from a review article in a 2001 issue of the 5 American Journal of Health Promotion that said, "The general conclusion is that smoking 6 exacts a large financial toll and that efforts to reduce smoking offer great potential for 7 cost savings. In annual terms, the medical care costs are 6 to 9% of total personal health 8 expenditures, and very likely closer to 12 to 14%. Estimates have generally increased 9 over time, reflecting better data and better refined and more comprehensive measures of 10 the effect of smoking on health." The portion of this excerpt that stated that smoking 11 attributable health care costs could be as high as 12 to 14% was also quoted in the 2004 12 Surgeon General's report.

The third quote in the exhibit is from a review article in a 1999 issue of Tobacco
Control that said, "The medical costs of smoking in the United States equal, and may
well exceed, the commonly referenced figure of 6-8%."

16Q: Doctor Wyant, please turn your attention again to page 1 of 2 in U.S. Exhibit1717738, titled "U.S. Health Care Costs in the Peer Reviewed Literature." How do the

18 various ranges that you just described apply to this exhibit?

19 A: The green zone, as I said, depicts the 6-9% range reported by the Surgeon

20 General. If we exclude the estimate from the Journal of Econometrics, which is unusual

- among these estimates because it limits itself to major diseases, 4 of the remaining 5
- 22 estimates fall in the green zone. The fifth estimate, at 11.8%, is above the green zone.

But as one of the review articles stated, the actual figure in the U.S. could be as high as
 12 to 14%. The Surgeon General did not disagree with this possibility.

There are other peer reviewed articles besides the six shown in this exhibit that

3

calculated estimates of the percentage of health care costs attributable to smoking. I
selected articles for this exhibit by first taking the articles for which results were
tabulated in the Tobacco Control review article from which I quoted the range of 6 to 8%,
or higher. Then I added the articles I found by surveying the peer reviewed literature that
was published since that Tobacco Control article. I then identified the articles in this
literature that made calculations of the smoking attributable costs in the United States,
expressed as a percentage of total costs.

Q: Doctor Wyant, please turn your attention again to the first page of two in
U.S. Exhibit 17740, titled "U.S. Health Care Costs in the Peer Reviewed Literature
Compared to United States Experts." What does this exhibit show?

A: This exhibit looks like the previous one, with different estimates from the peer reviewed literature represented by circles with letters in the middle that indicate the journal in which the estimates were published. The vertical scale showing smoking attributable percentage of U.S. health care costs still appears at the left, and the green zone showing the 6 to 9% range from the Surgeon General quote is still there.

What's new are the two red circles at the left. The lower one shows what happens when we apply the calculation methods we used to estimate the \$839.8 billion for major diseases in the Youth Addicted Population to the U.S. population in the year of the National Medical Expenditure Survey. This lower estimate is at 4.6%, just like the estimate at the right reported in Dr. Zeger's peer reviewed article. It is, of course, not surprising that these two estimates come out at the same place, since almost identical
 methodologies were used.

The other red circle shows what happens when we apply the calculation methods that we used to estimate the approximately \$1 trillion for major diseases plus fair-poor health in the Youth Addicted Population to the U.S. population as a whole. This application to the United States yields a smoking attributable percentage of 6%, right at the bottom of the green zone.

8 Based on this comparison of our methods to those in the peer reviewed literature, 9 we use methods that give results that are similar to published results, but on the low side. 10 This is expected, because what we were calculating, as one of our measures of the 11 adverse health effects of smoking in the Youth Addicted Population, was the health care 12 costs that are associated with major diseases only -- \$839.8 billion. These diseases are 13 generally among the most studied over time, include the ones that most people associate 14 with smoking, and have been the subject of extensive testimony in this case. But as a 15 measure, this figure is very likely to understate the total smoking attributable health care 16 costs in the Youth Addicted Population by a substantial amount.

Q: Doctor Wyant, please turn your attention again to the second page of the two
pages in this same exhibit, U.S. Exhibit 17740. What does this page show?

19 A: This page lists the full source citations for articles from which the health care cost

20 estimates were drawn. Two of the articles list Dr. Leonard Miller as a co-author. That is

- 21 the same Dr. Miller who worked with Dr. Zeger and me on the Youth Addicted
- 22 Population analysis. He should not be confused with Dr. Vincent Miller, who was a co-
- author on another of the articles.

1	Dr. Leonard Miller, in his previous academic work, calculated the highest of the
2	smoking attributable fractions among these studies of the U.S. population, 11.8%. We
3	did not use his methods in calculating the smoking attributable fractions for the Youth
4	Addicted Population. As I have testified, for the Youth Addicted Population we used
5	smoking attributable fractions calculated by Dr. Zeger. As page 2 of U.S. Exhibit 17740
6	shows, Dr. Zeger's peer reviewed article with Johnson and others in 2003, and
7	application of our Youth Addicted Population formulas to the U.S. population as a whole,
8	both yielded smoking attributable fractions of 4.6%.
9	Dr. Miller did contribute to our analysis of the Youth Addicted Population. His
10	contribution to that calculation, as I have testified, focused on estimating the overall
11	average annual costs for smokers of different ages and genders for the years 1954-2050.
12	In the third column of page 2 of U.S. Exhibit 17740, the Court can see that all of
13	these recent analyses from peer reviewed articles rely on the National Medical
14	Expenditure Survey for their calculation of smoking attributable fractions, just as we did
15	for the Youth Addicted Population. In the second column, we can see that the various
16	investigators – there are 19 in total if you add up the co-authors of the peer reviewed
17	articles – applied smoking attributable fractions from the National Medical Expenditure
18	Survey to the U.S. population for years as recent as 1998. In addition, although it is not
19	shown in this exhibit, the authors of the American Journal of Public Health article, Coller
20	et al, also applied their National Medical Expenditure Survey based smoking attributable
21	fractions to U.S. Medicaid populations in each year from 1970-2010.
22	Some of the variation among estimates reported in the peer reviewed literature is
23	not from technical choices in the multivariate calculation formulas, but from deliberate

1 decisions to focus on certain parts of the population, or certain categories of expenditures. 2 I mentioned that our calculations for the Youth Addicted Population do not include 3 smoking attributable costs for newborns, infants, and children. Some analysts publishing 4 in the literature include such costs; some do not. A similar consideration is illustrated by 5 the asterisks in column 1 of this exhibit. The asterisks show that some of the analysts 6 included smoking attributable nursing home fees in their health care costs, and some did 7 not. We did not include such fees on our calculations for the Youth Addicted Population. 8 **Q**: Doctor Wyant, did you do any other calculations to assess the reliability of 9 your health care cost calculations? 10 A: Yes. I just described a check in which we confirmed that our methods yield 11 results that are reasonable, and likely to understate total health care costs in the Youth 12 Addicted Population. This check involved applying our formulas to a standard 13 population – the population of the United States -- for which a number of other estimates 14 of smoking attributable health care costs have appeared in the peer reviewed literature. 15 Our estimates for the United States were similar to the other published estimates, but 16 tended to be at or just below the low end of the typical range within which these 17 estimates fall. 18 We can go in the other direction as well. That is, we can take some of the 19 methods described by other analysts in the peer reviewed literature, and apply them to the

20 Youth Addicted Population. We can then compare the resulting smoking attributable

21 health care costs to the ones that we calculated for this population. In doing such a

22 comparison, we would want to do more than simply take the overall smoking attributable

23 fraction reported in a peer reviewed article, and apply that fraction to the total health care

costs of the Youth Addicted Population. Such a calculation, if applied to all of these
costs from 1954-2050, would yield a crude estimate of smoking attributable costs that
might suffice in some contexts. But in general, the age and gender mix in any calendar
year for the Youth Addicted Population differs from that in the U.S. as whole, so a better
estimate is produced by applying smoking attributable fractions that are more age and
gender specific.

We obtained such age and gender specific attributable fractions from Dr. Glenn
Harrison. He was a co-author of the American Journal of Public Health article that was
listed in the exhibit that I just discussed. These smoking attributable fractions came from
the multivariate statistical model that he and his co-authors described in that article.

11 Dr. Harrison's model took a much more inclusive look at health care costs than 12 ours did. He did not just focus on costs that are associated with particular diseases and 13 conditions. He estimated smoking attributable costs for all diseases and conditions that 14 smoking can cause, including costs for children and costs related to smoking attributable 15 complications of pregnancy. He did so by simply estimating the extent to which costs 16 among smokers exceed costs among similar never smokers. He did not make the 17 intermediate step that we made – that is, he did not proceed by first estimating the 18 increased number of disease treatment years that occur among smokers, and then 19 estimating the excess costs associated with being treated during the course of a year for 20 one of the major diseases that are caused by smoking.

