IN THE CIRCUIT COURT OF THE FIFTEENTH JUDICIAL CIRCUIT IN AND FOR THE COUNTY OF PALM BEACH, STATE OF FLORIDA

THE STATE OF FLORIDA, LAWTON M. CHILES, JR., Individually and as GOVERNOR OF THE STATE 0F FLORIDA, DEPARTMENT OF BUSINESS AND PROFESSIONAL REGGULATIONS, and THE AGENCY FOR HEALTH CARE ADMINISTRATION,

Plaintiffs

v.

THE AMERICAN TOBACCO COMPANY, et al.,

Defendants

ACTION NO. 95-1466AO

AFFIDAVIT OF DAVID M. BURNS, M.D.

STATE 0F CALIFORNIA

COUNTY 0F SAN DIEGO

David M. Burns, M.D., being first duly sworn, deposes and states:

1. I am a Professor of Medicine, the Coordinator of the Developmental Pulmonary Clinical Research Laboratory, and the Medical Director of Respiratory Therapy at the University of California School of Medicine in San Diego.

2. My education; post graduate training, teaching assignments, and staff appointments; memberships and offices; awards; publications; and abstracts are reflected in the attached curriculum vitae marked exhibit "A" to this Affidavit.

3. I make this Affidavit on personal knowledge, and based on my education, expertise and experience.

4. I have reviewed Defendants' Affidavit of Robert P. Derhagopian, M.D. filed December 26, 1996, and attached exhibits in support of taking depositions of Medicaid patients in light of the evidence the State of Florida Will use to establish injury anl1 causation and damages. My conclusion is that such proof will he irrelevant and probative of nothing, as more fully explained below.

5. Taking discovery from a small sample of Medicaid recipients can add nothing to the vast body of scientific knowledge on the relationship between smoking behaviors and disease occurrence already in the public domain; nor can it be used to improve, adjust, quality or otherwise modify the calculation of heath care costs associated with cigarette smoking in the State of Florida. Calculation of heath care costs associated with cigarette smoking requires two fractions: the fraction of smoker's hearth care expenditures caused by cigarette smoking and the fraction of the population that smokes. Neither of these fractions can be reliably estimated from the deposition of current Medicaid recipients.

6. For the deposition of Medicaid recipients to be meaningful the information would have to be representative of the Medicaid population for which damages are being claimed and obtained with methods similar to those used in epidemiologic and survey studies of smoking behavior and its disease consequences to establish that smoking causes disease. Depositions of current Medicaid recipients or review of medical records would yield information that could not be used to define either the smoking behaviors of Medicaid recipients or the relationships of smoking behaviors in Medicaid recipients to disease related expenditures.

7. Deposition of current Medicaid recipients will not represent the Medicaid population in the year of interest. If the year 1994 is used for example, the depositions would need to be selected to represent those on Medicaid in 1994, not those on Medicaid in 1997. It is not possible to depose, in 1997, a set of individuals who represent those Medicaid recipients who incurred health care costs on Medicaid in 1994. A large fraction of the health care expenses for an individual occur during the period immediately preceding his or her death, and therefore many of those individuals who were the greatest users of health care services in 1994 have subsequently died and are unavailable for deposition. ~ sample of individuals who were Medicaid recipients in 1994, but who are alive in 1997, would be missing that group of individuals (those near death) who are responsible for the greatest per-capita use of Medicaid services. The same distortion occurs to only a slightly smaller extent when current Medicaid recipients are deposed to estimate current year expenses, those who were sickest and used the most care are either too sick to depose or are dead. In addition, many individuals on Medicaid in past years have moved out of state, become mentally

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incompetent or are untraceable. This is particularly true of those who were the largest users of medica1 services

8. Reviews of medical records also do not yield va1id population based data because they are not a random sample of the population as a whole (not everyone gets sick), nor of the sick population (not all sick individuals are seen with the same frequency). In addition, medical records are commonly incomplete with regard to behavioral information (e.g. smoking status). Patients are often seen by more than one physician and in more than one location making it difficult to obtain complete data from a single record or even be certain that all of the records have been obtained. Even modest numbers of individuals with incomplete records substantially increase the error margins of any estimates that arc made, and a small margin for error is necessary to determine whether the estimates obtained by this process arc significantly different from those used in the damages calculation.

9. Deposing an individual to define smoking status and medical expenditures does not allow a judgment to be reached as to which specific expenditures are caused by smoking. For example both smokers and nonsmokers develop heart disease, and the fact that heart disease develops in a smoker does not differentiate the possibility that the disease would have occurred anyway even if the individual had not smoked. It is only by comparing the frequency of heart disease in smokers to that in nonsmokers that the excess disease produced by smoking can be identified. In order to establish the relationship between smoking behavior and disease expenditures through a deposition process, a large number of individuals with all levels of severity of the multiple diseases associated with smoking, and with a full range of smoking behaviors, would have to be observed. This type of observation is the basis of many of the epidemiologic studies conducted over the past 50 years to establish the relationship between smoking and cancer or other diseases. A new study of a small number of individuals could have no value in examining these relationships.

