Review of Studies of Health Effects Possibly Related to the Operation of the Santa Susana Field Laboratory (SSFL)

June 18, 2014

Abraham Weitzberg, Ph.D., Principal Author

Contributions from the SSFL Community Advisory Group

Reviewed and Approved by the SSFL Community Advisory Group

Executive Summary

Since 1990, in response to community concerns, there have been at least nine epidemiological cancer studies of residents of neighborhoods in the vicinity of the Santa Susana Field Laboratory (SSFL) and two studies of Rocketdyne workers. The studies were conducted by:

- California Department of Health Services (1990 and 1992),
- Tri-County Cancer Registry (1990, 1997 and 2006),
- University of California at Los Angeles (UCLA) School of Public Health (1997, 1999, 2001),
- International Epidemiological Institute (2005),
- Dr. Hal Morgenstern of the University of Michigan School of Public Health (2007), and most recently
- Dr. Thomas Mack of the University of Southern California Keck School of Medicine (2014).

The universal outcome of the studies is the inability to establish any statistically significant relationship between chemicals and/or radionuclides used at SSFL and any adverse health effects on either workers or nearby residents.

In 1999, the then-available studies were reviewed by California Environmental Protection Agency (Cal/EPA), Department of Toxic Substances Control (DTSC) and the Agency for Toxic Substances and Disease Registry (ATSDR) of the U. S. Center for Disease Control (CDC). An additional review of the previous studies was conducted in 2014, by Dr. Thomas Mack. The reviewers confirmed both the results of the previous studies and their inherent limitations.

In his study, Dr. Mack concluded that while it is not possible to unequivocally rule out any offsite carcinogenic effects from SSFL, no evidence was found of measureable offsite cancer causation as a result of migration of carcinogenic substances from the SSFL. Dr. Morgenstern went further in his conclusions and expressed skepticism that "*any additional analyses or studies would be sufficient to determine whether operations and activities at Rocketdyne [SSFL] affected, or would affect, the risk of cancer in the surrounding neighborhoods.*"

Despite the consistent conclusions of the epidemiological studies of off-site effects, some community members continue to assert contrary conclusions and voice beliefs which contrast with the studies' findings. Similarly, they cite conclusions of the UCLA studies of worker health that are inconsistent with those of a more extensive Rocketdyne study, despite weakness in the UCLA studies which are identified in a review by ATSDR. The pattern is continued with regard to pathway studies, where an overly conservative UCLA study is used to support the claims of off-site health effects, despite substantial questions about the validity of the UCLA study.

The completely opposite conclusions of the UCLA researchers and the others exactly mirror the polarization within the community. Both views cannot be correct. It would be extremely beneficial to the resolution of the issues relating to purported health effects from SSFL operations, to have a public workshop where the various authors of these health studies can meet and discuss the reports and the comments and see if there is a technically sound commonality. The SSFL cleanup discussion needs to move beyond partisan advocacy into the realm of science-based decision-making.

The final recommendation of the 1999 Rocketdyne Inquiry [DTSC, 1999] was:

"Consider the employment of a mediation/arbitration consultant to develop a common plan and understanding between the Rocketdyne Advisory Panel community members, and appropriate government agencies."

There has been no improvement in the past 15 years and the lack of common understanding continues to this day.

This paper was reviewed and approved by members of the Santa Susana Field Laboratory Community Advisory Group.

Introduction

For over twenty years, some residents living in the vicinity of the Santa Susana Field Laboratory (SSFL) and their elected representatives have voiced concerns regarding the possibility that nuclear and rocket testing operations have increased the incidence of cancer and other illnesses in their neighborhoods. Concerns for the health and well being of former SSFL workers have also been expressed. To date, these concerns have resulted in at least eleven epidemiological cancer studies of workers and off-site residents. Additionally, two studies, called "pathway studies" have been made to evaluate the possibility that neighboring communities may have been exposed to harmful materials emanating from SSFL operations. This paper discusses these studies by taking the authors' information directly from their papers and augmenting with information from other sources. The information is divided into three sections:

1. Cancer Incidence in the Vicinity of the Santa Susana Field Laboratory,
2. Worker Health Studies, and
3. Pathway Studies.

References and links to the full papers are provided so that the reader can get a comprehensive picture of the issues, and review the source documents, if desired.

Discussion

1. Cancer Incidence in the Vicinity of the Santa Susana Field Laboratory

In 1990 and 1992, based on actual census tract cancer data, the California Department of Health Services Cancer Registry issued reports on the incidence of cancer in five Los Angeles County census tracts and Ventura County census tracts. In the 1990 study [CDHS, 1990], it was concluded:

> *"Census tract age-adjusted incidence rates were found to be significantly higher than comparable county rates in three comparisons:*
>
> 1. *tract 1352, all sites, 1978 to 1982;*
> 2. *tract 1132, bladder, 1983 to 1987; and*
> 3. *tract 1352, Acute Non-Lymphocytic Leukemia. (ANLL), 1983-1987.*
>
> *Three rates were found to be significantly lower. Given the large number of comparisons made (five census tracts, two time periods, eleven sites), these findings are consistent with random variation in cancer incidence rates."*

The 1992 study [CDHS, 1992] concluded:

> "*These follow-up analyses suggest that people living near the SSFL are not at increased risk for developing cancers associated with radiation exposure. The findings are consistent with earlier DHS report that indicated an increase in the incidence of bladder cancer in people living in Los Angeles County near the SSFL, although this increase appears to be restricted to men in Los Angeles County only. There was also an increased proportion of lung cancer among Ventura men. Lack of an increase in the most strongly radiosensitive cancers suggests causes other than radiation. Because lung and bladder cancers tend to be cancers that are strongly associated with other risk factors (smoking and non-radiation occupational exposures), it is important to consider these alternative explanations when initiating the DOE-sponsored worker health study among Rocketdyne employees.*"

In 1997, the Tri-County Regional Cancer Registry issued a report [Tri-Counties Regional Cancer Registry, 1997] on cancer incidence in Simi Valley. This study concluded that:

> "*…residents of the study area seem to have cancer incidence risk which is similar to that of the*

other residents of the Tri-Counties Region, except for leukemia in women which is significantly lower, and cancer of the lung and bronchus which is higher."