Dr. Harrison's more inclusive estimates address considerably more than just the smoking attributable costs associated with the major smoking related diseases on the list that Dr. Samet provided to us. Dr. Harrison's estimates also include the smoking

1 attributable costs associated with the complications, sequelae, and precursors of these 2 major diseases. They include smoking attributable costs associated with additional 3 diseases and conditions that Dr. Samet listed in his testimony in this case --such as peptic 4 ulcers, cataracts, and leukemia -- that we did not include on our list of the major diseases. 5 They include smoking attributable costs associated with complications, sequelae, and 6 precursors of these additional diseases and conditions. They include smoking attributable 7 costs associated with all of the manifestations of general diminished health that Dr. Samet 8 discussed in his testimony.

9 In the statistical models that Dr. Harrison designed to address this broad range of 10 costs, he adjusted for more potential confounding factors -- such as insurance coverage, 11 drug abuse, and alcohol abuse -- than Dr. Zeger did in his models. Published statistical 12 models that measure a wide range of smoking attributable costs -- and don't restrict 13 themselves to just costs associated with a limited set of diseases and conditions such as 14 the major diseases that are caused by smoking -- often adjust for more potential 15 confounding factors. As a rough general rule, the more diseases and conditions an 16 analyst addresses, the more potential confounders there are that might affect the 17 relationship between smoking and the extent of the costs that stem from the diseases and 18 conditions.

Application of Dr. Harrison's smoking attributable fractions to the Youth
Addicted Population provides another valid estimate of the smoking attributable health
care costs in that population. Dr. Harrison's methods result in an estimate for the Youth
Addicted Population that comes to more than \$1.4 trillion in 2001 dollars. This figure

1	provides a reasonable indicator of the extent to which focusing on the major diseases, as
2	we chose to do, understates total smoking attributable health care costs in this population.
3	Q: Doctor, what other calculations did you do to assess the reliability of your
4	health care cost calculations?
5	A: Earlier, I described two calculations we made for smoking attributable deaths.
6	We looked at what will happen if one defines the Youth Addicted Population differently.
7	We calculated that, among smokers in the smaller population comprised of people who
8	smoked more than ten cigarettes a day as youths, 9.4 million smoking attributable deaths
9	will occur through 2050. And we calculated that among smokers in the expanded
10	population that includes anybody who smoked regularly as youths, 15.6 million smoking
11	attributable deaths will occur. U.S. Exhibit 17410 summarized how those deaths will
12	distribute over time.
13	We made similar calculations for smoking attributable health care costs.
14	Q: Doctor, looking at U.S. Exhibit 17540 titled "Health Care Costs – Youth
15	Addicted Population." What does this exhibit show?
16	A: This exhibit shows for smoking attributable health care costs what the U.S.
17	Exhibit 17410 showed for smoking attributable deaths. It summarizes results for the two
18	alternative addiction standards that I just mentioned, as well as showing the \$839.8
19	billion estimate for the Youth Addicted Population as I have been defining it. The exhibit
20	also shows how the dollars in these three estimates distribute over time. The table at the
21	bottom of the exhibit shows that if we raise the threshold for entry as adults into the
22	Youth Addicted Population to more than 10 cigarettes a day as youths, the health care
23	costs are projected to be \$584.2 billion. If the threshold for entry stays at more than 5

cigarettes a day as youths, the health care costs are projected to be \$839.8 billion. And if
we relax the threshold for entry as an adult into the Youth Addicted Population to just
regular smoking, the health care costs are projected to be \$972.7 billion. All of these
costs are in 2001 dollars.

5 The chart at the top of the exhibit shows how the smoking attributable health care 6 costs distribute over time during the period 1954 to 2050 – rising to a peak in 2022, and 7 then declining. The line at the top set of bars shows the annual costs for the regular 8 smoking scenario, the line at the top of the middle set of bars shows the annual costs for 9 the Youth Addicted Population – that is, for the more than 5 cigarettes a day scenario – 10 and the line at the top of the lower bars shows the annual costs for the more than 10 11 cigarettes a day scenario.

12 The trends for all three scenarios are similar. The number of annual smoking 13 attributable deaths increases each year from 2001 through 2022, and then declines each 14 year through 2050. In the peak year in 2022, we projected about \$19 billion, \$17 billion, 15 and \$9 billion in annual costs for the regular smoking, more than 5 cigarettes a day, and 16 more than 10 cigarettes a day scenarios, respectively. This ranking may seem counter-17 intuitive at times – why are the costs for more than 10 cigarettes a day lower than the 18 costs for more than 5 cigarettes a day? This ranking order occurs because these smoking 19 levels are thresholds for entry into the populations. On a per person basis, people who 20 smoke more than 10 cigarettes a day on average will incur more health care costs than 21 people who smoke more than 5 cigarettes a day. But there are far fewer people who 22 smoked more than 10 cigarettes a day as youths than there are people who smoked more 23 than 5 cigarettes a day as youths. When we chart the total health care costs, as in this

exhibit, it is the much smaller number of smokers in the more than 10 cigarette a day
 category that results in that set of bars being the shortest in the chart.

All these costs are expressed in 2001 dollars. The costs in the peak year of 2022,
for example, are heavily discounted to reflect the fact that future dollars are worth less
than present dollars.

We projected that substantial health care costs will still be occurring in 2050 –
about \$8.0 billion, \$6.5 billion, and \$5.5 billion in annual costs for the daily smoking,
more than 5 cigarettes a day, and more than 10 cigarettes a day scenarios, respectively.
The fact that we stopped accumulating costs as of 2050 tends to make estimates like the
\$839.8 billion for major diseases in the Youth Addicted Population conservative. We
would expect additional smoking attributable costs to occur after that year.

12 Q: Doctor Wyant, what is multiple imputation?

A: In statistical data sources such as the National Medical Expenditure Survey, for
example, there is often some missing information. Some people refuse to answer or
forget to answer certain questions. Multiple imputation is a statistical method for making
appropriate adjustments for missing information of this sort.

17 Q: Did you use multiple imputation in your examination of smoking attributable
18 health care costs?

19 A: Yes. Dr. Zeger used multiple imputation in both his peer reviewed study from

20 2003, and in his statistical calculations for estimating smoking attributable health care

21 costs in the Youth Addicted Population.

1

Q: How important was multiple imputation, in this context?

2 A: Not very. Adjustment for missing information in the National Medical 3 Expenditure Survey, based on Dr. Zeger's multiple imputation calculations, did not 4 materially affect his estimates. Looking again at U.S. Exhibit 17416, he and his co-5 authors stated in their 2003 peer reviewed article, "Our estimates were not sensitive to the 6 adjustment for missing data, therefore only the estimates based on the complete data are 7 presented here." 8 **Q**: Doctor Wyant, to the extent that multiple imputation did change your health 9 care cost estimates, in what direction was the change? 10 A: For the Youth Addicted Population, using a multiple imputation adjustment to 11 adjust for missing information made the smoking attributable health care cost estimates 12 go up.

13 Q: Did you use this higher, adjusted estimate?

A: No. It is the lower, unadjusted estimate that results in our \$839.8 billion in
smoking attributable health care costs.

16 Q: Have any of defendant's experts recommended the use of multiple

17 imputation in this situation?

18 A: Yes. Dr. Donald B. Rubin, has recommended the use of multiple imputation for

19 smoking cost studies that rely on the National Medical Expenditure Survey. He has done

- 20 so in a number of court cases, and in at least one peer reviewed article that I know of. He
- 21 has also suggested some detailed methods for calculating this multiple imputation

22 adjustment.

1	Q: In the materials that you have reviewed, have you ever seen Dr. Rubin
2	actually report the results of doing a multiple imputation adjustment to the National
3	Medical Expenditure Survey, as far as how such an adjustment affects smoking
4	attributable health care cost estimates?
5	A: No.
6	Q: Doctor Wyant, you have covered a number of aspects of smoking
7	attributable health care costs, and described several calculations. Can you give a
8	brief summary of what these various aspects and calculations tell us about health
9	care costs in the Youth Addicted Population?
10	A: At the beginning of my testimony, I listed four main ideas that are integral to the
11	assessment of adverse health effects caused by smoking in the Youth Addicted
12	Population. All of these main ideas play a role in the health care cost calculations.
13	The first main idea was that the scale of smoking attributable adverse health
14	effects is enormous. I have described how smoking has been widely estimated to be
15	responsible for 6 to 9% or more of the total annual health care costs in the United States.
16	In the Youth Addicted Population, we project that smoking attributable costs will likely
17	total \$839.8 billion just for people being treated for the major diseases.
18	The second main idea was that most of the adverse health effects from smoking in
19	the Youth Addicted Population will occur in the future. In U.S. Exhibit 17540 I showed
20	how the smoking attributable health care costs in the Youth Addicted Population are
21	likely to distribute over time, with a peak in 2022 and substantial costs still occurring in
22	2050.