10. The process by which the information is generated is also a concern. Even if the depositions are not intended to examine the relationship between smoking and medical expenditures, but are simply intended to look at the prevalence of smoking or the accuracy of ICD-9 coding, the information generated would still need to be applied to the overall Medicaid population. For this linkage to be valid, the process of establishing smoking status or true ICD-9 code must be similar to that used by the scientific community to establish smoking as a cause of disease, define the prevalence of smoking or estimate smoking attributable costs. We know that even small variations in the questions used in surveys can generate marked differences in the responses, and it is highly unlikely that questions asked through the formal and adversarial process of a deposition would generate responses similar to the questions asked in surveys of smoking behavior or epidemiologic studies of disease risk. Questions in surveys and epidemiologic studies are commonly simple self reports to questions, and no survey or epidemiologic study of disease expenditure has ever generated data on smoking through a deposition process. Therefore, even if large numbers of depositions are conducted, the information generated cannot be used to establish or invalidate estimates of smoking attributable health care costs in any legitimate or scientific manner. The deposition process will almost certainly generate different estimates of smoking behaviors, costs and ICD-9 coding; but these estimates are simply different. These different estimates include different errors of measurement and sources of bias; and, in contrast to the estimates used in the existing scientific studies, these sources of error have not been examined by the scientific community to assess their likely impact on the accuracy of the results. As a result, estimates derived through the deposition process arc less valid rather than more valid for use in establishing smoking attributable health care costs.

11. Smoking and health is one of the most studied subjects in the field of public health. The *Bibliography on Smoking and Health Selected Annotations*, U.S. Department of Health and Human Services and Centers for Disease Control and Prevention, is a bibliographic database which covers over thirty years of information and abstracts over 60,000 items on smoking and health. The medical literature is replete with extensive epidemiological studies, conducted over decades, comparing the disease and death rates of hundreds of thousands of smokers and nonsmokers. Every relevant population and demographic grouping has been examined, including Floridians and those on public assistance. Examples of these studies are: *American Cancer Society Cancer Prevention Study I and II*, *British Physicians Study*, *Dorn Study of U.S. Veterans*, *National Health Interview Survey*, *Current Population Survey*, *Behavioral Risk Factor Survey*, and the *National Medical Expenditure Survey*. Still more studies have examined the induction of cancers and abnormal pathology in animals, organ systems and cells exposed to cigarette smoke and its constituents. The psychology of smoking behavior and the pharmacological addiction to nicotine have all been extensively studies.

12. It is these studies conducted -- not by

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lawyers -- but by the world's leading scientists and medical organizations that should be used to establish damages. Their results and methods have been critically examined by blue ribbon scientific teams and peers reviewers to ensure accuracy and adherence to generally accepted scientific procedures. These studies were performed by scientists for science' not for litigation. Examples of these organizations arc; the Surgeon General of the United States, the Centers for Disease Control, the World Health Organization, the American Medical Association, the American College of Chest Physicians, the American Cancer Society, the American Lung Association, the American Heart Association, and numerous other medical authorities and scientific organizations both in the united States and abroad.

13. The State of Florida is alleging that a subgroup of the Medicaid population in Florida suffered (or suffers) from smoking-related illnesses. And it intends to employ epidemiology to establish that smoking caused (or causes) disease in this population. 13pidemiology is the field of public health that studies the incidence, distribution and etiology of disease in human populations. Its purpose is to better understand disease causation in groups of individuals. Epidemiology is, therefore, particularly well-suited to prove causation in this case which concerns smokers as a group. The science of epidemiology is well-recognized as an integral part of medical science and a proper form of evidentiary proof. As evidenced by the Office on Smoking and Health, U.S. Department of Health and Human Services, *Reducing the Health Consequences of Smoking: 25 Years of Progress*, *Report of the Surgeon General*, 38, 43, 102 116 (1989), cigarette smoking, is one of the most studied subjects in epidemiology.

14. The individualized proof sought by the defendants would not be probative of the validity and reliability of any survey data or statistical models the State may use to prove its damages, which are the health care costs due to smoking. The damage estimate the State will employ uses population-based data acquired from representative samples of national and state populations and actual Florida Medicaid expenditures. The estimates are not produced by summin'6 damages to individuals on Medicaid or based on the characteristics and diseases of each of those individuals. The calculation of excess costs for smokers compared to nonsmokers will be based on a national sample of the population where a study of medical utilization expenses was conducted and the smoking behaviors and other factors were recorded. A "smoking-attributable fraction" will then be recalculated using the study and Florida-specific estimates of smoking and other behaviors. Given the nature of the State of Florida's proof, the gathering of individualized evidence proposed by the defendants would be absolutely useless.

15. The defendants are not prevented from defending against the claims made by the State of Florida. They are free to test the State's population evidence and present population proof of their own to contradict it. They may present their own epidemiologists, statistics and survey experts. Further, the Medicaid program is an enormous program and has been in place for over 25 years in Florida. It has been studied exhaustively by statisticians who have conducted frequent audits, including of error rates, diagnoses and in the program's cost. The defendants could offer experts of their own to testify about those error rates, a process which is much less costly and time consuming --and much more reliable -- than the depositions of Medicaid recipients.

Further affiant sayeth not, this the 14 day of January, 1997.

David M. Burns, M.D.

Sworn to and subscribed before me, this the 14th day of January, 1997.

Notary Public

My Commission Expires:

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