UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

KATHLEEN DONOVAN and PATRICIA CAWLEY, Plaintiffs, - against - PHILIP MORRIS USA, INC., Defendant.	**AFFIDAVIT OF CLAUDIA I. HENSCHKE, M.D.** MISC 11-0151 (Pending in the United States District Court for the District of Massachusetts 06-CV-12234 (NG))
BURT XAVIER and JAMES FRANKLIN, Individually and on Behalf of Themselves and All Others Similarly Situated, Plaintiffs, - against - PHILIP MORRIS USA, INC., Defendant.	MISC 11-0152 (Pending in the United States District Court for the Northern District of California C 10-02067 WHA)
CHRISTOPHER GARGANO, and others similarly situated, Plaintiffs, - against - PHILIP MORRIS USA, INC., Defendant.	MISC 11-0153 (Pending in the United States District Court for the Southern District of Florida 1:10-CV-24042-PAS)

STATE OF NEW YORK)
) ss:
COUNTY OF NEW YORK)

I, Claudia I. Henschke, M.D., under penalty of perjury, hereby state as follows:

1. I am over the age of eighteen and submit this affidavit in support of the motion brought by non-parties David Yankelevitz, M.D., Mount Sinai School of Medicine ("MSSM"), and myself (collectively, the "Non-Parties") to quash the subpoenas served upon the Non-Parties by Defendant Philip Morris USA, Inc. ("PMUSA"). I am fully familiar with the facts and circumstances set forth herein.

2. I am currently employed as Attending Radiologist and Director of the Lung Cancer Screening Program at The Mount Sinai Hospital. I am also on the part-time faculty at MSSM as Clinical Professor of Radiology, and am an Adjunct Professor at Arizona State University. Finally, I am President of the Early Diagnosis and Treatment Research Foundation (the "EDTR Foundation").

Introduction

3. On or about October 28, 2010, I was served with a subpoena in the above-captioned Donovan action at my home in New York, New York, and I was later served with virtually identical subpoenas in the above-captioned Xavier and Gargano actions (collectively, the "Henschke Subpoenas"). Copies of the Henschke Subpoenas are included as Exhibits 1-3 in the Appendix of Exhibits submitted herewith (the "Appendix"). My colleague David Yankelevitz, M.D., was served with similar subpoenas (collectively, the "Yankelevitz Subpoenas"). Copies of the Yankelevitz Subpoenas are included in the Appendix as Exhibits 4-6. MSSM was served with similar subpoena (collectively, the "MSSM Subpoenas"), copies of which are included in the Appendix as Exhibit 7-9. These subpoenas hereinafter are collectively referred to as the "Subpoenas."

4. PMUSA is a named defendant in four separate class actions, in New York, Massachusetts, California and Florida (the "Class Actions")[1], in which Plaintiffs are asserting medical monitoring claims seeking low-radiation-dose computed tomography ("LDCT") lung cancer screening for class members. I am not a retained expert in any of these Class Actions. In fact, I have been repeatedly solicited by various attorneys to serve as an expert in various litigations, including by Plaintiffs' counsel in these pending Class Actions. I have always refused to do so, because for nearly twenty years, I have been engaged in the extensive collection, research and analysis of data regarding lung cancer screening, and I do not wish to have this data or my research subject to production in litigation.

5. PMUSA's Subpoenas herein seek production of "raw data" and confidential health information, including hundreds of thousands of CT scans and hundreds of thousands of data forms involving over 55,000 individuals from the United States and around the world from 1993 through the present. The burdens involved in producing this amount of data are overwhelming. Further, this data is the focus of continuing academic research on lung cancer screening by myself and my colleagues (including the cancer care centers that furnish us with data), and represents our future life as scientific researchers. Our continuing research would be severely damaged by enforcement of the Subpoenas. PMUSA has served the Subpoenas

[1] The four Class Actions are: *Donovan v. Philip Morris USA, Inc.*, Civil Action No. 06 cv 12234-NG (D. Mass.), *Xavier v. Philip Morris USA, Inc.*, Case No. C 10-02067 WHA (N.D. Cal.), *Gargano v. Philip Morris USA, Inc.*, Case No. 10-cv-24042-PAS (S.D. Fla.), and *Caronia v. Philip Morris USA, Inc.*, Civil Action No. 06-0224 (CBA) (E.D.N.Y.) (in which the Court dismissed plaintiffs' medical monitoring claims -- a decision now on appeal to the Second Circuit).

purportedly because our program and its published studies "have been the principal studies upon which the plaintiffs have based their medical monitoring claims in all of the" Class Actions.[2]

6. Lung cancer is the most deadly cancer in the world, killing more people than the next three types of cancer combined (breast, colorectal and prostate cancers), and killing more women than breast cancer. Screening, *i.e.*, testing designed to detect disease in asymptomatic individuals, is recommended for each of these latter three cancers, and in recent decades that screening has contributed to reduction in mortality. At present, there is no similarly recommended screening for lung cancer. Each year, approximately 160,000 deaths in the United States are due to lung cancer, the majority of which are caused by the decedents' use of smoking products, including in many cases goods produced by PMUSA.

7. For nearly twenty years, I have devoted almost all of my professional efforts to a large-scale collaborative research program which is now known as the International Early Lung Cancer Action Program ("I-ELCAP"). I-ELCAP's objective is to broaden knowledge of early diagnosis and treatment of lung cancer through research. At present, over 55,000 individuals (hereinafter "Voluntary Participants") who are being or have been screened at over 60 cancer care centers and medical centers around the United States and the world (hereinafter, collectively, "cancer care centers") voluntarily participate in I-ELCAP, by agreeing to make their CT scans and other medical information (hereinafter, "Voluntary Participant Data") available to I-ELCAP for research purposes. I-ELCAP is an ongoing research program

[2] *See* page 1 of the December 16, 2010 pre-motion letter to the Court from Gary R. Long, Esq. of Shook Hardy & Bacon, in opposition to the Non-Parties' December 9, 2010 pre-motion letter regarding our intended motion to quash the Subpoenas (the "PMUSA 12/16/10 Letter"), a copy of which is included in the Appendix as Exhibit 11.

with many of our original participants continuing to contribute new information, and we continue to accrue new participants as well.

8. In a very real sense, compliance with PMUSA's Subpoenas would irreparably harm this lung cancer screening research which is the synthesis of my multidisciplinary education and subsequent life's work. The chilling effect of any production pursuant to the Subpoenas of the Voluntary Participant Data being examined in our ongoing I-ELCAP research program cannot be overstated. Court-ordered production of this data to PMUSA would severely hamper, if not destroy, the collaborative I-ELCAP research model. I-ELCAP's existence is possible only because of the continued willingness of Voluntary Participants to undergo screening and make their data available to the research program. Voluntary Participants agree to make their data available by signing consent forms, which state who may have access to the data. Copies of sample consent forms are included as Exhibit 16 in the Appendix. From an ethical point of view, we at I-ELCAP would be compelled to notify all Voluntary Participants and cancer care centers involved in the research that their information was to be turned over to PMUSA, as such a turnover would be a major change in the research program and in the terms of limited use and confidentiality under which the Voluntary Participant Data was provided to I-ELCAP. Once notified, individual Voluntary Participants on a large scale would surely rescind their participation in I-ELCAP rather than benefit one of the tobacco companies that caused them and their loved ones the harm in the first place. If the Subpoenas were enforced, we at I-ELCAP also would be ethically obligated to include directly on the consent forms that PMUSA, by subpoena, has had access in the past and could have access in the future to the Voluntary Participant Data. Similarly, many of the contributing cancer care centers would cease their participation in I-ELCAP rather than provide information for a

continuing research program that is subject to the tobacco industry's possession and distortion. Under such conditions, nobody would participate in screening connected with I-ELCAP, and our ability to collect new and follow-up Voluntary Participant Data would be destroyed. The ability of I-ELCAP and the contributing cancer care centers to secure funds to conduct this research would also be effectively destroyed if the Subpoenas are upheld as there would be no agency or institution that would want to provide funds to I-ELCAP as they would effectively be supporting data that would be given to PMUSA. Accordingly, enforcement of PMUSA's subpoenas will discourage participation in I-ELCAP, leading to fewer screening CT scans being performed, and to the worsening of problems caused by tobacco use, including the suffering and deaths of individual smokers.