1 The third main idea was that there have been many studies of smoking 2 attributable adverse health effects, and many peer reviewed articles summarizing the 3 results. For smoking attributable health care costs, I described six such articles that have 4 recently been published. I also described the findings on health care costs that were 5 reported in the 2004 Surgeon General's report, and I provided excerpts from other recent 6 articles that summarize the generally accepted findings from the peer reviewed literature 7 to date on smoking attributable health care costs.

8 The fourth main idea was that smoking causes a wide variety of adverse health 9 effects. Our \$839.8 billion estimate for the Youth Addicted Population was only for 10 people being treated for the major diseases such as lung cancer, COPD, CHD, and stroke. 11 I showed how application of more inclusive calculation formulas, developed by other 12 analysts in peer reviewed studies, suggest that costs in the Youth Addicted Population 13 could be as high as \$1.4 trillion for the full range of diseases and conditions that are 14 caused by smoking.

Q: Doctor, do health care costs have some particular importance among the
different measures you have discussed?

A: Smoking attributable health care costs represent only one of several measures of
adverse health effects that we calculated – we also calculated deaths, years of life lost,
and disease treatment years due to smoking in the Youth Addicted Population. I have
devoted more words of testimony to health care costs than to some of these other
measures. The extra words for health care costs do not reflect any additional importance
for smoking attributable health care costs as a measure. I needed more words because
1 estimating smoking attributable health care costs involved somewhat more complicated 2 calculation formulas than the other adverse health measures.

3

Smoking attributable health care costs represent just one measure of the adverse 4 impact of smoking in the Youth Addicted Population. This measure is no more important 5 than any of the others. Health care costs would not necessarily be the most important of 6 the measures I have discussed even if we were to restrict ourselves to monetary measures 7 of adverse impact. Epidemiologists and health economists often estimate the value of a 8 year of life lost in order to assess the importance of some public health problem. If one 9 were to multiply our projections of 13.4 million deaths or 173.5 million years of life lost in the Youth Addicted Population by the dollar values typically used in such assessments, 10 11 the resulting total dollars would far exceed the \$839.8 billion I have reported here.

12 **Q**: Doctor Wyant, please direct your attention to U.S. Exhibit 17417, titled "Dr. 13 Wecker's Adjusted Calculation of Smoking Attributable Health Care Costs." What 14 does this exhibit show?

15 A: William Wecker, Ph.D., is a statistician and applied mathematician whom 16 defendants have listed as an expert witness in this case. This exhibit displays a computer 17 printout that Dr. Wecker produced in February 2005. His February 2005 printout 18 corrected a previous version he had produced in December 2003. The earlier printout 19 contained some calculation errors that were identified by experts for the United States. 20 Dr. Wecker's printout summarizes adjustments he made to our \$839.8 billion 21 health care cost calculation. His adjustments purport to demonstrate that our calculation 22 overstated the smoking attributable health care costs that will occur in Youth Addicted 23 Population.

Q: What does U.S. Exhibit 17737, titled "Dr. Wecker's Adjusted Calculation of Smoking Attributable Health Care Costs (Highlighted)" show?

A: This exhibit shows Dr. Wecker's printout, but this time I have added some
highlighting to make his printout easier to understand. Towards the upper right, I have
highlighted the figure \$839,823,995,602. This figure represents Dr. Wecker's replication
of our smoking attributable health care costs calculation, which in rounded terms comes
to \$839.8 billion.

8 He then made four adjustments to the \$839.8 billion figure. Each subsequent line 9 in the printout shows the result of one of his adjustments. After making his four 10 adjustments, he arrived at the figure that is highlighted at the bottom right in this exhibit. 11 This highlighted figure, if we round it to the nearest tenth of a billion, comes to \$272.7 12 billion.

Another highlighted figure of 32% appears just to the left of the \$272.7 billion
figure. Dr. Wecker's adjusted health care costs calculation of \$272.7 billion equals 32%
of our health care cost figure of \$839.8 billion.

16 Q: Doctor Wyant, what can you say about these adjustments?

A: At one level we have little dispute with Dr. Wecker. Earlier in my testimony, I
tried to convey a general sense of the enormous magnitude of the adverse health effects
of smoking. I did so by characterizing disagreements as in a sense focusing on whether
this magnitude is better described as "enormous" or "colossal."

For health care costs, Dr. Wecker apparently agrees with us that, for the Youth Addicted Population, the smoking attributable costs are likely to be in the hundreds of billions of dollars. With regard to this particular measure of the adverse health effects of smoking, our dispute with him is over how many hundreds of billions of dollars. We
 calculated over \$800 billion. Dr. Wecker proposed some adjustments that resulted in a
 figure more like \$300 billion.

- 4 Q: Do you agree with Dr. Wecker's adjustments?
- 5 A: No. In my opinion, none of them are justified.

Q: Doctor, before discussing why you disagree with Dr. Wecker's proposed
adjustments to your \$839.8 billion health care cost figure, can you briefly describe

8 what adjustments Dr. Wecker made to your calculations of 13.4 million deaths and

9 173.5 million years of life lost in the Youth Addicted Population?

10 A: He didn't make any, to my knowledge.

He did at one point in his expert report criticize us in general terms for using "crude," "raw," or "uncontrolled" smoking attributable mortality rates. Dr. Wecker's three terms, as he noted in his report, are synonymous. They mean that we used ageadjusted mortality rates, separately by gender, in making our calculations. We did not adjust for other potential confounding factors.

In fact, use of age and gender adjusted rates is so common in epidemiology that analysts sometimes refer to such rates as "raw" rates. But this is not a pejorative term. It simply means the "basic" or "standard" or "simple age-adjusted" rates.

- 19 Dr. Wecker's original suggestion that age-adjusted rates do not accurately capture
- 20 the effects of smoking is contradicted by the peer reviewed literature on smoking
- 21 attributable mortality. By the time of his most recent deposition in December 2004, Dr.
- 22 Wecker said, "I don't think the mortality calculation has got that much potential to get far

off." (Deposition of William E. Wecker, United States v. Philip Morris, et al., December
 17, 2004, 202:19-202:22.)

3 0: Doctor Wyant, directing your attention once more to U.S. Exhibit 18240 4 titled "Age adjusted Mortality Rates in the Peer Reviewed Literature." Does this 5 exhibit have any relevance to your point about the peer reviewed literature 6 contradicting Dr. Wecker with regard to age-adjusted mortality rates? 7 A: Yes. This exhibit, as I described at some length earlier, gives excerpts from a 8 recent peer reviewed article, and from two Surgeon General's reports. All of them say 9 that additional adjustment of mortality rates for factors other than age and gender is neither necessary nor important. For example, in the journal article published in the 10 11 Journal of the American Medical Association in 2000, the authors said that "... estimates 12 of deaths caused by smoking are not substantially altered by adjustment for behavioral 13 and demographic factors associated with smoking beyond the current adjustments for age 14 and sex." This and other statements that are summarized in this exhibit support our view, 15 and also the most recent deposition testimony of Dr. Wecker, that the age-adjusted 16 mortality rates that we used are valid and appropriate. 17 **Q**: Doctor Wyant, did other individuals who appear on defendants' witness list

18 comment on your mortality calculations?