In 1999, disagreements between some members of the Oversight Panel (SSFL Advisory Panel co-chaired by Dan Hirsch of Committee to Bridge the Gap) and DHS staff over distribution of information, led to a request by then-Assemblywoman Sheila Kuehl for an investigation of California Department of Health Services (DHS) practices. [DTSC, 1999] Governor Davis asked Cal/EPA to head the investigation. As part of that investigation, the Hazardous Materials Laboratory (HML) of the Department of Toxic Substances Control (DTSC) identified and reviewed the reported health studies, and convened an expert panel of epidemiologists to review these earlier studies. The panel [Petreas, Myrto, 1999] concluded:

"Whereas there were some differences in the geographic areas, time periods, case definitions and level of significance used in these three studies, the combined evidence from all three does not indicate an increased rate of cancer incidence in the regions examined. The extremely modest cancer incidence increases associated with known radiosensitive tumors could be easily explained by uncontrolled confounding or imprecision in the data. The results do not support the presence of any major environmental hazard."

Also in 1999, in response to a petition request, the Agency for Toxic Substances and Disease Registry (ATSDR) of the U. S. Center for Disease Control (CDC) performed a comprehensive study and released its "Draft Preliminary Site Evaluation Santa Susana Field Laboratory (SSFL)." [ATSDR, 1999] During its studies ATSDR reviewed the above 1990, 1992 and 1997 cancer registry data studies conducted in response to community concerns about cancer occurrence surrounding the SSFL. Its report stated:

"The first of the community-based epidemiological investigations evaluated cancer incidence rates in five Los Angeles County census tracts within a five-mile radius of the SSFL. Ventura County was not included in this investigation because the cancer registry had not been established at that time…The report concluded that a significant increase was observed in bladder cancer during 1983-1987 for one census tract (tract 1132). This census tract adjoins the SSFL site, however it also extends more than five miles to the east, such the individual cases may not be close to the site.

"This study has several limitations; most of them inherent to this type of investigation. The accuracy of the population estimates at the census tract level is not known. Although standardized rates are useful as a summary measure, the rates are affected by random variation. Because multiple comparisons were made, the probability of finding a significant association by chance is increased even if there is no association at all. No information was available on actual exposures to contaminants from the SSFL sites. A five-mile radius within the SSFL site is a weak surrogate for exposures and no information is available regarding how long the residents lived in the area. No information was available on any other risk factors. This investigation serves the purpose of generating and refining questions on cancer incidence and cannot assess the cause and effect relationship of potential SSFL exposures.

"The second community health study was conducted as a follow-up in response to recommendations made in the 1990 investigation described above… Comparison groups were the rest of Los Angeles County residents for Los Angeles County and the rest of Ventura County residents for Ventura County. Cancer sites were grouped based on the evidence for radiogenic causes because of radiation exposure concerns. No increase was found in the "very radiosensitive" cancer group (cancers of the thyroid and bone, and all the leukemias except for chronic lymphocytic leukemia). The bladder cancer rate was elevated among Los Angeles men living near SSFL during 1983-1988.

The odds of having lung cancer among all cancers diagnosed was higher among Ventura men living near SSFL compared to that among the rest of Ventura men.

"The study methodology is generally sound, given the limited data and lack of exposure information. Most of the limitations of the 1990 study also apply to this study and they are acknowledged appropriately. The interpretation of the findings is reasonably cautious because lung and bladder cancers are "strongly associated with other risk factors (smoking and non-radiation occupational exposures), it is important to consider alternative explanations.

"The third community study was a follow-up to the 1990 and 1992 studies. It involved an analysis of the newly available cancer registry data for the years 1988-1995 for the Ventura census tracts that were included in the 1992 study. This study calculated Standard Incidence Ratios (SIRs) by using the 1990 census data. The Tri-Counties region population served as a comparison group. This preliminary analysis reported a significant decrease in the leukemia incidence in women. A significant increase in lung cancer was also reported for the combined group of men and women. However, this increase was small, and lung cancer was not significantly increased in men or women separately. The report acknowledged the lack of appropriate census tract level population estimates. If estimates of the base population are too low, the population-based number of expected cancer cases is also too low, which would lead to an overestimation of SIRs."

In September 1999 and October 2006, the Tri County Cancer Surveillance Program, responding to calls from the same Bell Canyon resident expressing concern about the possible increase in cancer cases in their specific neighborhood, conducted cancer registry studies. [Tri-Counties Regional Cancer Registry, 1999 and 2006]**.** The first study stated:

"During 1988 to 1996, a total of 129 newly diagnosed invasive cancer cases of all types were observed in census tract 75.03 in Ventura County that includes your neighborhood. For this same period, a total of 124 cases were expected. The difference between 129 and 124 is not significant and reflects normal variation in the occurrence of this type of biological phenomena…Based on this analysis, I am confident to state that residents of census tract 75.03 in Ventura county that includes your neighborhood, are not at higher risk of being diagnosed with cancer when compared to the rest of the population in the Tri-counties Region."