9. The destruction of I-ELCAP in this manner also likely would cause me to lose the various employment positions that I currently hold. If the Voluntary Participant Data from the open, active and ongoing I-ELCAP research program falls into the hands of PMUSA and/or other tobacco companies, there is no telling what they will do with the data in order to serve their own ends. In such circumstances, Voluntary Participants will no longer wish to participate in I-ECLAP research, funding for I-ELCAP will dry up, and it will not be possible to continue the I-ELCAP research to which I have devoted my life and career. My career and the careers of many other researchers will be drastically harmed and/or destroyed. My position is supported by research funds. Further, the public health benefits of our research will be denied.

10. Enforcement of the Subpoenas herein would not only damage I-ELCAP and my career. It would have a broader chilling effect on other kinds of large-scale collaborative research efforts to examine and fight public health dangers caused by corporate interests. If PMUSA can get access to our active Voluntary Participant Data even though we are Non-Parties

to the Class Actions, it would seem that the subpoena power of litigants is limitless, and anytime a litigant's expert relies on an article, then the authors of that article can be subjected to this same abuse. Researchers, administrators of medical schools and hospitals, foundations, and other entities dispensing grant monies will have little incentive to make the investment and effort needed to collect and examine broad-based data over the course of many years if that data can then be taken by those very corporate interests at their mere service of a litigation subpoena, allowing the corporate interests to analyze the data to suit their own goals, and usurping the original researchers' opportunity to conduct analysis and reach findings in a scientific fashion. The very foundation of research and development, whether in the medical, academic or commercial context, is threatened by PMUSA's Subpoenas. All of this would be of direct benefit to PMUSA, because it would limit research into the dangers of their products. Again, this would lead to adverse public health consequences.

11. Thus far, our publications regarding I-ELCAP screening research have been preliminary and have focused on information regarding the Voluntary Participants that is simple and indisputable, *e.g.*, age, gender, smoking history, nodules identified on the LDCT scan and the subsequent workup, date of lung cancer diagnosis, date of death if any, and date of surgery and type of procedure if any. We have looked at some aspects of the workup, but only in a preliminary way, and we have looked at some ancillary findings such as mediastinal masses, emphysema, and coronary artery calcifications. We have by no means examined the full set of data that we planned to examine. We have continued to analyze the Voluntary Participant Data, and plan to make further publications, regarding numerous other aspects of the data, including co-morbidities, ethnic differences, and environmental effects. The main purpose of our 2006 publication in the New England Journal of Medicine (discussed further below) setting forth

preliminary findings in the I-ELCAP research program, was to begin to estimate the overall cure rate of screen-detected lung cancers, and our published findings were merely interim results. One of the main criticisms of that article was that there were very few Voluntary Participants who were actually followed for a full 10 years; another criticism was that even 10 years was an insufficient length of time. As to most Voluntary Participants, we are still working to reach that 10 year evaluation point. In short, I-ELCAP is ongoing: from inception, its researchers have planned to screen at least 100,000 Voluntary Participants, and currently we are just over halfway to that goal, with follow-up screenings of existing Voluntary Participants also being performed.

12. Production of the data demanded by the Subpoenas thus would be devastating to our research. Having collected the Voluntary Participant Data, we should be entitled to explore it and publish our findings on our scientific terms and on our schedule, without having it snatched away by a class action Defendant because the class Plaintiffs' experts have relied on some of our earlier published preliminary findings. This is particularly true here because the Plaintiffs' experts have not seen I-ELCAP's Voluntary Participant Data as a whole either; to the extent they rely on I-ELCAP's findings, they do so only on the basis of our published articles. Plaintiffs' experts also rely on many other screening studies besides I-ELCAP, as well as their own lung cancer screening research, which PMUSA has not subpoenaed. Both Plaintiffs' and PMUSA's experts refer to many other screening studies beyond I-ELCAP in their expert reports and discuss the body of evidence from these multiple studies. They also rely on many non-screening studies to make their points regarding specific aspects of screening, and will surely rely on the many additional studies published in the last few years with data similar to I-ELCAP. Thus, access to the I-ELCAP Voluntary Participant Data is not essential to PMUSA's defense of the Class Actions.

13. There have been numerous lung cancer screening studies conducted by others over the past 20 years or more, many of which have been completed. PMUSA does not have a compelling need to have access to I-ELCAP's data, when I-ELCAP is an on-going and growing research program, which is being continuously updated with follow-up information on the enrolled Voluntary Participants, even through the present. Other studies have been completed and published, and their databases closed, and PMUSA should look to that information if it feels the need to examine raw data. Furthermore, some of PMUSA's own experts -- including Dr. Robert McCunney at Massachusetts General Hospital and Dr. Philippe Grenier in France -- are at institutions that performed or are performing CT screening.

14. In addition, a study called the National Lung Screening Trial ("NLST"), funded by the National Cancer Institute ("NCI") and the American Cancer Society, announced its results in November 2010, and has always been viewed by the overwhelming majority of the scientific community as the gold standard in lung cancer screening studies, eclipsing I-ELCAP and others. The NLST was an eight-year randomized trial following two groups totaling over 53,000 individuals aged 55 to 74 with heavy exposure to tobacco; one group was screened with CT scans and the other group was screened with chest x-rays. The NLST results showed that participants receiving low-dose CT scans had 20% fewer deaths from lung cancer than those receiving chest x-rays. The pre-eminence of the NLST, which was the most expensive screening study ever done by the NCI, as the definitive study as viewed by the medical community at large is manifest. The results were so powerful in showing the benefit of screening with CT scans that the study was closed abruptly in order to notify all of the participants, especially in the control arm who did not receive CT scan screening, about its results.

15. Although in many ways I-ELCAP has been a seminal and galvanizing research program that led the NCI to launch the NLST, its published preliminary findings have never been accepted by the medical community (including, in particular, medical societies that publish guidelines which influence the way patients are treated) as conclusive evidence that lung cancer screening saves lives and thus should be widely implemented. A principal reason for this is that I-ELCAP is not a randomized trial, in which results from one test group receiving CT screening are compared to results from anther "control" group that is not receiving CT screening. The NLST is such a randomized trial, and therefore its results have been received with far more acceptance in the medical community and by medical societies than I-ELCAP's preliminary findings ever have been. The NLST's results now set the terms of any debate on lung cancer screening.

16. In seeking to enforce the Subpoenas, PMUSA has downplayed the importance of the NLST, arguing that Plaintiffs' experts continue to rely on I-ELCAP findings in their reports even after the November 2010 release of the NLST results. *See* pages 6-7 of the PMUSA 12/16/10 Letter. This is misleading. Plaintiffs' experts will surely acknowledge the preeminent effect of the NLST and each of them reserved the right to add to their reports (which pre-date November 2010) as new information became available. Moreover, three of PMUSA's experts (Dr. Philip Goodman, Dr. Philippe Grenier, and Dr. Robert McCunney) have written articles discussing the preeminence of NLST and that it is definitive. *See* the following articles by these experts of PMUSA:

- McCunney RJ, *Should we screen for occupational lung cancer with low-dose computed tomography?*, Journal of Occupational and Environmental Medicine Dec. 2006; 48(12):1328-33, Exhibit 17 in the Appendix;

- Grenier P, *Does CT screening for pulmonary nodules decrease lung cancer mortality?*, Journal of Radiology Feb, 2007; 88(2):296 (article is in French), Exhibit 18 in the Appendix;

- Blanchon T, Bréchot JM, Grenier PA, Ferretti GR, Lemarié E, Milleron B, Chagué D, Laurent F, Martinet Y, Beigelman-Aubry C, Blanchon F, Revel MP, Friard S, Rémy-Jardin M, Vasile M, Santelmo N, Lecalier A, Lefébure P, Moro-Sibilot D, Breton JL, Carette MF, Brambilla C, Fournel F, Kieffer A, Frija G, Flahault A; Dépiscan Group, *Baseline results of the Dépiscan study: a French randomized pilot trial of lung cancer screening comparing low dose CT scan (LDCT) and chest X-ray (CXR)*, Lung Cancer Oct. 2007; 58(1):50-8, Exhibit 19 in the Appendix; and

- Goodman PC, *Computed tomography scanning for lung cancer screening: an update*, The International Journal of Tuberculosis and Lung Disease Jul. 2010; 14(7):789-91, Exhibit 20 in the Appendix.