A: Yes. Donald B. Rubin, Ph.D., appears on that list as an expert witness. He
commented on our death calculations. But the only criticism he had with regard to our
calculation methods for the number of smoking attributable deaths that will occur in the
Youth Addicted Population was, again, that we used age-adjusted mortality rates for
current and former smokers. He did not himself calculate the likely smoking attributable

Page 147

1	mortality in the Youth Addicted Population, or make any adjustments to our calculations
2	of 13.4 million deaths and 173.5 million years of life lost. He did not cite any peer
3	reviewed literature to support his contention that the use of age-adjusted mortality rates in
4	contexts similar to ours is inappropriate.
5	In fact, as I described a bit earlier, the generally accepted scientific opinion, based
6	on statements of the Surgeon General and on substantial and current peer reviewed
7	literature, is that age-adjusted mortality rates suffice for application such as ours.
8	Q: Doctor Wyant, please direct your attention to U.S. Exhibit 17742, titled "Dr.
9	Wecker's Adjusted Calculation of Smoking Attributable Health Care Costs –
10	Adjustment Steps." What does this exhibit show the Court?
11	A: This exhibit is very similar to U.S. Exhibit 17737, which we looked at a short
12	while ago. U.S. Exhibit 17742 again shows the printout produced by Dr. Wecker in
13	February 2005, with his adjusted health care costs figure of about \$273 billion at the
14	bottom right. As I did in U.S. Exhibit 17737, in this exhibit I have highlighted parts of
15	Dr. Wecker's printout for ease of explication. In this exhibit, what I highlighted is the
16	row for Step (1). This row describes the first of Dr. Wecker's four adjustments to our
17	health care cost calculation.
18	In this adjustment, Dr. Wecker reduces our health care costs by 28%, from about
19	\$840 billion to about \$602 billion. The basis for this adjustment is basically Dr.
20	Wecker's assertion that the Youth Addicted Population should be 28% smaller than what
21	Dr. Gruber calculated.

Q: Doctor Wyant, before discussing this one particular proposed adjustment, do
 you have any other general comments on Dr. Wecker's proposed health care cost
 adjustments as a whole?

A: Yes. One general comment is that it will require a substantial number of words
for me to talk about his proposed adjustments one by one, because they are somewhat
technical in nature. But the number of words it will take to discuss his proposed
adjustments to smoking attributable health care costs are in no way indicative that the
health care costs measure is somehow more important than other measures of adverse
health effects that we calculated.

10 The smoking attributable health care cost total is not a more important measure of 11 adverse health effects than smoking attributable deaths or smoking attributable years of 12 life lost. It is just a different measure. I am spending a disproportionate amount of time 13 talking about proposed adjustments to our health care costs measure only because (1) the 14 methods for calculating health care costs are a bit more complicated and harder to explain 15 than the methods for the other measures, and (2) defendants' experts did not calculate any 16 proposed adjustments specific to our mortality computations in the way that they did for 17 health care costs.

Q: Doctor Wyant, please direct your attention again to U.S. Exhibit 17737, titled
"Dr. Wecker's Adjusted Calculation of Smoking Attributable Health Care Costs
(Highlighted)." What other general comments do you have with regard to this
exhibit?

A: This is the exhibit that contains Dr. Wecker's printout, in which he makes a series
of four adjustments that reduce our \$839.8 billion health care costs estimate by about

68%, to \$272.7 billion. In this exhibit, I added highlights to Dr. Wecker's printout that
show these original and adjusted amounts, and the difference between them expressed as
a percent of the original.

4 As a general comment, Dr. Wecker's proposed adjustments do not provide a 5 balanced assessment of how our health care costs calculation might be off. He ignores 6 the many ways that, by design, our calculation was constructed to understate, rather than 7 overstate the total smoking attributable health care costs in the Youth Addicted 8 Population. Many of our deliberate efforts to understate total dollars did not involve 9 obscure methodological choices with regard to technical approaches, but rather stemmed 10 from simple decisions to omit time periods, groups of people, or disease categories. For 11 example, we did not extend our calculations beyond 2050. We omitted costs related to 12 many adverse health effects: second hand smoke, problem pregnancies, general 13 diminished health, and diseases and conditions such as peptic ulcers, cataracts, and 14 leukemia. We did not calculate health care costs for smokers under the age of 40. 15 Dr. Wecker presented no discussion of the extent to which his proposed 16 adjustments might be counter-balanced by reasonable adjustments that would increase 17 our health care cost estimates, rather than decrease them. For example, we presented one 18 alternative calculation of health care costs using a model that was presented by Dr. Glenn 19 Harrison in a peer reviewed study. His model took a more inclusive approach to 20 estimating smoking attributable health care costs. It included conditions such as 21 diminished health and groups such as smokers under age 40. Applying that model to the 22 Youth Addicted Population resulted in roughly a 67% increase to our \$839.8 billion 23 figure. Applying just that one percentage adjustment in conjunction with Dr. Wecker's

1	percentage adjustment yields an approximate health care costs figure of more than \$450
2	billion. Even this figure does not yet take into account all the reasons that our calculation
3	methods are likely to understate costs, rather than overstate them. It does not, for
4	example, extend any of our calculations beyond 2050.
5	Of course, that approximate \$450 billion figure still assumes that Doctor
6	Wecker's proposed adjustments are valid. I disagree with that proposition for a number
7	of reasons.
8	Q: Doctor Wyant, did Dr. Wecker use multiple imputation in any of his
9	adjusted calculations, the approach that Dr. Rubin endorsed and that you found
10	increases the smoking attributable health care cost estimate?
11	A: No.
12	Q: Doctor Wyant, I take it that you have some specific reasons for rejecting each
13	of Dr. Wecker's proposed adjustments to your calculation of \$839.8 billion in health
14	care costs, besides the general reasons you have been describing?
15	A: That's correct.
16	Q: Dr. Wyant, please direct your attention back to U.S. Exhibit 17742, titled
17	"Dr. Wecker's Adjusted Calculation of Smoking Attributable Health Care Costs –
18	Adjustment Steps" What does this exhibit show?
19	A: This exhibit has four pages. I described page one a little earlier in my testimony.
20	Each page highlights one line, with the highlighted line corresponding to one of Dr.
21	Wecker's four adjustment steps.
22	The first page relates to Dr. Wecker's adjustment to the size of the Youth
23	Addicted Population itself. This is the first of Dr. Wecker's four adjustment steps. In

this first page of the exhibit, I highlighted the line near the top of his printout in whichthis first adjustment is described.

3 But it will be easier with health care costs to start with the last of Dr. Wecker's 4 four adjustments and work backwards to our \$839.8 billion figure. 5 Dr. Wyant, does the fourth page of U.S. Exhibit 17742, denoted "page 4 of 4" **O**: 6 at the bottom, highlight the last of the Dr. Wecker's four adjustments? 7 A: Yes. At the top of the page is Dr. Wecker's printout, and I have highlighted the 8 line marked "Step (4)." This line describes the last of his four adjustments. I will go 9 over each of Doctor Wecker's adjustment steps, and summarize briefly my main 10 disagreements with his proposed approach. I disagree with Dr. Wecker on a number of 11 technical issues as well. But in this review, I will generally restrict my comments to the 12 main substantive areas of disagreement. 13 The printout in page four of this exhibit shows that after applying the his previous 14 three adjustments, and prior to applying his fourth adjustment, Dr. Wecker had estimated 15 the adjusted smoking attributable health care costs at about \$422 billion. Application of 16 this fourth adjustment brings his adjusted figure down to about \$273 billion. 17 One major problem with Dr. Wecker's calculation in this fourth step is that his 18 proposed method ignores the nature of the diseases with which we are dealing – lung 19 cancer, COPD, CHD, stroke, and so on. As Dr. Samet testified, these diseases have 20 precursors and sequelae and complications. We developed and applied statistical 21 formulas that reflect the medicine and science on the effects of these diseases. One way 22 we worked to assure that our formulas were reasonable in this regard was to discuss on a 23 number of occasions over the years, with Dr. Samet and other physicians and medical

researchers, the nature of these diseases. Dr. Samet testified in this case about our
 discussions with him. In these discussions, we reviewed aspects of these diseases such
 as typical course of progression, typical treatment, likely precursors, and typical
 complications.

5 In Dr. Wecker's fourth adjustment, he assumes that smoking attributable health 6 care costs should not, in general, address costs related to precursors and sequelae such as 7 the above. His adjustments limit the accumulation of smoking attributable health care 8 costs only to doctor visits and hospital stays that are coded specifically as being for 9 treatment of one of the major diseases, or for a few selected sequelae of these diseases 10 that are amenable to coding using the standard international disease codes -- also known 11 as the ICD-9 codes.

But Dr. Samet also testified in this case that not all of the sequelae of the major
diseases that are caused by smoking can be captured by ICD-9 codes such as the ones on
his list.

So for example, one segment of the population that has lung cancer will likely look something like this during the course of a year: (1) get treated for chest pain and difficulty breathing; (2) get treated for pneumonia, (3) get diagnosed and treated for lung cancer; (4) get treated for an infection contracted during surgery to treat lung cancer; and (5) get treated for bone conditions caused by spread of the lung cancer. Dr. Wecker's proposed adjustment would incorrectly remove costs associated with (1), (2), (4), and (5), from our \$839.8 billion figure, and restrict costs to only those associated with (3).

Q: Dr. Wyant, did your formulas attribute all the costs in the Youth Addicted
 Population for precursors and sequelae such as respiratory difficulties and surgical
 complications to smoking?

