EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: E. I. DU PONT DE NEMOURS AND COMPANY C-8 PERSONAL INJURY LITIGATION	CASE NO. 2:13-MD-2433 JUDGE EDMUND A. SARGUS, JR.
This document relates to: ALL ACTIONS.	MAGISTRATE JUDGE ELIZABETH P. DEAVERS

DECLARATION OF SAMUEL M. COHEN, M.D., Ph.D.

I, Samuel M. Cohen, declare and state as follows:

1. I prepared the Expert Report of Samuel M. Cohen, dated January 28, 2015 ("Expert Report"), and a true and accurate copy is attached as Exhibit 1.

2. Each of the opinions in the Expert Report is stated to a reasonable degree of scientific certainty, and was arrived at using reliable methods.

3. If called as a witness, I would testify competently to the matters stated in the Expert Report.

4. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: March 30, 2015

Samuel M. Cohen

EXHIBIT 1

Confidential Subject to Protective Order

Expert Report of Samuel M. Cohen, M.D., Ph.D.

Carla Marie Bartlett v. E. I. du Pont de Nemours and Company

Civil Action No. 2:13-CV-170 (S.D. Ohio)

January 28, 2015

I. Personal background

I am a professor in the Department of Pathology and Microbiology and the Eppley Cancer Center at the University of Nebraska Medical Center in Omaha, Nebraska, and I am the Havlik-Wall Professor of Oncology. In 1972 I received my M.D. and Ph.D. degrees from the University of Wisconsin-Madison. My Ph.D. was in experimental oncology from the McArdle Laboratories and my major professor was Dr. George T. Bryan. My graduate research focused on investigations on chemical carcinogenesis, which I have continued for my career, focusing on mechanisms of carcinogenesis in a variety of animal models and the evaluation of when and under what circumstances it is proper to extrapolate these findings to humans. I completed a residency in pathology at St. Vincent Hospital, Worcester, Massachusetts, with board certification in anatomic and clinical pathology in 1976. I have been a practicing pathologist, subspecializing in surgical pathology, since 1975, in addition to my teaching, research and administrative activities. I have been a professor at the University of Nebraska Medical Center in Omaha, Nebraska, since 1981.

My research has focused on mechanisms of carcinogenesis, involving investigations on toxicology, pathology, biochemistry and molecular biology, computer modeling and clinical investigations, and I have also been involved with the design and interpretation of epidemiology investigations. I have authored more than 350 articles published in peer reviewed scientific journals and nearly 50 chapters in various books. I have served on multiple editorial boards or associate editorships for various scientific journals, including five at the present time. I have also served as a reviewer for manuscripts for more than 90 scientific journals and as an invited reviewer for evaluation of research grants for more than 20 funding agencies from the United States and from all over the world.

I have served on numerous national and international committees and panels for several government and non-governmental agencies, including the US Environmental Protection Agency (EPA), US Food and Drug Administration (FDA), National Institutes of Health (NIH), National Toxicology Program (NTP), World Health Organization (WHO) International Agency for Research on Cancer (IARC), and WHO International Programme on Chemical Safety (IPCS). I have served on the NTP Scientific Board of Counselors and the NIH National Institute of Environmental Health Sciences (NIEHS) Scientific Board of Counselors

I have served on the Board of Trustees of the International Life Sciences Institute (ILSI), including as chairman (2012-2015), and the Board of Trustees of the ILSI Health and Environmental Sciences Institute (HESI), including as Chairman (2006-2008). My involvement with these institutes and with the WHO/IPCS has included participation on committees (mainly sponsored by EPA and Health Canada) that developed a framework for the evaluation of the mode of action of toxicologic events in animal models (Sonich-Mullin et al., 2001), and

importantly, an evaluation of when and how to properly extrapolate the findings from these animal models to possible human relevance (Meek et al., 2003; Cohen et al., 2003; Cohen et al., 2004; Seed et al., 2005; Boobis et al., 2006; 2008). This framework has evolved and continues to evolve (Pastoor et al., 2014; Embry et al., 2014; Simon et al., 2014), and is widely used by the EPA, Health Canada and other regulatory agencies around the world. In addition, I have been extensively involved in efforts by FDA, EPA and others to develop new and better testing methods for screening for carcinogenesis. My participation on these committees is based on my extensive experience and expertise in the use of animal models, and because of my continued participation in and knowledge of human medicine.

Since 2002, I have been a member of the FEMA Expert Panel that is responsible for evaluation of flavor ingredients in foods, with a determination of their acceptability and determination of their "Generally Regarded as Safe (GRAS)" status. I currently serve as chairman of the panel.

For my accomplishments in research, I have received several awards, including the Arnold J. Lehman Award from the Society of Toxicology, the George H. Scott Award from the Toxicology Forum, the Lifetime Achievement Award from the Association for Environmental Health and Sciences, and the Distinguished Scientist Award in Cancer Research from the Japanese Foundation for Cancer Research, the Japanese National Cancer Center and the Japan Academy.

Based on my expertise and experience in toxicology, carcinogenesis research, pathology and clinical medicine, I have served on numerous national and international committees, as described above, and also have been asked to serve on several expert panels and consultations for numerous private companies regarding chemicals, food ingredients and pharmaceuticals.

My research has been supported by grants and contracts from the State of Nebraska, NIH, and private industry, and I have an endowed professorship at the University of Nebraska Medical Center.

Additional details regarding my career, participation in various activities, and listing of publications are provided in the attached curriculum vita.

All of my opinions are stated to a reasonable degree of medical and scientific certainty. Also, I reserve the right to revise or supplement these opinions if additional information becomes available.

A listing of the cases in which I have given testimony in the past 4 years is attached as Exhibit B.

For my services on this case, I am being compensated at the rate of $600 per hour.

II. Summary of Opinions

I have been requested to opine, based on a reasonable degree of medical and scientific certainty, whether Mrs. Carla Bartlett's kidney tumor was caused by her claimed exposure to perfluorooctanoic acid (PFOA). I have also been requested to opine on the development over time of the evidence on PFOA's ability to cause cancer in humans.

I am aware that DuPont has agreed not to contest general causation (defined as whether "it is probable that exposure to C8 is capable of causing a particular Human Disease") for class members with kidney cancer, that Mrs. Bartlett claims to be a class member, and that DuPont has reserved the right to contest specific causation (defined as whether "it is probable that exposure to C-8 caused a particular Human Disease in a specific individual"). I am also aware that the Science Panel made Probable Link determinations in 2012, "that based upon the weight of the available scientific evidence, it is more likely than not that there is a link between exposure to C-8 and a particular Human Disease among Class Members," and I have reviewed the Probable Link finding related to cancer.

Mrs. Bartlett developed a kidney renal cell carcinoma that was surgically excised in 1997. It was grade 1, stage 1 and she has had no evidence of recurrence in the ensuing 17 years since the surgery. She has no family history of renal cell carcinoma, has no history of cigarette smoking and was not hypertensive at the time of her surgery in 1997. At the time of her kidney cancer surgery she weighed 250 pounds, which puts her in a category of morbidly obese. Obesity is a major risk factor for kidney renal cell cancer, especially in women. Some studies estimate the general attributable risk of obesity to kidney cancer is 40%, and other estimates are as high as 80-90% for someone with a BMI as high as Mrs. Bartlett. Attributable risk is the estimate of the percentage of the total number of cases of a given disease (in this case, renal cell carcinoma) that are likely to be caused by a particular factor (in this case, obesity). Her exposure to PFOA in the drinking water was relatively low, and she did not work in any position involving PFOA manufacture or direct handling.

Animal studies indicate that the only tumors associated with chronic high exposures of the non-genotoxic chemical PFOA are liver cell tumors, pancreatic acinar cell tumors, and testicular Leydig cell tumors. Subsequent studies have found that the modes of action by which these tumors are induced in rats are not relevant to human cancer risk. No increased risk of kidney tumors has been observed in any animal studies.

Epidemiology studies in workers involved with PFOA in various occupational settings have suggested only a few effects, which are not consistently observed between industrial sites. Only one study has found a suggestion of an association with kidney cancer, but only at the very highest exposures. These studies did not control for kidney tumor type or the known

confounding factors associated with kidney cancer, such as obesity and hypertension. Similarly, community studies have found few consistent associations with increased risk. The only relationship with kidney cancer in these community studies have not been statistically significant, are based on a trend analysis, and have the same limitations regarding tumor type ascertainment and lack of control of confounding factors as the occupational studies.

In light of Mrs. Bartlett's history and clinical presentation, her relatively low claimed exposure to PFOA, my understanding of carcinogenesis and the toxicology of PFOA, and the well-established scientific literature concerning the relationship between renal cell carcinoma risk and obesity, I conclude, to a reasonable degree of scientific and medical certainty, that Mrs. Bartlett's kidney tumor was most likely the result of her history of morbid obesity and not related to her claimed exposure to PFOA. Her cancer would have likely occurred even without any exposure to PFOA. She was successfully treated with surgery, and is not likely to have any further issues as a result of her prior kidney cancer.

III. Materials reviewed

To reach my conclusions in this matter, I have reviewed an extensive amount of material. Various specific references and materials are listed at the end of this report, but my general knowledge of the fields of pathology, toxicology and carcinogenesis have been utilized in this evaluation, including all of the articles and chapters listed in my CV and the articles cited in those publications. In addition, I have considered: the depositions of Carla Marie Bartlett (and exhibits), Dr. Robert R. Bahnson (and exhibits), Dr. Robert Rickard, Dr. Gerald Kennedy, Dr. John Whysner, and Dr. Dee Ann Staats; Mrs. Bartlett's available medical records; the profile for participant ID#63254 (Mrs. Bartlett), Mrs. Bartlett's Plaintiff Fact Sheet and its recently updated version; various documents concerning the medical surveillance programs at the Washington Works Plant, and the expert opinion reports of David L. MacIntosh, Barry R. DeYoung, Robert R. Bahnson, Vitaly Margulis, Cy A. Stein, Robert Rickard, Douglas Weed and Steve Washburn.

I will first review some aspects of kidney cancer, including some of the well-recognized causes of kidney cancer, then discuss basic principles of chemical carcinogenesis, followed by an overview of toxicological and epidemiological evidence concerning PFOA exposure and kidney cancer, and then a specific discussion of my analysis of specific causation for Mrs. Bartlett.

IV. Kidney cancer – clinical aspects

The term "kidney cancer" is often loosely used to refer to multiple diseases with different risk factors and different prognosis (Murphy et al., 2004). For example, tumors of the kidney pelvis are pathologically and etiologically similar to the urothelial (lining) tumors of the urinary bladder (Murphy et al., 2004; Johansson and Cohen, 1997; Cohen et al., 2000). Tumors of the renal parenchyma of epithelial origin predominantly arise from the renal tubules and are

classified as renal cell carcinomas (Murphy et al., 2004). Other renal tubular and collecting duct tumors have been identified over the years, some in the last decade, and these have very different histopathologic appearances, molecular biologic alterations, and causative factors, when known, from the more usual renal cell carcinomas.

Renal cell carcinomas commonly occur in the general United Stated population, and account for approximately 2-3% of adult malignancies. They comprise the vast majority of kidney tumors in adults, estimated at 80-85% of all kidney tumors (Murphy et al., 2004; Hakimi et al., 2013). In the United States it is estimated that there are about 35,000 new cases of renal cell carcinoma per year and approximately 12,500 deaths each year. Men are generally affected more commonly than women, approximately in a ratio of 3 to 2. These tumors can occur at any age, but the incidence increases with age, and they are usually detected after the age of 40. With modern day typical medical examinations, routine screening procedures, and various imaging procedures, kidney cancer is frequently detected early and treated with good success.

There are several types of renal cell carcinoma, but the most common is classified as clear cell renal cell carcinoma based on the clear appearance of the tumor cells in histopathologic sections (Murphy et al., 2004). This sub-type is the most common form of kidney cancer, and accounts for approximately 70% of renal cell carcinomas. This is the type of tumor that Mrs. Bartlett had, and there was nothing atypical in her presentation.

For clinical management purposes and for prognosis, clear cell renal cell carcinomas are also evaluated on the basis of grade and stage at the time the patient is diagnosed (Murphy et al., 2004; Chin et al., 2006). Grade refers to the degree of differentiation of the tumor (how closely it resembles normal), with a 4 grade system most commonly used (referred to as the Fuhrman grade). Grade 1, the grade of Mrs. Bartlett's tumor, is the most well differentiated and the least aggressive grade. It is associated with an excellent prognosis, is frequently in relatively small tumors (<4 cm.), and is usually treated only with surgery, especially if the tumor is confined within the kidney. Stage refers to the extent of the disease. Stage I includes tumors that are 7 cm. in greatest dimension or less and are confined to the kidney. Stage II includes tumors that are more than 7 cm. in greatest dimension but are still confined to the kidney. Stage III refers to tumors that have spread outside the kidney locally or have spread to lymph nodes. Stage IV includes tumors that have spread to distant tissues such as lung, bone, or elsewhere. Mrs. Bartlett's kidney tumor was Stage I.

Renal cell carcinomas of grade 1 and stage 1 tend to be slow growing. These low grade, low stage renal cell carcinomas are usually treated by surgical resection, either total or partial nephrectomy, and the patient is followed with imaging studies (CT, MRI or ultrasound) yearly for 5-10 years, depending on the urologist, and less frequently after that.

V. Kidney cancer – epidemiology and etiology

The reported incidence of renal cell carcinomas has been increasing in the United States over the past two decades, and this has been primarily due to the increased detection of small, low grade tumors (Hollingsworth et al., 2006; Murphy et al., 2004). Such tumors are frequently detected incidentally during imaging studies in patients being evaluated for some other disease. The newer imaging technologies, especially CT and MRI scans, are able to detect small kidney masses that could not be easily detected with standard x-rays (Jayson and Sanders, 1998; Hollingsworth et al., 2006). This is the scenario that occurred with Mrs. Bartlett.

The established causes of kidney cancer are dependent on the tumor type (Jonasch et al., 2012; Murphy et al., 2004). For renal cell carcinoma there are genetic factors and environmental factors that contribute to their causation (Murphy et al., 2004, Jonasch et al., 2012; Hakimi et al., 2013). Several rare genetic disorders, such as von Hippel-Lindau disease, are associated with the development of renal cell carcinomas. Through these rare genetic disorders, several genes have been identified that appear to be associated with the development of renal cell carcinoma, with different genes related to the different subtypes of renal cell carcinoma (Jonasch et al., 2012).

Various environmental factors have also been associated with an increased risk of renal cell carcinoma, including obesity (especially in women), hypertension and cigarette smoking (Murphy et al., 2004; Hakimi et al., 2013; Adams et al., 2008; Macleod et al., 2013; Chow et al., 2010; Dobbins et al., 2013; Calle and Kaaks, 2004; Roberts et al., 2010). Some studies have suggested a relationship with diabetes mellitus, but more specific investigations indicate that this is related to the commonly associated factors of obesity and hypertension (Macleod et al., 2013; Murphy et al., 2014). Obesity is well established as a major risk factor for the development of renal cell carcinoma. Some studies indicate that overall, approximately 40% of renal cell carcinomas can be attributed to obesity (Hakimi et al., 2013; Renehan et al., 2008; Adams et al., 2008; Chow et al., 2010; MacLeod et al., 2013; Pischon et al., 2006). Some studies estimate that the risk increases with the severity of the obesity, with those in the highest 5% by body mass index (BMI) having a five-fold higher risk than an individual with a normal BMI (Murphy et al., 2004). Some studies have reported that individuals with morbid obesity (BMI > 40), such as Mrs. Bartlett, have an attributable risk for developing renal cell carcinoma of 60-90%, with risk increasing by about 30% per 5 BMI units above normal (normal is usually defined as BMI <25, so Mrs. Bartlett is three sets of 5 BMI units greater than normal)(Hakimi et al., 2013; Renehan et al., 2008; Chow et al., 2010)

Other than cigarette smoking, there are no well-established, definitive relationships between specific chemicals and renal cell carcinoma (Murphy et al., 2004; MacLeod et al., 2013; Hakimi et al., 2013; Chow et al., 2010). However, there is some evidence relating trichloroethylene to

the development of renal cell carcinoma (IARC, 2014; Lock and Hard, 2004). Various occupations have also been observed to have an increased risk of renal cell carcinoma, but more specific studies have not been able to support the association suggested by these initial observations. Sometimes this is due to lack of control in the studies for confounding factors, such as obesity, hypertension, and cigarette smoking, or due to lack of specifying what kind of kidney cancer the patients had. For example, inorganic arsenic was initially shown to be related to an increased risk of kidney cancer, but when tumor type was specified the only tumor type related to arsenic exposure was kidney pelvis urothelial carcinomas, not renal cell carcinomas (Ferreccio et al., 2013). Although several chemicals have been associated with the development of renal cell tumors in animal models (e.g. Lock and Hard, 2004), including various nitrosamines, polycyclic aromatic hydrocarbons, estrogens, lead, and certain food ingredients such as d-limonene, none have been shown to be associated with an increase in renal cell carcinomas in humans. Certain viruses have also been associated with kidney tumors in animal models, such as polyoma virus, but these also do not appear to be related to human renal cell carcinomas (Murphy et al., 2004). Similarly, radiation has produced kidney tumors in animal models but has not been demonstrated in humans (Murphy et al., 2004). Some kidney cancer also arises spontaneously or is the result of idiopathic causes.

VI. Principles of carcinogenesis

To address the issue of specific causation of Mrs. Bartlett's kidney cancer, some basic principles of carcinogenesis need to be considered (Cohen and Arnold, 2011). The cause of many cancers are unknown, however, a variety of agents have been identified as etiologic factors for cancer, including but not limited to radiation, nutrition, infectious organisms, cigarette smoking and some chemicals. Extensive investigations during the past several decades have clearly demonstrated that cancer arises from multiple genetic errors occurring in a single tissue stem cell, which then multiplies into a malignant tumor. It is also well known that mistakes can occur spontaneously during DNA replication (the duplication of DNA during the process of a cell undergoing division into two daughter cells). Accordingly, it is well accepted that cancer can and does occur in some individuals without any external stimulus. Although numerous alterations to cellular DNA occur daily in virtually every cell, including oxidative damage, deamination, depurination, exocyclic adduct formation, and a variety of other modifications, only a few of these result in permanent damage to the DNA because of an extensive and exquisite system of DNA repair mechanisms present in cells. Nevertheless, although DNA replication is extraordinarily precise, permanent mistakes occur each time DNA replicates. If the mistake happens to be in one of the genes that are necessary for the development of cancer, then the cell takes a step towards the process of becoming a malignancy. For most tumors, we do not know the number or specific genetic alterations that are required for cancer development, but the basic principle of multiple genetic errors leading to cancer is well

established. Based on these principles, a tumor can arise spontaneously, unassociated with any external exposure, or the tumor can arise secondary to certain chemical, infectious, or radiation causes (Greenfield et al., 1984; Moolgavkar and Knudson, 1981; Knudson, 1971; Tomasetti and Vogelstein, 2015).

There are fundamentally only two ways that an external agent can increase the risk of cancer: 1) the agent directly damages the DNA, increasing the probability that a mistake will occur in one of the critical genes necessary for cancer to develop every time the DNA replicates; or 2) the agent can increase the number of cells that are replicating, increasing the opportunity for spontaneous mistakes to occur in the DNA (Knudson, 1971; Moolgavkar and Knudson, 1981; Greenfield et al., 1984; Cohen and Ellwein, 1990; 1991; Cohen and Arnold, 2011; Tomasetti and Vogelstein, 2015).

Agents that act by damaging DNA are referred to as genotoxic (or DNA reactive) and those that act by increasing DNA replication are referred to as non-genotoxic (Cohen and Arnold, 2011; Cohen and Ellwein, 1991). Genotoxic chemicals include several well known classes of human carcinogens, including polycyclic aromatic hydrocarbons, aromatic amines, N-nitrosamines, and aflatoxins. Numerous assays have been developed to assess the potential genotoxicity of a given agent, most notably the Ames mutagenicity assay in Salmonella bacteria. Pharmaceuticals, consumer chemicals, and agrichemicals that are developed undergo an extensive battery of tests to evaluate genotoxicity. Such an evaluation has been performed for PFOA, and the results show that it is not genotoxic (e.g. Lawlor, 1995; Sadhu, 2002; Murli, 1996; Eriksen et al., 2010; Klaunig et al., 2012).

If an agent that causes cancer does not increase the risk of cancer by directly damaging DNA, then it does so by increasing cell proliferation (Cohen and Arnold, 2011; Cohen and Ellwein, 1991). The agent can do this by acting directly on the target cell, or it can do so indirectly by affecting one or more of a variety of basic cellular processes. Increasing cell proliferation can occur either by increasing cell births or decreasing cell deaths (which would lead to an accumulation of cells). Cell births can be increased either by direct stimulation of cell proliferation, referred to as mitogenesis, or by damaging cells in the tissue (cytotoxicity) with consequent regeneration of the damaged tissue, such as occurs with a wound. Mitogenesis involves alterations in growth factors or endocrine functions, often through an effect on cellular receptors. For example, estrogen has been associated with endometrial cancer by interacting with the estrogen receptors, stimulating the endometrial cells to proliferate. Cytotoxicity is frequently involved as a carcinogenic mechanism, such as damage to the liver by ethanol or by hepatitis B virus (HBV), with extensive regeneration such as occurs in chronic liver disease (Cohen, 2010; Holsapple et al., 2006).

A key factor in addressing specific causation or the risk assessment of specific chemicals involves establishing whether they are genotoxic or not, since the dose response is usually quite different between genotoxic and non-genotoxic chemicals (Meek et al., 2003; Seed et al., 2005; Boobis et al., 2008). Non-genotoxic chemicals usually have a non-linear dose response, and it is well established that they have a threshold for the response (Boobis et al., 2006; 2008; Simon et al., 2014; Cohen and Arnold, 2011). The non-linearity and threshold are due to these chemicals affecting basic cellular processes, besides DNA, that are related with toxic effects, not damaging DNA directly or inducing cancer directly. It is the toxic reaction which leads to an increase in cell proliferation that ultimately leads to a cancer, and the toxic reaction only occurs once a threshold dose is reached. It has long been assumed that genotoxic chemicals have no threshold and the dose response is approximately linear. However, this paradigm has recently been challenged, at least for certain types of genotoxic chemicals, due to metabolic and kinetic factors (Kirsch-Volders et al., 2009). Non-linearity is actually relatively commonplace for genotoxic chemicals, but the possibility of a threshold remains controversial for these chemicals.

The standard screening process for chemicals regarding carcinogenic potential that is used by regulatory agencies, and involves long-term assays in rodents, usually rats and mice and usually for a period of 2 years (Cohen and Arnold, 2011). These assays are for screening purposes; they don't prove that the chemical causes cancer in humans but raise the possibility, so that more extensive investigations can take place to further evaluate the true risk, if any, for humans, and at what doses.

With all of these animal studies, there are two basic assumptions: (1) the response in the model system also can occur in humans (interspecies extrapolation); and (2) the doses used in the animal assays will produce the same effects at the exposure levels of humans (dose extrapolation). If no data are available addressing these assumptions, the default assumption made by the regulatory agencies is that they are correct. However, during the past six decades, extraordinary progress has been made in our understanding of the carcinogenic process in animal models and in humans, so that we can now better evaluate the interspecies and the dose extrapolation assumptions. This produces a more rational risk assessment for humans based on the findings in animals (Meek et al., 2003; Seed et al., 2005; Boobis et al., 2006; 2008).

These scientific developments have been incorporated into a framework to evaluate mode of action of a chemical-induced toxicologic effect, including cancer, and an evaluation of its human relevance. This framework has been developed over the past 18 years by committees of the IPCS and ILSI, sponsored primarily by EPA and Health Canada. I have had the good fortune to be on several of these committees developing this framework, which continues to evolve (Sonich-Mullin et al., 2001; Meek et al., 2003; Seed et al., 2005; Boobis et al., 2006; 2008; Simon

et al., 2014). This framework is widely used by regulatory agencies in their evaluation of the risk assessment of chemicals, whether agrichemicals, industrial chemicals, consumer products, food ingredients or pharmaceuticals.