17. The NLST, as the "definitive" study, is one of the necessary pillars on which changes to policies and guidelines on lung cancer screening may be based. However, the NLST acknowledges the need to collect more information and conduct more research before lung cancer screening will meet general acceptance. The NLST anticipates getting much of this from various sub-studies and modeling. I-ELCAP is uniquely positioned to assist in this effort. In particular, I-ELCAP intends to evaluate much additional information on a broader age range and smoking history (including people exposed to second hand smoke). Also, I have been working for the past several years with a member of the Cancer Intervention and Surveillance

Modeling Network ("CISNET"), the group charged with doing modeling, and this has led to an important paper. Now that the NLST results have been released, we at I-ELCAP will need to go back to Voluntary Participants to get more data (such as the reasons they did not come for screening every year and other issues about compliance, including anxieties), and we plan also to conduct multiple other studies about risk factors, going back and getting bloods and sputums, or seeing differences between groups that come every year or less frequently. All of these types of studies as well as others will be critical. The NCI has credited ELCAP as providing the impetus for NCI to recognize the potential of screening and to perform the NLST, the most expensive screening study, and in getting it started in the shortest amount of time ever for a large randomized screening trial. The NLST showed screening to be so beneficial that the study was stopped early, but for the many issues that remain, I-ELCAP will be invaluable. According to Dr. James L. Mulshine, Vice President and Associate Provost for Research at Rush University Medical Center and a leading cancer researcher, the NLST results are what cancer researchers have been waiting for: "With this positive trial result, we have the opportunity to realize the greatest single reduction in cancer mortality in the history of the war on cancer." That's how big lung cancer screening is, and destroying I-ELCAP by upholding PMUSA's Subpoenas would be devastating.

18. Moreover, as PMUSA well knows, "the medical community has repeatedly criticized the I-ELCAP research, citing data inconsistencies and inaccuracies, undisclosed financial interests, protocol irregularities, and even calling for a full audit." *See* page 2 of the PMUSA 12/16/10 Letter, and Exhibits D through J thereto. PMUSA thus is already well-armed to cross-examine Plaintiffs' experts about their alleged reliance on I-ELCAP

findings, particularly when those experts did not have access to I-ELCAP's Voluntary Participant Data either.

19. Further, PMUSA's Subpoenas constitute an invasion of my privacy and appear to be improperly calculated to raise questions concerning my personal and professional integrity, as they seek production of decades of information concerning conflicts of interest, sources of funds, communications with professional bodies and various professional journals. Academic freedom should be protected in the face of such attempts at *ad hominem* intimidation.

20. Why does PMUSA seek manuscripts that have been rejected by journal publications? Why does PMUSA have a right to information concerning grant applications that may not have been funded? The only possible purpose for its seeking these materials is to cause embarrassment to me and third parties I work with professionally or to seek information about our ideas and plans that have not yet been published.

21. I have read Dr. Yankelevitz's affidavit, which is submitted herewith, and concur in the points raised therein, which are incorporated herein by reference.

Affiant's Background and Experience

22. My curriculum vitae is included as Exhibit 21 in the Appendix, and is briefly summarized below.

23. After graduating from Southern Methodist University with a B.A. degree in French and Mathematics in 1961, I received an M.S. degree in Mathematical Statistics from Southern Methodist University in 1966 and my Ph.D. in Mathematical Statistics and Computer Science from the University of Georgia at Athens in 1969. During this time, I also worked as a

computer programmer, statistician, and systems analyst for various research institutes and other companies.

24. From 1969 to 1972, I was Assistant Professor of Mathematical Statistics and Computer Science in the School of Arts and Science and Assistant Professor of Management in the Business School at the University of Georgia.

25. From 1972 to 1974, I was an Assistant Professor of Biostatistics at Georgetown Medical School in Washington, D.C. During that time, I also served as Statistical Consultant for the National Clinical Trial of Narcotic Antagonists for the National Academy of Sciences, Statistical Consultant for the National Clinical Trial of Long Acting Methadone for the Veterans' Administration, and Consultant for Health Manpower Planning for the National Institutes of Health's Bureau of Health Manpower Education.

26. From 1972 to 1977, I also served as Consultant for the Federal Preparedness Agency on U.S. Civil Disasters and White House Planning and Briefing, and as a Statistical Consultant for Large Military Field Tests and Performance Analyses for the Institute for Defense Analysis and for Systems Planning Corporation.

27. I started medical school at Howard University College of Medicine in 1974 and received my medical degree in 1977, while continuing my consulting activities described above.

28. From 1977 through 1981 I completed a Residency in Radiology at Brigham and Women's Hospital in Boston, Massachusetts and a Clinical Fellowship in Radiology at Harvard Medical School.

29. In 1981, I became board-certified by the American Board of Radiology.

30. From 1981 through 1983, I was an Instructor and Assistant Professor of Radiology at Harvard Medical School. From 1983 through 2010, I progressed from Assistant Professor to become Professor of Radiology and Chief of the Chest-Imaging Division at the Weill Cornell Medical College and Attending Radiologist at New York Presbyterian Hospital – Cornell Medical Center. I also held various other academic, hospital, and editorial appointments and positions, authored numerous articles, and served on many national and international committees.

31. In 2010, I joined MSSM and The Mount Sinai Hospital.

The ELCAP Data Sought By the Subpoenas

32. In or around 1992, I embarked, with my colleagues, on The Early Lung Cancer Action Project, or ELCAP, which studied the use of LDCT screening, as applied to people at high risk for lung cancer due to their history of cigarette smoking. Our goal was to assess whether LDCT screening of people who do not yet have any symptoms of lung cancer could save lives. When lung cancer is diagnosed as a result of symptoms, it is nearly uniformly fatal.

33. ELCAP enrolled 1,000 Voluntary Participants with a history of cigarette smoking and each person underwent both a LDCT scan and chest x-ray. This was performed at two New York City hospitals. Each Voluntary Participant was interviewed and provided informed consent for participation in the research.

34. Based on initial ELCAP findings, I co-authored (with Dr. Yankelevitz and others) an article entitled "Early Lung Cancer Action Project: overall design and findings from baseline screening." This article appeared in volume 354 of The Lancet on July 10, 1999, and concluded that LDCT can greatly improve the likelihood of lung cancer being found at an earlier and potentially more curable stage. A copy of this article from The Lancet is included in the Appendix as Exhibit 23.

35. ELCAP was a groundbreaking research investigation because it showed that early stage lung cancer could be systematically detected at an earlier stage using LDCT than using chest x-rays. ELCAP placed CT scanning in the forefront of cancer detection.

36. Although ELCAP was the first American lung cancer screening investigation to be the subject of a published article, there were two Japanese publications that preceded the ELCAP publication in 1999. *See* Kaneko M, Eguchi K, Ohmatsu H, Kakinuma R, Naruke T, Suemasu K, Moriyama N, *Peripheral lung cancer: screening and detection with low-dose spiral CT versus radiography*, Radiology Dec. 1996; 201:3:798-802, Exhibit 24 in the Appendix; and Sone S, Takashima S, Li F, Yang Z, Honda T, Maruyama Y, Hasegawa M, Yamanda T, Kubo K, Hanamura K, Asakura K, *Mass screening for lung cancer with mobile spiral computed tomography scanner*, The Lancet 1998; 351:1242-5, Exhibit 25 in the Appendix.

37. In the ELCAP research, we compiled and analyzed the Voluntary Participant Data. (We continue to compile and analyze such data in the expanded successor research program of NY-ELCAP and I-ELCAP, as discussed below). Our findings were made on the basis of a simple set of Voluntary Participant Data, which included age, gender, smoking

history, method of diagnosis (CT scan or x-ray) and description of imaging findings, date of diagnosis, biopsy if performed, date of surgery if performed, and date and cause of death if any.