The second study was made after the release of studies suggesting possible increase in cancer cases due to the meltdown of the reactor at the Santa Susan Field Laboratory in the 1959 (Study Says Lab Meltdown Caused Cancer, Los Angeles Times October 6, 2006). It concluded:

"…occurrence of newly diagnosed invasive cancers in census tract 75.03 in Ventura County that includes your neighborhood does not show any unusual pattern and has actually decreased by 7.5 percent from 1988 through 2004."

In March 2007, Dr. Hal Morgenstern of the University of Michigan (formerly of UCLA) issued the final report [Morgenstern, H., et.al., 2007] entitled "Cancer Incidence in the Community Surrounding the Rocketdyne Facility in Southern California." After he summarizes his numerical results, he states

"It is important to recognize that associations observed between distance from SSFL and the incidence of specific cancers are based on small numbers of cases in the region closest to SSFL. Thus, these associations are estimated imprecisely and may represent chance findings. In addition, observed associations may have been biased by certain methodologic limitations—use of distance

from SSFL as a crude proxy measure for environmental exposures, mobility of the residential population before and during the follow-up period, and lack of information on other cancer risk factors, such as cigarette smoking and socioeconomic status, that might distort the observed associations…Despite the methodologic limitations of this study, the findings suggest there may be elevated incidence rates of certain cancers near SSFL that have been linked in previous studies with hazardous substances used at Rocketdyne, some of which have been observed or projected to exist offsite."

In his summary, Dr. Morgenstern states:

"The strongest and most consistent association observed in this study was for thyroid cancer, which was associated with distance from SSFL in both follow-up periods. This finding may have public-health significance because perchlorate, a component of rocket fuel used in large quantities at SSFL, is known to disrupt thyroid function, it has been shown to induce thyroid tumors in laboratory animals, and there is evidence from two other investigations that perchlorate migrated offside to contaminate the groundwater in areas surrounding SSFL."

His rationale is undermined by two facts. While perchlorate is a component of solid rocket *engine* fuel, it is not a component of liquid rocket engine fuel, which was used almost exclusively at SSFL. Some perchlorate was used, but the quantities were not large. Also, the DTSC Offsite Groundwater handout dated April 9, 2014 states that perchlorate was not detected in any of 71 off-site samples near SSFL, and that evaluation of surface and groundwater pathways of perchlorate offsite does not indicate a connection between the perchlorate detected in Simi Valley and perchlorate present in the soil and groundwater at SSFL. It should also be noted that perchlorate is produced naturally and has been used as a fertilizer and in many non-SSFL applications.

Dr. Morgenstern also concludes:

"There is no direct evidence from this investigation, however, that these observed associations reflect the effects of environmental exposures originating at SSFL. Given these provocative findings and unanswered questions, it is tempting to recommend further analyses or future studies to address the health concerns of the community. Unfortunately, it is not clear at this time whether such additional analyses or studies will be sufficient to determine whether operations and activities at Rocketdyne affected, or will affect, the risk of cancer in the surrounding neighborhoods."

Also in 2007, in response to a request by then-Senator Kuehl, the Cancer Surveillance Section reviewed the incidence of retinoblastoma in Los Angeles and Ventura Counties, with a focus on the area around the Santa Susana Field Laboratory (SSFL). There was a community concern that the risk of retinoblastoma (RB) was increased in children as a result of potential cancer-causing contaminants in the vicinity of SSFL. Senator Kuehl asked the Cancer Surveillance Section to update a 2005 analysis conducted by the University of Southern California (USC) Cancer Surveillance Program that included cases diagnosed through 2002 and showed no excess incidence of retinoblastoma in this area. The study [CCR, 2007] concluded:

"incidence of retinoblastoma among children under age 5 residing in the area around the SSFL between 1988 and 2005 was slightly, although not statistically significantly, higher than expected based on incidence statewide. The relatively young age of the cases, and the high proportion of cases with bilateral disease, is suggestive of a genetic origin. This analysis is consistent with the 2005 report that showed no significant increased risk of retinoblastoma between 1972 and 2002."

On April 8, 2014, Dr. Thomas Mack, epidemiologist and Professor of Preventative Medicine and Pathology at the USC Keck School of Medicine presented the results of his recent study, entitled "Cancer Occurrence in Offsite Neighborhoods near the Santa Susana Field Laboratory." [Mack, 2014] His presentation included the reasons for skepticism about previous cancer registry studies:

"•Ambiguous and controversial exposure estimates
•Absence of concrete dose-based hypotheses
•Alternative explanations not seriously considered
•Hard to explain how a sufficient dose would occur
•Absence of historical precedents
•Lack of any clear risk found by previous searches

"Specifically, the 1990 study suffered from: multiple comparisons, weak associations, bias from being a response to cluster report, and confounded by race and social class. The 1992 study suffered from multiple comparisons, weak associations, aggregation obfuscates location, and confounded by social class. The 1997 study suffered from multiple comparisons, weak associations, aggregation obfuscates location, low statistical power, and confounded by social class. The Morgenstern study suffered from multiple comparisons, weak associations, aggregation obfuscates location, distance is not dose, and confounding by social class."

Before describing his study of the cancer registry data for census tracts in the vicinity of SSFL, he presented a tutorial on the general methodology of these studies based on census tract cancer registry data.