By understanding the means by which a chemical produces a toxic effect in an animal model, one can develop a better understanding of the dose response in the animal model and the relevance of the mode of action and dose response to humans and specific exposures in humans. For some chemicals, such as aromatic amines and estrogen, the findings in the animal models are predictive of the human response, mechanistically and with respect to the dose response. However, for a large number of chemicals, especially those that are non-genotoxic (like PFOA), research has demonstrated that the findings in the animal models are not relevant to humans, or the dosages used to produce an effect in the animal do not apply at human exposure levels (Cohen and Arnold, 2011; Meek et al., 2003; IARC, 1999). For example, more than half of the drugs listed in the Physicians' Desk Reference have positive carcinogenicity tests in rats and/or mice, and yet they have been approved for human use by the FDA (Brambilla et al., 2012). One such drug (Betton et al., 1988; Hakanson and Sundler, 1990) that produces cancer in rodents (neuroendocrine tumors of the stomach) is omeprazole, which Mrs. Bartlett is currently taking for her gastrointestinal reflux disease.

A critical factor evaluating specific causation and in estimating risk of cancer for any chemical is dose (Simon et al., 2014). As described above, for some genotoxic substances risk is estimated based on a linear, non-threshold dose response. To estimate a safe dose for genotoxic substances, a calculation is made as to the dose that would be required to produce 1 new cancer case in one million people over a lifetime of exposure. For example, aflatoxins, the most potent genotoxic carcinogens known, are present in all peanut products, but the FDA has set a limit of 20 micrograms per kilogram (ppb)(US FDA Guidelines for Aflatoxin Levels) to be a safe level for human consumption.

For non-genotoxic agents (like PFOA), the dose response is non-linear and involves a threshold (Meek et al., 2003; Andersen et al., 2000). Thus, a certain level of exposure has to occur and be sustained for a long period of time for there to be an increased risk of cancer. The example of chloroform described below is a well-known example of a threshold, non-genotoxic carcinogen.

There are many natural and synthetic substances in drinking water and in food that are known to cause cancer in animal models at high doses (Ames et al., 1990a; 1990b; Ames and Gold, 1990). However, safe levels are estimated by various regulatory agencies, such as EPA and FDA, based on our understanding of the dose response and mode of action for a given chemical. For genotoxic chemicals such as aflatoxin, a linear extrapolation is made for an estimate of anticipated risk of 1 new case in 1 million individuals over a lifetime of exposure. For non-

genotoxic chemicals such as chloroform, safety factors, usually 100 or 1000, are applied to the lowest dose causing an effect in the animal models.

I will next provide some examples illustrating the application of this framework, and then show its application to specific causation analysis of whether Mrs. Bartlett's cancer was caused by PFOA.

VII. Chemical carcinogens – examples of modes of action and human relevance

2-Acetylaminofluorene is a genotoxic chemical in the aromatic amine class of chemicals (Cohen and Ellwein, 1990a; Cohen et al., 2006). It was shown to produce liver and urinary bladder tumors in mice in long term studies. The proposed mode of action involves metabolic activation, formation of a reactive metabolite, which then bind to DNA forming DNA adducts that are mutagenic, ultimately leading to permanent damage to the DNA and cancer. The same precursor steps were demonstrated in humans, including the same metabolic activation, formation of DNA adducts and mutations. Based on the mode of action analysis and examination of each of the key events, it would be predicted that 2-acetylaminoflourene would be carcinogenic to humans, similar to other aromatic amines and amides. Epidemiology of occupations involving various aromatic amines in the 1930s to 1950s (long before routine protective gear and precautions were part of the workplace) showed a marked increase in the risk of developing urinary bladder cancer (Clayson and Cooper, 1970). Cigarette smoke also generates substantial amounts of aromatic amines, and cigarette smokers are associated with a 3 to 4 fold increased risk of urinary bladder cancer.

The framework showed the qualitative similarity between mice and humans with respect to urinary bladder cancer. The framework, however, can also be useful in analyzing the quantitative aspects of carcinogenic risk (Cohen et al., 2006). At high doses there is both a genotoxic effect and increased proliferation secondary to toxicity. At lower doses, such as in cigarette smoking, it produces only the genotoxic effect while other substances in the smoke produce the proliferative response. The result is the same whether the genotoxic and proliferative effect are caused by one agent or a combination of agents.

For non-genotoxic chemicals, the framework also is useful both qualitatively and quantitatively. For example, chloroform has been shown to produce liver and kidney tumors in rats and mice, but it is non-genotoxic (Andersen et al., 2000; Meek et al., 2003). The mode of action for chloroform-induced cancer involves metabolism which forms a cytotoxic metabolite, leading to regenerative proliferation, which when sustained can lead to the development of cancer. Based on this mode of action, if the dose is not sufficient to produce the cytotoxicity, there is no increased cancer risk. A clear threshold is present for the toxic and carcinogenic effects. In humans, chloroform is metabolized the same way as in rodents, so that a potentially cytotoxic

metabolite is formed. Chloroform at high doses also produces liver toxicity (and possibly kidney toxicity) in humans, which goes away once the exposure to the chloroform stops. High doses of chloroform were used as an anesthetic in the 1930s to 1950s. Occasionally patients were given a high dose (exposure was not easily controlled) and developed liver toxicity, but it gradually resolved over time. Based on the animal model, if the high dose had persisted and the toxicity persisted, these patients would have had an increased risk of liver cancer.

Today, humans are exposed to extremely low doses in our drinking water since chloroform is a by-product of the chlorination of water. The framework indicates that these low doses would not be sufficient to produce a toxic effect in the liver (or kidney or other tissues) so the chloroform does not produce an increased cancer risk to humans. In short, a threshold is present for the toxic and carcinogenic effect.

Cytotoxicity with consequent regenerative proliferation is a well-known mode of action for many carcinogenic agents, not only chemicals such as chloroform for liver and kidney cancer, but also for certain infectious organisms, such as hepatitis B virus and liver cancer (Cohen and Arnold, 2011). These agents involve a threshold, a concept well established in toxicology, and this mode of action and threshold was also substantiated legally, specifically for the example of chloroform in the drinking water (Chlorine Chemical Council v. EPA, 2000).

Numerous examples have been identified of chemicals that produce cancer in animals but by a mode of action that is not applicable to humans, either qualitatively or quantitatively. Humans would not have an increased risk of cancer from such chemicals, no matter how much we were exposed to.

D-Limonene is a natural chemical that is present in many plants, but particularly in citrus fruits. There is epidemiologic evidence that ingestion of such fruits actually decreases the risk of certain cancers. However, in male rats high doses of d-limonene produce a small increase in the incidence of kidney cancer (Meek et al., 2003), but not in female rats or in male or female mice. D-Limonene is non-genotoxic, but in male rats it produces toxicity in the kidney with consequent increased cell proliferation. The mode of action for the d-limonene-induced toxicity and carcinogenicity involves metabolism to a form that can bind to a specific protein called alpha-2u-globulin. In the normal male rat, alpha-2u-globulin is produced in the liver, filtered in the kidney glomerulus but reabsorbed in the kidney tubule and then degraded and reused by the rat. However, when this protein is bound to the metabolite of d-limonene it is filtered through the glomerulus and reabsorbed by the tubules, but it cannot be degraded. Thus, it accumulates in the cell, eventually killing the tubular cell. If exposure continues for the 2 years of the male rat's lifetime, this chronic toxicity leads to sustained increased cell proliferation and eventually can lead to an increase in kidney tumors.

Female rats and male and female mice do not have alpha-2u-globulin, so there is no toxicity or regenerative cell proliferation, and no increase in the incidence of kidney cancer when treated with d-limonene. Humans also metabolize d-limonene the same way as the male rat, but we do not have alpha-2u-globulin (or a comparable protein that binds the d-limonene metabolite), so we, like the female rat and the male and female mouse, do not have a cancer risk from the ingestion of d-limonene, no matter how much we ingest.

Another example of a non-genotoxic group of chemicals that produce cancer in rodents but not in humans are the statins, widely used drugs that lower blood cholesterol, reduce cardiovascular risks and consequently reduce the risk of death. The statins produce a high incidence of liver cancer in male and female rats and in male and female mice (MacDonald and Halleck, 2004). The mode of action in rodents involves blocking cellular metabolism, which in the rodent at high doses leads to increased liver cell proliferation. The same initial block in metabolism, inhibiting a critical enzyme involved with cholesterol synthesis, HMG-CoA reductase, also occurs in humans. However, in humans this does not lead to an increase in cell proliferation so it would not be expected to lead to an increase in liver cancer. There is a fundamental difference in the way rodents respond to statins inhibiting HMG-CoA reductase and how humans respond. In rodents, there is an increase in liver cell proliferation but no decrease in blood cholesterol. In humans there is an opposite response, a decrease in blood cholesterol and no increase in liver cell proliferation. Extensive epidemiology studies involving several hundreds of thousands of patients have clearly shown no increased risk of liver cell cancer in people taking long term statins (Chiu et al., 2011), and for that matter, no increased risk of any other cancer or in cancer overall (Nielsen et al., 2012).

A common concern in extrapolating from animal models to humans regarding cancer risk has to do with organ specificity: could the cancer effect occur in one tissue in the animal models and in some other tissue in humans. For genotoxic chemicals, there sometimes is a difference in the tissue that has a cancer effect in the animal model compared to the cancer that is produced in humans. For example, many aromatic amines, such as 2-acetylaminofluorene described above, produce liver and urinary bladder cancer, and sometimes other cancers, in the rodent models but only urinary bladder cancer in humans (Cohen et al., 2006; Cohen and Arnold, 2011). These differences occur due to differences in the metabolism between species so that the DNA adduct formation and subsequent cancers occur in different tissues. However, the basic mode of action, metabolism to a reactive metabolite that binds to DNA and produces mutations, is the same for all of the tissues involved and the different species.

One issue in considering animal studies is organ specificity of a compound's effects. For non-genotoxic chemicals, like PFOA, the mode of action is tissue specific, or at least target tissue type specific. Thus, chloroform produces toxicity in the liver and kidney and produces cancer in

these same tissues, not in other tissues. d-Limonene produces a toxicity that can only occur in the male rat kidney, and that is where the tumors occur. No other toxicity is produced and no other cancers are produced (Meek et al., 2003). The recent extensive research on statins provides the strongest evidence for tissue specificity in extrapolating between species (MacDonald and Halleck, 2004; Chiu et al., 2011; Nielsen et al., 2012). Statins produce liver toxicity and liver cancer in rodents, but not cytotoxicity or cancer in other tissues. The toxicity and carcinogenicity is specific to the liver. This sustained toxicity and proliferation does not occur in humans and there is no increased risk of liver cancer. However, there is no sustained cytotoxicity in humans in other tissues and there is no increased risk of cancer in any other tissue, as well.

VIII. Brief comments regarding PFOA toxicology and epidemiology studies

I have reviewed the expert reports of Dr. Robert Rickard and Dr. Douglas Weed, and they have confirmed my understanding of the historical toxicology and epidemiology studies that have been performed on PFOA. I mention only a few of those studies below, although I have reviewed several others.

PFOA has been studied toxicologically in a number of species in a variety of short and long term studies by several routes of administration, including inhalation, dermal, and oral (drinking water and diet). It is only weakly to moderately acutely toxic, with an LD50 of 470 mg/kg in rats.

A chronic carcinogenicity study was initially performed by the primary manufacturer of PFOA in the United States, 3M, in the 1980s in male and female Sprague-Dawley rats at concentrations of 0, 30, or 300 ppm of the diet for 2 years (Sibinski, 1987; Butenhoff et al., 2012). Only at the high dose there was an increased incidence of Leydig cell tumors of the testis. There were no reports of kidney tumors related to this study. Subsequent animal toxicology studies have been performed over the years on a variety of different animals and at different dose levels, as referenced in the expert report of Dr. Rickard. None of these studies have shown any form of cancer being caused by PFOA at the relatively low dose level being claimed by Mrs. Bartlett. Indeed, none of these animal studies have shown kidney cancer being caused at any dose.

A subsequent study by DuPont completed in the early 1990s, only in male CD rats, at 300 ppm of the diet by DuPont showed an increased incidence of the Leydig cell tumors as well as an increase in pancreatic acinar cell tumors and liver cell tumors (Cook et al., 1992). Differences between the 2 studies are likely related to differences in the diets that were used. During the 1990s and later, a variety of specific investigations in animal models were performed to determine the mode of action for these tumors in rats (reviewed in Klaunig et al., 2003; 2012).

Epidemiologically there have been studies of various worker populations and of the general community around the Washington Works plant (which included workers and a very wide range of exposures), as described more fully in the expert report of Dr. Weed. Epidemiology studies are studies of groups or populations, and cannot prove specific causation in an individual. However, they are part of the body of evidence that should be considered in evaluating specific causation in a particular individual.

Ubel et al. (1980) were the first to report an evaluation of the health effects of PFOA in workers based on the 3M facility in Minnesota. They found no increased cancer or other health risks. A further analysis of workers at this plant was reported by Gilliland and Mandel (1993), again with no increased risks related to PFOA except for a slight increase in prostate cancer. However, the potential association with prostate cancer was based on only 4 cases and this finding has not been replicated at other work sites where PFOA has been manufactured or used. On further review, it turned out that only 1 of the 4 men with prostate cancer had actually worked with PFOA (Olsen et al., 1998). This cohort was further evaluated by Lundin et al. (2009), who again determined no overall increased cancer risk. They found a slightly higher rate of prostate cancer in highly exposed workers compared to controls, but it appears that the incidence in the controls was considerably lower than in the general Minnesota population. No increased risk of kidney cancer was detected in any of these studies. A recent follow up of the employees at the various 3M facilities in Minnesota again showed no evidence of an increase in kidney tumors (Raleigh et al., 2014).

Leonard et al. (2008) studied a cohort made up of employees at DuPont's Washington Works Plant. Leonard reported no increase in tumors except for thyroid, and actually found a decreased incidence of prostate cancer in the workers exposed to PFOA. This cohort was further evaluated by Steenland and Woksie (2012) who observed a slightly increased rate of kidney cancer, but only at the highest quartile of worker exposure. A more recent evaluation of this cohort by Steenland et al. (2015) found no evidence of an increase in kidney tumors nor any other tumor type. They did detect a decreased incidence of urinary bladder tumors. I have also reviewed the earlier surveillance data gathered on the entire Washington Works plant, and the follow up that was done to investigate work histories for persons with incidence of disease, and medical records for those workers with higher PFOA blood levels.

An overall evaluation of workers at US and European sites was conducted by Consonni et al. (2013) and found no overall increased risk of any cancer (actually observed an overall decreased cancer risk). This study had several limitations compared to the site specific studies.

Epidemiological investigations including more than occupationally exposed persons have primarily involved the Mid-Ohio Valley community studied by the C-8 Science Panel and Dr. Emmett, which included more highly exposed workers as well as lower exposed non-workers

with wide ranges of exposures and blood levels. Mr. Washburn and Dr. Weed describe more about the range of blood levels of PFOA and other details about these studies in their reports. The Emmett study was published in 2006, and did not involve cancer. The Science Panel probable link findings came out in 2011 and 2012, and in publications in the scientific literature since then. In these investigations, the only tumor for which they found statistically significant associations for cancer risk was germ cell tumors of the testis.

Based on the Science Panel's work, Barry et al. (2013) reported a weak association with kidney cancer (i.e. adjusted odds ratio 1.58) at the highest quartile of exposure. The AORs were lower in the lower-exposed quartiles (i.e., AOR 1.23 and 1.48 for quartiles 2 and 3 respectively). These weak associations were not statistically significant. In Barry et al. (2013), a very complex set of models involving environmental fate, transport and kinetics and numerous general, group assumptions for evaluation of exposure is used. They did not verify type of kidney cancer, did not have available data to evaluate confounding factors such as obesity and hypertension, and did only a very limited evaluation for cigarette smoking. The report also does not indicate that they have dealt with the issue of chance findings, even though they are statistically evaluating a large number of comparisons.

Vieira et al. (2013) reported inconsistent associations with kidney cancer in an ecologic epidemiology study. Overall, it found non-statistically significant and very weak association (i.e., RR 1.1) between residence in one of six water districts studied by the C-8 Health Project and kidney cancer. This study looked only at residence at the time of cancer diagnosis. It did not control for confounding factors, and does not control for an estimated dose of PFOA. In certain sub-analyses Vieira et al. (2013) claim to have identified associations between kidney cancer and PFOA exposure, but only for those in the highest exposure categories. Vieira et al. (2013), however, relies on an even less precise geographic model to assess exposure than in Barry et al. (2013). Vieira et al. assumes that individuals identified by cancer registry data lived at the same site for 10 years. Mrs. Bartlett illustrates the problem with this assumption, since she did not live in the same place for the 10 years prior to her kidney tumor diagnosis, and not even in the assessed area for part of the time. Nor does Vierra et al. control for confounding factors such as obesity or hypertension.

IX. Animal models of PFOA carcinogenesis

PFOA produces tumors when administered to rats in high doses, and it produces liver, pancreatic and Leydig cell testicular tumors (Cook et al., 1992; Sibinski, 1987: Butenhoff et al., 2012; Klaunig et al., 2003; 2012). The liver tumors are hepatocellular tumors (benign and malignant). The pancreatic tumors are classified as acinar cell tumors (mostly benign), and the testicular tumors are Leydig cell tumors (benign). This is the typical spectrum of tumors that are produced by chemicals classified as peroxisome proliferators, because of their ability to

increase peroxisomes in the liver (Klaunig et al, 2003). Peroxisomes are a subcellular organelle involved in processing degraded and foreign material to maintain cellular homeostasis. Chemicals that have these effects in rodent models are quite diverse and include such chemicals as phthalates (used in plastics) and fibrates (drugs used to lower blood lipids).

The primary mode of action for these chemicals has been shown to involve their interaction with a cellular nuclear receptor called peroxisome proliferator-activated receptor alpha, or PPAR alpha (Klaunig et al., 2003; 2012; Corton et al., 2014). Since this leads to activation of the receptor, the chemicals are referred to as PPAR alpha agonists. In rodents, the chemicals interact with the receptor in the liver cells (hepatocytes) which leads to effects on lipid metabolism and also leads to proliferation of the hepatocytes. If exposure continues for long periods of time, the sustained increased proliferation can lead to the development of benign and malignant hepatocellular tumors. In humans, there are significantly fewer PPAR alpha receptors, but the metabolic effects on the hepatocytes regarding lipid metabolism is qualitatively similar to that observed in rodents. However, in humans, in contrast to rats and mice, these chemicals do not increase hepatocyte proliferation (Tateno et al., 2014; Corton et al., 2014).

Beginning in the early 1990s, considerable evidence supporting a lack of human relevance of the rodent tumor findings was developed, and by 2003 an international panel concluded that the rodent tumors were not predictive of a human cancer risk. Furthermore, lack of cancer risk extrapolation to humans was recently convincingly demonstrated in a model in which human liver cells were incorporated into the liver of mice, so called chimeric mice (Tateno et al., 2014). When administered the PPAR alpha agonist, the effects on lipid metabolism occur in both the mouse and human hepatocytes. However, increased proliferation only occurs in the mouse hepatocytes but not in the human hepatocytes. Without this increased cell proliferation there is no increased risk for the development of liver tumors in humans.

Also, recently it has been demonstrated that many of these chemicals that are PPAR alpha agonists also can interact with another liver cell receptor named constitutive androstane receptor (CAR)(Rosen et al., 2008a; 2008b; Cheng and Klaassen, 2008;Corton et al., 2014; Elcombe et al., 2012; 2014). This interaction is weaker than with PPAR alpha, so the effect is considerably less. However, if the PPAR alpha receptor is eliminated from the mouse, using sophisticated molecular biologic techniques, the interaction with CAR becomes significant. The interaction with CAR also produces cellular effects in hepatocytes, primarily with the metabolism of foreign substances to which the animal is exposed. In rodents, activation of CAR also leads to hepatocellular proliferation, the same as seen with PPAR alpha agonists (Elcombe et al., 2014). Like the PPAR alpha agonists, the metabolic effects also occur in humans, but the proliferative effects that occur in rodents do not occur in humans (Elcombe et al., 2014;

Yamada et al., 2014). Thus, an effect on CAR or PPAR alpha in humans would not lead to increased hepatocellular proliferation and there would be no increased risk of cancer.

Supporting the conclusion of no risk to humans regarding liver cancer for PPAR alpha (IARC, 1996) and CAR (IARC, 2001) agonists are several epidemiology studies that have shown that they are not associated with an increase in liver tumors. Such epidemiology studies have primarily been performed in patients treated with the fibrates (PPAR alpha agonists used to lower blood lipids) and with phenobarbital (CAR agonist used for the treatment of seizures)(IARC, 2001), but have also been examined for other pharmaceuticals and chemicals, such as pyrethroids (CAR agonist) that are used as environmental pesticides (Rusiecki et al., 2009).

The pancreatic tumors produced in rats administered PPAR alpha agonists are acinar cell tumors. Like the kidney, the pancreas can give rise to several types of tumors. In rats, they most often are acinar cell tumors, which are relatively common in rats (Rao and Haseman, 1993; Obourn et al., 1997). In humans, acinar cell tumors are rare. In mice they are also rare. The reason for the rat's sensitivity to the development of pancreatic acinar cell tumors is due to their reaction to a hormone produced primarily in the liver that is called cholecystokinin (CCK). In rats, this hormone stimulates secretion by the acinar cells in the pancreas, but it also stimulates them to proliferate. If the increased acinar cell proliferation continues for long periods of time, it can lead to the development of tumors. CCK is produced in response to lipids in the diet, stimulation of lipid metabolism or cholestasis such as occurs with activation of PPAR alpha (Obourn et al., 1997). Thus, administration of high fat diets or PPAR alpha agonists to rats leads to acinar cell tumors in the rat.

CCK also is produced in mice and humans (most mammals) in response to dietary fat. However, pancreatic acinar cells respond to CCK by stimulating secretions but it does not stimulate the acinar cells to proliferate. Thus, this mode of action does not result in an increased risk of pancreatic acinar cell tumors (or other pancreatic tumors) in humans.

Leydig cell testicular tumors are also very common in rats, with incidences in controls of nearly 100% in some laboratory strains (Cook et al., 1999). Leydig cells in the testis are the interstitial cells that are present between the seminiferous tubules which contain the germ cells. The Leydig cells are endocrine cells that produce hormones, mainly androgens such as testosterone. In rats, many treatments that affect testosterone levels and associated hormones from the pituitary lead to increased Leydig cell proliferation (Cook et al., 1992; 1999). Again, if cell proliferation is prolonged in the rat, there can be an increase in tumors, nearly always benign. PPAR alpha agonists are amongst the chemicals that can cause this effect (Cook et al., 1999; Klaunig et al., 2003). Like the hepatocytes in the liver and pancreatic acinar cells, humans do not have this same proliferative response so there is no increased risk of Leydig cell tumors in

humans. The PPAR alpha agonists have no proliferative or tumorigenic effects on the germ cells in the testis in rats or mice.

In animal models, long term administration of PPAR alpha agonists, such as PFOA, do not produce tumors of the kidney or tumors of other tissues other than the ones described above (Klaunig et al., 2012).

X. Carla Bartlett

Mrs. Carla Bartlett had a renal cell carcinoma that was initially detected by CT scan during a work-up for abdominal pain and gall bladder disease. A mass was initially visualized in 1996 and observed by scans until it was resected in 1997, when she was 41 years old. There was nothing atypical in her presentation or treatment for renal cell carcinoma. She has had no recurrence of her kidney tumor nor development of new kidney cancers or other malignancies. The kidney tumor was diagnosed as a clear cell renal cell carcinoma, grade 1 and stage 1. Grade 1, stage 1 renal cell carcinoma has an excellent prognosis. Indeed, she has been free of recurrence for 17 years, and her risk for recurrence or progression is negligible, although her continued obesity places her at continued increased risk for development of another renal cell carcinoma as well as being at increased risk of other malignancies and health issues.

I have considered the established risk factors for renal cell cancer in Mrs. Bartlett's case.

There is no evidence of Mrs. Bartlett ever being a cigarette smoker and she was not hypertensive at the time of her original diagnosis. She has subsequently become hypertensive, and has also developed several other manifestations associated with obesity including gastroesophageal reflux disease (GERD), diabetes and hypercholesterolemia.