4 A: Absolutely not. I have testified in some detail about how our methods made use 5 of a standard measure in epidemiology, the attributable fraction. In the \$839.8 billion in 6 health care costs, we included only a fraction of people with the major diseases – the 7 fraction for which the diseases are attributable to smoking – and for this fraction of 8 people, only a fraction of their average annual health care costs – the fraction attributable 9 to having one or more of the major diseases. So our formulas were designed to include, 10 in a reasonable manner and consistent with similar efforts in the peer reviewed literature, 11 costs for conditions such as respiratory difficulties and surgical complications only to the 12 extent that such conditions increase the average annual costs of people with the major 13 diseases.

Q: Dr. Wyant, did you have any other major disagreements with Dr. Wecker's fourth adjustment?

A: Yes. Not only did he remove from our \$839.8 billion figure all the costs that are
associated with many precursors and complications of the major diseases, he also
removed costs for people being treated for one the major diseases if the total annual costs
for direct treatments – doctor visits coded for COPD, for example – were "too low" – less
than \$100 in 1987 dollars (The National Medical Expenditure Survey was conducted in
1987.)

As one example of why I disagree with this part of Dr. Wecker's fourth adjustment, such a cutoff ignores costs for people who are just being diagnosed for

COPD at the end of a year. So if adults in the Youth Addicted Population, for example,
 are having respiratory difficulties and pneumonia during the course of a year, and at the
 end of the year are diagnosed with COPD during a doctor's visit that cost \$95, Dr.
 Wecker in effect asserts that we should remove all health care costs for such people from
 our \$839.8 billion figure. It is inappropriate to do this.

6 As another example of why I disagree with this part of Dr. Wecker's fourth 7 adjustment, consider Dr. Samet's testimony in this case with regard to available 8 treatments for COPD. Dr. Samet stated that the treatments for COPD are limited, and 9 consist mostly of medications similar to those prescribed for asthma, and for more severe cases of COPD, oxygen therapy. Dr. Wecker in effect asserts that costs for adults in the 10 11 Youth Addicted Population who are being treated for respiratory difficulties, but whose 12 only direct costs for COPD are \$95 (in 1987 dollars) for medication, should be removed 13 from our \$839.8 billion figure. Based on Dr. Samet's testimony, it is inappropriate to 14 exclude such people.

15 In addition, there is the issue of balance. Dr. Wecker's removal of some 16 categories of people from our calculation – despite the fact that people in these categories 17 have doctor visits coded explicitly for one of the major diseases that are caused by 18 smoking – apparently attempts to correct for possible overdiagnosis of these diseases – 19 "false positives." Doctor Samet's testimony indicates that underdiagnosis may be of 20 more concern than overdiagnosis, at least for COPD. Underdiagnosis is consistent with 21 my own understanding, arrived at from discussions with Dr. Samet and other medical 22 experts. I also understand that underdiagnosis of COPD has been reported in peer 23 reviewed studies.

1	Q: Dr. Wyant, please return your attention to the fourth page of U.S. Exhibit
2	17742, denoted "page 4 of 4" at the bottom. Just to clarify what you have been
3	discussing, does this exhibit show what eliminating Dr. Wecker's fourth adjustment
4	would yield in terms of adjusted health care costs?
5	A: Yes. It shows that if he had just applied the first three of his four adjustments,
6	and not the fourth adjustment that I have been discussing, his adjusted health care costs
7	figure would have been about \$422 billion.
8	Q: And that \$422 billion figure comes from Dr. Wecker's own calculations, is
9	that correct?
10	A: Yes. It comes from his computer printout, which is reproduced at the top of this
11	exhibit. The printout shows the health care costs figure after applying the first three
12	adjustments, but before applying the fourth adjustment.
13	Q: Doctor, there are some comments below Dr. Wecker's printout in this
14	exhibit. Are those your comments?
15	A: Yes. They summarize what Dr. Wecker did in this adjustment, and the most
16	important disagreements I have with what he did. The disagreements are the same two I
17	have been discussing – his adjustment removes costs that are associated with precursors,
18	sequelae, and complications of the major diseases from our \$839.8 billion figure, and it
19	also removes costs for whole groups of people even though the data show these people
20	had medical encounters coded specifically for one of the major diseases.

1 Q: Doctor Wyant, please turn your attention to the preceding page of U.S.

2 Exhibit 17742, which is denoted "page 3 of 4" at the bottom. What does this page 3 show?

A: This page shows Dr. Wecker's printout, but this time I have highlighted the line in
the printout that corresponds to the third of his four adjustments. Just below the
reproduction of Dr. Wecker's printout, this page of the exhibit gives my summary of
what Dr. Wecker did in his third adjustment, and my main disagreements with what he
did.

9 Q: What was your main disagreement with Dr. Wecker's third adjustment?

Dr. Wecker essentially did separate analyses of health care costs in the Youth 10 A: 11 Addicted Population, one analysis for those members whom he projected will quit 12 smoking by age 35, and one for everyone else. Without getting into occasional 13 exceptions that can occur, in general youth smokers who quit smoking for good before 14 age 35 tend to have lower smoking attributable health care costs at older ages, on 15 average, than youth smokers who continue smoking past that point. So the accuracy of 16 Doctor Wecker's adjustment depended on his having a reasonable estimate of the number 17 of adults in the Youth Addicted Population who quit for good by age 35. If he overstated 18 the number of people in this category, his adjusted health care costs would tend to 19 understate the total smoking attributable health care costs in the Youth Addicted 20 Population, assuming other factors remained unchanged. 21 Dr. Wecker did not make a reasonable estimate of the number of adults in the 22 Youth Addicted Population who quit for good by age 35. Instead, Dr. Wecker used

23 methods that would typically overstate the number of people in his "quit for good under

1 age 35" category. This overstatement occurred because his methods ignore the published 2 science on smoking cessation and addiction. He could have checked his calculations 3 against published data on the number of smokers who appear to have quit for good before 4 age 35, but according to his deposition testimony, he did not do so. 5 Dr. Wecker based his estimates of how many people will quit for good by age 35 6 in essence by looking at data on 35 year-olds, seeing how many reported at age 35 that 7 they were not currently smoking, and assuming that none of these people would resume 8 smoking ever again. His approach ignores the fact that it is very difficult to quit smoking 9 for good, and that many people who have quit temporarily will relapse and resume 10 smoking. Dr. Benowitz testified in this case that relapse rates are quite high – similar to 11 relapse rates for substances such as heroin. He testified that relapse rates in the three to 12 six months after quitting range from 60% to 75%. 13 Doctor Wyant, does page 3 of 4 in U.S. Exhibit 17742 show the effect of Dr. **Q**: 14 Wecker's third adjustment on the health care costs figure? 15 A: Yes. Based on Dr. Wecker's printout, if he had stopped after applying the first 16 two of his adjustments, and not applied his third adjustment that assumed no relapses 17 among former smokers, his adjusted health care cost calculation would have yielded 18 about \$519 billion in smoking attributable health care costs. Doctor, I'm now moving to page 2 of 4 in U.S. Exhibit 17742. What does this 19 **Q**: 20 page show? 21 This page is similar to pages three and four of this exhibit, except in this page the A:

22 focus is on the second of Dr. Wecker's four adjustments.

Q: Briefly, Doctor, what was your main disagreement with Dr. Wecker with regard to his second adjustment?

A: Our analysis focused on the fraction of health care costs among smokers that is attributable to smoking. It costs money to treat diseases such as lung cancer, COPD, CHD, and stroke, and their complications. Smokers on average get these diseases more often than never smokers, and on average are treated for these diseases more often than never smokers. We calculated the extent to which smoker disease rates exceed that of never smokers, by age and gender, and calculated the fraction of smoker health care costs that are associated with their elevated rates of treatment.

10 Dr. Wecker, in his second adjustment, focused on certain ages in which data 11 indicate that the overall average health care costs for current smokers in the United States 12 is less then the overall average health care costs for never smokers. His adjustment 13 assumes that even if current smokers in these age groups have higher rates of diseases 14 such as lung cancer, COPD, CHD, and stroke than never smokers, their smoking 15 attributable health care costs must nonetheless be zero. His adjustment removes any 16 health care costs that are associated with excess occurrences of smoking caused diseases 17 among these smokers from our \$839.8 billion health care cost figure.