"•The characteristics of SSRL offsite tracts are that they are not characteristic of their respective Counties in terms of income and, doubtless, education and race/ethnicity.
•In the selection of malignancies
–Every cancer has a unique set of causes and the rate of cancer at all sites is not informative.
•The cancers selected for assessment included thirteen different malignancies
–Four most common cancers
–Cancers thought caused by chemicals/radiation

"*Cancers Selected for Study*

Neoplasm	***Major Causes***	***Descriptive Predictors***
Lung	*Cigarette smoking*	*Blue collar occupation*
Bladder	*Cigarettes, aniline dyes (rare)*	*Race*
Pancreas	*Cigarette smoking*	*None strong*
Oropharynx	*Tobacco, Alcohol, Virus*	*None strong*
Leukemia	*Genes, benzene, ? virus*	*None strong*
Breast	*Genes, Hormones*	*Higher education*
Colorectal	*Genes, Diet, Activity*	*None strong*
Prostate	*Genes, Diet*	*Race, Age, Access to screening*
Thyroid	*Ionizing radiation (rare)*	*Access to screening*
Brain	*Ionizing Radiation (rare)*	*None strong*
Liver	*Hepatitis B, C viruses*	*National origin*
NHL	*Immune depletion*	*None strong*
Melanoma	*Sunlight, light skin*	*Race, Higher education*

"The screening covered:

- *Separate assessment by gender*
- *Three time periods:*
  - *–1988-95, 1996-2003, 2004-2010*
  - *–Separate denominators from 3 censuses*
- *All census tracts within 5 miles of SSFL*
  - *–1988-95: 22 VEN, 16 LA census tracts*
  - *–1996-2003: 29 VEN, 17 LA census tracts*
  - *–2004-2010: 29 VEN, 17 LA census tracts*
- *Number of comparisons:*
  - *–130 period-tracts X 24 gender-cancers= 3120 searches, which would contain up to 78 (3 per gender-cancer) "significantly" high-risk tracts by chance*

"Screening Criteria:

- *Significantly higher rate than County mean*
  - *–Outside the 95% confidence interval ($p < 0.05$)*
- *At least a 50% increase in risk ($RR > 1.5$)*
- *Histological (Causal) homogeneity*

"To find a result consistent with local cancer causation by disbursed carcinogen, one requires:

- *Consistent risk over calendar time*
- *High risk for both genders in the same area*
- *Higher risk proximate to SSRL*
- *Geographic clustering of high risk areas*
- *Pattern consistent with dispersion flow*
- *We screen by a relative risk (RR) of 1.5, but if RR is below 2.0, any observed case would likely have occurred anyway*
- *No plausible alternative explanation is available*

"Reasons for Caution in Assessing Impact

- *3 "Significant" excesses each are expected by chance*
- *No known clear evidence of personal exposure*
- *Waterborne and airborne dispersion imprecise*
- *Dosage is unknown*
- *Exposed workers are likely to reside together*
- *Census errors: rapid local growth may distort incidence estimates*
- *Evaluation is based on residential address at diagnosis*

"Summary of Screening Findings

Neoplasm	***"Significant" tract-periods***	***In Both genders***	***In Adjacent tracts***	***In 2 or more periods***
Lung	*4 (6 exp)*	*0*	*0*	*1*
Bladder	*1 (6 exp)*	*---*	*---*	*---*
Pancreas	*0 (6 exp)*	*---*	*---*	*---*
Oropharynx	*0 (6 exp)*	*---*	*---*	*---*
Leukemia	*1 (6 exp)*	*---*	*---*	*---*
Breast	*26 (3 exp)*	*---*	*8*	*6*
Colorectal	*7 (6 exp)*	*2*	*0*	*0*
Prostate	*4 (3 exp)*	*---*	*0*	*0*
Thyroid	*3 (6 exp)*	*0*	*0*	*0*
Brain	*3 (6 exp)*	*0*	*0*	*0*
Liver	*0 (6 exp)*	*---*	*---*	*---*
NHL	*2 (6 exp)*	*0*	*0*	*0*
Melanoma	*23 (6 exp)*	*8*	*17*	*7*

"These cancer rubrics oversimplify causal heterogeneity:

- *Brain: many reported cases are benign, slow-growing tumors with different causes*
- *Non-Hodgkin lymphoma includes at least five different malignancies known to have different causes*
- *Leukemia also is made up of three common and several uncommon varieties*
- *In this case, each of the apparently "high-risk" tracts were no more numerous than expected by chance, and included cases of diverse, most having no known environmental causation*

"For the excess of bladder cancer in one tract in 2004-2010

- *Extreme finding: RR >5*
  - *Case tumors had the same common histology*
  - *Most residences scattered, but several are within one mile*
  - *The most prevalent cause of bladder cancer is smoking*
  - *Environmental causes are industrial, waterborne arsenic*
  - *Diagnoses not clustered in time*
  - *The tract is more than 5 miles to the west of SSFL*
  - *Residential community: no known exposure, specifically no high arsenic in tap water, no local industry, no increase in kidney cancer (another arsenic outcome)*
  - *66% of the cases were >75 at diagnosis, and all but one of those were over 85*
  - *Census may have undercounted seniors*

Neoplasm	*"Significant" tract-periods*	*Observed/Expected number per tract*	*Interpretation*	*Estimated number of CA tracts with that many or more cases*
Non-Hodgkins Lymphoma	*2 (3 exp. by chance)*	*8/2.5 12/5.3*	*No clustering of high-risk tracts No evidence of proximity to SSFL Mixture of cell types, no trend*	*50-100*
Brain	*3 (3 exp. by chance)*	*6/0.9 8/2.3 11/3.5*	*No clustering of high-risk tracts No consistent proximity to SSFL Mixture of cell types, no trend*	*10-50*
Leukemia	*1 (3 exp. by chance)*	*7/1.3*	*No clustering of high risk tracts No evidence of proximity to SSFL Mixture of cell types, no trend*	*10*
Bladder	*1 (3 exp. by chance)*	*11/2.5*	*No clustering of high risk tracts No evidence of proximity to SSFL No evidence of carcinogens Preponderance of elderly cases ? Smoking, census error*	*1-2*

Dr. Mack concluded:

"•It is not possible to completely rule out any offsite carcinogenic effects from SSFL
•No evidence of measureable offsite cancer causation occurring as a result of emissions from the SSFL was found."