38. After the 1999 Lancet article, new Voluntary Participants were added to ELCAP and existing Voluntary Participants are still engaging in follow-up CT screenings. In addition, we are able to contact prior Voluntary Participants to participate in sub-studies such as one currently ongoing with the Weizman Institute in Israel and Johns Hopkins University in Maryland. As a result of the NLST releasing its results, there will be a need for further studies before medical societies will determine whether they will recommend that lung cancer CT screening should be provided to certain at-risk groups within the general population. I-ELCAP is uniquely situated to perform and assist in these studies.

39. The Voluntary Participant Data compiled and analyzed in ELCAP is currently in the custody of MSSM. I do not have personal custody of the ELCAP Voluntary Participant Data. New Voluntary Participants were added to ELCAP, and existing Voluntary Participants are still engaging in follow-up annual CT screenings. Important data continues to accrue on these Voluntary Participants as we follow them over time, which adds to our knowledge of how well they survive and other facts.

Further Inquiries Spurred by ELCAP: Does Cessation of Smoking Reduce Cancer Risk?

40. The preliminary findings of our ELCAP research spurred a great deal of interest and galvanized further study in certain fields of medical oncology. Indeed, our ELCAP research is a good example of how a research investigation can create major changes in how medicine confronts a public health problem.

41. For example, ELCAP led us to engage in further research and publications to see whether CT screening and the information gleaned from Voluntary Participants enhanced smoking cessation and then how much smoking cessation will reduce an individual's prospective risk of suffering from lung cancer. Further investigation of these findings is now ongoing in one of our funded foundation grants. Our research in this area was the first on the subject of the unanticipated benefit of CT screening in helping with smoking cessation. *See, e.g.*, Ostroff J, Buckshee N, Yankelevitz DF, Henschke CI, *Smoking Cessation: An unexpected benefit of screening CT for detection of early lung cancer*, Preventive Medicine 2001; 33:613-621, Exhibit 26 in the Appendix. Our research has stimulated a growing body of literature on the topic and, in particular, we have recommended integration of smoking cessation programs in screening programs in general. This thesis is likely to cause more individuals to quit smoking (because in doing so they will reduce their risks of developing lung cancer as well as other diseases caused by tobacco), but it is also a thesis that the tobacco industry would prefer that I not pursue. My pursuit of the thesis is likely to cause cigarette sales to decline.

42. ELCAP also led us and others to pursue the field of radiological medicine that studies the CT appearance of different types of nodules and their likelihood of being lung cancer. This led to grants from the NCI, and a whole body of medicine developed that uses three-dimensional tumor volumes to examine the nature of the tumors, changing the way medicine is practiced in this field. The pulmonary nodule is a major problem in health care. In the course of our work, we developed an entirely new approach to evaluate these nodules because other techniques, such as positron emission tomography ("PET") scans, do not work well for small lesions. ELCAP led us to develop new techniques to measure change in size of

nodules and these techniques are now becoming widely accepted as a major advance in the management of this extremely important and common problem. *See, e.g.*:

- Yankelevitz DF, Reeves A, Kostis W, Henschke CI, *Small pulmonary nodules: volumetrically determined growth rates based on CT evaluation*, Radiology Oct. 2000; 217(1):251-256, Exhibit 27 in the Appendix;

- Kostis WJ, Reeves AP, Yankelevitz DF, Henschke CI, *Three-dimensional segmentation and growth-rate estimation of small pulmonary nodules in helical CT images*, IEEE Transaction on Medical Imaging 2003; 22:1259-1274, Exhibit 28 in the Appendix;

- Kostis WJ, Yankelevitz DF, Reeves AP, Fluture SC, Henschke CI, *Small pulmonary nodules: reproducibility of three-dimensional volumetric measurement and estimation of time to follow-up CT*, Radiology 2004; 231:446-452, Exhibit 29 in the Appendix;

- Jirapatnakul AC, Fotin SV, Reeves AP, Biancardi AM, Yankelevitz DF, Henschke CI, *Automated Nodule Location and Size Estimation Using a Multi-scale Laplacian of Gaussian Filtering Approach*, Conf. Proc. IEEE Eng Med Biol Soc. 2009; 1028-31, Exhibit 30 in the Appendix; and

- Reeves A, Chan A, Yankelevitz DF, Henschke CI, Kostis WJ, *On measuring the change in size of pulmonary nodules*, IEEE Transactions on Medical Imaging, Apr. 2006; 25(4): 435-450, Exhibit 31 in the Appendix.

43. The Netherlands-Leuvens Longkanker Screenings Onderzoek ("NELSON") study is an important Dutch-Belgian randomized lung cancer screening trial currently being conducted with approximately 15,000 Voluntary Participants. An article on the NELSON study was recently published at:

- Van Klaveren RJ, Oudkerk M, Prokop M, Scholten ET, Nackaerts K, Vernhout R, Van Iersel CA, Van Den Bergh KAM, Van't Westeinde S, Wan Der Aalst C, Thunissen E, Xu DM, Wang Y, Zhoa Y, Gietema HA, De Hoop B-J, Groen HJM, De Bock GH, Van Ooijen P, Weenink C, Verschakelen J, Lammers JWJ, Timens W, De Koning HJ, *Management of Lung Nodules Detected by Volume CT Scanning*, The New England Journal of Medicine, 3 December 2009; 361:2221-2229, Exhibit 32 in the Appendix.

The NELSON study relied on nodule volume assessment techniques, a field developed by my colleague David Yankelevitz, M.D., and such reliance was recognized in the New England Journal of Medicine editorial that accompanied the NELSON article. *See* Mulshine JL, Jablons DM, *Volume CT for diagnosis of nodules found in lung-cancer screening*, New England Journal of Medicine Dec. 3, 2009; 361(23):2281-2, included as Exhibit 33 in the Appendix.

44. ELCAP also led us to investigate other diseases related to smoking, such as coronary artery disease, as shown in the following recently published article: Shemesh J, Henschke CI, Shaham D, Yip R, Farooqi AO, Cham MD, McCauley DI, Chen M, Smith JP, Libby DM, Pasmantier MW, Yankelevitz DF, *Ordinal scoring of coronary artery calcifications on low-dose CT scans of the chest is predictive of death from cardiovascular disease*, Radiology Nov. 2010; 257(2):541-8, included as Exhibit 34 in the Appendix. Other such research, for

example into emphysema, is currently ongoing. Thus, further investigation continues regarding the key tobacco-related diseases of lung cancer, emphysema and coronary artery disease, the three biggest reasons for premature death in the United States. Follow-up information from Voluntary Participants in I-ELCAP is important in each of these research articles. PMUSA cannot realistically argue that they only seek Voluntary Participant Data from before a certain date; the Voluntary Participants initially screened years ago continue to contribute data.

45. Furthermore, the Radiology article referenced in the preceding paragraph was accompanied by an editorial that explains that an entirely new field of medicine is now opening up because of this type of investigation, namely that we can now look at things that were not the initial primary intent of the exam. For example, in this case, the scan was done for screening purposes for lung cancer, but we also were able to find important information about the heart, and develop an approach for assessing risk that had not even been thought of when the patient's exam was initially ordered. The editorial recognizes that this may represent a new paradigm in medicine. *See* Lee CI, Forman HP, *What we can and cannot see coming*, Radiology Nov. 2010; 257(2):313-4, Exhibit 35 in the Appendix. Thus, Voluntary Participant Data incorporated in our research program which we published years ago continues to be a source of scientific investigation and the basis for future (not yet published) studies.

46. It is also not a stretch to say that ELCAP stimulated the NCI to undertake the NLST, a large-scale lung cancer screening study whose results are now considered the gold standard on the subject. After the publication of ELCAP's preliminary findings, the NLST investigators stated that they were able to get their study up and running faster than any other large scale screening study that NCI had ever performed.