In my opinion, such an assumption is unfounded and inappropriate. The relevant focus for an adverse health effects calculation is the portion of smoker costs that is due to their smoking. The fact that survey data show current smokers at selected ages spending less on average in a year on health care than never smokers – due to sampling variability in the survey or other unspecified reasons -- is irrelevant. We focused on the appropriate measure – that portion of the health care costs of adult smokers in the Youth Addicted

Population that is attributable to their smoking, and calculated that portion using standard
 and appropriate methods from epidemiology.

3 Q: Doctor, what was the effect of Dr. Wecker's second adjustment on the health 4 care costs figure?

5 A: Based on Dr. Wecker's printout, as the Court can see on page two of U.S. Exhibit

6 17742, if Dr. Wecker had stopped after applying the first of his adjustments, and not

7 applied his second adjustment that ignored elevated rates of diseases such as lung cancer

8 among current smokers, his adjusted health care cost calculation would have yielded

9 about \$602 billion in smoking attributable health care costs.

10 Q: Doctor Wyant, I'm now moving to page one of four in U.S. Exhibit 17742.

11 What does this page show?

A: This page is similar to pages two through four of this exhibit, except in this page
the focus is on the first of Dr. Wecker's four adjustments. In this adjustment, Dr. Wecker
contends that our counts of the number of adults in the Youth Addicted Population are
too large. He adjusts those counts downwards.

16 Q: Briefly, Doctor, what was your main disagreement with Dr. Wecker with

17 regard to his first adjustment?

18 A: As I testified earlier, Dr. Gruber supplied the Youth Addicted Population counts

19 for our calculations. Earlier in my testimony, I described Dr. Gruber's qualifications, and

- 20 how he went about calculating the size and characteristics of the Youth Addicted
- 21 Population. In my description, I noted that Dr. Gruber made use of 10 core NHIS
- surveys in calculating the counts that he supplied to us. Dr. Gruber used all of the
- 23 relevant information in those surveys. For example, when he was calculating the number

of 49 year-old male current smokers in 1999 who started smoking before age 21, he
 looked at the number of 49 year-old males in this category reported in the 1999 NHIS
 survey.

4	Dr. Wecker, in contrast, completely ignored the number of 49 year-old male
5	current smokers reported in this 1999 survey when he calculated his adjusted number of
6	smokers in this category in 1999. Dr. Gruber's counts agree with this survey. Dr.
7	Wecker's counts fall well below the counts reported in this survey for this group of
8	smokers, and in general for the other groups as well.
9	The reason for this discrepancy is that Dr. Wecker failed to use all of the wealth
10	of data available for estimating the size of the Youth Addicted Population. Instead, for
11	each cohort of smokers, he looked at only one age-gender cell. In total, Dr. Wecker used
12	data from only three percent of the available age-gender cells in the NHIS data.
13	Good statistical practice would entail using all of the available data on counts of
14	smokers who started before age 21.
14 15	smokers who started before age 21.Q: Did you discuss Dr. Wecker's proposed adjustment with Dr. Gruber?
14 15 16	 smokers who started before age 21. Q: Did you discuss Dr. Wecker's proposed adjustment with Dr. Gruber? A: Yes. Dr. Gruber called this adjustment inappropriate, and said that it can result in
14 15 16 17	smokers who started before age 21.Q:Did you discuss Dr. Wecker's proposed adjustment with Dr. Gruber?A:Yes. Dr. Gruber called this adjustment inappropriate, and said that it can result inmisleading answers. As one demonstration of this fact, Dr. Gruber used one age-gender
14 15 16 17 18	 smokers who started before age 21. Q: Did you discuss Dr. Wecker's proposed adjustment with Dr. Gruber? A: Yes. Dr. Gruber called this adjustment inappropriate, and said that it can result in misleading answers. As one demonstration of this fact, Dr. Gruber used one age-gender cell of data for each cohort, but used the age-gender cell from the most recent NHIS
14 15 16 17 18 19	smokers who started before age 21.Q:Did you discuss Dr. Wecker's proposed adjustment with Dr. Gruber?A:Yes. Dr. Gruber called this adjustment inappropriate, and said that it can result inmisleading answers. As one demonstration of this fact, Dr. Gruber used one age-gendercell of data for each cohort, but used the age-gender cell from the most recent NHISsurvey available at the time, the 1999 Survey. Dr. Gruber then filled in backwards using
 14 15 16 17 18 19 20 	 smokers who started before age 21. Q: Did you discuss Dr. Wecker's proposed adjustment with Dr. Gruber? A: Yes. Dr. Gruber called this adjustment inappropriate, and said that it can result in misleading answers. As one demonstration of this fact, Dr. Gruber used one age-gender cell of data for each cohort, but used the age-gender cell from the most recent NHIS survey available at the time, the 1999 Survey. Dr. Gruber then filled in backwards using methods corresponding to those of Dr. Wecker. The result was a Youth Addicted
 14 15 16 17 18 19 20 21 	 smokers who started before age 21. Q: Did you discuss Dr. Wecker's proposed adjustment with Dr. Gruber? A: Yes. Dr. Gruber called this adjustment inappropriate, and said that it can result in misleading answers. As one demonstration of this fact, Dr. Gruber used one age-gender cell of data for each cohort, but used the age-gender cell from the most recent NHIS survey available at the time, the 1999 Survey. Dr. Gruber then filled in backwards using methods corresponding to those of Dr. Wecker. The result was a Youth Addicted Population very similar to the one that Dr. Gruber actually supplied us.
 14 15 16 17 18 19 20 21 22 	 smokers who started before age 21. Q: Did you discuss Dr. Wecker's proposed adjustment with Dr. Gruber? A: Yes. Dr. Gruber called this adjustment inappropriate, and said that it can result in misleading answers. As one demonstration of this fact, Dr. Gruber used one age-gender cell of data for each cohort, but used the age-gender cell from the most recent NHIS survey available at the time, the 1999 Survey. Dr. Gruber then filled in backwards using methods corresponding to those of Dr. Wecker. The result was a Youth Addicted Population very similar to the one that Dr. Gruber actually supplied us. What this demonstration confirms is that if an analyst chooses to use only 5% of

1 he or she chooses to use. Dr. Wecker could equally well have chosen to use the subset of 2 data that Dr. Gruber chose to use in his counter-example. But in fact there is no need to 3 choose any subset – the best method is to use all of the relevant available data, which is 4 what Dr. Gruber used in calculating the population counts that he supplied to us. 5 **O**: Doctor Wyant, directing your attention again to the first page of U.S. Exhibit 6 17742, can you briefly summarize the points you have made with regard to Dr. 7 Wecker's proposed adjustments to the health care costs calculation? 8 A: The exhibit shows that Dr. Wecker's proposed adjustment to the size of the Youth 9 Addicted Population would have resulted in a health care costs figure of about \$602 10 billion for population members with diseases such as lung cancer, COPD, CHD, and 11 stroke. Without this adjustment, or any of his subsequent adjustments, his health care 12 costs figure would be the \$839.8 billion that we calculated. But even with all four of his 13 proposed adjustments, the health care costs figure is still in the hundreds of billions – 14 about \$273 billion. These figures ignore other reasonable adjustments that Dr. Wecker 15 could have included that would tend to increase the \$839.8 billion figure, not decrease it. 16 These latter adjustments include such things as adding in estimates of the smoking 17 attributable costs of additional conditions such as diminished health, or extending cost 18 estimates beyond 2050. 19 In addition, the main disagreements I have listed with regard to Dr. Wecker's 20 proposals do not center on any arcane technical methodologic issues, although I have 21 some disagreements of that nature. Rather, my main disagreements center on what I 22 regard to be fundamental flaws in Dr. Wecker's approach -- failing to use available data 23 on factors like smoker counts; assuming -- contrary to scientific testimony -- that smokers who have quit will never relapse; and removing from our \$839.8 billion figure the costs
that are associated with well known side effects of diseases caused by smoking, such as
surgical complications.

4 Q: Do you have any other comments on Dr. Wecker's four proposed

5 adjustments to your \$839.8 billion health care cost figure for diseases such as lung

6 cancer, COPD, CHD, and stroke?

7 A: Yes. Another way to address the question of whether or not Dr. Wecker's

8 adjustments are well founded is to look at relevant peer reviewed articles on smoking

9 attributable health care costs, and see whether any of the articles use the methods that Dr.

Wecker used in making his adjustments. Recent articles on smoking attributable healthcare costs provide no support for Dr. Wecker's proposed methods.

12 Q: Doctor Wyant, please direct your attention to U.S. Exhibit 17743 titled "Dr.

13 Wecker's Methods for Calculating Smoking Attributable Health Care Costs." Does

14 this exhibit summarize the results of your review?