Her father had a kidney cancer, but according to his death certificate this was a transitional cell carcinoma, indicating that it arose from the kidney pelvis, not the kidney tubules, and would not pertain to a family history of renal cell carcinoma. Also, I did not find other documents indicating that Mrs. Bartlett had any family history of renal cell carcinoma.

According to her medical records at the time of diagnosis, she was 250 pounds (morbidly obese), and in the reports of the plaintiff's experts she is listed as being 265 pounds in 2014, a net gain of 15 pounds in 17 years. She listed her weight as 230 pounds at the time of the collection of her demographic and other data for evaluation for inclusion in the C8 Health Project. Thus, she has a history of some variability in her weight over the past 17 years, ranging from 230 to 265 pounds in the data I currently have available. She has had, or continues to have, several other medical problems including the gall bladder disease for which she had her gall bladder removed, irritable bowel syndrome, removal of uterine fibroids (leiomyomas) during pregnancy, a subsequent hysterectomy for fibroids, a vesicovaginal fistula, back surgery,

diabetes mellitus, GERD, hypertension, hypercholesterolemia, depression and anxiety. Although she has had a number of medical issues, she has been a regular member of the workforce, and is not a member of any sensitive subpopulations.

Of the well-established risk factors for renal cell carcinoma, the only one that was pertinent at the time of her diagnosis and surgery in 1997 was obesity. As noted above, obesity is a major risk factor for the development of renal cell kidney cancer in humans, especially women. At the time of her kidney cancer diagnosis, Mrs. Bartlett weighed approximately 250 pounds and had a BMI of approximately 40. As I explained above, as a result of her obesity, Mrs. Bartlett was at significant increased risk of developing renal cell carcinoma.

I have considered the claim made by Mrs. Bartlett's experts that PFOA was a substantial factor in the development of her specific kidney cancer. As mentioned above, dose is a significant factor in evaluating the potential carcinogenicity of any substance, especially for a non-genotoxic chemical like PFOA. There are a number of epidemiological studies that have attempted to estimate the risk of developing cancer as a result of PFOA exposure. To understand Mrs. Bartlett's risk, her exposure needs to be understood in the context of these various studies.

Mrs. Bartlett appears to have had very low exposures to PFOA compared to the animal studies and the human populations in the studies referenced above. She lived in Coolville, Ohio from 1960 to 1989 based on the assessment reported by Dr. David L. MacIntosh, and she has lived in Guysville, Ohio since 1993. Mrs. Bartlett's water supply (according to Dr. MacIntosh) was estimated to contain PFOA at a level of 0.17-0.24 ppb in 1983 when her water supply was connected to the Tuppers Plains Water District. While in Guysville, her water was estimated to contain PFOA at levels of 0.29-0.47 ppb prior to 1997. These claimed levels of drinking water exposure are below the EPA's current provisional health advisory level (0.4 ppb) in all but one year considered by Dr. Macintosh. This strongly suggests that she was at very low risk for PFOA-related health effects.

Even amongst those exposed to PFOA in these water districts, her blood level of PFOA was low; her blood level measured in 2005 was 19.5 ng/mL (ppb). Blood level is a better measure of actual exposure than drinking water levels as it accounts for the way the person is handling the substance, and for substances like PFOA is a better indicator over time. For the C8 Health Project the average blood PFOA level for women 40-59 years of age was 80.2 ng/mL(median 25.7) , but there was very wide variability as indicated by a standard deviation of 260.7 ng/mL The average for women of all ages was 68.8 ng/mL (median 23.6), again with very large variability (standard deviation of 190.6) (Frisbee, 2009). Her levels are also low compared to other residents of Tuppers Plains (Washburn)

In the ecologic analysis by Vieira et al. (2013), they classified the participants into low, medium, high and very high groupings. Based on their analysis, Mrs. Bartlett would have been included in the lower half of the medium group (blood levels 12.9-30.8 ng/mL). According to their analysis, however, there was an association with increased kidney cancer risk only at the high and very high blood levels. The problems with the dose assumptions used in Vieira et al. (2013) are also discussed above. I note that Vieira et al. also report a potential increased risk of kidney cancer for residents of Tuppers Plains, but that study is based on residence at the time of diagnosis, not estimated PFOA dose. Note that in the overall C8 Health Project (Barry et al., 2013), the increase in kidney cancer risk was not statistically significantly increased ($p>0.05$). Furthermore, a recent publication evaluating the worker cohort at the DuPont West Virginia plant shows no increased risk of any tumor type, with a decreased cancer risk for urinary bladder cancer (Steenland et al., 2015)

In addition, Mrs. Bartlett's claimed exposures are significantly lower than the PFOA levels in the blood of definitely exposed workers that worked in the industries involved with the production and use of PFOA. In studies of the workers at the West Virginia plant (Steenland and Woksie, 2012), measured blood levels ranged from 160 to 2,880 ng/mL. An association with kidney cancer was observed only at the highest quartile estimated cumulative exposure group (i.e. >2,700 ppm-years). This was not corroborated in their most recent evaluation of this worker cohort (Steenland et al., 2015).

In workers in various other studies, no relationship between kidney cancer and PFOA exposures even at much higher occupational levels were consistently found (Lundin et al., 2009; Chang et al., 2014; Steenland et al., 2015). In the animal studies, no kidney tumors were found at any dose, and the concentration required to produce other tumors was 300 ppm of the diet, whereas the dose of 30 ppm did not significantly increase the incidence of tumors. No animal studies support the claim that any cancer tumor could be caused at the low dose of PFOA claimed by Ms. Bartlett. Likewise, in all of the epidemiology studies, including the Science Panel studies, a possible relationship between PFOA and kidney cancer was only observed at much higher exposures than Mrs. Bartlett likely experienced. The exposure that Mrs. Bartlett claims was not associated with an increased risk of kidney cancer.

In sum, it is my opinion, based on a reasonable degree of medical and scientific certainty, that the renal cell carcinoma of Mrs. Bartlett resulted from her history of morbid obesity, and was not caused by or related to her low exposure to PFOA.

XI. Additional Opinions Concerning Reports Submitted By Mrs. Bartlett's Experts

I have reviewed the expert reports of Drs. Stein, Margulis and Bahnson. Obviously, I disagree with them to the extent that they make statements different from what I have said above. I also note the following:

The written reports of the plaintiff's experts are incorrect when they indicate that they can dismiss Mrs. Bartlett's obesity. As explained above, obesity is a very well-established risk factor of the development of renal cell kidney cancer.

Although some of the expert opinion reports for the plaintiff list many potential risk factors for kidney cancer, in fact many of the substances on their lists refer to risks associated with kidney pelvis urothelial tumors, not for renal cell carcinomas. For example, phenacetin is listed by them as a cause of renal cell carcinoma. Although it is associated with kidney damage (to the renal papilla), it is only associated with urothelial tumors, most commonly of the kidney pelvis but also of the ureters and urinary bladder (IARC, 2012). Based on the CV's provided of the plaintiff's experts, it does not appear that they have experience with investigations concerning animal carcinogenesis or human cancer epidemiology, nor do they appear to have experience on committees or panels related to an evaluation of cancer etiology or extrapolation from animal models to humans. They appear to be relying on published reports without a background to critically analyze them.

In the reports of Dr. Margulis and Dr. Stein, they claim that PFOA could be acting synergistically with obesity to produce her kidney cancer. There is nothing in the scientific literature to support any claim of a synergistic effect between PFOA and obesity as it relates to kidney cancer. Indeed, there is no theoretical basis to consider a synergy between obesity and PFOA. Neither acts as a genotoxic agent, and for a non-genotoxic agent there will be a threshold dose that needs to be attained before there is any effect, whether by itself or in synergy with other agents. As indicated above, there has been a suggestion of a possible relationship in some studies between PFOA and kidney cancer. However, this only occurs at exposures considerably higher than Mrs. Bartlett's exposure. There is no scientific evidence that the low exposures that Mrs. Bartlett claims would act synergistically with other risk factors to increase kidney cancer risk.

In the reports of Dr. Stein and Dr. Margulis, they refer to her kidney tumor as stage 2. That is incorrect as the tumor would have had to have been >7 cm. in greatest diameter for such a classification, and Mrs. Bartlett's tumor was up to 3.2 cm. in diameter according to the pathology report and was never measured greater than 5 cm. in diameter in imaging studies.

Samuel M. Cohen, M.D., Ph.D. January 28, 2015

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Murphy, W.M., Grignon, D.J., and Perlman, E.J. Tumors of the Kidney, Bladder, and Related Urinary Structures. AFIP Atlas of Tumor Pathology, Fourth Series, Fascicle 1. American Registry of Pathology, Washington, DC, 2004. P. 1-240.

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Pastoor et al., Crit. Rev. Toxicol., 44(S3): 1-5, 2014

Raleigh et al., Occup. Environ. Med., in press, 2014 (available online)

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Renehan et al., Lancet, 371: 569-578, 2008

Roberts et al., Annu. Rev. Med., 61: 301-316, 2010

Rosen et al., Toxicol. Sci., 103: 46-56, 2008a

Rosen et al., Toxicol. Pathol., 36: 592-607, 2008b

Rusiecki et al., Env. Health Persp., 117: 581-586, 2009

Sadhu, Report No. 01-7019, Toxicon Corp., 2002

Seed et al., Crit. Rev. Toxicol., 35: 664-672, 2005

Shin et al., Env. Health Persp., 119: 1760-1765, 2011

Sibinski, Experiment No. 0281CR0012, Riker Laboratories, EPA Public Docket AR-226-0437, 1987

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Sonich-Mullin et al., Reg. Toxicol. Pharmacol., 34: 146-152, 2001

Steenland and Woksie, Am. J. Epidemiol., 176: 909-917, 2012

Steenland et al., Occup. Environ. Med., in press, 2015

Tateno et al., Toxicol. Pathol., available on line, 2014

Tomasetti and Vogelstein, Science, 347: 78-81, 2015

Ubel et al., Am. Ind. Hyg. Assoc. J., 41: 584-589, 1980

Vieira et al., Env. Health Persp., 121: 318-323, 2013

Winquist and Steenland, Env. Health Persp., 122: 1299-1305, 2014

Winquist et al., Env. Health Persp., 121: 893-899, 2013

Yamada et al., Toxicol. Sci., 142: 137-157, 2014

Curriculum Vitae

Name: Samuel Monroe Cohen, M.D., Ph.D.

Address: University of Nebraska Medical Center
983135 Nebraska Medical Center
Omaha, Nebraska 68198-3135
(402) 559-6388
(402) 559-8330 (F)
E-mail: scohen@unmc.edu

Personal:

Place of birth: Milwaukee, Wisconsin
Date of birth: September 24, 1946
Citizenship: United States citizen by birth
Marital Status: Married to Janet Lu Olson, January 27, 1968 (Died December 22, 2011)
Children: Sheri Lyn: July 20, 1971
Benjamin Aaron: November 15, 1972
Daniel Eric: February 15, 1974
Erica Ann: November 18, 1975

Education:

1963-1967 – B.S. University of Wisconsin, Madison
Major: Medical Science (Honors)

1966-1972 – M.D. University of Wisconsin, Madison

1968-1972 – Ph.D. University of Wisconsin, Madison
Major: Oncology

Theses:

Cohen, S.M. Studies on N-[4-(5-nitro-2-furyl)-2-thiazolyl] formamide, a potent bladder carcinogen. B.S. Thesis, University of Wisconsin, 1967

Cohen, S.M. Carcinogenicity of 5-nitrofurans: Formic acid 2-[4-(5-nitro-2-furyl-2-thiazolyl]hydrazide and N-[4-5-nitro-2-furyl)-2-thiazolyl]acetamide. Ph.D. Thesis, University of Wisconsin, 1972

Post-degree training:

Internship: St. Vincent Hospital, Worcester, Massachusetts, July 1, 1972-June 30, 1973 (Straight Pathology)

Residency: St. Vincent Hospital, Worcester, Massachusetts, July 1, 1973-October 31, 1975

Academic and staff appointments:

2010 -	Adjunct Professor, Program on Toxicologic Pathology, Sao Paulo State University Medical School, Botucatu, Brazil
2010 -	Staff pathologist, Nebraska Orthopaedic Hospital, Omaha, Nebraska, and Bellevue Medical Center, Bellevue, Nebraska
1992-2007	Chairman, Department of Pathology and Microbiology, University of Nebraska Medical Center, Omaha, Nebraska
1988, 1992	Acting Chairman (during Chairman's sabbaticals), Department of Pathology and Microbiology, University of Nebraska Medical Center, Omaha, Nebraska
1981-	Professor, Department of Pathology and Microbiology, University of Nebraska Medical Center, Omaha, Nebraska
1981-	Professor, Eppley Institute for Research in Cancer, University of Nebraska Medical Center, Omaha, Nebraska
1981-1992	Vice Chairman (Acting Chairman during Dr. David Purtilo's absences), Department of Pathology and Microbiology, University of Nebraska Medical Center, Omaha, Nebraska
1977-1981	Associate Professor, Department of Pathology, University of Massachusetts Medical School, Worcester, Massachusetts
1977-1981	Staff Pathologist, St. Vincent Hospital, Worcester, Massachusetts
1976-1977	Visiting Professor, First Department of Pathology, Nagoya City University Medical School, Nagoya, Japan (sponsored by the United States-Japan Co-operative Cancer Research Program)
1975-1976	Staff Pathologist, St. Vincent Hospital, Worcester, Massachusetts
1974-1977	Instructor, Department of Pathology, University of Massachusetts Medical School, Worcester, Massachusetts
1974-1976	Physician, Massachusetts Rehabilitation Hospital, Boston, Massachusetts

Certifications and licenses:

Board Certified in Anatomic and Clinical Pathology, American Board of Pathology, 1976

Massachusetts, by examination, 1973-2013

Maine, by reciprocity, 1975 - 1976

Nebraska, by reciprocity, 1981-(active)

Grant Support (active):

1. NIH (R21NS084391). Therapeutic Targeting of Aberrant Glial Function During Juvenile Batten Disease. 2% effort, Co-Investigator, 9/01/14 – 12/31/15, $250,000 (annual direct cost).

2. NIH (2P20GM103480) COBRE Nebraska Center for Nanomedicine, 3% effort, Co-Investigator, 9/15/13 - 5/31/18.

3. Sumitomo Chemical Company, Principal Investigator, 2013-2015, $30,000 (total costs).

4. Inorganic Arsenic Task Force, Principal Investigator, Investigations on the Mode of Action of Inorganic Arsenic Carcinogenesis and Toxicity, 2013-2015, $105,000 (total costs).

5. ILSI North America, Principal Investigator, Inorganic Arsenic Investigations, $28,000 (total costs).

6. Laboratoire Paréva, Evaluation of the Proliferative Effects of Chronic Treatment with PHMB in the Liver Tissue of Male Sprague Dawley Rats, Principal Investigator, 1/01/2015 – 7/31/2015, $47,840 (total costs).

7. Laboratoire Paréva, Early Proliferative Effects of PHMB on the Liver Tissue of Male Wistar Han Rats, Principal Investigator, 2/01/2015 – 9/30/2015, $181,057 (total costs).

8. Electric Power Research Institute (EPRI), Low-Dose Dose-Response Relationship for Cell Death Induced by Exposure to Inorganic Arsenite, Principal Investigator, 2/01/15-7/31/15, $114,669 (total costs).

Grant Support (completed):

1. Pareva, Principal Investigator. Assessment of Bioavailability and Distribution of PHMB in the Rat and Its Effects on Oxidative Stress, Cytotoxicity, Mitogenicity, and Histologic Alterations. $163,434 (total costs), 2013-2014.

2. Inorganic Arsenic Task Force, Principal Investigator, Investigations on the Mode of Action of Inorganic Arsenic Carcinogenesis, 2012-2013, $150,000 (total costs).

3. NIH COBRE: Nebraska Center for Nanomedicine, Core B, Collaborator, 9/08-6/13, $36,500/yr. (total costs).

4. H. Lundbeck A/S, Principal Investigator, Cytotoxicity, proliferation and apoptosis in mouse and human endothelial cells, 2012, $107,420 (total costs).

5. Dainippon Sumitomo Pharma, Principal Investigator, Mechanistic Study for Carcinogenicity of DSP-8658 in Male Rats. Follow-up Urinalysis Evaluation in Rats, 7/2012-7/2013, $32,618 (total costs).

6. Pfizer, Principal Investigator, Immunohistochemical Markers of Human Vascular Tumors, 2012, $17,203 (total costs).

7. Minnesota Mining and Manufacturing, Principal Investigator, Effects of Administration of MTDID 25575 by Oral Gavage on the Urinary Bladder of Male Rats, 2012, $96,108 (total costs).

8. NIH R01 CA 143460. NOC in processed meat as a likely cause of colon cancer. Co-investigator (4% effort). (Dr. S. Mirvish, P.I.). 2010-2013, $145,250 (total direct costs for first year).

9. DuPont, Principal Investigator, Time Course of Early Effects of Treatment with Diuron (DPX-14740) Technical in the Diet on the Bladder Epithelium of Male Wistar Rats, 2011-2012, $64,512 (total costs).

10. Inorganic Arsenic Task Force, Principal Investigator, Investigations on the Mode of Action of Inorganic Arsenic Carcinogenesis, 2011-2012, $75,000 (total costs).

11. Sumitomo Chemical Company, Principal Investigator, 2010-2012, $20,000 (total costs).

12. Makhteshim Agan of North America, Principal Investigator, 2012, $10,000 (total costs).

13. Organic Arsenical Products Task Force, Principal Investigator, 2011-2012, $30,000 (total costs).

14. Electric Power Research Institute, Collection of Epithelial Cells from Human Ureters, Principal investigator, 4/08-6/12, $17,236 (total costs).

15. FEMA, Principal Investigator, The Effects of Oral Administration of Pulegone on the Urinary Bladder of Female F344/N Rats, $62,815 (total costs).

16. Teva Pharmaceutical Industries Ltd., The Effects of Materials on Rodent and Human Urothelial and Keratinocyte Cell Lines, Principal Investigator, 7/8/10-2/28/11, ($27,971 total costs).

17. Takeda Pharmaceutical Co., PPARγ-induced endothelial cell proliferation, Principal Investigator, 2007-2010, $50,000 (total costs).

18. Sumitomo Chemical Company, 2008-2010, Principal Investigator, $10,000/yr.

19. Landis International, The Effects of Dietary Administration of Pyroxasulfone on the Urinary Bladder of Male Rats, Principal Investigator, 7/27/10-11/26/10, ($51,321 total costs).

20. Lexicon, The Effects of Oral Gavage Administration of LX3305 for 4 weeks in Female Rats. 2009-2010, $78,382 (total costs).

21. Bayer Crop Science, The Effects of Transfluthrin on the Urinary Bladder of Rats and Mice (*In Vivo*). 2009-2010, $78,382 (total costs).

22. Bayer Crop Science, The Effect of Transfluthrin on the Urinary Bladder of Rats and Mice (*In Vitro*) 2009-2010, $23,475 (total costs).

23. Dainippon Sumitomo Pharma Co., Ltd. 26-Week Oral Gavage Chronic Toxicity and Toxicokinetic Study with DSP-8658 in Rats with a 13-Week Recovery Period. Follow-up Urine Examination in Rats, Principal Investigator, 04/09-04/10, $54,132 (total costs).

24. Merck & Co., Inc., Investigation of potential mechanisms of rat bladder tumorigenesis and carcinogenicity, Principal Investigator, 2006-2007, $30,900 (total costs).

25. Covance Laboratories, Inc. Urinary precipitate and urine chemistry evaluations for a carcinogenicity study with CS-011 in rats, Principal Investigator, 2006-2007, $27,544 (total costs).

26. Theravance, TD: 5108: 28-day oral study in male rats with 28-day recovery period, 2006-2007, Principal Investigator, $47,075 (total costs).

27. Bristol-Myers Squibb, Three month oral investigative study of urine composition in Winstar and Sprague Dawley male rats, Principal Investigator, 2006-2007, $71,825 (total costs).

28. Bristol-Myers Squibb, Three-month oral investigative study of urine composition in male rats years, Principal Investigator, 2005-2006, $80,847 (total costs).

29. Bristol-Myers Squibb, Six-month oral investigative urinary bladder reversibility study in male rats years, Principal Investigator, 2005-2006, $175,292 (total costs).

30. Sumitomo Chemical Company, 2004-2007, Principal Investigator ($10,000 per year).

31. Covance Labs, Urinary precipitate and urine chemistry evaluations for carcinogenicity study with CS-011 in rats, 2161-001, 3/6/06-9/30/06, $27,833.

32. Bristol-Myers, One month oral investigative study of urinary bladder effects in male rats, 2183-001, 2005-2006, $76,944.

33. Bristol-Myers Squibb, Three-month oral investigative urinary bladder and metabonomics study in young versus aged male and female rats, 2004-2005, Principal Investigator, $40,761 (total costs).

34. Bristol-Myers Squibb, Twenty-one month investigative urinary bladder study of urinary bladder effects in male rats, 2003-2006, Principal Investigator, $292,420 (total costs).

35. Aventis, Exploratory 28-Day oral Gavage Toxicity in Male Rats, 2004-2005, Principal Investigator, $44,204 (total costs).

36. Wrigley, The Effects of Oral Gavage Administration of Two Bioglass Substances for 13 Weeks in Male Rats, 2004, Principal Investigator, $28,100 (total costs).

37. Bristol-Myers Squibb, Three-month oral investigative urinary bladder study in young versus aged male and female rats, 2003-2004, Principal Investigator, $201,531 (total costs).

38. Merck, Potential role of urinary physiologic changes in urinary bladder tumorigenesis by a Merck compound, 2002-2003, Principal Investigator, $88,194 (total costs).

39. Sumitomo Chemical Co., 2000-2003, Principal Investigator, $10,000 per annum.

40. Monsanto, The Effect of Sulfosulfuron on Urinary Parameters and Bladder Epithelium in Male Sprague-Dawley Rats, 2000, Principal Investigator, $86,768 (total costs).

41. Sumitomo Chemical Co., 1996-2000, Principal Investigator, $10,000 (total costs per annum).

42. National Cancer Institute, CA32513, Studies on Experimental Bladder Tumors, 1993-1999, Principal Investigator, 20% effort.

43. Luxembourg (Pamol), Ltd., Effects of Cacodylic Acid on the Rat Urinary Bladder, 1998, Principal Investigator, 10% effort, $123,174 (total costs).

44. International Life Sciences Institute-NA, Mechanistic Research on Bladder Carcinogenesis, 1997-1998, Principal Investigator, 10% effort, $125,000 (total costs).

45. Bayer Corp., YRC 2388, 1997, Principal Investigator, $8,500 (total costs).

46. International Life Sciences Institute-NA, Mechanistic Research on Bladder Carcinogenesis, 1994-1997, Principal Investigator, 30% effort, $1,055,000 (total costs).

47. Bayer Corp., Ortho-phenylphenol, 1996, Principal Investigator, $66,800 (total costs).

48. American Cancer Society, Auger Electron Emitters for Treating Bladder Cancer, 1995-1996, Co-investigator, 5% effort, $75,000 (total costs).

49. Synthetic Organic Chemical Manufacturers Association (SOCMA), Tributyl Phosphate, 1995, Principal Investigator, $56,450 (total costs).

50. Sumitomo Chemical Co., 1992-1995, Principal Investigator, $30,000 (total costs).

51. International Life Sciences Institute-NA, Mechanistic Research on Bladder Carcinogenesis, 1993-1994, Principal Investigator, 30% effort, $480,000 (total cost).

52. E. I. DuPont de Nemours & Co., Scanning Electron Microscopy Studies, 1992, Principal Investigator, $35,000 (total costs).

53. Miles, Inc., Ortho-phenylphenol, 1992-1994, Principal Investigator $70,000 (total costs).

54. Miles, Inc., Propoxur, 1992, Principal Investigator, $9,324 (total costs).

55. National Cancer Institute, CA32513, Studies on Experimental Bladder Tumors, 1990-1992, Principal Investigator, 20% effort, $241,686 (total direct costs).

56. International Life Sciences Institute-Nutrition Foundation, Mechanistic Research on Bladder Carcinogenesis, 1990-1993, Principal Investigator, 30% effort, $1,450,000 (total cost).