In summary, not one of the SSFL-focused epidemiological studies using actual Cancer Registry data concluded that there was evidence of increased cancer rates in the vicinity of SSFL caused by contamination from the site. Additionally, as stated above, Dr. Morgenstern expressed skepticism that *"any additional analyses or studies would be sufficient to determine whether operations and activities at Rocketdyne affected, or would affect, the risk of cancer in the surrounding neighborhoods."*

2. Worker Health Studies

In June 1997, the University of California, Los Angeles (UCLA) released the first of two worker health studies, entitled "Epidemiologic Study to Determine Possible Adverse Effects to Rocketdyne/ Atomics International Workers from Exposure to Ionizing Radiation." [Morgenstern, H., et.al., 1997] The study was in response to a 1990 request by the legislature for an investigation of SSFL Rocketdyne workers to be overseen by the CDHS Occupational Health Branch. The UCLA study included 4, 607 employees who worked at Rocketdyne between 1950 and 1993. This group had been monitored for radiation exposure and was enrolled in the company's Health Physics Radiation Monitoring Program. The researchers searched death certificates to find out which Rocketdyne workers have died and the causes of death. The study investigators found that among Rocketdyne workers who were monitored for external radiation, those who received higher doses (especially more than 200 mSv) had an increased risk of dying from cancers of the blood and lymph system (such as leukemia and lymphoma), and from lung cancer. As the dose of external radiation among Rocketdyne workers increased, the investigators also found an increased risk of dying from all cancers. They also found that among Rocketdyne workers who were monitored for internal radiation, those who received a relatively higher dose (especially more than 30 mSV) had an increased risk of dying from cancers of the blood and lymph system, and upper aero-digestive tract cancers (mouth, throat, esophagus and stomach).

In January 1999, an Addendum Report entitled "Epidemiologic Study to Determine Possible Adverse Effects to Rocketdyne/Atomics International Workers from Exposure to Selected Chemicals" was released by UCLA. [Morgenstern, H., et.al., 1999] This final report for the second part of the DOE-

funded occupational study focused on the chemical exposure portion, and included a cohort based on presumed exposure to hydrazine (6,107 workers with 176,886 person-years) and a cohort with presumed exposure to asbestos (4,563 workers with 118,749 person-years). Employing an internal comparison method described in the 1997 report, this study reported the observed positive association between presumptive exposures to hydrazine and the rates of dying from cancers of the lung.

Also in 1999, in response to a petition request, the Agency for Toxic Substances and Disease Registry (ATSDR) of the U. S. Center for Disease Control (CDC) performed a comprehensive study and released its "Draft Preliminary Site Evaluation Santa Susana Field Laboratory (SSFL)." [ATSDR, 1999] During its studies ATSDR reviewed the above UCLA worker health studies. The ATSDR report states:

> *"ATSDR reviewed two occupational studies of SSFL workers. The first of these was a retrospective cohort study to determine whether workers at the SSFL nuclear sites experienced excessive mortality from specific cancers, total cancers, or other causes as a result of their work-related exposures to radiation. The cohort consisted of the SSFL workers enrolled in the Health Physics Radiation Monitoring Program, for external (4,563 workers) and internal (2,289 workers) radiation exposures. The internally monitored group was mostly a subset of the externally monitored group. A fairly long follow-up period is included, extending from 1950 to 1993. The study estimated radiation effects by employing internal comparisons of monitored workers according to level of cumulative radiation doses. Conditional logistic regression was used to examine the dose-response relationships by controlling for potential confounders and effect modifiers. Variables controlled for were (1) the other type of radiation exposure, (2) age at risk, (3) time since first radiation monitoring, (4) pay type, and (5) exposures to asbestos and hydrazine. External comparisons were also conducted by using two external reference populations to describe the mortality experience of the study population. The study found that mortality rates of the study cohort were lower for all causes, all cancers, and heart disease compared to the rates of the general U.S. population. Compared with NIOSH cohort members of similar pay type, the monitored workers experienced lower mortality rates for all causes and heart disease, but similar rates for total cancers. Although none of the 95% confidence intervals exclude the null value, there appear to be some excess mortality from leukemias in the monitored workers compared with either reference population. In the dose-response analyses of monitored workers, external-radiation dose was positively associated with the mortality rate for hemato-lymphopoietic cancers and for lung cancer. For dose levels greater than 200 mSv, the mortality rates for both types were particularly elevated. Increasing trends in mortality rates were found with internal-radiation dose for upper aerodigestive tract cancers and for hemato-lymphopoietic cancers."*

> *"This study is well designed and the data analysis is rigorous. The major strength of the study is the ability to examine the dose-response relationships by reconstructing internal and external doses received by the individual workers in the past. The choice of the study cohort and availability of the radiation monitoring records at the SSFL benefitted the study; however, they also pose some problems because of incomplete records. In particular, for internal radiation doses, uncertainty of the estimates appears to be high. The study measured cumulative SSFL exposures, however exposures received before employment at SSFL could not be accounted for because of inconsistency in the recording practice. Although the study attempted to control for the effect of other chemical exposures (i.e., hydrazine and asbestos), misclassification of the chemical exposures is highly likely. The use of the upper aerodigestive tract cancers group is somewhat unusual, although it is meant to take consideration the properties of internally deposited radionuclides. Another problem of the study is the small number of cancer deaths, particularly in the high dose group (e.g., >200 mSv). Most of these limitations are acknowledged appropriately in the report. Given the limitations, the most*

consistent and biologically plausible finding of the study is the hemato-lymphopoietic cancers. The observed positive relationship between external radiation and lung cancer mortality has not been reported consistently in other studies of nuclear workers.