15 Yes. I looked at recent peer reviewed articles that estimate the percent of U.S. A: 16 health care costs attributable to smoking. These are the same six articles that appeared in 17 U.S. Exhibit 17738. I discussed this exhibit, and a number of aspects of these peer 18 reviewed articles, earlier in my testimony. There are other recent articles on smoking 19 attributable health care costs that, for example, estimate costs for a particular state or 20 Canadian province or health care program such as Medicare. But to keep the scope of 21 my review manageable, I restricted it to the national estimates. I have reviewed many of 22 the more narrowly focused articles, and I believe that the methods from the articles that

make national estimates are representative of the methods that are employed in the
 broader set.

3	In this exhibit, the Court can see that Dr. Wecker's adjustment steps are
4	summarized in the rows, starting with his first adjustment at the top and ending with his
5	fourth adjustment at the bottom. I have also included a very brief summary of what I
6	consider to be the most important element of each of Dr. Wecker's adjustments.
7	At the right hand side of the exhibit are two shaded areas. The one in green
8	shows the number of peer reviewed articles in which the methods proposed by Dr.
9	Wecker were used, and the number of authors of these articles. There is a separate line or
10	set of lines for each of Dr. Wecker's adjustment steps.
11	The red shaded area at the far right shows the number of peer reviewed studies
12	that did not use the methods proposed by Dr. Wecker, and the number of authors of these
13	articles. In the red "did not use" zone there are again separate lines or sets of lines for
14	each of Dr. Wecker's adjustment steps.
15	Q: What does the first row show?
16	A: I examined six peer reviewed articles. There were 19 different individual authors,
17	each of whom participated in the writing of one or more of these articles.
18	The first row of the exhibit relates to Dr. Wecker's first adjustment step, in which
19	he relied on a small subset of the available data on such elements as the number of
20	smokers. At the right side of the first row, the Court can see from the two shaded areas
21	that none of the six articles or 19 authors used just a small subset of the available data on
22	elements such as smoker counts, in the manner that was employed by Dr. Wecker.

1 All of these articles started with the National Medical Expenditure Survey for 2 1987. Some of them were looking only at specific subgroups of the U.S. populations 3 such as adults who were age 40 and over. These articles restricted their attention to 4 appropriate subsets of the survey data. But none of the articles limited their analysis to a 5 small percentage of the age-gender cells within their target groups, as Dr. Wecker did. 6 None of them looked at earlier surveys, and extrapolated counts of smokers from the 7 earlier surveys to adjust the counts of smokers in the National Medical Expenditure 8 Survey. And even though some of the articles used results from the 1987 survey to 9 project U.S. costs in subsequent years, none of them calculated counts of smokers in 10 subsequent years by simply extrapolating smoker counts from the 1987 data. They used 11 more recent surveys to the extent they were available.

12

Q: Doctor, what does the next row of the exhibit show?

A: It shows that none of the six peer reviewed articles and none of the 19 authors used the method that Dr. Wecker used in his second adjustment. That is, none of them assumed that smoking attributable health care costs are zero for groups of smokers that might have overall average health care costs less than the overall average for similar never smokers.

18 Q: What does the third row show?

A: This row contains two paragraphs. Both relate to Dr. Wecker's third adjustment step, in which he attempted to analyze smoking attributable health care costs separately for smokers who quit before age 35, and smokers who quit after age 35. As the third row shows, none of the six peer reviewed articles or 19 authors analyzed health care costs separately by quit over or under age 35, as Dr. Wecker attempted. Because none of the

1	authors or articles made this distinction, none of them had the opportunity to assume, as
2	Dr. Wecker did, that smokers who quit do not relapse. This "never relapse" assumption
3	is the subject of the second paragraph at the left of this row in the exhibit.
4	In his December 2004 deposition, Dr. Wecker stated that, consistent with my
5	points here, that he knew of no peer reviewed studies that used his proposed method:
6	Q. Are you aware of any published work that applies a
7	split between those who quit before age 35 and
8	those who quit after 35 when estimating smoking-
9	related health care costs?
10	A. No.
11	(Deposition of William Wecker, Ph.D., United States v. Philip Morris, et
12	al., December 17, 2004, Volume 1, pages 189:13-189:17.)
13	Q: Did Dr. Wecker consult with medical experts on the issue of smokers
14	relapsing?
15	A: Not according to his testimony in the deposition I just referenced
16	Q: Doctor, in this exhibit, U.S. Exhibit 17743, the last row is set apart from the
17	first three that you just discussed. Why is that?
18	A: The last row relates to Dr. Wecker's fourth proposed adjustment, which in turn
19	relates to health care costs that are associated with specific diseases. Only two of the six
20	peer reviewed articles in my survey addressed specific diseases. So in the last two rows
21	of this exhibit, we are looking to see which of these two peer reviewed articles, and the
22	seven authors who worked on them, used methods that are similar to those that were
23	proposed by Dr. Wecker.

1 The first paragraph relates to Dr. Wecker's assertion that costs should only be 2 accumulated for doctor visits, hospital stays, and other medical encounters that are 3 specifically for treatments of diseases that are caused by smoking. Earlier in my 4 testimony, I noted that doing so essentially ignores sequelae of these diseases such as 5 surgical complications.

6 In this case one of the peer reviewed articles, from the American Journal of Public 7 Health in 2002, did what Dr. Wecker proposed, and performed a calculation that was 8 restricted to medical encounters with disease codes specific to diseases caused directly by 9 smoking. However, the authors noted that they did so only in effect as a check on their 10 main estimate, which was not restricted in this manner. The authors echoed the same 11 opinion that I expressed earlier – that restricting cost estimates to encounters with 12 specific smoking related disease codes results in an understatement of smoking 13 attributable health care costs. Such estimates ignore legitimate indirect causes of 14 smoking attributable health care costs such as those from surgical complications. 15 The other peer reviewed article that looks at costs that are associated with specific 16 diseases such as lung cancer, COPD, CHD, and stroke is the 2003 article in the Journal of 17 Econometrics. As I have testified, Dr. Zeger, who contributed to the health care cost 18 calculations for the Youth Addicted Population, was a co-author of that article. The 19 study described in that article used essentially the same methods for U.S. smokers that we 20 used for the Youth Addicted Population. We identified smokers being treated for one of 21 the major diseases during the course of a year, but then we looked at all of their health 22 care costs for the year in order to assess costs from factors such as surgical complications. 1 So in summary, in the upper part of the fourth row of U.S. Exhibit 17743, the 2 Court can see that one recent peer reviewed article with four authors disagrees with Dr. 3 Wecker that costs can only be accumulated for encounters specifically to treat a disease 4 caused by smoking. The Court can also see that one recent peer reviewed article agrees 5 with Dr. Wecker on this point, but only if the associated health care cost calculation is 6 treated as a lower bound check on the actual costs.

7 Q: Doctor, what does the lower half of the fourth row in U.S. Exhibit 17743 8 show?

9 A: Another element of Dr. Wecker's fourth proposed adjustment to our \$839.8 10 billion smoking attributable health care cost figure for the Youth Addicted was that he 11 further restricted the accumulation of health care costs to smokers whose encounters to 12 treat the specific diseases that are caused by smoking cost more than \$100, in 1987 13 dollars. The last line of this exhibit shows that neither of the two peer reviewed articles 14 that focus on specific diseases that are caused by smoking used such a restriction. 15 Doctor, in summary, do the peer reviewed articles on health care costs that **0**: you examined provide any support for the main methods used by Dr. Wecker in his 16 17 proposed adjustments to your \$839.8 billion cost figure? 18 No. A:

19 Q: Has Dr. Wecker subjected his ideas to peer review, in the same manner that
20 Dr. Zeger and the other 18 investigators did?

21 A: Not to my knowledge.

Q: Doctor, do you have any other comments with regard to the comparison of
 Dr. Wecker's proposed methods and the methods that actually were used in the peer

3 reviewed literature, as summarized in U.S. Exhibit 17743?

4 A: No two studies use identical methods and data sources.

5 So for any proposed approach to an analysis, we can find some set of factors that 6 are either unique to that approach, or that are not found some other studies that have a 7 similar intent. In considering whether a proposed approach is reasonably consistent with 8 the peer reviewed literature, it is useful to look not only at whether there are some unique 9 and unusual methods involved in the proposed approach – there will almost always be 10 some -- but also at considerations such as: (1) Do the unique or unusual methods in the 11 proposed approach substantially impact the results? (2) Is the impact always in the same 12 direction? (3) Does the combined impact of the unique or unusual methods generate a 13 result that is consistent with the overall result from other peer reviewed studies? (4) Are 14 the unique or unusual methods consistent with generally accepted scientific knowledge? 15 (5) How many unique and unusual methods are there? (6) Do the unique and unusual 16 methods involve fundamental issues, or technical details like whether to group age in 5-17 year intervals versus 10-year intervals? (7) To what extent have the unique or unusual 18 methods in the proposed approach passed through peer review? (8) Are the unique or 19 unusual methods required in order to address some unique or unusual feature of the 20 immediate problem?