47. After our initial publication of preliminary findings on ELCAP in The Lancet in 1999, ELCAP was expanded and our lung cancer screening has continued through the present. If, however, ELCAP's Voluntary Participant Data had been subpoenaed back in the 1990s and turned over to a tobacco industry litigant such as PMUSA, it is likely that ELCAP would have withered and the scientific community would not have experienced the expansion of medical knowledge and benefits that followed the publication of ELCAP preliminary findings in 1999.

48. Begun in 1993, ELCAP (and its successors, including NY-ELCAP and I-ELCAP) is one of the longest running longitudinal research programs on lung cancer screening and survival in the world. It continues even now and promises numerous future research benefits because of its duration. If the Subpoenas are enforced, participation in I-ELCAP will certainly decline drastically, and it is likely that funding will no longer be available. Under such circumstances, we will be unable to continue the I-ELCAP research program and the cancer care centers in the United States and around the world will cease their I-ELCAP CT screening programs. This is precisely the result that PMUSA would like to see. Tobacco companies have long held I-ELCAP in disfavor and would like nothing more than to see it stopped. Our goal is to screen at least 100,000 Voluntary Participants, and with approximately 55,000 so far, we are just over half way to that goal. For the program to be successful, we require longer follow-up on the majority of participants who have been found to have lung cancer. (Our collection really expanded in or around 2000 after the publication in 1999 of our preliminary findings on the first 1000 Voluntary Participants.) The finding that cessation of smoking leads to a decline in the risk of an individual developing lung cancer only serves to threaten the tobacco industry, as could other studies of tobacco-related harms such as emphysema, heart disease and others. If the

Subpoenas are enforced and the Voluntary Participant Data is ordered to be produced, the I-ELCAP research program will be irreparably damaged, perhaps even destroyed, and many, if not all, of the long-term benefits of I-ELCAP will be lost.

NY-ELCAP: ELCAP Evolves

49. Based on the ELCAP findings, our research program was expanded in or around 2000 to an additional 6,295 Voluntary Participants at 12 New York cancer care centers to accumulate further data for analysis. This program was called the New York Early Lung Cancer Action Project ("NY-ELCAP"). The findings were substantially similar to those concluded following ELCAP and reported in The Lancet. Dr. Yankelevitz and I and others continued to update and improve the ELCAP algorithm in analyzing the NY-ELCAP data.

50. NY-ELCAP procedures, analysis and preliminary findings were published in an article I co-authored (again with Dr. Yankelevitz and others) entitled "CT Screening for Lung Cancer: Diagnoses Resulting from the New York Early Lung Cancer Action Project." This article was published in the April 2007 volume of Radiology, and is included as Exhibit 36 in the Appendix. The Radiology article sets forth the methodology used through the course of our research, basic information regarding the Voluntary Participants screened, and a detailed description of the research protocol. A thorough discussion and our findings are provided in that article.

51. Voluntary Participant Data collected and analyzed in NY-ELCAP is in the custody of MSSM. I do not have personal custody of the NY-ELCAP Voluntary Participant Data. While no new Voluntary Participants are being added to NY-ELCAP, existing Voluntary

Participants are still engaging in follow-up annual CT screenings. All of this follow-up data is contributed to I-ELCAP.

I-ELCAP: The Evolution of ELCAP Continues

52. In or around 2000, due to the interest generated by our publication of ELCAP's preliminary findings, and because it was recognized that pooling data from multiple institutions around the world would be a beneficial new approach to answering the manifold questions that arise in the context of screening, it was decided to expand the ELCAP research program to include the participation of national and international cancer care centers, and I-ELCAP was born. This development resulted from our International Conferences on Screening for Lung Cancer, which cancer care centers, researchers and investigators around the United States and elsewhere in the world attended as they were clamoring to participate in I-ELCAP to get involved in cutting edge research which held out the most promise for success against lung cancer, the major cancer killer in the world, and to provide the benefits for their patients.

53. I-ELCAP is remarkable because it created a new paradigm of research that can be performed on a global level. It is an outstanding example of many of the recommendations that the Institute of Medicine (the health arm of the National Academy of Sciences) makes for advancing medical research. Such recommendations include collecting ongoing clinical practice data, quasi-experimental designs as an alternative to randomized trials, data mining from a large and growing database, and mathematical modeling. *See* paragraph 10 of the Affidavit of James L. Mulshine, M.D., submitted herewith.

54. I-ELCAP is a unique and unprecedented cooperative collaboration of cancer care centers world-wide, which are now more than 60 in number. There are currently 50

participating cancer care centers in the United States, 2 in Spain, 2 in China, and 1 each in Canada, Israel, Italy, Japan, Switzerland, and Taiwan. Some have completed their enrollment but are still engaged in providing follow-up information and in participating in future publications. I-ELCAP is the most broad-based ongoing lung cancer screening research program in the world, with Voluntary Participants and participating cancer care centers located across the United States and beyond.

55. Further, because it raises the issues of positive effects from smoking cessation, it goes to the heart of the tobacco industry's interests: cigarette sales. PMUSA's Subpoenas threaten to block and undo many of the benefits of I-ELCAP.

56. Preliminary I-ELCAP findings were published in the New England Journal of Medicine ("NEJM") on October 26, 2006 in an article entitled "Survival of Patients with Stage I Lung Cancer Detected on CT Screening." I also co-authored this article with Dr. Yankelevitz. A copy of this NEJM article is included as Exhibit 37 in the Appendix. As with our published articles on ELCAP and NY-ELCAP, our preliminary I-ELCAP findings in this article again were made on the basis of a simple set of Voluntary Participant Data, which included age, gender, smoking history, presence and characteristics of nodules, date of diagnosis, date of biopsy and surgery if any, and date and cause of death if any.

I-ELCAP's Requirement of Strict Confidentiality

57. In my opinion as a lifelong medical researcher, the key to getting individuals to voluntarily participate in research such as I-ELCAP is a promise to the individuals that their health information will remain strictly confidential, with only the individuals' clinicians and the research investigators having access to the information.

58. I-ELCAP had enrolled 31,567 Voluntary Participants screened between 1993 and 2005 using the continually updated I-ELCAP protocol which was established in ELCAP and refined in NY-ELCAP. Today, there are an estimated 55,000 Voluntary Participants who have allowed their health data to be analyzed in these studies. The complete protocol for I-ELCAP collaboration is included as Exhibit 38 in the Appendix.

59. The Voluntary Participants whose information is provided to I-ELCAP undergo screening at one of the more than 60 participating cancer care centers in the United States and abroad, and if lung cancer is diagnosed, undergo treatment. Each cancer care center is home to one or more lung cancer investigators and their multidisciplinary teams, who are involved in performing CT scans, workup and ultimately treatment of lung cancer, if necessary, on the Voluntary Participants. The data are maintained in separate databases at each cancer care center, according to their rules and regulations. In addition, each cancer care center sends the data and a copy of each CT scan to I-ELCAP. Each cancer care center continues to "own" its Voluntary Participant Data. No cancer care center has access to any Voluntary Participant Data other than its own.

60. To my knowledge, none of the cancer care centers that provide Voluntary Participant Data has been served with a subpoena by PMUSA seeking these Voluntary Participants' health records.

61. All cancer care centers participating in I-ELCAP voluntarily compile and have provided confidential Voluntary Participant Data to I-ELCAP, but did so only with the expectation that the data will remain confidential. Use of the data for any purpose must be

approved by each of the institutions, and the institutions can withdraw from I-ELCAP at their own discretion.

62. I-ELCAP's research model is notably different from the NLST's research model. The NLST was funded primarily by a central source (the federal government), and the cancer care centers furnishing data to the NLST did not control their own data and could not publish it on their own. I-ELCAP's model is the opposite: the contributing cancer care centers do own their data, can review it on their own, and publish it on their own, with or without I-ELCAP approval. Some I-ELCAP cancer care centers have done just that, including centers in China, Toronto, Israel, Spain, and the Department of Energy study conducted by Plaintiffs' experts Drs. Miller and Markowitz.