57. Norden-SmithKline Beecham, Scanning Electron Microscopic Evaluation of a New Product, 1988-1992, Principal Investigator, $8,559 (total costs).

58. National Cancer Institute, CA44886, Acrolein and Urinary Bladder Carcinogenesis, 1987-1992, Principal Investigator, 10% effort, $481,850 (total direct costs).

59. National Cancer Institute, CA36727, Laboratory Cancer Research Center Support (CORE) Grant, 1987-1990, Co-Investigator, 2.5% effort.

60. Summit Corp., Scanning Electron Microscopy of new product, Principal Investigator, 1989-1990, $3,620 (total costs).

61. International Life Sciences Institute-Nutrition Foundation, Saccharin Initiation-Promotion Bioassay, 1988-1990, Principal Investigator, 5% effort, $260,656 (total costs).

62. International Life Sciences Institute-Nutrition Foundation, Mechanistic Research on Bladder Carcinogenesis, 1987-1990, Principal Investigator, 25% Effort, $900,000 (total costs).

63. International Life Sciences Institute-Nutrition Foundation, Effect of Sodium Saccharin Administration on Lipid Levels in the Rat: Dose Response and Reversibility, 1989, Co-Investigator, 5% effort, $128,301 (total costs).

64. Hoechst Co., The Evaluation of the Protective Effects of Chitosan in Preventing the Hemorrhagic Cystitis Secondary to Cyclophosphamide Administration, 1988, Secondary Investigator, $5,600 (total costs).

65. National Cancer Institute, CA32513, Studies on Experimental Bladder Tumors, 1987-1990, Principal Investigator, 20% effort, $301,043 (total direct costs).

66. National Cancer Institute, CA28015, Bladder Cancer: Metabolism of Carcinogens and Prevention, consortium grant between Dr. Terry Zenser, St. Louis University, and Dr. Samuel M. Cohen, University of Nebraska Medical Center, 1986-1989, Co-Principal Investigator, 10% effort, $149,905 (total costs).

67. International Life Sciences Institute Nutrition Foundation, Effects of High Doses of Sodium Saccharin on the Neonatal Rat Bladder, 1986-1987, Principal Investigator, 5% effort, $33,840 (total direct costs).

68. Norden Laboratories, Scanning Electron Microscopic Evaluation of a New Product, 1987, Principal Investigator, $1,500 (total costs).

69. International Life Sciences Institute Nutrition Foundation, Relationship Between High Doses of Sodium Saccharin to the Maternal Rat and Pup Metabolic/Nutritional Status, 1986-1987, Principal Investigator, 5% effort, $63,407 (total direct costs).

70. National Cancer Institute, CA36727, Laboratory Cancer Research Center Support (CORE) Grant, 1984-1987, Co-Investigator, 2.5% effort, $891,043 (total direct costs).

71. State of Nebraska, Relationship of Acrolein to Cigarette Smoking-Induced Bladder Cancer, 1986-1987, Principal Investigator, 5% effort, $38,988 (total direct costs).

72. State of Nebraska, Male/Female Differences in Neonatal Cell Proliferation in Experimental Urinary Bladder Carcinogenesis, 1986-1987, Co-Investigator, 5% effort, $33,939 (total direct costs).

73. International Life Sciences Institute, Mechanistic Research on Bladder Carcinogenesis, 1985-1987, Principal Investigator, 25% effort, $787,584 (total direct costs).

74. State of Nebraska, Relationship of Acrolein to Cigarette Smoking-Induced Bladder Cancer, 1985-1986, Principal Investigator, 5% effort, $36,634 (total direct costs).

75. National Cancer Institute, CA28015, Bladder Cancer: Metabolism of Carcinogens and Prevention, consortium grant between Dr. Terry Zenser, St. Louis University, and Dr.

Samuel M. Cohen, University of Nebraska Medical Center, 1983-1986, Co-Principal Investigator, 10% effort, $270,520 (total direct costs).

76. National Cancer Institute, CA33368, Urinary Bladder Cancer Promotion by Dietary L-Tryptophan, 1983-1986, Co-Investigator, 5% effort, $173,591 (total direct costs).

77. State of Nebraska, Analysis of Neonatal Cell Kinetics and Experimental Urinary Bladder Carcinogenesis, 1985-1986, Co-Principal Investigator, 5% Effort, $32,807 (total direct costs).

78. National Cancer Institute, CA38150, Cruciferae and Carcinogenesis, Co-Investigator, 5% effort, $429,430 (total direct costs).

79. State of Nebraska, Experimental and Computer Modeling of 2-Stage Carcinogenesis, 1984-1985, Co-Investigator, 5% effort, $28,032 (total direct cost).

80. State of Nebraska, Scanning Electron Microscopic Urinary Cytology, 1984-1985, Principal Investigator, 5% effort, $24,330 (total direct costs).

81. National Cancer Institute, CA32313, Non-mutational Multistage Urinary Bladder Carcinogenesis, 1982-1985, Principal Investigator, 10% effort, $214,904 (total direct costs).

82. International Life Sciences Institute, Contract with ILSI for Study with Intox, 1985, $3,397.50 (total direct costs).

83. State of Nebraska, Scanning Electron Microscopic Urinary Cytology, 1983-1984, Principal Investigator, 10% effort, $32,164 (total direct costs).

84. National Cancer Institute, CA32513, Studies on Experimental Bladder Tumors, 1982-1985, Principal Investigator, 20% effort, $243,094 (total direct costs).

85. National Cancer Institute, CA32513, Studies on Experimental Bladder Tumors, 1981-1982, Principal Investigator, 30% effort, $181,223 (total direct costs).

86. University of Nebraska Foundation, Automatic Image/X-ray Analysis System for scanning electron microscope, $76,365 (total award).

87. National Cancer Institute, CA28015, Bladder Cancer: Metabolism of Carcinogens and Prevention; consortium grant between Dr. Terry Zenser, St. Louis University, and Dr. Samuel M. Cohen, St. Vincent Hospital and University of Nebraska Medical Center, 1980-1982, Co-principal Investigator, 10% effort, $81,247 (total Direct costs to Dr. Cohen's institution).

88. RR05660, Subgrant #31; Biomedical Research Support Grant, St. Vincent Hospital; 1980-1981; Principal Investigator, 5% effort, $3,600 (total award).

89. National Cancer Institute, CA21612, Cyclic AMP Metabolism in Transitional Epithelium, 1980-1983, Co-Investigator, 5% effort, $252,402 (total direct costs).

90. RR05660, Subgrant #21; Biomedical Research Support Grant, St. Vincent Hospital; 1979-1980; Principal Investigator, 5% effort, $5,875 (total award).

91. National Cancer Institute, CA15945, Studies on Experimental Bladder Tumors, 1979-1981, Principal Investigator, 30% effort, $233,622 (total direct costs).

92. National Cancer Institute, CA15945, Studies on Experimental Bladder Tumors, 1976-1979, Principal Investigator, 30% effort, $233,584 (total direct costs).

93. National Cancer Institute, CA15945, Studies on Experimental Bladder Tumors, 1973-1976, Co-Investigator, 20% effort, $155,475 (total direct costs).

Grant Support (pending): None

Study Sections:

NIH	Chemical Pathology, 1982-6
NAS/NRC	Associateship Program, 1987-8
NIH	Immunology, Virology, Pathology, 1989-93 (Chair, 1991-93)
NIH	Special Study Section, Outstanding Investigator Grants, 1993
NIH	Special Study Section, Chemoprevention, 2002
NTP	National Toxicology Program Board of Scientific Counselors, 2002-4
NIEHS	Superfund Review, 2006
FDA	Review Panel on Melamine, 2007
NIEHS	Board of Scientific Counselors, 2008 – 2013

Site Visits:

1978	Eppley Cancer Institute
1980	New York University
1983	McArdle Laboratory
1984	Memorial Sloan Kettering Institute
1985	University of Idaho
1988	Los Alamos, New Mexico
1988	Sloan Kettering Institute
1998	National Center for Toxicologic Research
2000	Memorial Sloan Kettering Institute
2001	National Cancer Institute, Intramural Program
2002	New York University
2004	National Toxicology Program, Intramural Program
2004	National Institute of Environmental Health Sciences, Intramural Program
2004	Environmental Protection Agency, Intramural Program

2006 National Cancer Institute, Intramural Program
2007 Environmental Protection Agency, Intramural Program

Patents: None

Other appointments: None

Consulting positions: Numerous

Grant Reviews:
- American Association for Cancer Research, Henry Shepard Trust Grants for Bladder Cancer Research
- Austrian Science Fund
- Czech Science Foundation
- Dutch Cancer Society
- Environmental Protection Agency (grants; intramural research programs)
- Food and Drug Administration
- Hong Kong Food and Health Bureau
- International Programme on Chemical Safety
- International Research Program on Tea
- Israel Research Foundation
- Kentucky Science and Engineering Foundation
- Medical Research Council (MRC), United Kingdom
- National Academy of Sciences (fellowships and grants)
- National Center for Toxicological Research
- National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), Great Britain
- National Institutes of Health (extramural grants and contracts; intramural research programs)
- Netherlands Organization for Health Research and Development
- Office of Technology Assessment, United States Congress
- U.S. Army (breast cancer grants)
- University of North Carolina Center for Environmental Health and Susceptibility
- Veterans Administration (grants)
- Wellcome Trust
- Yorkshire Cancer Research Center

Journal Reviews:
- Acta Anatomica
- American Journal of Clinical Nutrition
- American Journal of Pathology
- Annals of Surgical Oncology
- Archives of Environmental Contamination & Toxicology
- Belgian Journal of Zoology
- Biochemica Biophysica Acta
- Biochemical Pharmacology
- BJU International

Bulletin of Mathematical Biology
Cancer
Cancer Causes and Control
Cancer Chemotherapy Reports
Cancer Detection and Prevention
Cancer Epidemiology, Biomarkers and Prevention
Cancer Journal
Cancer Letters
Cancer Research (Associate Editor, 1982-1990)
Cancer Science
Carcinogenesis
Cell Biochemistry and Function
Cell Biology and Toxicology
Cell and Molecular Biology Letters
Chemico-Biological Interactions
Clinical Cancer Research
Critical Reviews in Toxicology (Editorial Board, 2009 -)
Current Pharmaceutical Design
Electrophoresis
Environment International
Environmental and Molecular Mutagenesis
Environmental Health Perspectives
Environmental Research
Environmental Toxicology
Environmental Toxicology and Pharmacology
Expert Opinion on Drug Safety
Food Additives and Contaminants
Food and Chemical Toxicology (Editorial Board, 1990-2009; Associate Editor, 2009-2010; Editorial Board, 2011-)
Fundamental and Applied Toxicology (Editorial Board, 1992-1997)
Genes and Environment
Hepatology
Histochemical Journal
Human and Experimental Toxicology
Industrial Health
International Journal of Cancer
International Journal of Environmental Research and Public Health
International Journal of Oncology (Editorial Board, 1996-2010)
International Journal of Radiation Biology
Journal of Agricultural and Food Chemistry
Journal of Biological Chemistry
Journal of Environmental Sciences
Journal of Luminescence
Journal of Pathology
Journal of Pharmacology and Experimental Therapeutics
Journal of the American Association for Laboratory Animal Science

Journal of the American Medical Association
Journal of the National Cancer Institute
Journal of Toxicology (Editorial Board, 2008-2011)
Journal of Toxicology-Clinical Toxicology
Journal of Translational Medicine Research
Journal of Urology
Kidney International
Laboratory Investigation (Editorial Board, 1993-2008)
Liver International
Molecular Biology of Cancer
Molecular Cancer Therapeutics
Molecular Carcinogenesis
Mutation Research
Nature Reviews Drug Discovery
Nutrition Journal
Nutrition Research
Oncology
Oxford University Press
Pathology International (Editorial Board, 2001- 2013)
PLoS ONE
PPAR Research
Proceedings of the Japan Academy, Series B
Proceedings of the National Academy of Sciences
Proteomics
Regulatory Toxicology and Pharmacology (Editorial Board, 2014 -)
Research in Health Risk Assessment
Risk Analysis
Scanning Microscopy
Science
Teratogenesis, Carcinogenesis, Mutagenesis
Toxicologic Pathology (Associate Editor, 2005-)
Toxicological Sciences (Editorial Board, 1998-2003)
Toxicology (Editorial Board, 2003-)
Toxicology and Applied Pharmacology
Toxicology In Vitro
Toxicology Letters
Urologic Oncology (Editorial Board, 1995-2010)
Veterinary Pathology

Abstract Reviews:

American Association for Cancer Research
American Urological Association

Military service: None

Honors and Awards:

1964	Phi Eta Sigma
1966	Phi Kappa Phi
1967	Phi Beta Kappa
1968	Sigma Sigma
1969	James M. Price Cancer Research Award, University of Wisconsin College of Medicine
1968-1972	NIH Medical Scientist Trainee (GM01932)
1982-	Who's Who in Frontiers of Science and Technology
1982-1990	Associate Editor, Cancer Research
1985-	Havlik-Wall Professor of Oncology, Endowed Chair
1988	Alpha Omega Alpha
1990	University of Nebraska Outstanding Research and Creative Activity Award
1990-2009	Editorial Board, Food and Chemical Toxicology
1990-	Who's Who in the Midwest
1991-	Who's Who in Health and Medical Services
1991-	Who's Who in Science and Engineering
1992	Fuji-Otsuka Lectureship at the University of Tokushima School of Medicine, Tokushima, Japan
1992-1997	Editorial Board, Fundamental and Applied Toxicology
1993-2008	Editorial Board, Laboratory Investigation
1993-1996	Chloroform Scientific Advisory Board, Chemical Industry Institute of Toxicology
1993-1996	National Research Council Committee on Comparative Toxicity of Naturally Occurring Carcinogens
1994-	American Men and Women of Science
1995-2010	Editorial Board, Urologic Oncology
1995-	Elected fellow, The Academy of Toxicological Sciences (Board of Directors, 2014-2016)
1996	Dean's Award for Outstanding Service to the College of Medicine, University of Nebraska
1996-2013	Best Doctors in America: Central Region
1996-2013	Best Doctors in Omaha, Nebraska
1996-2010	Editorial Board, International Journal of Oncology
1996	John Doull Medal, Central States Chapter, Society of Toxicology
1997-2003	Science Advisory Committee, Chemical Industry Institute of Toxicology (CIIT)
1998	Pathology/Microbiology/Molecular Biology-Genetics/Health Risk Assessment, Environmental Protection Agency Peer Review Panel
1998-2003	Editorial Board, Toxicological Sciences
1999	Distinguished Alumnus Citation, University of Wisconsin Medical School
2000-	Biographical Candidate, Lexington Who's Who
2001	Arnold J. Lehman Award, Society of Toxicology
2001-2013	Editorial Board, Pathology International
2002-	Flavor and Extracts Manufacturers Association Expert Panel (Vice Chairman, 2011-2013; Chairman, 2014-2016)
2002-2004	Board of Scientific Counselors, National Toxicology Program

2002-2003	National Research Council Subcommittee on Dietary Supplements
2003-	Editorial Board, Toxicology
2003-	Elected Fellow, International Academy of Toxicologic Pathology
2004	Distinguished Scientist in Cancer Research, Japanese Foundation for Cancer Research, Japanese National Cancer Center and Japan Academy
2005-	Associate Editor, Toxicologic Pathology
2008-2011	Journal of Toxicology, Editorial Board
2008-2013	Board of Scientific Counselors, National Institute of Environmental Health Sciences
2009-	Editorial Board, Critical Reviews in Toxicology
2009-2010	Associate Editor, Food and Chemical Toxicology
2010-	Editorial Board, Food and Chemical Toxicology
2010	Distinguished Scientist Award, University of Nebraska Medical Center
2012	George H. Scott Award, Toxicology Forum
2012	Lifetime Achievement Award, Association for Environmental Health and Sciences
2014	One of the Best Papers Demonstrating Application of Risk Assessment, in 2013, SOT Risk Assessment Specialty Section (for Cohen et al., Crit. Rev. Toxicol., 43:711-752, 2013).
2014-	Editorial Board, Regulatory Toxicology and Pharmacology

Memberships and offices in professional societies:

Academy of Toxicological Sciences (fellow) (Board of Directors, 2014-2016), 1995-
American Association for Advancement of Science, 1980-2006
American Association for Cancer Research, 1975-
American Association of Pathology, 1975-1992
American Medical Association, 1988-2007
American Society of Clinical Pathology, 1989-2012
American Society for Investigative Pathology, 1993-2013
Association of Medical School Microbiology and Immunology Chairs, 1992-2007
Association of Pathology Chairs, 1992-2007
Central States Chapter, Society of Toxicology (President 2004-2005), 1994-
College of American Pathologists (diplomate), 1994-2011
Gann, The Japanese Cancer Association, 1976-
International Academy of Pathology, United States and Canadian Academy of Pathology, 1986-2012
International Academy of Toxicologic Pathology (fellow), 2003 –
International Life Sciences Institute Board of Trustees (Vice Chairman, 2010 -2012; Chairman, 2012-2015), 2007-
International Life Sciences Institute-Health and Environmental Sciences Institute Board of Trustees (Vice Chairman, 2004-2006; Chairman, 2006-2008), 2001-
International Society of Urologic Pathology, 1993-2012
Nebraska Association of Pathologists, 1982-
Nebraska Medical Association, 1986-2007
Omaha Medical Society, 1986-2007

Society for Environmental Geochemistry and Health, 1998-2006
Society of Toxicologic Pathologists, 1990-
Society of Toxicology, 1986-
Society of Toxicology, Carcinogenesis Specialty Section, Vice President-Elect (2000), Vice President (2001), and President (2002), 1998-

Committee assignments:

Local (completed):

Hospital Infections Committee, St. Vincent Hospital Medical Staff, 1978-1981

Animal Care Committee (Chairman), St. Vincent Hospital, 1978-1981

Laboratory Committee, St. Vincent Hospital Medical Staff, 1980-1981

Cancer Education Committee, University of Massachusetts Medical School, 1978-1981

Chemical Hazards Committee, University of Massachusetts Medical School, 1978-1981

Research Council, St. Vincent Hospital, 1980-1981

Academic Computing Advisory Committee, University of Nebraska Medical Center, 1981-1983

Safety Committee, Eppley Institute, University of Nebraska Medical Center, 1981-1983

Research and Development Committee, University of Nebraska College of Medicine, 1981-1984

Seed Grant Review Committee (Chairman, Basic Sciences Section), University of Nebraska Medical Center, 1982

Cancer Research Grant Review Committee, University of Nebraska Medical Center, 1982

Seed Grant Review Committee (Chairman, Clinical and Behavioral Sciences Section), University of Nebraska Medical Center, 1983

Cancer Research Grant Review Committee (Chairman), University of Nebraska Medical Center, 1983

Tissue and Transfusion Review Committee (Chairman), University of Nebraska Hospital Medical Staff, 1983-1984

Search Committee for Chairman of the Department of Surgery, University of Nebraska Medical Center, 1983-1984

Quality Assurance Committee, University of Nebraska Medical Center, 1983-1984

Toxicology Task Force, University of Nebraska Medical Center, 1983-1984

Biannual Continuing Medical Education Program Committee, Nebraska Association of Pathologists, 1983-1984

Cancer Research Grant Review Committee, University of Nebraska Medical Center, 1984

Advisory Committee, Dean Selection, College of Medicine (Chairman), University of Nebraska Medical Center, 1984-1985

Graduate Committee, Department of Pathology and Laboratory Medicine (Chairman), University of Nebraska Medical Center, 1981-1985

Medical Sciences Interdepartmental Area Graduate Committee, University of Nebraska Medical Center, 1982-1985

Diagnostically-Related Group Committee, University of Nebraska Medical Center, 1983-1985

Tenure and Promotion Committee, Eppley Institute (Chairman, 1984), University of Nebraska Medical Center, 1983-1986

Director's Advisory Committee, Eppley Institute, University of Nebraska Medical Center, 1983-1992

NMR Committee, University of Nebraska Medical Center, 1984-1992

Outpatient Diagnostic and Treatment Programs Task Force, University of Nebraska Medical Center, 1984-1986

Nebraska Association of Pathologists - Continuing Medical Education, State of Nebraska, 1984-1986

Advisory Committee, Biochemistry Chairman Search Committee, College of Medicine, University of Nebraska Medical Center, 1985-1986

Advisory Committee, Pediatric Chairman Search Committee, College of Medicine, University of Nebraska Medical Center, 1985-1986

Advisory Committee, Pediatric Chairman Search Committee, College of Medicine, University of Nebraska Medical Center, 1985-1986

University of Nebraska Medical Center/Share Liaison Committee – Information System, Sub-Committee of Clinical Practice Board, University of Nebraska Medical Center, 1986

Advisory Committee to President Roskens, Foundation Awards, University of Nebraska, 1986

Outstanding Research and Creativity Award Committee (Chairman, 1986-1987), University of Nebraska, 1985-1987

Clinical Practice Board, University of Nebraska Medical Center, 1988

Clinical Practice Board Executive Committee, University of Nebraska Medical Center, 1988

Eppley Institute Promotion and Tenure Committee, University of Nebraska Medical Center, 1987-1988

Board of Directors, Nebraska Clinicians Group, University of Nebraska Medical Center, 1983-1989

Audit Committee, Nebraska Clinicians Group (Chairman, 1987-1989), University of Nebraska Medical Center, 1986-1989

Cancer Education Committee, University of Nebraska College of Medicine, 1981-1990

Carcinogenesis/Nutrition Group, Eppley Institute (Chairman, 1989-1991), University of Nebraska Medical Center, 1983-1990

College of Medicine Tenure and Promotion Committee (Chairman, 1989-1991), University of Nebraska Medical Center, 1985-1991

Committee on Selection of Student Nominees, Alpha Omega Alpha, University of Nebraska Medical Center, 1988-1990

College of Medicine Blue Ribbon Committee on the Curriculum, University of Nebraska Medical Center, 1988-1990

Hospital Executive Planning Council, University of Nebraska Medical Center, 1986-1992

Department of Pathology and Microbiology Promotion and Tenure Committee (Chairman, 1988), University of Nebraska Medical Center, 1988-1992

M.D.,-Ph.D. Committee, University of Nebraska Medical Center, 1988-1992

Committee to Recommend Cancer Activities Strategies, University of Nebraska Medical Center, 1990-1993

Dean of the College of Medicine Search Committee (Chairman), University of Nebraska Medical Center, 1992-1993

Curriculum Oversight Group, University of Nebraska Medical Center, 1992-1993

Toxicology Program, University of Nebraska Medical Center, 1985-1992

Nebraska Medical Association Coordinating Committee, 1993-1994

Search Committee for Deputy Director of University of Nebraska Comprehensive Cancer Center (Chairman), 1994-1995

College of Medicine Strategic Planning Oversight Committee, 1994-1995

University of Nebraska Medical Staff Executive Committee, 1994-1996

College of Medicine Howard Hughes Institute Grant Committee, 1995

University of Nebraska Medical Center Redesign Executive Team, 1995-1996

University of Nebraska Medical Center Redesign Research and Education Steering Team (Director), 1995-1996

Chancellor's and President's Advisory Committee for Research and Education, 1996

University of Nebraska Medical Center Partnership Internal Assessment Committee, 1996

Howard Hughes Candidates Nominating Committee, 1996

Graduate Committee, Department of Pathology and Microbiology (Chairman, 1985-1992), University of Nebraska Medical Center, 1985-1997

Search Committee for the Director of University of Nebraska Medical Center/Eppley Cancer Center, University of Nebraska Medical Center, 1997

University Hospital Board of Governors, 1995-1997

Outcomes Management Pre-Merger Transition Team, University of Nebraska Medical Center, 1997

Genetics Research Space Executive Committee (Chairman), 1994-1998

Environmental and Occupational Medicine Coordinating Council, 1994-1999

University of Nebraska Medical Center and University of Nebraska Marshall Professorship in Biotechnology Selection Committee, 1998

College of Medicine Genetics Strategic Planning and Implementation Committee (Chairman), 1994-1998

College of Medicine Definition of Productive Space Committee, 1998

University Medical Associates Executive Committee, 1994-1998

Chancellor's Research and Education Advisory Panel, 1996-1998

University of Nebraska Medical Center/Molecular Genetics Director Search Committee, 1997-1999

Education Planning Work Group Committee, 1999

University of Nebraska Medical Center/Research Planning Work Group Committee, 1999

Chancellor's Investiture Committee (Co-Chair), 1999

Interactions Between Centers and Departments at University of Nebraska Medical Center (Chairman), 1999-2000

Review of the Department of Internal Medicine, 1999-2000

Research Centers of Excellence Steering Committee (Chair of Laboratory Support Subcommittee), 1999-2000

University of Nebraska Medical Center/Ad Hoc Committee on Volunteer Faculty, 2000

University of Nebraska Medical Center/Seed Grant Subcommittee, 2000

Breast Cancer Research Program Internal Advisory Committee, 1994-2000

Pancreas Cancer Research, Internal Advisory Committee, 1995-2000

Search Committee for Chair of Internal Medicine, 1999-2001

University of Nebraska Minority Faculty Symposium, 2000-2001

Biotechnology Program on Infectious Diseases, University of Nebraska Medical Center (Director), 1988-2001

Technology Evaluation and Protection Committee, University of Nebraska Medical Center, 1992-2001

Animal Care Committee, Eppley Institute, University of Nebraska Medical Center, 1981-2001

University of Nebraska Medical Center Research Council, 1993-2002

Search Committee, Chair of the Department of Cell Biology, Anatomy and Genetics, 2002-2003

Radiolabelled Antibody Advisory Committee, University of Nebraska Medical Center, 1991-2003

University of Nebraska Medical Center/Eppley Center for Cancer Research and Care, Internal Advisory Committee, 1993-2003

University of Nebraska Medical Center/Eppley Cancer Center, Leadership Council, 1996-2003

Strategic Planning Committee, UNMC, 2002-2004

University Medical Associates, Executive Committee, 2000-2004

Latta Lectureship Committee, University of Nebraska Medical Center, 1988-2004

University of Nebraska Medical Center, Strategic Recruitment Proposal Review Committee, 1998-2005.