In various places in my testimony I have touched on these considerations. My testimony as a whole supports my opinion that the peer reviewed literature on health care costs does not provide any support for the methods used by Dr. Wecker in his proposed

1	adjustments. Calculating health care costs for the Youth Addicted Population is an
2	exercise very similar to that undertaken in numerous peer reviewed studies of similar
3	populations. No radical innovations in methodology are required. Dr. Wecker did not
4	propose one or two technical refinements that would move cost estimates by, say, 2-5%
5	in different directions. He proposed four sets of adjustments, each of which moved
6	health care costs by 10-28 percentage points, and always in a downwards direction. He
7	made these downwards adjustments to a peer reviewed methodology that is known to
8	produce cost estimates consistent with those of other peer reviewed studies. His
9	adjustments involved fundamental issues like whether to ignore complications due to
10	smoking caused diseases, and are in conflict with medical opinion that such
11	complications occur. To my knowledge, the unique and atypical methods that played a
12	role in Dr. Wecker's adjustments to our \$839.8 billion health care cost figure have not
13	themselves passed peer review.
14	Q: Doctor Wyant, I am now turning for a moment from smoking attributable
15	health care costs to smoking attributable mortality. Would any of Dr. Wecker's
16	proposed adjustments to smoking attributable health care costs have been relevant
17	to your mortality calculations?
18	A: Yes, the first one. I testified earlier that Dr. Wecker did not calculate any
19	alternative measure to our 13.4 million smoking attributable deaths, although he did
20	suggest that we should have adjusted our mortality rates for other factors besides age and
21	gender. I addressed that particular criticism earlier in my testimony.
22	But for health care costs, Dr. Wecker did propose a calculation of the Youth
23	Addicted Population smaller than what Dr. Gruber estimated this was his first proposed

1	adjustment. Using a smaller Youth Addicted Population would also tend to produce a
2	mortality measure of fewer than 13.4 million smoking attributable deaths, although still
3	approximately in the 10 million range. But as I have testified, Dr. Wecker's proposed
4	adjustment to this size of the population is inappropriate.
5	Q: Dr. Wyant, I'm now moving to a different topic – the source of your various
6	smoking attributable fractions for death, disease, and health care costs. You
7	testified that these fractions are derived from studies conducted in the late 1980s, is
8	that correct?
9	A: Yes. We derived them from the Cancer Prevention Study II, and from the
10	National Medical Expenditure Survey.
11	Q: Is it accepted practice to use rates from such sources to calculate the scale of
12	smoking attributable adverse health effects in more recent years?
13	A: Yes. It is commonly done. I have cited numerous peer reviewed studies that
14	estimate the scale of different adverse health effects, both in my testimony and in the
15	demonstrative exhibits that I prepared. Among those studies are many that estimate the
16	scale of adverse health effects from the late 1990s forward. They all use attributable
17	fractions derived from the same sources we used - the Cancer Prevention Study II, or the
18	National Medical Expenditure Survey. I would say that this is the commonly accepted
19	practice.
20	Q: Is it also accepted practice to use rates from these sources to calculate the
21	scale of smoking attributable adverse health effects in the future?
22	

22 A: Yes. A number peer of reviewed studies do just that.

Q: Do your future projections assume that smoking rates will decline in the future?

A: Yes. Our calculations project that current smokers in the Youth Population will
continue to quit. As the years go by, the Youth Addicted Population will consist more
and more of former smokers, and less and less of continuing smokers.

6 Q: Could your future projections of adverse health effects be off?

7 A: Yes. As a general rule, projections are guaranteed to be off by some amount. 8 Humans for the most part are not able to foretell the future perfectly. Our projections of 9 smoking attributable adverse health effects could turn out to be on the high side, or on the 10 low side, although not necessarily by a substantial amount. But as peer reviewed articles 11 that I have cited demonstrate, projecting smoking attributable adverse health effects into 12 the future is a standard thing to do. We used standard methods in making our projections. 13 And as I have testified, we took a number of steps that would tend to make our 14 projections understated rather than overstated.

15 When there are standard and accepted methods for doing projections, as is the 16 case for smoking attributable adverse health effects, applied statisticians will typically 17 stick closely to what others have done. Of course, statisticians might run projections for 18 some alternative scenarios, as we did for different definitions of the Youth Addicted 19 Population, in order to assess the sensitivity of projections to specific assumptions. But 20 typically, the only time a statistician would deviate from standard approaches would be in 21 situations where there is a compelling reason to believe some important factor will differ 22 significantly in the future. For example, if the National Cancer Institute had announced 23 in 2004 that it would definitely be able to cure 50% of lung cancer cases by 2006, at a

cost of \$100,000 a case, a different projection might be warranted for the Youth Addicted
 Population.

3 Q: Dr. Wyant, to your knowledge is there any definitive future change of this 4 sort that you believe warrants a change in projection methods?

5 A: No. There are some reasons why adverse health effects might increase, and some 6 reasons why they might decrease, relative to our projections. For example, there is some 7 evidence that smokers have been smoking fewer cigarettes. There have also been 8 changes in cigarette design. Such factors could eventually reduce adverse health effects. 9 But working against these factors is the tendency of smokers to compensate, and change 10 the way they smoke so as to maintain a fixed level of nicotine consumption. Doses of 11 nicotine are likely to correlate with doses of carcinogens. Dr. Benowitz and Dr. Samet 12 testified about these issues.

Also, I understand that a number of experts in this case will be testifying about steps that could be taken to reduce future smoking. Effective implementation of such programs is another factor that could cause future adverse health effects in the Youth Addicted Population to be lower than what we have projected – our projections assume that current patterns of smoking behavior will tend to persist.

There are a number of reasons why future adverse health effects might exceed our projections. Smoking rates among youth smokers increased substantially during the 1990s. Increases in smoking rates could occur again, or cessation rates could tail off. One concern I have heard expressed in my general work on smoking issues over the last few years is that state budget difficulties will cause the reduction or elimination of many state sponsored programs that encourage cessation and reduce initiation rates.

Elimination of such programs could lead to higher smoking rates in the future than what we project. Another concern I have heard expressed is that smoking cessation rates will decline in the future, and may be declining now, even without reductions in budgets for smoking reduction programs. These concerns arise from the perception that the smokers who have not been affected by previous cessation promotion efforts will be harder to influence than those who have quit so far.

7 Medical treatment costs could go up faster than we project – the projections we 8 relied on were quite conservative. In addition, there has been a consistent trend over the 9 years for the Surgeon General to identify additional diseases as caused by smoking. There are already several such diseases that we did not include in our health care cost 10 11 calculation for major diseases, as I mentioned in my earlier testimony. According to the 12 2004 Surgeon General's report, "Cost estimates have tended to increase over time, 13 reflecting improvements in methodology, increases in medical expenditures for smoking-14 related diseases because of inflation and/or technology, and expansion of the list of 15 diseases caused by smoking." (U.S. Exhibit 88847, page 871.) Continued expansion of 16 the disease list and continued increases in costs of treating the diseases could make total 17 future costs for treating people with specific smoking-related diseases substantially 18 higher than what we project.

Dr. Samet, in his testimony in this case, suggested that estimates of the relative risks of COPD in the United States have tended to increase from 1955 to 2000. If the relative risk estimates that we used are too low, or if there is an upwards trend in relative risks for which we have not accounted, then future adverse health effects will tend to exceed our projections. 1 The point is not that I am an expert in any of these specific areas. The point is 2 that the kinds of general inquiries a statistician typically makes in these situations do not 3 lead me to believe that deviating in any substantial way from standard approaches is 4 warranted. Or in other words, I see no compelling reason to disagree with the statement 5 made by the Surgeon General in the 2004 report with regard to future projections of 6 premature deaths due to smoking, or to assume that similar statements would not apply to 7 the other adverse health measures. 8 Doctor Wyant, does U.S. Exhibit 17552, titled "The Burden of Smoking **Q**: 9 Attributable Mortality," contain the statement you to which you are referring?

10 A: Yes. The Surgeon General said, "The burden of smoking attributable mortality
11 will remain at current levels for several decades."

12 **Thank you, Doctor Wyant.**