63. Voluntary Participant Data from each cancer care center is made available to I-ELCAP via a web-based interactive system designed specifically for I-ELCAP research. Each cancer care center can only access its own site's data. As reflected in the I-ELCAP protocol, confidentiality is assured:

> The system assures confidentiality and reliability. In the transmission, secure scripts are used. Unique passwords are required for access to particular segments of the central database. Accessing the data from each institution involves built-in encryption to maintain security over the Internet (ssh2 and SSL for web access). Identification of the subject is available only to the participating institution, as only the system-assigned code-identifier is available in the I-ELCAP database.

See page 10 of the I-ELCAP protocol, at Exhibit 38 in the Appendix.

64. The Voluntary Participant Data is submitted by contributing cancer care centers with the understanding that such data will be used by I-ELCAP investigators, including

me, only for the purposes of scientific inquiry and research. I do not have personal authority to provide this Voluntary Participant Data to anyone, including particularly PMUSA.

Proprietary Software Code

65. Over the course of my working career and particularly over the last 20 years, I, working together with other investigators, have devoted thousands of hours to developing proprietary software code relating to statistical analysis, including the data collection forms on which I-ELCAP information is entered. PMUSA is not entitled to this software code, which it requests in the Subpoenas. I have no intention of turning it over to the tobacco industry. The code is extremely valuable intellectual property and is proprietary to me and my employers.

66. In addition to my medical degree and experience, I hold a Ph.D. in Mathematical Statistics and Computer Science from the University of Georgia at Athens. As part of my Ph.D. studies, I did coursework in mathematical statistics, experimental designs, and advanced computing. My Ph.D. thesis involved statistical methodology and analysis of data applied to the United States Air Force recruitment program and assignment of recruits to jobs. The large-scale program development and computing requirements for the Air Force program helped to provide me with the necessary skills for the development of the proprietary software code.

67. To conduct our research using the Voluntary Participant Data contributed to I-ELCAP and its predecessors ELCAP and NY-ELCAP, Dr. Yankelevitz and I, together with the other investigators around the United States and the world, developed and continuously updated a management algorithm. This algorithm is reviewed and updated if needed every six

months when the investigators meet. The algorithm has been updated on our website, www.ielcap.org, and changes to the algorithm are evident in our published articles.

68. One major benefit of our research was that our algorithm was instrumental in helping to formulate current guidelines in clinical practice (outside of the screening) for the workup of nodules. With the increased use of CT scanning, the detection of small lung nodules has increasingly become a major healthcare concern. Our published results helped in formulating the new guidelines for workup of nodules.

69. The development of our proprietary software code has played an important role in enabling our large collaborative effort on lung cancer screening research. As part of this developmental work, we also invested many years of effort in developing and adapting the various data collection forms that we use in our research.

70. In later stages, I enlisted the help and support of computer programmers and specialists at Cornell University at Ithaca to assist in the transfer of this code into I-ELCAP's web-based system. This includes the important development of the web forms to collect data. These efforts have been a critical component of our ability in I-ELCAP to collect and interpret Voluntary Participant Data.

MSSM and the EDTR Foundation

71. MSSM is a cancer care center that currently contributes Voluntary Participant Data to I-ELCAP, and maintains Voluntary Participant Data collected from the Voluntary Participants treated at MSSM.

72. During the years I was employed there, Weill Cornell Medical College served as the I-ELCAP Coordinating Center and also participated in I-ELCAP. The Voluntary Participant Data collected during that time at Weill Cornell Medical College, including from some of the I-ELCAP cancer care centers, is now in the custody of MSSM. Continuing Voluntary Participants previously screened at Weill Cornell Medical College are now given CT scans at MSSM.

73. During 2009, the EDTR Foundation was created. The EDTR Foundation is an independent entity that currently has custody of Voluntary Participant Data which were contributed by many of the cancer care centers that participate in I-ELCAP, other than those at MSSM, which are sought by the Subpoenas.

74. As mentioned above, I do not have personal ownership or custody of any of the Voluntary Participant Data that has been contributed to I-ELCAP. As I-ELCAP's principal investigator, I merely have been permitted to access such data over the years to conduct the I-ELCAP research.

75. I do not have unfettered access to the Voluntary Participant Data. Although I plan to perform future I-ELCAP research and investigation, I need the approval of the participating cancer care centers prior to publication of any results involving the Voluntary Participant Data from their institutions.

76. Institutional Review Boards ("IRBs") are committees that have been formally designated to approve, monitor and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects. In the United States, regulations of the Food and Drug Administration and the Department of Health

and Human Services have empowered IRBs to approve, require modifications or reject planned research. IRBs perform critical scientific, ethical and regulatory oversight functions for research conducted on human subjects.

77. Contributing cancer care centers independently determine whether they want to participate in any particular research. Only with their approval can we access their Voluntary Participant Data. Accordingly, it is not the expectation or desire of any contributing cancer care center for me, Dr. Yankelevitz, or MSSM to produce any of this information to PMUSA.

78. Indeed, PMUSA's subpoenas are an attempt by a tobacco company to subvert the federal regulatory scheme governing human subject research participants. When research, including certain lung cancer screening studies, is performed on human subjects, exacting federal regulations must be followed, and these require, among other things, registration of IRBs which conduct reviews of such research. If PMUSA is able to take possession of I-ELCAP Voluntary Participant Data, it could conduct research while avoiding any IRB or federal regulation oversight.

79. Rather than conducting its own lung screening trial or seeking to acquire such data from elsewhere, PMUSA in the Subpoenas impermissibly seeks raw data from the ongoing I-ELCAP research program on the pretext that I-ELCAP has published several articles. These articles, however, set forth merely interim findings. Under PMUSA's faulty logic, it has a right to subpoena and receive raw data underlying any published articles that Plaintiffs' experts may have cited, as well as all emails sent or received by the hundreds of researchers at the various cancer care centers that contribute data to I-ELCAP. If PMUSA's Subpoenas are

enforced here, there would seem to be little or no protection offered to ongoing research studies, trade secrets, or proprietary information used in creating intellectual property.

Further Anticipated Research

80. The articles we have published in The Lancet, Radiology, and the NEJM, summarizing our findings, were interim reports of research performed thus far. I-ELCAP is very much an ongoing research program, and our research has continued subsequent to these publications, as evidenced by our recent publications, referenced above. Much additional follow-up and analysis is being performed and will continue, and these results published in the future. The follow-up analysis of data from long-participating individuals provides some of the most valuable information for our research. We also continue to enroll Voluntary Participants, and receive new data from them as well.

81. Follow-up data on existing Voluntary Participants contributes to our I-ELCAP research on the long-term benefit of CT screening, as shown by the following recent publications:

- Henschke CI, Boffetta P, Gorlova O, Yip R, Delancey JO, Foy M, *Assessment of lung-cancer mortality reduction from CT Screening*, Lung Cancer Mar. 2011; 71(3):328-32, Epub 2010 Dec 17, Exhibit 39 in the Appendix; and

- Foy M, Yip R, Chen X, Kimmel M, Gorlova OY, Henschke CI, *Modeling the mortality reduction due to computed tomography screening for lung cancer*, Cancer Jan. 10, 2011, Exhibit 40 in the Appendix.

The question of which patients should be screened remains a major issue to be determined. I-ELCAP has Voluntary Participant Data on people who are younger and older and have different smoking histories than were considered in the NLST. The articles we have published by no means signal that I-ELCAP is complete, nor do they entitle PMUSA to the materials sought in the Subpoenas. Many Voluntary Participants are being added and existing ones continue to be screened, allowing us the opportunity to refine our methods and findings, incorporate new technology and knowledge, and reach more up-to-date meaningful results.

82. Although we have published our preliminary and interim reports, our research is very much ongoing. We have plans to perform multiple further reports and investigations, undertaking them after funding and appropriate IRB approval. Among the further investigations we have under consideration are the following.

(a) Examine various ethnic differences in types of cancers and associated risk factors.

(b) Study various aspects of stage shift based on models we are working on.

(c) See how results of finding a cancer are influenced by estimating the amount of emphysema or coronary artery disease.

(d) Look at influence of environmental exposure.

(e) Study annual rates of cancers based on probabilities derived from various aspects of their history.

(f) Find other features on the CT image that might be correlated to risk of lung cancer such as chronic bronchitis or pulmonary fibrosis.