University of Nebraska Medical Center, Strategic Recruitment Proposal Review Committee, 1998-2005.

Core Facility Advisory Council, UNMC, 2002-2005.

Clinical Oncology Planning Committee, UNMC, 2004-2005

University of Nebraska Medical Center/Research Development Board, 1999-2005

Dean's Committee, Veterans Administration Hospital, Omaha, Nebraska, 1992-2007

University Medical Associates Benefits Committee (Chairman), 1995-2007

University Medical Associates Board of Directors (Vice President, 1996-1999), 1995-2007

University of Nebraska Federal Relations Team, 2000-2007

Durham Research Center Management Council, UNMC, 2003-2007

University of Nebraska Medical Center/Eppley Cancer Center, Scientific Advisory Council (Vice-Chair, 1996-2000), 1996-2007

Pathology Residency Program (Director) 2009-2013

Graduate Medical Education Committee, 2009-2013

Local (Active):

University of Nebraska College of Medicine Grievance Committee (Chair 2011-2016), 2010-2016

University of Nebraska Medical Center Subcommittee of Equity Office Working Group on Under Represented Minorities Faculty, 2014-

National and International (completed):

Special Study Section, NIH, 1980

Chemical Pathology Study Section, NIH, 1982-1986

Program and Organizing Committee, International Symposium on the Role of Co-Carcinogens and Promoters in Human and Experimental Carcinogenesis; Budapest, Hungary, May 16-18, 1983

Membership Committee, American Association for Cancer Research, Inc., 1985-1986

U.S.-Japan Co-Operative Cancer Research Program, Recent Advances In Bladder Cancer Research, Organizing Committee (Co-Chair), 1985-1986

Chemical Pathology B Study Section Special Review (Chairman), 1988

Program Committee, The Fourth International Symposium, Foundation for Promotion of Cancer Research, Japan, March 26-28, 1991

Mini-Symposium on Chemical and Viral Carcinogenesis, Federation of American Societies of Experimental Biology, (Organizer and Chairman), Anaheim, California, April 8, 1992

Immunology, Virology, Pathology Study Section, NIH (Chairman, 1991-1993), 1989-1993

Special Study Section, NIH, Outstanding Investigator Grants, 1993

Finance Committee, American Association for Cancer Research, 1991-1994

Forestomach Subgroup of the Carcinogenicity Working Group, International Life Sciences Institute, Washington, D.C., 1988-1994

Cell and Tissue Biology 3 (CTB3) Review Committee, United States Army Research and Development Command Breast Cancer Research Program (Chairman), 1994

Nomenclature Committee, Society of Toxicologic Pathologists, 1992-1995

Working Group on Bladder Cancer, International Life Science Institute, Risk Science Institute and Environmental Protection Agency, 1992-1995

American Association of Cancer Research, Program Committee, 1993-1995; International Cancer Congress, "Novel Mechanisms Chemical Carcinogenesis (Organizer and Co-Chairman), New Delhi, India, 1994

American Association for Cancer Research, Program Committee, Genitourinary Tract Cancers (Chairman), 1994-1995

Special Study Section, NIH (Chairman), 1995

International Life Sciences Histopathology Workshop-Urinary Tract (Organizer), Hannover, Germany, 1995

National Research Council Committee on Comparative Toxicity of Naturally Occurring Carcinogens, 1993-1996

Scientific Advisory Panel on Chloroform, Chemical Industry Institute of Toxicology, 1992-1996

International Life Sciences Institute-Environmental Protection Agency Working Group on Cancer Bioassay Dose-Selection Modeling, 1990-1996

Environmental Protection Agency/FIFRA Scientific Advisory Panel, 1996-1997

Expert Panel on Arsenic Carcinogenicity, U.S. Environmental Protection Agency, 1997

International Life Sciences Institute/Environmental Protection Agency Expert Panel to Evaluate EPA's Proposed Guidelines for Carcinogenic Risk Assessment, 1996-1998

Environmental Protection Agency/FIFRA Scientific Advisory Panel, 1997

Editorial Board of Fundamental and Applied Toxicology, 1992-1997

International Agency for Research on Cancer, Working Group, 1997

Scientific Advisory Group on Cellular Telephone Research, 1995-1998

Pathology/Microbiology/Molecular Biology-Genetics/Health Risk Assessment, Environmental Protection Agency Peer Review Panel, 1998

Electric Power Research Institute; Scientific Advisory Panel, 1994-1998

Scientific Advisory Committee (SAC), Chemical Industry Institute of Toxicology (CIIT), 1997-1998

International Agency for Research on Cancer, Working Group, 1998

Cell Death Nomenclature Committee, Society of Toxicology Pathology, 1997-1999

Program Committee, Carcinogenesis Specialty Section, Society of Toxicology, 1997-1999

Princess Takamatsu Cancer Research Symposium Organizing Committee (Co-Chair), 1998-1999

International Academy of Pathology Symposium Organizing Committee (Co-Chair), 1999-2000

Arsenic Expert Panel, U.S. Environmental Protection Agency, 2000

International Life Sciences Institute/Risk Sciences Institute Annual Meeting Scientific Session (Organizer and Chair), 2000-2001

International Life Sciences Institute/N.A. Apoptosis Joint Subcommittee of the Committees on Proposition 65 and the Technical Committee on Food Toxicology and Safety Assessment (Chairman), 1998-2001

Society of Toxicology Workshop Organizing Committee for 2001 Annual Meeting (Co-Chair), 2000-2001

National Cancer Institute, Intramural Program Site Visit and Review, 2001

International Life Sciences Institute/Alternatives to Carcinogenicity Testing Committee (ACT), 1997-2002

International Life Sciences Institute/AFIP, Working Group on Mesenchymal Tumors of the Mouse Urinary Bladder, 1997-2001

Society of Toxicology Task Force to improve the scientific basis of Risk Assessment (RATF), 1999-2001

International Programme on Chemical Safety Panel, London, 2000-2001

International Life Sciences Institute/Health and Environmental Sciences Institute, Mechanisms and Risk Assessment Committee (Vice Chair), 2001-2002

Search Committee for Director of International Life Sciences Institute/Health and Environmental Sciences Institute, 2002

Society of Toxicology Workshop Organizing Committee for 2003 Annual Meeting (Co-Chair), 2002-2003

Editorial Board of *Toxicological Sciences*, 1998-2003

International Life Sciences Institute/RSI Peroxisome Proliferator and Human Relevance Committee, Chair, 2001-2003

National Research Council Working Group of the Committee on the Framework for Evaluating the Safety of Dietary Supplements, 2002-2003

Schering-Plough Research Institute Consultants Panel, 2001-2004

National Toxicology Program Board of Scientific Counselors of the Office of the Assistant Secretary for Health, 2002-2004

International Life Sciences Institute/Risk Science Institute Board of Scientific Advisors, 1998-2005

Pfizer Carcinogenesis Advisory Board, 2000-2005

International Life Sciences Institute/RSI Dose Response II Committee, 2001-2005

Astra Zeneca Science Advisory Board (Chair), 2002-2005

International Life Sciences Institute/RSI Human Relevance II Committee, 2003-2005

Environmental Protection Agency, Intramural Research Program Site Visit and Review, 2004

International Life Sciences Institute/Health and Environmental Sciences Institute, Editorial Review Committee (Chair), 2002-2006

International Programme on Chemical Safety (IPCS), World Health Organization, Cancer Working Group, 2003-2006

National Cancer Institute, Intramural Program Site Visit and Review, 2006

International Life Sciences Institute/Health and Environmental Sciences Institute, Emerging Issues Committee, 2000-2006

International Life Sciences Institute/Health and Environmental Sciences Institute, Liver Tumor Working Group, 2004-2006

International Life Sciences Institute/Health and Environmental Services Institute, Search Committee, 2006-2007

National Comprehensive Cancer Network, Bladder Cancer Working Group, 1996-2007

Research Committee, Association of Pathology Chairs, 1997-2007

International Life Sciences Institute/Health and Environmental Sciences Institute, Nominating Committee, 2002-2007

International Life Sciences Institute/Health and Environmental Sciences Institute, Cancer Hazard Identification Strategies Committee, 2004-2007

Organizing Committee, International Federation of Societies of Toxicologic Pathology, 2007 symposium (Sept), Board, Basel Switzerland, 2006-2007

Society of Toxicologic Pathology, Membership Committee, 2007-2008

Editorial Board of *Laboratory Investigation*, 1993-2008

Society of Toxicologic Pathology, 2008 Annual Meeting, Symposium Organizing Committee (Co-Chair), 2007-2008

International Life Sciences Institute/Health and Environmental Sciences Institute, PPAR Working Group, 2005-2009

Society of Toxicologic Pathology, Awards Committee, 2008-2009

Society of Toxicologic Pathology, Nominations Committee, 2008-2009

Society of Toxicology/Health and Environmental Sciences Institute, Current Concepts in Toxicology (CCT) Workshop, "Hemangiosarcomas in Rodents: Understanding Modes of Action and Human Relevance", Organizing Committee (Co-Chair), 2008- 2009

Scientific Review Committee, American Association for Cancer Research, Henry Sheperd Trust grants for bladder cancer research, 2008 – 2009

Schering-Plough Science Advisory Board, 2009

Editorial Board of *Food and Chemical Toxicology*, 1990-2009

Sanofi-Aventis Science Advisory Board, 2006-2009

Editorial Board of Journal of Toxicology, 2008-2011

Society of Toxicologic Pathology, 2009 Annual Meeting Organizing Committee, 2008-2009

American Urological Association Abstract Review Team, 2009

International Life Sciences Institute, Risk Science Institute and Health and Environmental Sciences Institute, and ECETOC Mode of Action, Conference Organizing Committee, 2009

Associate Editor, *Food and Chemical Toxicology*, 2009-2010

International Life Sciences Institute/Health and Environmental Sciences Institute, Executive Committee (Member at Large, 2002-2004, 2008-2010; Vice Chairman of the Board, 2004-2006; Chairman of the Board, 2006-2008)

Society of Toxicology Current Concepts in Toxicology, Workshop on New Approaches to Carcinogenicity Testing, Organizing Committee, 2010

Editorial Board of *Urologic Oncology*, 1995-2010

Editorial Board of *International Journal of Oncology*, 1996-2010

EPRI Arsenic Scientific Review Panel, 2008-2012

International Life Sciences Institute, Nominations Committee, 2010-2012

Society of Toxicologic Pathology, Editor Search Committee, 2012-2013

Board of Scientific Counselors, National Institute of Environmental Health Sciences, 2008-2013

International Life Sciences Institute/Health and Environmental Sciences Institute, Executive Committee, 2011-2012

International Life Sciences Institute, Board of Trustees, Scientific Issues Committee, 2007-2014

International Life Sciences Institute, Board of Trustees, Tripartite Committee, 2007-2014

Society of Toxicology, Awards Committee (elected), 2012-2014

Editorial Board of *Pathology International*, 2001-2013

International Academy of Toxicologic Pathology, Membership committee, 2007-2013

Health and Environmental Sciences Institute, Risk Assessment for the 21st Century Committee (Co-Chair of Dose Response Team), 2009-2014

International Life Sciences Institute Board of Trustees, Executive Committee, 2010-2015

Society of Toxicologic Pathology Working Group on Cell Proliferation and Apoptosis, 2013-2015

National and International (current):

International Life Sciences Institute/Health and Environmental Sciences Institute Board of Trustees (Vice Chairman, 2004-2006; Chairman, 2006-2008), 2001-2016

International Life Sciences Institute/Health and Environmental Sciences Institute Program Strategy and Stewardship Committee (Vice Chair, 2001-2004; Chair, 2004-2006), 2001-2016

Flavor and Extract Manufacturers Association of the United States, Expert Panel, 2002- (Vice Chairman, 2011-2013; Chairman, 2014-2016)

Editorial Board of *Toxicology*, 2003-

Associate Editor of *Toxicologic Pathology*, 2005-

Editorial Board of *Critical Reviews in Toxicology*, 2009-

International Life Sciences Institute, Board of Trustees, 2007-2016 (Vice Chairman, 2010-2012; Chairman, 2012-2015)

International Life Sciences Institute/Health and Environmental Sciences Institute Global Platform Initiative Steering Team, 2014-

International Life Sciences Institute Malaspina Intenational Scholars Travel Award Selection Committee, 2014-

Editorial Board of Regulatory Toxicology and Pharmacology, 2014-

Michigan State University's Center for Research on Ingredient Safety (CRIS) Emerging Issues Committee, 2014-

Service Pathology:

Current**:** Surgicals (approximately 1,700/year)

Teaching:

Current**:** Small groups and laboratories in second year medical school courses

Pathology residents
Interdepartmental and intradepartmental conferences

Graduate Students:

Thesis Advisor to:
Daniel Williamson (M.D., Ph.D.)
Irene A. Sysel (M.D.)
Susan Speaks (M.D., Ph.D.)
Theodore D. Miller (M.D.)
Maria Louisa de Oliveira (Ph.D.) (Sao Paulo State University, Botucatu, Brazil)
Merielen Nascimento (Ph.D.) (Sao Paulo State University, Botucatu, Brazil)
Satako Kiyota (Ph.D.)
Mitscheli Sanches da Rocha (Ph.D.) (Sao Paulo State University, Botucatu, Brazil)
Ana Paula Cardoso (Ph.D.) (Sao Paulo State University, Botucatu, Brazil)
Lora Arnold (M.S.)
Margaret St. John (M.S.)
Maria Jackson (B.S.)
Amy Salem (B.S.)
Denise Demers (B.S.)
Donald Headley (B.S.)
John Wittenberg (B.S.)
Eric Boyd (B.S.)

Supervisory Committee for:
Christine Eccleston (Ph.D.)
Thomas Gross (M.D., Ph.D.)
Susan Speaks (M.D., Ph.D.)
Julie Gulizia (M.D., Ph.D.)
Shadia M. Ihlaseh (Ph.D.)
Aniruddha Chatterjee (Ph.D.) (University of Calcutta, External Reviewer)
Hang Su (Ph.D.)
Matthew T. McLeay (M.D., M.S.)
Terry N. Wooldridge (M.D., M.S.)
Michael W. Davis (M.S.)
Deborah L. Hassler (M.S.)
Sally G. Johnson (M.S.)
Krysten Knott (M.S.)
James Burgart (M.S.)
Denise Kolbet (M.S.)
James H. Lichty (M.S.)
Nancy A. Riesberg (M.S.)
James D. Sargeant (M.S.)

Alice M. Schumaker (M.S.)
Shirley Shepherd (M.S.)
Justin Hobbs (M.S.)

Post-Doctoral Fellows (present positions):

Masayuki Arai, M.D. (Professor and Chairman, Department of Pathology, and Dean, School of Medical Technology and Nursing, Fujita-Gakuen University, Toyoake, Japan) (Deceased)
Shoji Fukushima, M.D., Ph.D. (Professor and Chairman, Department of Pathology, Osaka City University Medical School, Osaka, Japan, retired; Director, Japan Bioassay Research Center, Japan Industrial Safety and Health Association)
Gen'i Murasaki, M.D. (Director of Shutoken JP Health Care Center, Tokyo, Japan)
Toru Suzuki, M.D. (Associate Professor, Department of Urology, Dokkyo University School of Medicine, Mibu, Japan)
Michael J. Becich, M.D., Ph.D. (Professor, Department of Pathology; Chairman, Department of Biomedical Informatics, University of Pittsburgh, Pittsburgh, Pennsylvania)
Ryohei Hasegawa, M.D. (Chiba, Japan)
Raymond A. Smith, Ph.D. (Pharmacist, Marinette, Wisconsin)
Takao Sakata, M.D. (Department of Urology, Nagoya University Medical School, Nagoya, Japan)
Angela Mann, Ph.D. (Assistant Professor, University of Massachusetts Medical Center, Worcester, Massachusetts)
Tsuneo Masui, M.D., Ph.D. (General Director, Aichi Prefectural Government, Public Health Science, Aichi, Japan)
Emily Garland, Ph.D. (Research Associate, Vanderbilt University)
Takehiko Okamura, M.D. (Assistant Professor, Department of Urology, Nagoya City University Medical School, and Chief of Urology, Meijo Hospital, Nagoya, Japan)
Makoto Asamoto, M.D., Ph.D. (Associate Professor, First Department of Pathology, Nagoya City University Medical School, Nagoya, Japan) (Deceased)
Kumiko Ogawa, M.D., Ph.D. (Head, Division of Pathology, National Institute of Health Sciences, Tokyo, Japan)
Masahiro Ito, M.D. (Associate Professor, Department of Surgery, Fujita-Gakuen University, Toyoake, Japan)
Shinji Yamamoto, M.D. (Physician, Osaka, Japan)
Min Wei,, M.D., Ph.D. (Associate Professor, Department of Pathology, Osaka City University, Osaka, Japan)
Mitsuru Futakuchi, M.D., Ph.D. (Associate Professor, Dept. of Molecular Toxicology, Nagoya City University Medical School, Nagoya, Japan)
Takamasa Ohnishi, M.D., Ph.D. (Professor and Chairman, Nutrition Division, Department of Health and Science, Hyogo University, Hyogo, Japan)
Shugo Suzuki, M.D., Ph.D., (Assistant Professor, First Department of Pathology, Nagoya City University Medical School, Nagoya, Japan)
Masanao Yokohira, M.D., Ph.D., (Assistant Professor, Department of Pathology, Kagawa Medical School, Kagawa, Japan)
Satoko Kakiuchi-Kiyota, Ph.D. (Scientist, Pfizer, Groton, CT)

Puttappa Dodmane, Ph.D. (Present fellow)

Presentations:

07/05/72 "Carcinogenesis caused by nitrofuran derivatives," Fifth International Congress of Pharmacology, San Francisco, California

10/21 – 10/25/75 "Early lesions in experimental bladder cancer: Experimental design and light microscopic findings," International Symposium on Early Lesions and the Development of Epithelial Cancer, Bethesda, Maryland

07/21 – 07/22/76 "Tissue culture characteristics of bladder carcinoma cells," Annual Meeting of the Japanese Bladder Cancer Group, Unuma, Japan

09/16/76 "Bladder cancer," Osaka University, Osaka, Japan

09/26 – 09/28/76 Etiology of Bladder Cancer, U.S.-Japan Cancer Research Program, Kyoto, Japan

10/08 – 10/09/76 Conference on Analytical Epidemiology, U.S.-Japan Cancer Research Program, Tokyo, Japan

10/29/76 "Scanning electron microscopy of bladder carcinogenesis," Tukushima University, Tokushima, Japan

12/12/76 "Use of scanning electron microscopy in the diagnosis of urinary bladder cancer," 150th Meeting of the Okayama Urological Association, Okayama, Japan

01/22/77 "Neovascularization in bladder carcinogenesis," Japanese Study Group on Epithelial-Mesenchymal Interactions, Tokyo, Japan

01/28 – 01/29/77 "Bladder carcinogenesis," Annual Meeting of the Japanese Bladder Cancer Group, Unuma, Japan

02/07 – 02/08/77 "Nitrofuran carcinogenesis," Tohoku University, Sendai, Japan

02/15/77 "Effects of nitrofurans on the immune system," Radiation Effects Research Foundation, Hiroshima, Japan

02/16/77 "Urinary bladder carcinogenesis," Hiroshima University, Hiroshima, Japan

02/23/77 "Bladder cancer," Kyoto University, Kyoto, Japan

03/08/77 "Ultrastructural aspects of bladder cancer," Aichi Cancer Center, Nagoya, Japan

03/14/77 "Bladder cancer," Gifu University, Gifu, Japan

03/22/77 "Nitrofuran carcinogenesis," Cancer Institute, Tokyo, Japan

03/23/77 "FANFT metabolism and bladder carcinogenesis," Biochemical Research Institute, Tokyo, Japan

04/21/77 "Nitrofuran carcinogenesis," Nara Medical University, Nara, Japan

04/23/77 "Experimental bladder cancer research," Masuko Hospital, Nagoya, Japan

05/10/77 "Nitrofuran carcinogenesis," National Institute of Hygienic Sciences, Tokyo, Japan

05/16/77 "Nitrofuran carcinogenesis," Kyoto University, Kyoto, Japan

11/07 – 11/11/78 "Urinary cytology as examined by scanning electron microscopy," Symposium on Tumors of the Urothelium, American Society of Cytology, Miami, Florida

11/07 – 11/11/78 "Experimental urinary bladder carcinogenesis," Symposium on Tumors of the Urothelium, American Society of Cytology, Miami, Florida

07/11/79 "Morphological and biochemical markers of bladder cancer in man and animals," Department of Human Oncology Grand Rounds, Clinical Science Center, University of Wisconsin, Madison, Wisconsin

11/02/79 "Initiation and promotion of cancer," New England Cancer Society, Boston, Massachusetts

11/07 – 11/09/79 "Urinary bladder carcinogenesis with N-substituted aryl compounds: Initiation and promotion," International Conference on Carcinogenic and Mutagenic N-Substituted Aryl Compounds, Rockville, Maryland

12/10/79 "Urinary bladder cancer," Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois

12/11/79 "Urinary bladder carcinogenesis," Northwestern University Medical School, Chicago, Illinois

03/12 –
03/15/81 "Promotion in urinary bladder carcinogenesis," International Symposium on Health Effects of Tumor Promotion, Cincinnati, Ohio

03/00/81 "Promotion of urinary bladder carcinogenesis," International Symposium on Organ and Species Specificity in Chemical Carcinogenesis, Raleigh, North Carolina

11/04/81 "Urinary bladder cancer," University of Baroda Medical School, Baroda, India

11/11 –
11/12/81 "Promotion in urinary bladder carcinogenesis," Symposium on Tumor Promotion, Nagoya, Japan

03/30 –
04/01/82 "Multistage carcinogenesis in the urinary bladder," Second International Conference on Carcinogenic and Mutagenic N-Substituted Aryl Compounds, Hot Springs, Arkansas

12/09 –
12/10/82 "A probabilistic model of carcinogenesis," Rush-Presbyterian-St. Luke's, Chicago, Illinois

01/05 –
01/08/83 "Diagnostic electron microscopy," Second National Bladder Cancer Conference, Sarasota, Florida

05/16 –
05/18/83 "Urinary bladder carcinogenesis," International Symposium on Role of Co-Carcinogens and Promoters in the Human and Experimental Carcinogenesis," Budapest, Hungary

05/05/83 "Multi-stage carcinogenesis in the urinary bladder," Scientific Review Panel on Saccharin: An Update, Duke University Medical Center, Durham, North Carolina

11/01 –
11/02/83 "Promotion in urinary bladder carcinogenesis," Environmental Health Seminar Series, University of Cincinnati, Cincinnati, Ohio

01/04 -
01/07/84 "Unmet needs and available models," Session Co-Chairman, Tenth National Bladder Cancer Project Investigators' Workshop, Sarasota, Florida

01/04 –

01/07/84 "Tumor dissemination," Session Chairman, Tenth National Bladder Cancer Project Investigators' Workshop, Sarasota, Florida

01/04 – 01/07/84 "Growth factors and membrane receptors in tumor growth and progression," Session Chairman, Tenth National Bladder Cancer Project Investigators' Workshop, Sarasota, Florida

05/03 – 05/04/84 "Aspirin inhibition of N-[4-(-nitro-2-furyl)-2-thiazolyl]formamide (FANFT) in urinary bladder carcinogenesis," Development of Cancer Chemopreventive Agents, National Cancer Institute, Gaithersburg, Maryland

10/15 – 10/18/84 "Saccharin: Past, present and future," 67th Annual Meeting of the American Dietetic Association, Washington, D.C.