"The second occupational study is part of the 1997 study described above. This addendum report focused on the chemical exposure portion, and included a cohort based on presumed exposure to the hydrazine (6,107 workers with 176,886 person-years) and a cohort with presumed exposure to asbestos (4,563 workers with 118,749 person-years). Employing an internal comparison method described in the 1997 report, this study reported the observed positive association between presumptive exposures to hydrazine and the rates of dying from cancers of the lung.

"The weakness of this study mainly stems from the unavailability of adequate information on past exposures for individual workers. Even though the study was able to identify work locations with a high probability of exposure to hydrazine and asbestos at the SSFL site, information was not sufficient to link individual workers with job locations. As a result, the exposure classification was based on job titles. In addition to the possible exposure misclassification, bias may also have been introduced by confounding. Exposure information on other risk factors, such as exposure to other chemicals (e.g., trichloroethylene and nitrosamines) or personal characteristics is not available for the study. There is also a possibility that the radiation exposures are misclassified, hindering the ability to control for confounding by radiation exposures. Despite the limitations, the observed increase in the lung cancer risk associated with presumptive hydrazine exposure is noteworthy. The direction of the bias caused by the exposure misclassification may be toward the null value, because individual subject's exposure classification did not depend on the subject's disease status. This increase is observed after taking into account the effects of other potential confounding factors on which the relevant data were available. The increase is consistent across two hydrazine compounds. Given the uncertainties, the authors' recommendation that the worker group should be followed further is reasonable since the result shows a positive association, and health effects of exposure to these chemicals in humans are not well understood.

In 2006, the Boeing Company released the July 13, 2005 "Rocketdyne Worker Health Study, IEI Executive Summary," produced by the International Epidemiology Institute. [IEI, 2005] It states:

"A retrospective cohort mortality study was conducted of 46,970 Rocketdyne workers employed for at least 6 months in either nuclear technology development or in rocket engine testing since 1948 at the Santa Susana Field Laboratory (SSFL) and at nearby facilities, including Canoga Park and De Soto Avenue in California. The Rocketdyne workers were grouped into three populations: those monitored for radiation (Radiation Cohort), those who worked at SSFL (Chemical Cohort) and those who worked at all other facilities (Comparison Cohort). The Radiation Cohort consisted of 5,801 workers monitored for radiation of whom 2,232 were also monitored for internal radionuclide uptake. The Chemical Cohort consisted of 8,372 workers at SSFL of whom 1,651 were test stand mechanics assumed to have the greatest potential for exposure to chemicals such as hydrazines and trichloroethylene (TCE). The Comparison Cohort consisted of 32,979 workers employed at the other Rocketdyne facilities. There were 182 workers who during their career at Rocketdyne had been monitored for radiation and also had worked as test stand mechanics. These workers, 30 of whom were found to have died, are included in both the Radiation and the Chemical Cohorts.

"Overall, the 46,970 Rocketdyne workers (including both radiation and chemical cohorts together) accrued 1.3 million person-years of observation (average 27.6 years). Vital status was determined for 99.2% of the workers: 11,118 (23.7%) had died and only 368 (0.8%) were lost to follow-up. Cause

of death was determined for all but 280 (2.5%) of those who had died. The overall mortality experience among all Rocketdyne workers was lower than that of the general population of California, i.e., the ratio of observed to expected numbers of deaths (the Standardized Mortality Ratio, or SMR) was less than 1.0 (SMR 0.87; 95% CI 0.85-0.88). Low overall mortality was seen among radiation workers (SMR 0.79; 95% CI 0.75-0.83; n=1,468 deaths), SSFL workers (SMR 0.83; 95% CI 0.80-0.86; n=2,251 deaths) and among the other Rocketdyne workers (SMR 0.90; 95% CI 0.88-0.92; n=7,429). The observed numbers of cancer deaths also were slightly below population expectation for all workers (SMR 0.93; 95% CI 0.89-0.96; n=3,189 deaths), radiation workers (SMR 0.90; 95% CI 0.82-0.99; n=456 deaths), SSFL workers (SMR 0.89; 95% CI 0.82-0.96; n=655) and the other Rocketdyne workers (SMR 0.94; 95% CI 0.90-0.98). The ratios of observed to expected deaths (SMRs) computed using United States rates were lower than those computed using California rates, whereas county rates (combined Los Angeles and Ventura Counties) were similar to those computed using California rates. No cause of death was significantly elevated. There were no notable increases in cancer deaths over time since first hire, or by duration of employment at SSFL or at the other Rocketdyne facilities.

"Among the 5,801 radiation workers, the mean dose from external radiation was 13.6 mSv (maximum 1,000 mSv); the mean lung dose from external and internal radiation combined was 19.1 mSv (maximum 3,600 mSv). Only 69 workers had career doses from external radiation greater than 200 mSv, and only III workers had lung doses greater than 200 mSv when internal doses were considered. Deaths from all cancers taken together (SMR 0.90; 95% CI 0.82-0.99, n = 456), all leukemia excluding chronic lymphocytic leukemia (CLL) (SMR 1.16; 95% CI 0.69-1.84; n = 18), and lung cancer (SMR = 0.89; 95% CI 0.76-1.05; n = 151) were not significantly elevated. Internal cohort dose-response analyses revealed no significant trends over categories of increasing radiation dose for all cancers taken together, leukemia, lung cancer or any other cancer. There were no significant associations found among the 2,232 workers who were monitored for internal radionuclide intakes. For all cancers excluding leukemia, the RR at 100 mSv was estimated as 1.04 (95% CI 0.86-1.26) and for all leukemia excluding CLL it was 1.32 (95% CI 0.71-2.45).