(g) Apply different mathematical models to predict death from lung cancer in specific cohorts where this information is available.

(h) Develop more efficient guidelines for the workup of nodules.

(i) Look for other risk factors either in images or clinically that influence risk of lung cancer.

(j) Look for other factors that might influence prognosis given that an individual has lung cancer.

(k) Review the pathology database to look for additional clues as to prognosis.

(l) Use the time equivalent data to compare to NLST and other NCI screening (*e.g.*, the Prostate, Lung, Colorectal, and Ovarian Screening Trial) data (over the same time periods).

(m) Obtain further follow up on our cases.

(n) Collect long term data and have enough participants so as to look at the various subtypes of cancer and their long term outcomes.

The above is but a partial list, and there are a variety of other topics we want to study, including the role of needle biopsy, and the use of computer aided techniques for early detection of nodules, finding missed cases, psychological impact of participating, and distinguishing benign from malignant nodules.

83. Further, the NLST is planning to conduct various secondary studies, including those on the following partial list. I-ELCAP is well-positioned to contribute unique information to validate and supplement these secondary NLST studies.

(a) Assessment of the impact of lung cancer screening on smoking behaviors.

(b) Assessment of the characteristics of NLST participants with regard to age, race, location, smoking history, etc.

(c) Comparison of the differences in the stage of lung cancer detected between the CT and chest x-ray study arms in persons who had lung cancer diagnosed on a screening examination.

(d) Comparison of issues of quality of life and psychological effects associated with annual lung cancer screening between the CT and chest x-ray study arms.

(e) Comparison of the amount of lung cancer-related medical resources used between the two arms of the study.

(f) Assessment of the economic consequences of lung cancer screening with CT versus chest x-rays.

(g) Evaluation of the correlations between smoking history and screening results.

(h) Investigation of the extent and significance of incidental findings (something discovered not related to lung cancer) reported as a result of lung cancer screening.

(i) Exploration of the estimated radiation dose to participants in both the CT and chest x-ray study arms.

84. In addition to the above topics that NLST plans to pursue, I-ELCAP is also uniquely positioned to provide information that will be necessary to support the NLST results and move screening research and practice forward on the following subjects.

(a) Determining what factors affect a participant's compliance with the screening program.

(b) Determine the frequency at which screening should be performed.

(c) Develop risk profiles for populations that were not included in the NLST. The NLST only investigated a particular age and smoking history population. However, in order to understand the potential benefit to other populations at risk, additional data is needed, which can be provided by I-ELCAP. This would include younger and older participants or people with a lesser smoking history.

(d) Examine the effect of second hand smoke, which incidentally is a topic that PMUSA very much does not want investigated.

(e) CT scanners have continued to improve and thus find many nodules not previously seen. For screening to be useful we must minimize the harms associated with it, including doing too many tests or performing unnecessary procedures. Accordingly, the workup algorithm regarding nodules found needs to be refined. In active, ongoing work, I-ELCAP has continually updated its algorithm.

(f) Obtain biological samples from those diagnosed with cancer from screening.

85. I anticipate that all of these future research investigations will have important effects on CT screening of persons at risk for lung cancer. They will address who would most benefit from a CT screening, how to reduce potential harms of screening by reducing the number of additional tests, and procedures and thus also reduce the radiation dose.

Logistical Problems with Production of the Confidential Information Sought

86. There are numerous logistical problems with the production sought by PMUSA through its Subpoenas. These problems are insurmountable, and make the issuance of an effective protective order infeasible. Arguments by PMUSA that a protective order may be entered by the Court to address these problems should be rejected.

87. First, portions of the Voluntary Participant Data sought by the Subpoenas are in two places, at MSSM and at the EDTR Foundation. Neither I nor Dr. Yankelevitz has control of the data.

88. In any event, the Voluntary Participant Data has been made available to I-ELCAP by Voluntary Participants and by contributing cancer care centers only for the limited purpose of use in the I-ELCAP research programs.

89. The Voluntary Participant Data also is, of course, personal health information of approximately 55,000 individuals. Under no circumstances should the confidentiality of even one such individual's personal health information be compromised.

90. The redaction of confidential histories, scans, charts and other data that has been collected in I-ELCAP would be a gargantuan task. It is not a simple matter of redacting Voluntary Participants' names and identifying information. Every single record and every single CT scan, of which there are literally hundreds of thousands, would have to be reviewed. (Some participants have had many scans, either from multiple screenings or for workup of their findings). There are probably well over a million documents.

91. The Voluntary Participant Data stored in the I-ELCAP research program is in paper, electronic and other forms, including plastic sheets (similar to overhead projector "transparency" sheets) which each contain dozens of CT scan images on each Voluntary Participant. Each CT scan contains multiple sheets and each sheet contains 12 images each with Voluntary Participant identifying information in small print. How these hundreds of thousands of images could be redacted is unclear.

92. PMUSA's argument that it would be willing to reimburse duplicating costs associated with compliance with the Subpoenas does not begin to come close to addressing the scope of production that the Subpoenas call for.

93. The preparation of the Voluntary Participant Data for production, so that it would be in a form which could then be redacted, would require a large time commitment from myself and Dr. Yankelevitz. Both of us have extremely heavy workloads and in particular have time commitments over the next few months.

Likely Harm That The Subpoenas Will Cause

94. Production of I-ELCAP's "raw data," including Voluntary Participant Data, would undercut our years of data collection and not-yet-completed research. If, after all our years of collecting and analyzing data for academic research purposes, PMUSA is allowed to harvest the I-ELCAP Voluntary Participant Data, and conduct its own tests in support of its own goals, our years of painstaking work and future research plans will be irreparably damaged. We will have lost control of the program we created and developed. The I-ELCAP Voluntary Participant Data would be taken from us and subjected to litigation-driven analysis by the parties' experts who are paid to support the Plaintiffs' or PMUSA's litigation positions. In similar lawsuits that are proliferating, other tobacco companies and other plaintiffs could similarly claim a right to receive such data.

95. The chilling effect of such a result on academic freedom and research, and all the benefits that result therefrom, cannot be overstated. Researchers, administrators and grantors will see no incentive to conduct and/or support years of clinical research, data collection and analysis on matters that may lead to results adverse to large corporate interests if at any moment, their raw data, even if not yet the subject of published findings, can be taken from them and used by those corporate interests. Moreover, PMUSA has asked for much more than raw data; PMUSA's requests, for example, for emails and other correspondence related to grants and rejected articles are overbroad and unnecessarily intrusive to the point that, if enforced, they would negatively impact the conduct of most researchers.

96. In addition to the harm to our academic research that is being performed in connection with I-ELCAP, as alluded to in the preceding paragraphs, the Non-Parties' forced

compliance with the Subpoenas herein would undoubtedly result in Voluntary Participants and contributing cancer care centers withdrawing from I-ELCAP, leading to untoward health consequences on a macro scale.

97. For example, if Voluntary Participant Data contributed to I-ELCAP from a particular cancer care center were to be turned over pursuant to the Subpoenas, that cancer care center likely would withdraw and object to turning over such data, as such turnover violates both the cancer care center's understanding as well as the understanding of all Voluntary Participants enrolled at the cancer care center, whose private and confidential Voluntary Participant Data has been contributed to I-ELCAP.

98. There are many cancer care centers participating in I-ELCAP that are currently able to run their screening programs because of the infrastructure and support from the I-ELCAP leadership. I believe that many cancer care centers would discontinue their screening programs rather than turn over their data to PMUSA, where it would be subject to PMUSA's re-analysis. It is not just existing data; enforcement of the Subpoenas would set a precedent for PMUSA to come back again in the future and seek underlying data for future research studies that might occur. The effect of cancer care centers leaving I-ELCAP will be screening programs throughout the world either closing or refusing to share data with I-ELCAP, and refusing to conduct research of any kind with I-ELCAP.

99. Other entities, such as the Lung Cancer Alliance, that currently refer people at risk for lung cancer to cancer care centers affiliated with I-ELCAP for screening, also would stop making such referrals if I-ELCAP's Voluntary Participant Data had to be turned over to PMUSA.