01/08/86 "Effects of Different Salt Forms of Saccharin on the Rat Urinary Bladder," Meeting of the Saccharin Technical Committee, International Life Sciences Institute - Nutrition Foundation, Omaha, Nebraska

01/21/86 "Saccharin," International Life Sciences Institute – Nutrition Foundation, Annual Meeting of the Food, Nutrition and Safety Committee, meeting Dates: 01/20-01/23/86, Naples, Florida

03/20/86 "Urinary Bladder Carcinogenesis," National Institute of Hygienic Sciences, Tokyo, Japan

03/20/86 "Importance of cell proliferation in urinary bladder carcinogenesis," Urology and Biochemistry Divisions, National Cancer Center Research Institute, Tokyo, Japan

03/25/86 "Modifiers of carcinogenesis," U.S.-Japan Cooperative Cancer Research Program Seminar; Recent Advances in Bladder Cancer Research, meeting Dates: 03/24-03/25/86, Nagoya, Japan

03/26 – 03/29/86 "Effects of Urinary Parameters on Bladder Carcinogenesis," International Symposium and International Life Sciences Institute Histopathology Seminar on the Urinary System of Laboratory Animals, Nara, Japan

04/13 – 04/16/86 "Bladder Tumor Promotion," Non-genotoxic Mechanisms in Carcinogenesis, Banbury Center, Cold Spring Harbor Laboratory.

05/21/86 "Multi-stage Carcinogenesis in the Urinary Bladder: Rats, Humans and Computer Models," Northwestern University Cancer Center, Chicago, Illinois

05/21/86 "Importance of Cell Proliferation in Carcinogenesis," Department of Pathology, Northwestern University Medical School, Chicago, Illinois

06/09/86 "Bladder cancer in rats, humans and computers," Wisconsin Clinical Cancer Center, Department of Human Oncology, University of Wisconsin Medical School, Madison, Wisconsin

10/30/86 "Multi-Stage Carcinogenesis," Chemical Carcinogenesis/Molecular Biology Interface Working Session, sponsored by the Bladder Cancer Working Group of the Organ Systems Program, National Cancer Institute, Michigan Cancer Foundation, Detroit, Michigan

12/17/86 "Saccharin," Food and Drug Administration, Washington, D.C.

01/14/87 "Role of saccharin in bladder cancer research," Optimist Club Luncheon, Omaha, Nebraska

01/17/87 "Computer modeling in cancer research," Board of Regents, Lincoln, Nebraska

01/22/87 "Computer modeling in cancer research," University of Nebraska Medical Center Chancellor's Board of Counselors, Omaha, Nebraska

02/02/87 "Cancer: Cause and Prevention," Sertoma Club, Kearney, Nebraska

04/03/87 "Saccharin," Food and Drug Administration, Washington, D.C.

04/13/87 "Mechanistic Research on Bladder Carcinogenesis," International Life Sciences Institute-Nutrition Foundation, Washington, D.C.

09/21 – 09/22/87 "Cancer: Etiology and Pathogenesis," University of Massachusetts Medical School, Worcester, Massachusetts

09/24/87 "Saccharin Mechanistic Research," Sweetener Safety/Regulatory Symposium, Pepsi Somers Conference Center, Valhalla, New York

09/28/87 "Basic Research Directions," Moderator Chairman, Second International Consensus Development Conference on Guidelines for Clinical Research in Bladder Cancer, Hakone, Japan

09/28/87 "Carinoma in Situ," Second International Consensus Development Conference on Guidelines for Clinical Research in Bladder Cancer, Hakone, Japan

09/28/87 "Evaluation and Clinical Follow-Up," Second International Consensus Development Conference on Guidelines for Clinical Research in Bladder Cancer, Hakone, Japan

09/30/87 "Basic Research Directions," Moderator Chairman, Second International Consensus Development Conference on Guidelines for Clinical Research in Bladder Cancer, Hakone, Japan

10/02/87 "Genotoxic versus Non-Genotoxic Mechanisms of Carcinogenesis," National Cancer Institute, Tokyo, Japan

10/05/87 "Initiation and Promotion in Urinary Bladder Carcinogenesis," Nagoya City University Medical School, Nagoya, Japan

11/04/87 "Cell Growth in Long-Term Bladder Carcinogenesis," 17th Conference on Toxicology, Fairborn, Ohio

12/08/87 "Restructuring the Department of Pathology's Charge Capture System," Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois

02/10/88 "Cell Growth Dynamics in Bladder Carcinogenesis: Implications for Risk Assessment," Brookings Institute, Washington, D.C.

05/03/88 "Saccharin," Symposium on Human Cancer Risk Assessment Based on Experimental Data, Wrightsville Beach, North Carolina

06/15/88 Forestomach Subgroup of the Carcinogenicity Working Group, International Life Sciences Institute, Risk Science Institute, Washington, D.C.

09/26 – 09/27/88 "Cancer: Etiology and Pathogenesis," University of Massachusetts Medical School, Worcester, Massachusetts

10/06/88 "The Role of Cell Dynamics in Multi-stage Carcinogenesis: Implications for Risk Assessment," Japanese Cancer Association Symposium, Contributions of Rodent Carcinogenesis Studies to Human Health, Nagoya, Japan

02/01/89 "Bladder Carcinogenesis: Non-genotoxic and Genotoxic Agents," University of Wisconsin Clinical Cancer Center, Department of Human Oncology, Madison, Wisconsin

02/28/89 "Toxic and Nontoxic Changes Induced in the Urothelium by Xenobiotics," Symposium II. Correlation Between Morphologic and Functional Changes Induced by Xenobiotics: "Is Every Change a Sign of Toxicity?," Society of Toxicology Meeting, Atlanta, Georgia

02/28/89 "The Relationship of Androgens/Estrogens to Proliferative Changes in the Prostate," Symposium II. Correlation Between Morphologic and Functional Changes Induced by Xenobiotics: "Is Every Change a Sign of Toxicity?," Society of Toxicology Meeting, Atlanta, Georgia

03/08/89 "Cell Proliferation and Its Implications for Risk Assessment," Mobay Corp., Kansas City, Missouri

03/22/89 "Overview of Initiation and Promotion; Genotoxic and Non-genotoxic Mechanisms of Carcinogenesis," The Biology of Bladder Cancer: The Potential Clinical Implications, Organ Systems Coordinating Center, Organ Systems Program, NCI, Bethesda, Maryland

03/31/89 "Morphologic Changes During Urinary Bladder and Kidney Carcinogenesis," Great Lakes Regional Discussion Group, Society of Toxicologic Pathologists, Spring Meeting, Madison, Wisconsin

06/17 – 06/22/89 "Cell Growth Dynamics and DNA Alterations in Carcinogenesis," Scientific Issues in Quantitative Cancer Risk Assessment, Societal Institute of the Mathematical Sciences, Snowbird, Utah

09/11 – 09/12/89 "Bladder Cancer," Immunology of Solid Tumors: Animal Models, Cancer Immunology Branch, Division of Cancer Biology and Diagnosis, NCI, Rockville, Maryland

09/18 – 09/22/89 "Update on Sweeteners – Saccharin," Toxicology Forum, Toulouse, France.

09/27 – 09/28/89 "Cancer: Etiology and Pathogenesis," University of Massachusetts Medical School, Worcester, Massachusetts

10/10 – 10/11/89 "Saccharin," International Life Sciences Institute, Washington, D.C.

11/01/89 "Role of cell proliferation and genotoxicity in bladder carcinogenesis: Implications for Risk Assessment," E. I. DuPont de Nemours and Co., Neward, Delaware

11/29 – 12/02/89 "Chemically Induced Cell Proliferation: Implications for Risk Assessment," Austin, Texas

04/09/90 "Sweet Daggers, Chemicals, Cells, and Cancer," University of Nebraska Medical Center, Omaha, Nebraska

05/23/90 "New Technology, Your Pathologist, and You," Workshop, American Association for Cancer Research, Washington, D.C.

09/20 – 09/21/90 "Cancer: Etiology and Pathogenesis," University of Massachusetts Medical School, Worcester, Massachusetts

10/01/90 "Bladder Cancer," Noble-Foundation, Inc., Fifth Annual Mid-America Molecular and Cellular Biology Colloquium, Ardmore, Oklahoma

10/15/90 "Saccharin," International Life Sciences Institute, Washington, D.C.

10/22/90 "Role of Cell Proliferation on the Dose Response of Genotoxic and Nongenotoxic Carcinogens," 1990 Drug Safety Meeting, Pharmaceutical Manufacturers Association, Tampa, Florida

11/08/90 "Two-stage Models of Carcinogenesis: Applications and Implications in Risk Assessment," National Research Council, Committee on Risk Assessment Methodology (CRAM), Washington, D.C., 1990

12/07/90 "Relevance of Animal Studies to Evaluate Human Cancer Risk," University of Texas, M.D. Anderson Cancer Center-Science Park. Barton Creek Conference Resort, Austin, Texas

12/12/90 "Saccharin," International Life Sciences Institute, Washington, D.C.

12/13/90 "Saccharin," Federal Drug Administration, Washington, D.C.

12/13/90 "Biological Models and Risk Assessment," Federal Drug Administration, Washington, D.C.

12/18/90 "Cell Proliferation in Carcinogenesis," First Department of Pathology, Nagoya City University Medical School, Nagoya, Japan

12/18/90 "Cell Proliferation in Carcinogenesis," First Department of Pathology, Osaka City University Medical School, Osaka, Japan

12/19/90 "Cell Proliferation in Carcinogenesis: Implications for Risk Assessment," Food and Drug Administration, Rockville, Maryland

02/06/91 "Cell Proliferation in Carcinogenesis: Implications for Risk Assessment," Food and Drug Administration, Rockville, Maryland

02/26/91 "Simvastatin: Risk Evaluation," Merck Sharp and Dohme Research Laboratories, West Point, Pennsylvania

03/08/91 "Simvastatin," Food and Drug Administration, Rockville, Maryland

03/26 – 03/28/91 "Cell Proliferation, Genotoxicity, and Carcinogenesis," Fourth International Symposium, Fundamental and Clinical Research in Urogenital Cancer, Foundation for Promotion of Cancer Research, Tokyo, Japan

04/24/91 "Solid Wastes and Toxics," Nebraska Wesleyan University, Lincoln, Nebraska

06/11 – 06/14/91 "Cell Proliferation in Mutagenesis and Carcinogenesis," Gordon Conference-Genetic Toxicology, Colby-Sawyer College, New London, New Hampshire

08/26/91 "Of Mice and Men: Carcinogenesis and Risk Assessment," NIEHS, Research Triangle Park, North Carolina

09/05/91 "Cancer Modeling," Harvard University, Boston, Massachusetts

09/19 – 09/20/91 "Cancer: Etiology and Pathogenesis," University of Massachusetts Medical School, Worcester, Massachusetts

09/22 – 09/23/91 "Classification of 3,4'methylene *bis*(2-chloraniline) (MOCA)," American Conference of Governmental Industrial Hygienists Threshold Limit Values Committee, Cincinnati, Ohio

10/10/91 "Chemicals, Biology and Potential Cancer Risk," American Chemical Society, Anaheim, California

11/11/91 "Genetic Alterations and Cell Proliferation in Chemical Carcinogenesis," National Cancer Institute-Frederick, Frederick, Maryland

11/20/91 "Cell Proliferation and Carcinogenesis: Implications for Risk Assessment," Merck Sharp and Dohme Research Laboratories, West Point, Pennsylvania

12/05 – 12/06/91 "Biological Theory of Carcinogenesis and Characteristics of Bladder Tumors from Mutagenic and Nonmutagenic Compounds," International Life Sciences Institute Risk Science Institute Cancer Dose-Response Working Group, Herndon, Virginia

01/13 – 01/16/92 "Modeling Urinary Bladder Carcinogenesis Using Cell Proliferation Data," NIEHS Symposium on Cell Proliferation and Carcinogenesis, Research Triangle Park, Raleigh-Durham, North Carolina

03/10/92 Seminar, "Of Mice and Men: A Biological Basis for Carcinogenesis Risk Assessment," Kansas University Medical Center, Kansas City, Kansas

03/24/92 Nagoya City Seminar, "Genetic Errors, Cell Proliferation and Carcinogenesis," Nagoya, Japan

03/27/92 Tokushima Lectureship, "Saccharin: A Rat Bladder Carcinogen," Fuji-Otsuka Lecture at University of Tokushima, College of Medicine, Tokushima, Japan

04/07 – 04/08/92 FASEB Meeting, "Saccharin and urothelial proliferation: A threshold phenomenon," Anaheim, California

04/15/92 "Saccharin," International Life Sciences Institute-North America, Saccharin Committee Meeting, Washington, D.C.

04/16/92 "Saccharin is a rat carcinogen," Food and Drug Administration, Beltsville, Maryland

04/21/92 "Is saccharin a human carcinogen?," Osaka City University Medical School, Osaka, Japan

04/22 – 04/24/92 "Bladder calculi and proliferative effects on bladder carcinogenesis," First International Federation of Societies of Toxicologic Pathologists, Nagoya, Japan

05/05/92 "Propoxur," U.S. Environmental Protection Agency, Arlington, Virginia

07/02 – 07/09/92 "Cell Division in Dose-Response Models," ETH and University of Zurich, Zurich, Switzerland

08/26/92 "Urine physiology and chemistry," Rodent Bladder Carcinogenesis Working Group, International Life Sciences Institute/Environmental Protection Agency, Washington, D.C.

09/10/92 "Cancer Modeling," Harvard University, Boston, Massachusetts

09/22/92 "The Interpretation of Rodent Bioassays," International Life Sciences Institute, Brookings Institute, Washington, D.C.

09/24 – 09/25/92 "Cancer Etiology and Pathogenesis," University of Massachusetts School of Medicine, Worcester, Massachusetts

11/06 – 11/07/92 "Role of Cell Proliferation in Carcinogenesis," Fred Hutchinson Cancer Research Center, Seattle, Washington

11/09/92 "Current Trends in Food Safety Evaluation," Calorie Control Council Annual Meeting, LaJolla, California

02/10/93 "Role of Toxicologic Pathology in Safety Assessment," National Research Council Environmental Studies and Toxicology, Washington, D.C.

03/16/93 "Recent Results of Research Concerning the Carcinogenicity of Saccharin," Environmental Protection Agency, Washington, D.C.

04/16/93 "Risk Assessment Based on High Dose Animal Exposure Experiments," Central States Chapter Society of Toxicology, Creighton University, Omaha, Nebraska

04/19 – 04/20/93 "Importance of Toxicologic Pathology in Determining Mechanisms for Risk Assessment Extrapolations," International Life Sciences-Japan, Symposium, Tokyo, Japan

04/21/93 "Applications of Pathology to Risk Assessment: The Sodium Saccharin Case," Sumitomo Chemical Co., Osaka, Japan

04/27/93 "Chemical Carcinogenesis," University of Kansas Medical Center Mid-America Toxicology Course, Kansas City, Missouri

04/29/93 "Mechanistic Research on Bladder Cancer," International Life Sciences Saccharin Committee Meeting, Washington, D.C.

05/03/93 "Cell Proliferation, Genetics and Carcinogenesis," Northwestern University Medical School, Chicago, Illinois

05/24/93 University of Nebraska Medical Center Overview Presentation, Rotary Club, Ashland, Nebraska

06/24/93 University of Nebraska Medical Center Overview Presentation, Rockbrook Rotary Club, Omaha, Nebraska

06/29 – 06/30/93 "Mechanistic Studies of Bladder Tumors Associated with Sodium Saccharin in the Rat," Ottawa, Canada

09/07/93 "Replication Errors and Cancer," Genetics Interest Group, University of Nebraska Medical Center, Omaha, Nebraska

09/14/93 "Biological Models for Carcinogenesis Risk Assessment," Toxicology Round Table Meeting, Washington, D.C.

09/20/93 "Cell Kinetics and Carcinogenesis," Department of Anatomy and Cell Biology, University of Nebraska Medical Center, Omaha, Nebraska

09/27/93 "Cancer Etiology and Pathogenesis," University of Massachusetts School of Medicine, Worcester, Massachusetts

09/29/93 "Advances in Cancer Modeling," Harvard University, Boston, Massachusetts

10/22 – 10/24/93 "Bladder Cancer: New Concepts in Biology and Therapy," NIH-sponsored Bladder Cancer Conference, Prout's Neck, Maine

11/02 – 11/04/93 "Cell Proliferation in the Bladder and Implications for Cancer Risk Assessment," Health Effects Research Laboratory (HERL) Symposium on Biological Mechanisms in Quantitative Risk Assessment, Research Triangle Park, North Carolina

01/18/94 "Genetic Errors, Cell Proliferation, and Carcinogenesis Risk Extrapolation," Risk Assessment in Environmental Carcinogenesis, American Association for Cancer Research, Whistler, British Columbia, Canada

01/24/94 "Saccharin: Rodent Bioassays and Human Risk," Washington State University, Pullman, Washington

02/18/94 "Advances in Cancer Modeling," National Institute for Occupational Safety and Health (NIOSH), sponsored by the Cincinnati Carcinogenesis and Mutagenesis Consortium, Cincinnati, Ohio

03/23 – 03/24/94 "Human Relevance of Animal Carcinogenicity Studies," Symposium on Design and Interpretation of Animal Carcinogenicity Studies, Great Lakes Region Discussion Group Meeting of the Society of Toxicologic Pathologists, Cincinnati, Ohio

04/06/94 "Biological Mechanisms in Carcinogenesis Risk Assessment," Department of Pathology, Osaka City University, Osaka, Japan

04/13 – 04/15/94 "A non-DNA reactive mechanism involving urothelial proliferation," U.S.-Environmental Protection Agency and California-Environmental Protection Agency, San Francisco, California

04/26/94 "Chemical Carcinogenesis," University of Kansas Medical Center Mid-America Toxicology Course, Kansas City, Missouri

05/24/94 "Saccharin, Vitamin C and Bladder Cancer," Veterans Administration Medical Center, Omaha, Nebraska

06/06/94 "Relationship of DNA Adducts Derived from 2-AAF to Cell Proliferation and the Induction of Rodent Liver and Bladder Tumors," 13th International Symposium, Role of Drug Metabolism and Pharmacokinetics in Toxicologic Pathology, Society of Toxicologic Pathologists, Charleston, South Carolina

09/07/94 "Biologic Approaches to Bioassay Interpretation," Pharmaceutical Research and Manufacturers of America (PhRMA), Washington, D.C.

09/28/94 "Cancer Etiology and Pathogenesis," University of Massachusetts School of Medicine, Worcester, Massachusetts

09/29 – 09/30/94 "Advances in Cancer Modeling," Harvard University, Boston, Massachusetts

10/24/94 "Biological Basis for Risk Assessment," American College of Toxicology, Willliamsburg, Virginia

01/20/95 "DNA Replication, DNA Damage and Carcinogenesis," Vanderbilt University School of Medicine, Nashville, Tennessee

04/09/95 "Urinary Bladder Carcinogenesis and Cancer Prevention," Experimental Biology (FASEB), Atlanta, Georgia

04/25/95 "Chemical Carcinogenesis," University of Kansas Medical Center Mid-American Toxicology Course, Kansas City, Missouri

07/03/95 "Role of Cell Proliferation in Regenerative and Neoplastic Disease," International Congress on Toxicology VII, Symposium on "Cell Proliferation: Biological Effects and Carcinogenic Risk Assessment," Seattle, Washington

09/13/95 "The role of urinary physiology and chemistry in urothelial toxicity and carcinogenicity," Histopathology Seminar, International Life Sciences Institute, Hannover, Germany

09/14/95 "Urinary calculi, crystals, and precipitate and the role of increased cell proliferation in carcinogenesis," Histopathology Seminar, International Life Sciences Institute, Hannover, Germany

09/25 – 09/26/95 "Cancer Etiology and Pathogenesis," University of Massachusetts School of Medicine, Worcester, Massachusetts

09/27/95 "Advances in Cancer Modeling," Harvard University, Boston, Massachusetts

10/06/95 "Saccharin – A case study," Federal Focus, Inc., London, England

12/04/95 "Laboratory Investigations of Dietary Carcinogens," Netherlands Food Council, Leiden, The Netherlands

12/05/95 "Conclusions and Recommendations Reached by the NRC/NAS Committee," Netherlands Food Council, Leiden, The Netherlands

02/15/96 "Carcinogens and Anticarcinogens in the Human Diet," United States Congress, Washington, D.C.

02/15/96 "Carcinogens and Anticarcinogens in the Human Diet," National Academy of Sciences, Washington, D.C.

02/19/96 "Cell Proliferation and Carcinogenesis: Implications for Risk Assessment," University of Arizona, Southwest Environmental Health Science Center, Tucson, Arizona

04/23/96 "Chemical Carcinogenesis," University of Kansas Medical Center Mid-America Toxicology Course, Kansas City, Missouri

05/06/96 "Comments on Proposed EPA Cancer Risk Assessment Guidelines," Environmental Protection Agency, Washington, D.C.

06/25/96 "Cell Proliferation and Carcinogenesis," University of Pittsburgh, Pittsburgh, Pennsylvania

08/06/96 "Chemical Carcinogenesis: Implications for Dose and Species Extrapolations," American Industrial Hygiene Association (AIHA).

09/23 – 09/24/96 "Cancer Etiology and Pathogenesis," University of Massachusetts School of Medicine, Worcester, Massachusetts

09/30/96 "Tributylphosphate," United States Environmental Protection Agency, Tributylphosphate Task Force, EPA, Washington, D.C.

01/10/96 "Cell Proliferation and Carcinogenesis":, Arkansas Symposium, Understanding the Causes of Aging and Cancer, Little Rock, Arkansas

11/08/96 "Mechanisms of Carcinogenesis," 13th Annual Meeting, Central States Chapter Society of Toxicology (SOT), Kansas City, Kansas

02/05 – 02/06/97 "Update on Saccharin Safety," ISA/CIFTI Seminar on Low-Calorie Sweeteners, New Delhi, India

04/22/97 "Recent investigations on bladder cytotoxicants and mitogens and their relationship to carcinogenesis," Osaka City University Medical School, Osaka City, Japan

04/24/97 "The role of urinary physiology and chemistry in urothelial toxicity and carcinogenicity," International Life Sciences Institute Nara International Symposium and Histopathology Seminar on the Urinary System of Laboratory Animals, Nara, Japan

04/25/97 "Urinary calculi, crystals, and precipitate and the role of increased cell proliferation in carcinogenesis," International Life Sciences Institute Nara International Symposium and Histopathology Seminar on the Urinary System of Laboratory Animals, Nara, Japan

05/01/97 "Experimental models for the study of mechanisms of chemical carcinogenesis," 21st Brazilian Congress of Pathology, Brasilia, Brazil.

05/02/97 "Mechanisms of chemical carcinogenesis," 21st Brazilian Congress of Pathology, Brasilia, Brazil

05/05/97 "Chemical carcinogenesis," State University of Sao Paulo, Botucatu, Brazil

05/06/97 "Risk Factors for Human Cancer," State University of Sao Paulo, Botucatu, Brazil

05/19/97 "Saccharin," Food and Drug Administration, Washington, D.C.