"Overall, 1,651 test stand mechanics were identified and assumed to have the greatest potential exposure to chemicals associated with the testing of rocket engines. Compared with the general population of California, test stand mechanics had a lower risk of dying overall (SMR 0.90; 95% CI 0.82-0.98) and a similar risk of dying from cancer (SMR 1.03; 95% CI 0.88-1.20). The mortality experience of the other male hourly workers at SSFL was similar to that of the test stand mechanics for all causes (SMR 0.97; 95% CI 0.91-1.03), all cancers (SMR 0.93; 95% CI 0.82-1.06), and all specific cancers. No cancer of a priori interest among test stand mechanics was significantly increased: lung (SMR 1.07; 95% CI 0.8-1.4), esophagus (SMR 1.03; 95% CI 0.3-2.4), kidney (SMR 1.78; 95% CI 0.8-3.5), bladder (SMR 0.98; 95% CI 0.3-2.5), liver (SMR 0.97; 95% CI 0.3-2.5), and non-Hodgkin's lymphoma (SMR 0.80; 95% CI 0.3-1.9). Among the 315 male test stand mechanics with likely exposure to hydrazines, there were no significant increases for any cancer and, based on internal cohort analyses, no evidence of a dose response over years of potential exposure for all causes of death (SMR 0.89, n=101), all cancers taken together (SMR l.09, n= 33), lung cancer mortality (SMR 1.45, n= 15), or any specific cancer. Among the 1,114 workers potentially exposed to TCE, there were no significant increases for all causes of death (SMR 0.87; 95% CI 0.78-0.96), all cancers taken together (SMR 1.00; 95% CI 0.83-1.19) or any specific cancer. Based on internal cohort analyses, there was no significant dose response over years of potential exposure to TCE for all cancers combined, lung cancer or any other cancer. Cancer of the kidney was elevated based on 7 deaths (SMR 2.22; 95% CI 0.89-4.57) and there was a suggestion of a dose response over years of potential TCE exposure, although the trend was not significant. For the three malignancies most frequently

found to be elevated in studies of TCE exposure (i.e., cancers of the kidney and liver and non-Hodgkins lymphoma), the combined SMR based on 12 deaths was not significantly increased (SMR 1.09; 95% CI 0.56, 1.90).

"A questionnaire survey of 139 workers indicated that hourly workers (n=66) were significantly more likely than salaried workers (n=71) to have smoked cigarettes (61 % vs 41 %; p=0.02). The smoking prevalence of hourly workers who responded to this survey were also greater than smoking prevalence in the general population of California, and indicate the need for caution when interpreting comparisons with the general population for these subgroups because of the likely differences in tobacco use. All test stand mechanics were hourly workers. National surveys also indicate that blue collar workers smoke cigarettes to a greater extent than both white collar workers and people in the general population.

"The Rocketdyne workforce overall, including those monitored for radiation, those employed at SSFL and test stand mechanics potentially exposed to hydrazines or TCE, did not experience a statistically significant increased mortality for any cancer, including lung cancer, that could be linked to radiation dose, years of employment at SSFL, years of employment as a test stand mechanic, or years of potential exposure to hydrazines or TCE. No statistically significant internal cohort dose-response relationship was seen for leukemia, lymphoma, or cancers of the esophagus, liver, bladder, kidney or any other cancer over categories of radiation dose or years of potential chemical exposure. We conclude that radiation exposure has not caused a detectable increase in cancer deaths in this population and that work at the SSFL rocket engine test facility or as a test stand mechanic is not associated with a statistically significant increase in cancer mortality overall or for any specific cancer. A slight non-significant increase in leukemia (excluding CLL) was seen among radiation workers, although a similar non-significant increase in CLL (a malignancy not associated with radiation) was also observed. A slight non-significant increase in kidney cancer and a slight non-significant decrease in bladder cancer was also seen among radiation workers. Additional follow-up would be needed to clarify the inconsistent finding with regard to radiation and kidney cancer (a cancer not generally found increased in radiation exposed populations) as well as the non-significant association observed for kidney cancer and potential TCE exposure. Additional follow-up might also clarify the non-significant elevated risk of lung cancer among workers potentially exposed to hydrazines when compared with the general population. "

In summary, the IEI study when compared with the UCLA studies, covered more workers over a longer period of time and estimated radiation doses from biokinetic models for 16 organs or tissues and combined external and internal dose measurements in their analyses of specific cancers. They also included radiation doses received before and after employment at Rocketdyne; using other databases, and to estimate radiation effects, they compared radiation-monitored workers with unmonitored workers assumed to be unexposed. While the less rigorous UCLA studies showed some possible health effects from worker chemical and radiation exposures, the IEI studies showed none, with the exceptions of cancer of the kidney (SMR 2.22) which was based on only 7 deaths. The importance of these findings is that the lack of statistically significant health effects among workers would translate to essentially no health effects among the off-site population who would have received much lower exposures, if they were exposed at all by releases from the site. This is consistent with the findings presented for the off-site cancer studies discussed in the first section, above.