100. In the first instance, all of this would mean that many people at high risk for lung cancer will no longer have a high quality screening program available to them and therefore some proportion of people will die as a result of their cancers not being found early. That screening can save lives is now beyond question with the results of the NLST.

101. In the second instance, I-ELCAP is the only ongoing collaborative longitudinal research program in the United States and the only ongoing international collaboration as well. It is the only multi-institutional research program in the United States that is collecting data that has remained current with technology. Unlike the NLST, I-ELCAP is a continuing research program. The NLST stopped accruing new patients 5 years ago and has not updated its protocol since starting in 2002. Since I-ELCAP remains current with technology and continuously updates its protocol, it can provide critical information that will be unavailable from any other source. Thus, the withdrawal of cancer care centers, or their refusal to allow data to be used in new publications, and the possible ultimate disbanding of I-ELCAP would have severe consequences in terms of I-ELCAP not providing critical information to help manage the most deadly cancer killer in the United States and abroad.

102. Global networks are now in the planning phase throughout the world and would like to use I-ELCAP as their infrastructure. For example, a large proposal is being planned for Europe by one of the I-ELCAP investigators in Spain, and he has asked for I-ELCAP support for its infrastructure and will share data with I-ELCAP. Two Spanish cancer care centers already participate in I-ELCAP. This collaboration will not occur were I-ELCAP to be giving out their data without their permission.

103. In addition, collaboration with the International Lung Cancer Consortium ("ILCCO") is being planned. This large international consortium has investigators from institutions around the world, focusing on the biology of early lung cancer as well as other means for detection and diagnosis of it. They just held their annual meeting in February 2011 in conjunction with I-ELCAP, where together they discussed joint projects. However, they would immediately withdraw if PMUSA were to gain access to I-ELCAP data, as any new information that results from a collaboration would be in jeopardy. Also, China is planning a massive screening trial and has asked I-ELCAP to assist in its planning and possibly act as coordinating center. This also would stop immediately if the Subpoenas were enforced. Furthermore, MSSM and The Biodesign Insititute of Arizona State University ("ASU") have recently finalized an affiliation with lung cancer being a primary focus. Researchers at ASU are now expressing concern and will not contribute as they are concerned about proprietary information being taken. Cancer care centers in the United States and around the world are asking to join forces with I-ELCAP, but we would be obliged to tell them and also to let their participants know that their data may be subject to subpoena by PMUSA, and this will undoubtedly cause most of these centers to back away.

104. Turnover of the Voluntary Participant Data also would, on a variety of levels, undermine research which is ongoing and planned at institutions participating in I-ELCAP. First, many cancer care centers are creating and testing new software to evaluate the CT scan images, and use their Voluntary Participant Data in those efforts. Accordingly, production of the images in the I-ELCAP Voluntary Participant Data would mean that the images can no longer be guaranteed to have been sequestered and the testing of new software could no longer be performed as before against a "pristine" data set. There is tremendous

intellectual content to this data. For example, we have been discussing with the National Institute of Standards as well as with Food and Drug Administration the possibility of providing a pristine dataset that could be used in the future to test new medical software for detecting abnormalities. Once the data is in the hands of PMUSA, its value is gone.

105. Second, there are numerous essential planned I-ELCAP publications that will rely on the Voluntary Participant Data, including that data gathered prior to 2006. Participating cancer care centers also have data from prior to 2006 and are planning to use that data in their own publications. That enforcement of the Subpoenas would also give PMUSA the ability to look at Voluntary Participant Data from different countries and analyze the data separately would be totally unacceptable to cancer care centers outside the United States, especially since they are bound by different legal systems and have voluntarily provided data to I-ELCAP with certain expectations as to how it would be used, and surely not to be given to PMUSA. Those cancer care centers that have already published a portion of their own data would now be placed in the position of having PMUSA auditing their studies as well, without their permission.

106. Finally, I-ELCAP depends on philanthropy from individuals and not-for-profit foundations, as do the various cancer care centers involved in the collaboration. Based on conversations I have had with individuals involved in philanthropy, the turnover of Voluntary Participant Data sought in the Subpoenas to PMUSA would severely limit the ability to raise funds. Were it to be known that screening data was being turned over to PMUSA, especially before cancer care centers have had a chance to publish their own results or use their image data for independent software development, it would severely limit ability to raise funds of the cancer care centers and of I-ELCAP's coordinating center.

107. If the Subpoenas are enforced, I-ELCAP research that is currently ongoing and funded by Foundations such as the American Legacy Foundation, which for example look at how screening will help people to quit smoking will be forced to close before they are finished. I-ELCAP's ability to recruit participants for the research would be lost. In this way, PMUSA's Subpoenas would close down important research that would potentially be harmful to the sale of tobacco.

Conclusion

108. In summary, if the I-ELCAP Voluntary Participant Data and other requested documents were forced to be turned over pursuant to the Subpoenas, it would have numerous untoward effects.

109. The I-ELCAP research program is heavily dependent on fundraising and the philanthropy of others. Each of the contributing cancer care centers can remain involved with I-ELCAP only if there is funding for the collaborative effort. Also, each of the contributing cancer care centers raises their own funds to maintain their research infrastructure. As the principal investigator in the I-ELCAP research program, I spend a lot of time applying for grants and communicating with philanthropists. I have been told and do believe that funds for I-ELCAP and the contributing cancer centers would dry up if the I-ELCAP Voluntary Participant Data had to be turned over to the tobacco industry pursuant to PMUSA Subpoenas.

110. Less funds to support I-ELCAP will result in fewer and delayed publications of important new information, and may lead to the collapse of a highly innovative unique global research program. Further, if an ongoing research effort such as I-ELCAP is required to turn over its Voluntary Participant Data to a tobacco company, administrators in

cancer care centers, hospitals and educational institutions will be reluctant to commit their resources and efforts to such time-consuming and expensive research projects, even if the potential benefits are great as might be realized from I-ELCAP, in which we are trying to reduce the development of cancer and deaths resulting from the use of tobacco products.

111. Compliance with the Subpoenas will also lead to the withdrawal from I-ELCAP of Voluntary Participants and contributing cancer care centers.

112. The public health consequences from enforcement of the Subpoenas will be substantial. It is not an exaggeration to say that, ultimately, forced compliance with PMUSA's Subpoenas will lead to the death of potential participants who will be deprived of participating in the most up to date CT screening program in the world.

113. Enforcement of the Subpoenas would also lead to the end of my career, as it would severely damage or even destroy my research. My job depends on having the Voluntary Participant Data at MSSM and the EDTR Foundation. If forced to produce that data to PMUSA, my ability to publish any articles and obtain new grants going forward would be sharply curtailed as I would be using data that PMUSA has and at any time could have one of their experts challenge in a manner that is outside of the standard peer review process.

114. All of these results can and should be avoided, if for no other reason than that PMUSA does not need the documents and materials it seeks with the Subpoenas. The NLST has taken on authority as the gold standard of lung cancer screening studies. If CT screening becomes a recommended way to detect lung cancer, and is a proper basis for Plaintiffs' medical monitoring claims, it will be because of the NLST's recently published findings, not the preliminary I-ELCAP findings published years ago, which, although influential, were criticized

by many and have not swayed a single guideline agency in North America or Europe. Plaintiffs' experts who cite those I-ELCAP findings did not have access to the I-ELCAP Voluntary Participant Data, and neither should PMUSA have such access to the data set of a continuing research program. Having marshaled the public criticisms of I-ELCAP, PMUSA already has plenty of ammunition with which to cross-examine Plaintiffs' experts. The entire scientific community responsible for guidelines has reviewed the published I-ELCAP preliminary findings and decided not to recommend screening based on them. Moreover, PMUSA has not sought to subpoena Plaintiff's experts to provide the Voluntary Participant Data that was collected at their own cancer care centers.

115. Accordingly, I respectfully request that the Non-Parties' motion to quash the subpoenas served upon them by PMUSA be granted in its entirety.

Claudia I. Henschke

Sworn to before me this
2d day of March, 2011

David J. Clark
Notary Public

DAVID J. CLARK
Notary Public, State of New York
No. 02CL5080066
Qualified in New York County
Commission Expires October 23, 2013