05/21/97 "Fundamentals of Carcinogenesis," Expert Panel on Arsenic Carcinogenicity, Environmental Protection Agency, Washington, D.C.

06/25/97 "Urinary Bladder Carcinogenesis," 16th Annual Symposium, Society of Toxicologic Pathologists, Beaver Creek, Colorado

07/28/97 "Chemical Carcinogenesis: Implications for Dose and Species Extrapolations," AIHA Toxicology Symposium, Seattle, Washington

09/09/97 Environmental Protection Agency-FIFRA-Scientific Advisory Panel, Arsenic Presentation, Arlington, Virginia

04/21/98 "Chemical Carcinogenesis," University of Kansas Medical Center Mid America Toxicology Course, Kansas City, Missouri

07/06/98 "Cell Proliferation and Carcinogenesis," International Union of Toxicology (IUTOX) Continuing Education Course, Paris, France

07/14/98 "Evaluation of cell proliferative activity in the rat urinary bladder after feeding high doses of cacodylic acid," Society of Environmental Geochemistry and Health (SEGH), Arsenic Conference, San Diego, California

08/19/98 "Saccharin," International Life Sciences Institute, Saccharin Technical Committee, Washington, D.C.

11/09/98 "Carcinogenesis," Osaka City University Medical School, Osaka, Japan

11/09/98 "Bladder Carcinogenesis," Osaka City University Medical School, Osaka, Japan

11/17/98 "Cell Proliferation as the Basis for Carcinogenesis of Non-Genotoxic Chemicals," Alternative Bioassays for Carcinogen Detection, 5th Congresso Latino-Americano De Mutagenese, Carcinogenese E Teratogenese Ambiental, Curitiba, Parana, Brazil

11/19/98 "Methods for Evaluating Cell Proliferation," 5th Alexander Hollaender Training Course in Genetic Toxicology, Curitiba, Parana, Brazil

12/02/98 "Saccharin," Health Protection Branch, Ottawa, Canada

01/25/99 "The Use of Animal Data in Risk Assessment," International Life Sciences Institute Risk Science Institute Advisors' Forum, Nassau, Bahamas

01/26/99 "Saccharin," International Life Sciences Institute Food, Nutrition and Safety Committee, Nassau, Bahamas

02/10/99 "Relationship of Apoptosis and Necrosis to Carcinogenesis," Apoptosis Working Group, International Life Sciences Institute-North America Technical Committee on Food Toxicology and Safety Assessment and the Proposition 65 Technical Committees' Joint Subcommittee on Apoptosis, Washington, D.C.

03/16/99 "SOT/EUROTOX Debate: The Results of Mechanistic Toxicity Studies Should Supercede Ambiguous Epidemiological Data," Society of Toxicology, New Orleans, Louisiana

04/27/99 "Chemical Carcinogenesis," Midwest Toxicology Course, Kansas City, Missouri

04/28/99 "Cell Proliferation and Carcinogenesis: Implications for Risk Assessment," Michigan Society of Toxicology, Lansing, Michigan

06/29/99 "SOT/EUROTOX Debate: The Results of Mechanistic Toxicity Studies Should Supercede Ambiguous Epidemiological Data," EUROTOX Meeting, Oslo, Norway

08/12/99 "Carcinogenesis: Of Mice and Men," American Industrial Hygiene Association, 14th Annual Toxicology Symposium, Williamsburg, Virginia

12/16 – 12/18/99 "Lesions of the Bladder I – Structure/Spontaneous/Induced Changes; Lesions of the Bladder II – Proliferative/Dysplastic Changes; Lower Urinary Tract Conditions – Practical; Human LUT Pathology," British Society of Toxicological Pathologists, Cambridge, England

01/10/00 "Apoptosis and its implications for toxicity, carcinogenicity and risk: Fumonisin B_1 as an example," Fumonisins Risk Assessment Workshop, Food and Drug Administration, Washington, D.C.

01/19/00 "Fetal Cell Research: Science and Politics," University of Nebraska Medical Center, Board of Counselors Annual Meeting, Omaha, Nebraska

02/23/00 "Fetal Tissue Research," Judiciary Committee Testimony, Lincoln, Nebraska

03/09/00 "Fetal Tissue Research," Testimony to the Health and Environment Subcommittee of the Commerce Committee, United States House of Representatives, Washington, D.C.

03/21/00 "Saccharin: Overview and History," Society of Toxicology, Philadelphia, Pennsylvania

03/21/00 "Saccharin: Epidemiology," Society of Toxicology, Philadelphia, Pennsylvania

03/22/00 "Apoptosis and its implications for toxicity, carcinogenicity and risk: Fumonisin B_1 as an example," Society of Toxicology, Philadelphia, Pennsylvania

04/20/00 "Isocyanuric acid," U.S. Environmental Protection Agency, Washington, D.C.

05/02/00 "Chemical carcinogenicity," Mid-America Toxicology Course, Kansas City, Missouri

06/20/00 "The carcinogenicity of dimethylarsinic acid (DMA) in rats," Fourth International Conference on Arsenic Exposure and Health Effects, San Diego, California

06/22/00 "Research needs to refine MCL," Fourth International Conference on Arsenic Exposure and Health Effects, San Diego, California

06/24/00 "Comparative pathology of proliferative lesions of the urinary bladder in man, rat and mouse," National Toxicology Program Satellite Symposium to annual meeting of Society of Toxicologic Pathologists, Phoenix, Arizona

07/18/00 Bioethics Panel, University of Nebraska Medical Center, Omaha, Nebraska

07/28/00 "Difficult ethical and political issues facing tissue brokers," Association of Pathology Chairs, Boulder, Colorado

10/12/00 Mentoring Institute, University of Nebraska Medical Center, Omaha, Nebraska

10/17/00 Introduction, Comparative Pathology of Carcinogenesis Symposium, International Academy of Pathology, Nagoya, Japan

10/17/00 "The two diseases of bladder cancer in rodents and humans," Comparative Pathology of Carcinogenesis Symposium, International Academy of Pathology, Nagoya, Japan

10/23/00 "Recent advances in urinary bladder carcinogenesis research," Takeda Chemical Industries, Ltd., Osaka, Japan

10/24/00 "Carcinogenicity of dimethylarsinic acid," Osaka City University, Osaka, Japan

11/03/00 "Weight of evidence evaluation across models," International Life Sciences Institute Alternatives to Carcinogenicity Testing Workshop, Leesburg, Virginia

11/09/00 "Human relevance case studies: What have we learned?" International Programme on Chemical Safety/International Life Sciences Institute, London, England

01/22/01 "The dose makes the poison: Did Paracelsus throw us a curve?," International Life Sciences Institute 2001 Annual Meeting, Montego Bay, Jamaica

01/22/01 "What do the data tell us?," International Life Sciences Institute 2001 Annual Meeting, Montego Bay, Jamaica

01/22/01 "Alternatives to Carcinogenicity Testing: Why Bother?," International Life Sciences Institute 2001 Annual Meeting, Montego Bay, Jamaica

01/29/01 "Use of Pathology in Risk Assessment," Expert Panel of the Flavor and Extract Manufacturers Association (FEMA), Miami, Florida

02/09/01 "Fetal Cell Research," Testimony to State of Nebraska Legislative Judiciary Committee, Lincoln, Nebraska

03/29/01 "Summary of findings across the models examined in the ILSI-HESI evaluation of alternatives for carcinogenicity testing," Workshop on Use of Transgenic Models for Carcinogenicity Testing—A Data-Based Evaluation. Society of Toxicology, San Francisco, California

03/29/01 "Introduction," Workshop on Risk Assessment: Science, Regulation and Legislation. Society of Toxicology, San Francisco, California

04/17/01 "Fetal Cell Research," Testimony to Omaha City Council, Omaha, Nebraska

04/24/01 "Chemical Carcinogenesis," Mid-America Toxicology Course, Kansas City, Missouri

12/04/01 "UNMC Rapid Autopsy Program," State Legislature, Lincoln, Nebraska

04/23/02 "Chemical Carcinogenesis," Mid-America Toxicology Course, Kansas City, Missouri

07/17/02 "Carcinogenicity of dimethylarsinic acid in rats," Fifth International Conference on Arsenic Exposure and Health Effects, San Diego, California

09/25/02 "All models are wrong; some are useful," Aventis Pharmaceuticals, Bridgewater, New Jersey

10/14/02 "Ethics of Stem Cell Research – The Pathologists' Perspective," College of American Pathologists Annual Meeting, Washington, D.C.

10/18/02 "Alternatives to carcinogenicity testing," Schering-Plough Corporation, Morristown, New Jersey

12/10/02 "Analysis of mode of action of carcinogenesis in animal models," International Life Sciences Institute Society for Risk Analysis Symposium, New Orleans, Louisiana

01/20/03 "Cancer causation," International Life Sciences Institute Annual Meeting, Miami, Florida

01/28/03 "Cancer causation: Of mice (and rats) and men," Fujita-Gakuen University, Nagoya, Japan

01/30/03 "Transgenic mice as alternative models for carcinogenicity testing," Daiyu-Kai Symposium, Nagoya, Japan

03/11/03 "Mode of action in assessing human relevance of animal tumors," Society of Toxicology Symposium, Salt Lake City, Utah

04/23/03 "Special study to characterize the changes in the lower urinary tract of rats associated with chronic administration of LY519818," Eli Lilly and Company, Greenfield, Indiana

04/29/03 "Chemical Carcinogenesis," Mid-America Toxicology Course, Kansas City, Missouri

06/16/03 "Risk assessment in the genomic era," Society of Toxicologic Pathology, Savannah, Georgia

09/23/03 "Carcinogenesis: of mice and men," New York Medical College, Valhalla, New York

12/11/03 "Lesions of the Bladder I – structure/spontaneous/induced changes," British Society of Toxicologic Pathology, Cambridge, England

12/11/03 "Lesions of the Bladder II – proliferative/dysplastic changes," British Society of Toxicologic Pathology, Cambridge, England

12/11/03 "Lesions of the Bladder – Practical," British Society of Toxicologic Pathology, Cambridge, England

12/11/03 "Human urinary tract pathology and drug development," British Society of Toxicologic Pathology, Cambridge, England

01/14/04 "Carcinogenicity of methylated arsenicals," U.S. Environmental Protection Agency, Alexandria, Virginia

01/23/04 "Urinary bladder carcinogenicity of pioglitazone in rats," French Drug Agency (AFSSAPS), Paris, France

02/09/04 "Human risk of environmental chemicals: Man is not a rat or a mouse," National Cancer Center, Tokyo, Japan

02/12/04 "Urinary bladder carcinogenesis: Aromatic amines to arsenic," Nagoya City University, Nagoya, Japan

02/17/04 "Human relevance of carcinogenesis in rodents," Plenary Lecture, International Society of Toxicologic Pathology, Kobe, Japan

02/20/04 "Urinary bladder carcinogenesis," Takeda Chemical Company, Osaka, Japan

07/22/04 "Alternatives to the 2-year bioassay in detecting potential risk of chemical carcinogens," Toxicology Forum, Aspen, Colorado.

07/27/04 "Flonicamid," Environmental Protection Agency, Washington, D.C.

07/28/04 "Arsenic," Environmental Protection Agency, Washington, D.C.

09/15/04 "Bladder carcinogenesis -- a 40-year sojourn," Pathology/Microbiology Grand Rounds, University of Nebraska Medical Center, Omaha, Nebraska

09/17/04 "Toxicological testing versus science," Central States Chapter, Society of Toxicology, Kansas City, Kansas

09/24/04 "Urinary bladder carcinogenesis: Rodents and humans," Roche Pharmaceutical Company, Basel, Switzerland

10/12/04 "Pioglitazone," CHMP Science Working Party, London, England

03/03/05 "Flonicamid: Evaluation of the relevance of mouse lung tumors to humans," Brazilian Ministry of Health, Brasilia, Brazil.

03/08/05 "Framework for Evaluating the Human Relevance of Carcinogenetic Modes of Action in Animals," Society of Toxicology, New Orleans, Louisiana

03/19/05 "Bladder Urothelial Tumors," National Comprehensive Cancer Network, Hollywood, Florida

04/21/05 "Human Relevance Framework," International Programme on Chemical Safety (WHO), Bradford, England

04/26/05 "Chemical Carcinogenesis," Mid-American Toxicology Course, Kansas City, Missouri

05/11/05 "Mechanisms of Bladder Carcinogenicity," American College of Toxicology, Lincolnshire, Illinois

05/20/05 "Bladder Carcinogenesis: From Rodents to Humans," C.L. Davis Seminar, Bridgewater, New Jersey

09/09/05 "Bladder Carcinogenesis: from Rodents to Humans," for Glaxo-Smith Kline (by video)

09/12/05 "Arsenic Carcinogenesis," U.S. EPA Science Advisory Board, Washington, D.C.

09/30/05 "PPAR Agonists and Bladder Cancer," International Life Sciences Institute/Health and Environmental Sciences Institute Committee on PPAR Agonists, Washington, D.C.

10/11/05 "Cancer: Recent Aspects in Human Risk Assessment," XIV Brazilian Congress of Toxicology, Recife, Brazil

10/12/05 "An Alternative to the 2-Year Rodent Bioassay," XIV Brazilian Congress of Toxicology, Recife, Brazil

10/28/05 "Bladder Carcinogenesis in Animals and Humans: It's All in the Details," Merck Seminar Series Co-Sponsored with the Toxicology Seminar Series, University of Illinois at Urbana-Champaign, Urbana, Illinois

11/15/05 "Framework for Evaluating the Human Relevance of Carcinogenic Modes of Action in Animals," International Life Sciences Institute/Health and Environmental Sciences Institute, Rodent Liver Tumor Session, Nice, France

11/15/05 "Liver Cytotoxicity as a Mode of Action," International Life Sciences Institute/Health and Environmental Sciences Institute, Rodent Liver Tumor Session, Nice, France

02/09/06 "Carcinogenesis: Human Relevance of Animal-derived Data," Roche, Palo Alto, California

03/07/06 "Carcinogenicity of Arsenicals in Human and Animal Models," Workshop on Arsenic Toxicology, Society of Toxicology, San Diego, California

04/25/06 "Chemical Carcinogenesis," Mid-America Toxicology Course, Kansas City, Missouri

05/31/06 "Arsenic-induced Bladder Cancer in an Animal Model," U.S. EPA Workshop on Arsenic Research and Risk Assessment, Shepherdstown, Pennsylvania

06/17/06 "Urinary Bladder Lesions," NTP Symposium, Vancouver, British Columbia

06/18/06 "The Human Relevance of Urothelial Tumors in Rodents," Society of Toxicologic Pathology, Vancouver, British Columbia

07/04/06 "Carcinogenic Modes of Action of PPAR Agonists: the HESI Initiative," Japanese Society of Toxicology, Nagoya, Japan

07/05/06 "PPAR Agonists and Carcinogenesis," Nagoya City University, Nagoya, Japan

07/06/06 "PPAR Agonists and Carcinogenesis," Eisai Pharmaceuticals, Gifu, Japan

08/01/06 "PPAR Agonists and Carcinogenesis," Sanofi-Aventis, Great Valley, Pennsylvania

10/23/06 "Urothelial Carcinoma: Two Diseases," Cancer Molecular Diagnosis and Gene Therapy: 2006 International Symposium, Xi'an Jiaotang Medical University, Xi'an, China

10/27/06 "Urothelial Carcinoma: Two Diseases," Fourth Chinese Conference on Oncology, Tianjin, China

10/30/06 "Urinary Bladder Cancer Pathology," Beijing Association of Pathologists, Beijing, China

11/30/06 "Carcinogenicity of Arsenicals," U.S. EPA, Washington, D.C.

12/13/06 "Hyperplasia and Carcinogenesis," Proctor & Gamble Pharmaceuticals, Inc., Cincinnati, Ohio

02/15/07 "Mechanism-Based Cancer Risk Assessment," Society of Toxicology Current Concepts in Toxicology, Arlington, Virginia

04/24/07 "Chemical Carcinogenesis," Mid-America Toxicology Course, Kansas City, Missouri

05/14/07 "Of Mice and Men: Extrapolating from Animal Models to Humans for Cancer Risk Assessment". Alfred I. duPont, Hospital for Children, Wilmington Delaware

07/12/07 "Inorganic and Organic Arsenics and Bladder Carcinogenesis," Toxicology Forum, 33rd Annual Meeting, Aspen, Colorado

08/29/07 "Carcinogenicity Data in Mice", HESI PPAR Agonist Project Committee, Sarcomas Data Sharing Meeting, Washington, DC

9/16/07 "The Human Relevance of Urothelial Tumors in Rodents", International Academy of Toxicologic Pathology Satellite Symposium, Basel, Switzerland

9/18/07 "An Enhanced 13 Week Bioassay: An Alternative to the Two-Year Bioassay to Screen for Human Carcinogenesis," European Society of Toxicologic Pathology/ International Federation of Toxicologic Pathology Congress of Toxicologic Pathology 2007, Basel, Switzerland

10/05/07 "Chemical Carcinogenesis", International Workshop on Toxicology Towards Diplomate of American Board of Toxicology, Bangalore, India

11/08/07 "Mouse Liver Tumors: Benefits and Constraints on Use in Human Health Risk Assessment, Qualitative and Quantitative Aspects," Third Workshop of the

Standing Committee on Risk Analysis Issues and Reviews. National Academy of Sciences, Washington DC

11/22/07 "An Enhanced Thirteen Week Bioassay: An Alternative for Screening for Carcinogenesis Factors," DIMS 30th Anniversary Symposium, Nagoya, Japan

11/26/07 "The Human Relevance of Urothelial Tumors in Rodents," Japan Bioassay Research Center, Hadano, Japan

11/27/07 "Liver Carcinogenesis: Human Relevance of Animal Tumors," Sumitomo Chemical Co., Osaka, Japan

02/06/08 "A Framework of Human Relevance Analysis of Information of Carcinogenic Modes of Action in Animals," Japanese Society of Toxicologic Pathology, Nagoya, Japan

02/08/08 "PPAR Agonists and Bladder Carcinogenesis," Dainippon Sumitomo Pharma, Osaka, Japan

04/22/08 "Chemical Carcinogenesis", Mid-America Toxicology Course, Kansas City, Missouri

6/19/08 "Carcinogenicity of Arsenic," Institute of Medicines Committee on Review of the Health Effects in Vietnam Veterans of Exposure to Herbicides, San Antonio, Texas

7/23/08 "Thresholds in Genotoxicity and Carcinogenicity: Urniary Bladder Carcinogenesis", International Symposium on Genotoxic and Carcinogenic Thresholds, Tokyo, Japan

7/24/08 "Evaluation of the Human Relevance of Animal Studies for Cancer Risk Assessment", Food Safety Commission of Japan, Tokyo, Japan

7/25/08 "Rats and Mice are not Small Humans; Human Risk Assessment Based on Animal Studies", Food Safety Commission of Japan, Public Session, Tokyo, Japan

8/18/08 "Current Concepts in Carcinogenesis and Susceptibility: What do we know about Bladder Cancer", BCAN's Bladder Cancer Research Network Think Tank, Quebec, Canada

8/18/08 "What Can Animal Models Teach Us About Human Bladder Cancer", BCAN's Bladder Cancer Research Network Think Tank, Quebec, Canada

12/04/08 "Troglitazone Effects on Endothelial Cells In Vivo and In Vitro: Differences Between Mice and Humans", SOT Contemporary Concepts in Toxicology

Workshop, Hemangiosarcoma in Rodents: Mode of Action Evaluation and Human Relevance, Arlington, VA.

1/28/09 "Carcinogenicity of PPARγ and Dual α/γ Agonists: Mode of Action and Human Relevance." Planary Lecture, Japanese Society of Toxicologic Pathology. Hamamatsu, Japan.

1/30/09 "Carcinogenicity of PPAR Agonists: Are They Rodent Specific Carcinogens?" Nagoya City University Medical School. Nagoya, Japan.

3/15/09 "The Development and Significance of Mode of Action/Human Relevance Analysis. Characterizing Modes of Action and Their Relevance in Assessing Human Health Risks". Society of Toxicology Continuing Education Course, Baltimore, Maryland.

3/23/09 "How Predictive Are 3M, 6M, and Transgenic Studies for Carcinogenic Risk". British Toxicology Society, University of Warwick, Warwick, England.

3/23/09 "Relevance of Rodent Bladder Carcinogens to Man". British Toxicology Society, University or Warwick, Warwick, England.

4/02/09 "Bladder Practical". Modular Education Programme in Toxicological Pathology., Module 14: Urinary System, Cambridge University, Cambridge England.

4/02/09 "Lesions of the Bladder Proliferative/Dysplastic Changes". Modular Education Programme in Toxicological Pathology., Module 14: Urinary System, Cambridge University, Cambridge England.

4/02/09 "Lesions of the Bladder. Structure/Spontaneous/Induced Changes". Modular Education Programme in Toxicological Pathology., Module 14: Urinary System, Cambridge University, Cambridge England.

4/02/09 "Human Urinary Tract Pathology and Drug Development". Modular Education Programme in Toxicological Pathology., Module 14: Urinary System, Cambridge University, Cambridge England.

4/21/09 "Chemical Carcinogenesis". Mid-America Toxicology Course, Kansas City, Missouri.

4/28/09 "Urothelial Carcinogenesis in Experimental Models and Humans". State University of San Paulo, Botucatu, Brazil.

4/30/09 "Human Relevance of Experimentally Induced Rodent Tumors". State University of San Paulo, Botucatu, Brazil.

1/26/10 "Mode of Action Human Relevance Framework". International Life Sciences Institute Annual Meeting, Rio Grande, Puerto Rico.

1/28/10 "Relevance of Arsenic Mode of Action for Human Carcinogenicity". Arsenic Workshop and EPRI Scientific Review Panel, Hamner Institute for Health Sciences, Research Triangle Park, North Carolina.

2/26/10 "Inorganic Arsenic". US EPA, Washington, DC.

4/06/10 "Inorganic Arsenic Carcinogenesis, Mode of Action". US EPA Sciences Advisory Board Special Panel, Washington, DC.

4/27/10 "Chemical Carcinogenesis". Mid-America Toxicology Course, Kansas City, Missouri.

8/18/10 "Liver Tumorigenesis Modes of Action". Liver Tumorigenesis & PPAR Workshop, Research Triangle Park, North Carolina.

10/12/10 "Evaluation of the Relevance to Humans of Animal Models of Environmental Toxicants". Environmental Pathology Symposium, 28th International Congress of the International Academy of Pathology, Saõ Paulo, Brazil.

10/18/10 "Carcinogenicity Testing – Where to Go?" First Meeting of the Latin American Association of Toxicologic Pathology, Botucatu, Brazil.

10/19/10 "Bladder Carcinogenesis". Program in Toxicology, Saõ Paulo State University Medical School, Botucatu, Brazil.

4/6/11 "Mode of Action and Toxicological Studies". ILSI – Brazil, Pre-Congress, Saõ Pedro, Brazil.

4/7/11 "Risk Assessment for the 21st Century (Risk 21)". 21st Annual Congress of ILSI – Brazil, Saõ Pedro, Brazil.

5/3/11 "Chemical Carcinogenesis". Mid-America Toxicology Course, Kansas City, Missouri.

5/4/11 "Arsenic, A Natural Carcinogen: What Is Safe?". Grand Rounds, Department of Pathology and Microbiology, University of Nebraska Medical Center, Omaha, Nebraska.

5/18/11 "Mode of Action and Human Relevance: Risk Assessment for the 21st Century." HESI Asia Webinar Series.

6/13/11 "Mode of Action and Weight-of-Evidence Approach Into Toxicological Evaluation". ILSI-Brasil Workshop, Scientific Basis to Pesticides Toxicological Evaluation, Risk Assessment and Risk Management, Brasilia, Brazil.

7/14/11 "Liver Cancer Etiology". 66th Meeting of Japanese Society of Gastroenterological Surgery, Nagoya, Japan.

7/19/11 "Mode of Action and Human Relevance: Risk Assessment for the 21st Century". Ministry of Environment, Tokyo, Japan.

7/19/11 "Mode of Action and Human Relevance: Risk Assessment for the 21st Century". Food Science Commission, Tokyo, Japan.

10/24/11 "Mode of Action and Human Relevance". Pathology Graduate Program, State University of Saõ Paul, Botucatu, Brazil.

10/26/11 "Research and Graduate Education in the United States". Pathology Graduate Program, State University of Saõ Paulo, Botucatu, Brazil.

11/22/11 "Mode of Action and Human Relevance Framework: Some Recent Examples of Pharmaceuticals, Pesticides and Food Additives". National Institute of Health Sciences, Tokyo, Japan.

11/23/11 "Urinary Bladder Carcinogenesis by DNA Reactive and Non-Reactive Chemicals: Non-linearities and Thresholds." Symposium on Genotoxic and Carcinogenic Threshold, Tokyo, Japan.

12/1/11 "Evaluation of the Carcinogenecity of Monomethylarsonic Acid". US EPA, Washington, DC.

3/13/12 "Inorganic Arsenic". US EPA, San Francisco, CA.

4/23/12 "New Angle to Screen Carcinogenesis Factors". Workshop on Selected Topics in Carcinogenicity, US FDA, Silver Spring, MD.

4/24/12 "Chemical Carcinogenesis". Mid-America Toxicology Course, Kansas City, MO.

4/27/12 "Evaluation of the Potential Carcinogenicity Due to Exposure to Inorganic Arsenic". US EPA, Washington, DC.

6/27/12 "The Two-Year Bioassay as a Carcinogenesis Screen: A Useless and Often Misleading Waste of Resources". Drug Information Association Annual Meeting, Philadelphia, PA.

7/11/12 "Comparing Rat CPN to Human Kidney Disease". Toxicology Forum, Aspen, CO.

8/17/12 "Relevance of Rodent Renal Tumors for Human Health Risk Assessment". Charles Louis Davis Foundation Seminar on Renal Carcinogenesis, Raritan, NJ.

9/11/12 "Risk 21". 8th Congress of Toxicology in Developing Countries, Bangkok, Thailand.

9/16/12 "Lower Urinary Tract: Normal Structure, Toxicity, and Carcinogenesis". Sixth RTP Rodent Pathology Course, Urinary Pathology, NC.

10/22/12 "Mode of Action and Human Relevance Framework". Pathology Graduate Program, State University of Saõ Paulo, Botucatu, Brazil.

10/26/12 "Arsenic Carcinogenesis: How to Critically Read the Scientific Literature". Pathology Graduate Program, State University of Saõ Paulo, Botucatu, Brazil.

11/23/12 "Mode of Action as the Scientific Basis for Human Risk Assessment for Bladder Carcinogens: Pioglitazone as a Case Study". Swiss Society of Toxicology, Basel, Switzerland.

1/8/13 "Mode of Action of Arsenic Carcinogenesis". US EPA Workshop on Arsenic Risk Assessment, Research Triangle Park, NC.

1/22/13 "Arsenic in Food". ILSI North America Food and Chemical Safety Committee, Miami, FL.

1/23/13 "Key Events Dose Response Framework (KEDRF)". Weight of Evidence Workshop, ILSI North America, Miami, FL.

4/3/13 "Inorganic Arsenic Toxicity and Carcinogenicity." US FDA, College Park, MD.

4/4/13 "Mode of Action and Mechanism Identification and Implications for Low Dose Assessments." Workshop on Inorganic Arsenic: Scientific Considerations for Hazard Identification and Dose-Response Analysis; National Academy of Sciences, Washington, DC.

4/25/13 "Chemical Carcinogenesis". Mid-America Toxicology Course, Kansas City, MO.

5/8/13 "Mode of Action of Arsenical Carcinogenesis". US EPA Webinar.

6/27/13 "Safety Assessment of Sugar Alternatives: Case of Saccharin Safety Assessment and Perspectives for Industrial Uses." International Symposium on Understanding Carbohydrates: Controversies, Regulation and Future Direction. ILSI Korea-Korean Nutrition Society, Seoul Korea.

6/30/13 "Trends in Chemical Carcinogenesis." Continuing Education Course in Genotoxicology and Carcinogenesis, XIII International Congress of Toxicology, Seoul, Korea.

7/4/13 "Lesions of the Bladder – Structure/Spontaneous/Induced Changes – Lecture I". Modular Education Programme in Toxicological Pathology, Module 12, Urinary System. British Society of Toxicologic pathology, Cambridge University, England.

7/4/13 "Lesions of the Bladder – Structure/Spontaneous/Induced Changes – Lecture II". Modular Education Programme in Toxicological Pathology, Module 12, Urinary System. British Society of Toxicologic pathology, Cambridge University, England.

7/4/13 "Lesions of the Bladder – Practical". Modular Education Programme in Toxicological Pathology, Module 12, Urinary System. British Society of Toxicologic pathology, Cambridge University, England.

7/4/13 "Human Urinary Tract Pathology and Drug Development". Modular Education Programme in Toxicological Pathology, Module 12, Urinary System. British Society of Toxicologic pathology, Cambridge University, England.

8/14/13 "Mode of Action for Arsenic Toxicity and Carcinogenesis". 10th International Symposium on Persistent Toxic Substances. Edmonton, Alberta, Canada.

11/3/13 "Using Mode of Action in Determining Relevance in Human Carcinogenesis Risk Assessment." Continuing Education Course, American College of Toxicology. 34th Annual Meeting, San Antonio, Texas.

11/7/13 "Urinary Bladder Carcinogenesis in Animals and Humans". Pathology Graduate Program, State University of Saõ Paulo, Botucatu, Brazil.

11/9/13 "Medicine and Science: Where Have We Been, Where Are We Going". 50th Anniversary Celebration of Faculdade de Medicina de Botucatu, Botucatu, Brazil.

12/4/13 "Chemical Carcinogenesis, Toxicology and Risk Assessment." Symposium on Mechanistic Paradigms for Toxicological Regulation, Society of Toxicology of Canada, Ottawa, Canada.

12/9/13 "A Common Mode of Action for Arsenical Toxicity." Symposium on Understanding Human Health Risks from Dietary Arsenic Exposure, Society for Risk Analysis, Baltimore, Maryland.

1/21/14 "Arsenic in Food: Sources and Issues in Assessment of Its Risk." Symposium, Food Safety Case Study: Arsenic, ILSI North America, Bermuda.

3/26/14 "A mutagen is a carcinogen b3ecause it is a mutagen." Debate, Regulatory and Safety Evaluation Specialty Section, Society of Toxicology, Phoenix, Arizona.

4/9/14 "The FEMA GRAS Program and the FEMA Expert Panel." IOFI Meeting with Japanese Scientists, Tokyo, Japan.

525/14 "FEMA GRAS: The Safety Evaluation of Flavoring Ingredients in the United States." International Symposium on Safety, Regulation of Food Flavorings and Their Best Practices. Food and Drug Administration of Taiwan Workshop on Flavoring Safety Evaluation, Taipei, Taiwan.

5/30/14 "Arsenic in Rice: Toxicological Issues and Implications for Human Health Risk Assessment." ILSI Southeast Asia and Agri-Food & Veterinary Authority of Singapore Symposium on Arsenic in Rice – Risk Assessment and Standards, Singapore.

6/4/14 "The FEMA GRAS Program and FEMA Expert Panel." ConAgra Food Safety Committee, Omaha, Nebraska.

6/25/14 "Rodent vs. Human Lung Cancer: The Good, the Bad, and the Ugly." Symposium on Environmental Toxicologic Pathology and Prediction of Human Health Risks, 33rd Annual Meeting of Society of Toxicologic Pathology, Washington, DC.

10/16/14 "Two-year Rodent Cancer Bioassay: Human Relevance?" Annual Meeting of the Southern California Chapter of the Society of Toxicology, La Jolla, California.

10/28/14 "Chemical Carcinogenesis." Food and Drug Administration, College Park, Maryland.

11/12/14 "In Vitro to In Vivo Extrapolation." Pathology Graduate Program, State University of Saõ Paulo, Botucatu, Brazil.

11/13/14 "Arsenic Carcinogenesis." Pathology Graduate Program, State University of Saõ Paulo, Botucatu, Brazil.

Community service: Numerous (Venerini Academy, Marian High School, Creighton Preparatory School, University Hospital Auxiliary, Mary Our Queen Parish, Sacred Heart Ministry)

Publications:

a. Articles published in scholarly journals

1. Erturk, E., Price, J.M., Morris, J.E., Cohen, S., Leith, R.S., Von Esch, A.M. and Crovetti, A.J. The production of carcinoma of the urinary bladder in rats by feeding N-[4-(5-nitro-2-furyl)-2-thiazolyl]foramide. Cancer Res., 27: 1998-2002, 1967.

2. Erturk, E., Cohen, S.M., Price, J.M., Von Esch, A.M., Crovetti, A.J. and Bryan, G.T. The production of hemangioendothelialsarcoma in rats by feeding 5-acetamido-3-(5-nitro-2-furyl)-6H-1,2,4-oxadiazine. Cancer Res., 29: 2212-2218, 1969.

3. Erturk, E., Cohen, S.M., Price, J.M. and Bryan, G.T. Pathogenesis, histology, and transplantability of urinary bladder carcinomas induced in albino rats by oral administration of N-[4-(5-nitro-2-furyl)-2-thiazolyl] formamide. Cancer Res., 29: 2219-2228, 1969.

4. Cohen, S.M., Erturk, E., Price, J.M. and Bryan, G.T. Comparative carcinogenicity in the rat of 2-hydrazinothiazoles with nitrofuryl, nitrophenyl, or aminophenyl substituents in the 4-position. Cancer Res., 30: 897-901, 1970.

5. Cohen, S.M., Erturk, E. and Bryan, G.T. Carcinogenicity of formic acid 2-[4-(5-nitro-2-furyl)-2-thiazolyl] hydrazide in Swiss mice. Cancer Res., 30: 906-912, 1970.

6. Erturk, E., Cohen, S.M. and Bryan, G.T. Carcinogenicity of N-[4-(5nitro-2-furyl)-2-thiazolyl] acetamide in female rats. Cancer Res., 30: 936-941, 1970.

7. Erturk, E., Cohen, S.M. and Bryan, G.T. Urinary bladder carcinogenicity of N-[4-(50nitro-2-furyl)-2-thiazolyl] formamide in female Swiss mice. Cancer Res., 30: 1309-1311, 1970.

8. Erturk, E., Morris, J.E., Cohen, S.M., Price, J.M. and Bryan, G.T. Transplantable rat mammary tumors induced by 5-nitro-2-furaldehyde semicarbazone and by formic acid 2[4-(50nitro-2-furyl)-2-thiazolyl]-hydrazide. Cancer Res., 30: 1409-1412, 1970.

9. Erturk, E., Cohen, S.M. and Bryan, G.T. Induction, histogenesis, and iso-transplantability of renal tumors induced by formic acid 2[4-(5-nitro-2-furyl)-2-thiazolyl] hydrazide in rats. Cancer Res., 30: 2098-2106, 1970.

10. Cohen, S.M., Erturk, E. and Bryan, G.T. Production of leukemia and stomach neoplasms in Swiss, RF, BALB/c, and C3H female mice by feeding N-[4-(5-nitro-2-furyl)-2-thiazolyl] acetamide. Cancer Res., 30: 2320-2325, 1970.

11. Erturk, E., Atassi, S.A., Yoshida, O., Cohen, S.M., Price, J.M. and Bryan, G.T. Comparative urinary and gallbladder carcinogenicity of N-[4(5-nitro-2-furyl)-2-thiazolyl] formamide and N-[4-(5-nitro-2-furyl)-2-thiazolyl]-acetamide in the dog. J. Natl. Cancer Inst., 45: 535-542, 1970.

12. Erturk, E., Morris, J.E., Cohen, S.M., Von Esch, A.M., Crovetti, A.J., Price, J.M. and Bryan, G.T. Comparative carcinogenicity of formic acid 2-[4-(5-nitro-2-furyl)-2-thiazolyl] hydrazide and related chemicals in the rat. J. Natl. Cancer Inst., 47: 437-445, 1971.

13. Cohen, S.M., Headley, D.B. and Bryan, G.T. The effect of adult thymectomy and adult splenectomy on the production of leukemia and stomach neoplasms in mice by N-[4-(5-nitro-2-furyl)-2-thiazolyl] acetamide. Cancer Res., 33: 637-640, 1973.

14. Cohen, S.M., Lower, G.M., Jr., Erturk, E. and Bryan, G.T. Comparative carcinogenicity in Swiss mice of N-[4-(5-nitro-2-furyl)-2-thiazolyl] acetamide and structurally related 5-nitrofurans and 4-nitrobenzenes. Cancer Res., 33: 1593-1597, 1973.

15. Cohen, S.M., Erturk, E., Von Esch, A.M., Crovetti, A.J. and Bryan, G.T. Carcinogenicity of 5-nitrofurans, 5-nitroimidazoles, 4-nitrobenzenes and related compounds. J. Natl. Cancer Inst., 51: 403-417, 1973.

16. Cohen, S.M., Alter, A. and Bryan, G.T. Distribution of radioactivity and metabolism of formic acid 2-[4-(5-nitro-2-furyl)-2-14C-2-thiazolyl]-hydrazide following oral administration to rats and mice. Cancer Res., 33: 2802-2809, 1973.

17. Cohen, S.M. and Bryan, G.T. Carcinogenesis caused by nitrofuran derivatives. In: Pharmacology and the Future of Man, Proc. Fifth Intl. Congr. Pharmacology, San Francisco, 1972, Vol. 2, pp. 164-170, 1973.

18. Cohen, S.M., Erturk, E., Von Esch, A.M., Crovetti, A.J. and Bryan, G.T. Carcinogenicity of 5-nitrofurans and related compounds with aminoheterocyclic substituents. J. Natl. Cancer Inst., 54: 841-850, 1975.

19. Beal, D.D., Skibba, J.L., Croft, W.A., Cohen, S.M. and Bryan, G.T. Carcinogenicity of the antineoplastic agent, 5-(3,3-dimethyl-1-triazeno) imidazole-4-carboxamide, and its metabolites in rats. J. Natl. Cancer Inst., 54: 951-957, 1975.

20. Soloway, M.S., Cohen, S.M., deKernion, J.B. and Persky, L. Failure of ascorbic acid to inhibit FANFT-induced bladder cancer. J. Urol., 113: 483-486, 1975.

21. Cohen, S.M., Wittenberg, J.F. and Bryan, G.T. Effect of avitaminosis A and hypervitaminosis A on urinary bladder carcinogenicity of N-[4-(5-nitro-2-furyl)-2-thiazolyl]foramide. Cancer Res., 36: 2334-2339, 1976.

22. Jacobs, J.B., Cohen, S.M., Arai, M., Friedell, G.H., Bulay, O. and Urman, H.K. Chemically induced smooth muscle tumors of the mouse urinary bladder. Cancer Res., 36: 2396-2398, 1976.

23. Cohen, S.M., Jacobs, J.B., Arai, M., Johansson, S. and Friedell, G.H. Early lesions in experimental bladder cancer: Experimental design and light microscopic findings. Cancer Res., 36: 2508-2511, 1976.

24. Jacobs, J.B., Arai, M., Cohen, S.M. and Friedell, G.H. Early lesions in experimental bladder cancer: Scanning electron microscopy of cell surface markers. Cancer Res., 36: 2512-2517, 1976.

25. Jacobs, J.B., Arai, M., Cohen, S.M. and Friedell, G.H. Light and scanning electron microscopy of exfoliated bladder epithelial cells in rats fed N-[4-(5-nitro-2-furyl)-2-thiazolyl]foramide. J. Natl. Cancer Inst., 57: 63-66, 1976.

26. Cohen, S.M., Erturk, E. and Bryan, G.T. Comparative carcinogenicity of 5-nitrothiophenes and 5-nitrofurans in rats. J. Natl. Cancer Inst., 57: 277-282, 1976.

27. Jacobs, J.B., Cohen, S.M., Arai, M. and Friedell, G.H. SEM on bladder cells. Acta Cytol., 21: 3-4, 1977.

28. Tatematsu, M., Cohen, S.M., Fukushima, S., Shinohara, Y. and Ito, N. Vascular changes during rat urinary bladder carcinogenesis induced by N-butyl-N-(4-hydroxybutyl) nitrosamine. Gann, 68: 127-128, 1977.

29. Headley, D.B., Cohen, S.M. and Bryan, G.T. Suppression of antibody-mediated and cell-mediated murine immunity by the carcinogen N-[4-(5-nitro-2-furyl)-2-thiazolyl] acetamide. Cancer Res., 37: 974-979, 1977.

30. Cohen, S.M., Ichikawa, M. and Bryan, G.T. Carcinogenicity of 2-(2-0furyl)-3-(5-nitro-2-furyl) acrylamide (AF-2) fed to female Sprague-Dawley rats. Gann, 68: 473-476, 1977.

31. Shirai, T., Cohen, S.M., Fukushima, S. and Ito, N. Production of reversible papillary proliferation of the urinary bladder in rats. Gann, 68: 521-522, 1977.

32. Jacobs, J.B., Arai, M., Cohen, S.M. and Friedell, G.H. A long-term study of reversible and progressive urinary bladder cancer lesions in rats fed N-[4-(5-nitro-furyl)-2-thiazolyl] formamide. Cancer Res., 37: 2817-2821, 1977.

33. Friedell, G.H., Jacobs, J.B., Nagy, G.K. and Cohen, S.M. The pathogenesis of bladder cancer. Am. J. Pathol., 89: 431-442, 1977.

34. Johansson, S., Cohen, S.M., Yang, J.P.S., Arai, M. and Friedell, G.H. The influence of N-[4-(5-nitro-2-furyl)-2-thiazolyl] formamide and phenacetin on the immune status in male Fischer rats. Invest. Urol., 15: 308-311, 1978.

35. Cohen, S.M. and Bryan, G.T. Effect of p-hydroxyacetanilide, sodium sulfate, and L-methionine on the leukemogenicity of N-[4-(5-nitro-2-furyl)-2-thiazolyl] acetamide. Cancer Res., 38: 1398-1405, 1978.

36. Shirai, T., Cohen, S.M., Fukushima, S., Hananouchi, M. and Ito, N. Reversible papillary hyperplasia of the rat urinary bladder. Am. J. Pathol., 91: 33-48, 1978.

37. Tatematsu, M., Cohen, S.M., Fukushima, S., Shirai, T., Shinohara, Y. and Ito, N. Neovascularization in benign and malignant urinary bladder epithelial proliferative lesions of the rat observed *in situ* by scanning electron microscopy and autoradiography. Cancer Res., 38:1792-1800, 1978.

38. Pauli, B.U., Cohen, S.M., Alroy, J. and Weinstein, R.S. Desmosome ultrastructure and the biological behavior of chemical carcinogen-induced urinary bladder carcinomas. Cancer Res., 38: 3276-3285, 1978.

39. Cohen, S.M., Fukushima, S., Tsuda, H., Murasakki, G. and Ito, N. Effect of azathiopurine and OK-432 on urinary bladder carcinogenesis in rats. Gann, 69: 773-779, 1978.

40. Cohen, S.M., Jacobs, J.B., Arai, M. and Friedell, G.H. Co-carcinogenicity testing of saccharin and DL-tryptophan following oral initiation with N-[4-(5-nitro-2-furyl)-2-thiazolyl] formamide. Health and Sugar Substitutes, Proc. European Res. Grp. Oral Biol. (ERGOB) Conf., S. Karger, Basel, pp. 70-75, 1978.

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b. Articles accepted for publication in scholarly journals:

1. Marnett, L.F., Cohen, S.M., Fukushima, S., Gooderham, N.J., Hecht, S.S., Rietjens, I.M.C.M., Smith, R.R., Adams, T.B., Bastaki, M., Harman, C.L., McGowan, M.M., and Taylor, S.V. GRASr2 evaluation of aliphatic acyclic and alicyclic terpenoid tertiary

alcohols and structurally related substances used as flavoring ingredients. J. Food Sci., in press.

2. Rietjens, I.M.C.M., Cohen, S.M., Fukushima, S., Gooderham, N.J., Hecht, S., Marnett, L.J., Smith, R.L., Adams, T.B., Bastaki, M., Harman, C.L., and Taylor, S.V. The impact of structureal and metabolic variation on the toxicity and carcinogenicity of hydroxy- and alkoxy-substituted allyl- and propenylbenzenes. Chem. Res. Toxicol., in press.

3. Cohen, S.M., Arnold, L.L., Klaunig, J.E., and Goodman, J.I. Letter to the Editor, Re: Waalkes et al., Response to Cohen et al., Arch. Toxicol., in press.

4. Wood, C.E., Hukkanen, R.R., Sura, R., Boyce, R., Jacobson-Kram, D., Nolte, T., Odin, M., and Cohen, S.M. Scientific and regulatory policy committee (SRPC) review: Interruption and use of cellular proliferation in cancer risk assessment, in press.

c. Articles submitted for publication in scholarly journals:

1. Adams, T.B., Cohen, S.M., Fukushima, S., Gooderham, N.J., Hecht, S.S., Marnett, L.J., Portoghese, P.S., Rietjens, I.M.C.M., Smith, R.L., Waddell, W.J., and Taylor, S.V. The FEMA GRAS assessment of allyl esters used as flavor ingredients. Submitted.

2. Marnett, L.J., Cohen, S.M., Fukushima, S., Gooderham, N.J., Hecht, S.S., Rietjens, I.M.C.M., Smith, R.L., Adams, T.B., Bastaki, M., Harman, C.L., McGoven, M.M., and Taylor, S.V. GRASr evaluation of substituted thiophenes used as flavoring ingredients. Submitted.

3. Smith R.L., Cohen, S.M., Fukushima, S., Gooderham, N.J., Hecht, S.S., Marnett, L.J., Rietjens, I.M.C.M., Adams, T.B., Bastaki, M., Harman, C.L., McGowan, M.M., and Taylor, S.V. The Safety Evaluation of Food Flavoring Substances: The Role of Metabolic Studies. Submitted.

4. Dodmane, P.R., Arnold, L.L., Pennington, K.L., Cardoso, A.P.F., and Cohen, S.M. Effect of trivalent arsenicals on mouse and human microvascular endothelial cells. Submitted.

5. Ptaszynska, A., Cohen, S.M., Messing, E.M., Reilly, T., Johnsson, E., and Johnsson, K. Assessing bladder cancer risk in type 2 diabetes clinical trials: a case study from the dapagliflozin drug development program. Submitted.

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h. Published audiovisual or computer-based educational materials and computer software: None

i. Published continuing education materials: None

Exhibit B

Past Depositions and Trial Testimony (last 4 years)

Stephen Hynds and Sylvia Hynds v. Dow Chemical Company, et al., State of Illinois, Circuit Court of the Sixth Judicial Circuit, County of Macon

Henry v. Takeda, Circuit Court of Cook County, Chicago, IL

MDL 2299-In RE: Actos Products Liability Litigation- Plaintiffs' Steering Committee v. Takeda Pharmaceutical Company, Western District of Louisiana, United States District Court

Kincaid v. Eli Lilly, Takeda et al., Court of State of Indiana, County of Marion, Marion Superior Court Civil Division, Cause No. 49DO3-1206-CT-024661

Jack Cooper et al. vs. Takeda Pharmaceuticals America, Inc., et al., Superior Court of the State of California for the County of Los Angeles

Camhong An et al. vs. Takeda Pharmaceuticals America, Inc., et al., Circuit Court for Baltimore City, Case No. 24-C-12-003565, Baltimore, MD

Terrence and Susan Allen v. Takeda Pharmaceuticals International, Inc., et al., United States District Court for the Western District of Louisiana, Lafayette Division, Lafayette, LA, MDL No. 6:11-md-2299, Case No. 6:12-cv- 00064-RFD-PJH

Bertha Triana vs. Takeda Pharmaceuticals America, Inc., et al., District Court, Clark County Nevada, Las Vegas, NV, Case No. A-13-680556-C, and Delores Cipriano et al., v. Takeda Pharmaceuticals America, Inc., et al., Case No. A-13-680922-C

Diane Whitlatch, individually and as special administrator for the estate of William M. Whitlatch vs. Takeda Pharmaceuticals America, Inc., et al., Circuit Court of Cook County, Illinois County Department – Law Division, Chicago, IL, No. 2011 L 010011, No. 2012 L 006087