3. Pathway Studies

In 1999, in response to a petition request, the Agency for Toxic Substances and Disease Registry (ATSDR) of the U. S. Center for Disease Control (CDC) performed a comprehensive study and released its "Draft Preliminary Site Evaluation Santa Susana Field Laboratory (SSFL)." [ATSDR, 1999] The Executive Summary states:

> *"Process operations and activities at the Santa Susana site have resulted in the release of chemicals and radionuclides to the environment. The release of hazardous substances does not necessarily result in harm to humans. There must be human contact with these substances at levels of health concern before there is a potential for exposure-related health effects. Human contact of hazardous substances may occur through the air, soil, water, or food chain. ATSDR has evaluated these pathways relative to chemical and radioactive releases from the Santa Susana Field Laboratory.*
>
> *"This is a preliminary evaluation of the potential exposure pathways and associated health studies which ATSDR has reviewed for the Santa Susana site. Based on currently available data:*
>
> - *The preliminary results of the exposure pathway analyses for air, ground water and surface water, and soil and sediment indicate that it is unlikely that people living in communities near the site have been exposed to substances from the site at levels that would have resulted in adverse health effects.*
> - *Although chemicals and radionuclides were released from the site, the likelihood of those releases resulting in human exposure is limited by a number of factors, including;*
>
> *1) the distance from the release sources to the offsite residential areas that results in rapid dispersion and degradation of oxidants and solvents in air;*
> *2) the predominant wind patterns that normally blow away from the nearest residential areas;*
> *3) other meteorological conditions at the site such as the atmospheric mixing height; and*
> *4) drawdowns in ground water levels that reduce the rates of contaminant migration.*
>
> *Considering these factors, it is unlikely that residents living near the site are, or were exposed to SSFL-related chemicals and radionuclides at levels that would result in adverse human health effects. Changes in site operations, such as reduced frequency of rocket engine testing, discontinuation of trichloroethylene use, and shut down of nuclear operations make it unlikely that future exposures to the offsite community will occur.*
>
> - *A more in-depth evaluation of exposure pathways that addresses past, current, and future exposure to chemicals and radionuclides from the SSFL should be conducted to improve the assessment of potential offsite exposures and public health implications associated with this site. Such an assessment must be facilitated through community outreach and participation and must include health education activities. We further recommend that this assessment address the following related issues:*
> - *More in-depth evaluation of airborne chemical releases from SSFL operations, including air dispersion modeling of past accidents and disposal activities, and compilation and use of a consistent, site-specific meteorological data set to improve the assessment of past exposures to these substances.*
>   - *Development of a regional hydrogeological flow model and additional monitoring at down-gradient springs or seeps in Simi Valley and Santa Susana Knolls to evaluate the potential for deep fracture flow and potential future exposure. Also, even though it may not be related to SSFL, additional source characterization of the perchlorate detection in Simi Valley should be conducted.*
>   - *Additional radiological characterization of Area IV with more sensitive instrumentation and appropriate grid spacing to assure a lower detection limit.*

- *A re-analysis of the cancer registry data including additional years of newly available cancer data and updated demographic information should be conducted to see if the apparent increase in the incidence rates of bladder and lung cancers persist. A more in-depth evaluation of cancer data should be conducted that addresses environmental exposures from the SSFL, possible confounding exposures from other nearby contaminant release sources, and residential histories."*

In 2006, February 2, 2006 - UCLA's Center for Environmental Risk Reduction released the final report entitled, "The Potential for Offsite Exposures Associated with Santa Susana Field Laboratory, Ventura County, California." [UCLA, 2006] This report, led by Professor Yoram Cohen, was funded by ATSDR with the intent of providing more in-depth evaluations in accord with the ATSDR 1999 recommendations. The study's pathway conclusions were:

"*Migration pathways from SSFL to offsite areas include (but cannot be limited to):*

- *Surface water runoff (controlled and natural) to the north, south and east.*
- *Groundwater migration to the northeast and northwest.*
- *Air dispersion and deposition.*
- *In general, the contribution of soil to offsite exposure was found to be low compared to that of other pathways.*

"Past community exposures of concern include (but cannot be limited to):

- *Potential chronic exposures to TCE and hydrazine resulting from emissions associated with rocket engine testing and open-pit burning between 1953 and early 1980s. Potential residential receptor locations of inhalation exposure include West Hills, Bell Canyon, Dayton Canyon, Simi Valley, Canoga Park, Chatsworth, Woodland Hills, and Hidden Hills.*
- *Chronic exposure to TCE and associated degradation products in groundwater from 1953 to the late 1970s via use of private wells east and north of SSFL. Potential receptors include residents using private wells and residents who habitually ingested area-grown crops or livestock.*

"There is potential for chronic exposures, in areas within ~1-2 miles of SSFL, which include, but are not limited to:

- *TCE, vinyl chloride, and 1, 1-DCE in the northeast quadrant off site of SSFL through use of private groundwater wells or from habitual home-grown crop ingestion.*
- *Arsenic (source unknown) via habitual home-grown crop ingestion in Bell Canyon, Brandeis-Bardin, and potentially all areas north and east of SSFL, including Simi Valley, Dayton Canyon, and West Hills.*
- *Lead (source unknown) via incidental soil ingestion/inhalation or from habitual home- grown crop ingestion in Bell Canyon and potentially areas east of the facility; as well as extended use of private water wells or habitual home-grown crop ingestion.*

"Removal of the large amount of TCE that is estimated to reside in the soil subsurface and groundwater at SSFL is beyond the capabilities of current remediation technologies. Therefore, there is potential for long-term exposure to TCE if contaminated groundwater if it comes in contact with human and ecological receptors and also due to volatilization from the soil subsurface.

"Areas of exposure concern (AEC) include...the upper northeast (offsite) quadrant and Bell Canyon, West Hills, and Dayton, Woolsey, Meier, Runkle, and Black Canyons."

Late in 2006, The Boeing Company provided detailed comments to Professor Cohen on the UCLA report. [Boeing, 2006] The Boeing general comments included the following:

> *"…Boeing has a number of general concerns and comments regarding the overall approach taken in preparing the report, which is set forth below. Taken as a whole, these concerns seriously question the validity of the report's conclusions…*
>
> *"First, Boeing has numerous concerns related to the methodology and use of data in the report. The report includes many worst-case assumptions and conservative toxicity factors, which result in overly inflated dose ratios. Multiple conservative assumptions, when compounded, result not in a worst-case scenario but one that is highly improbable, if not impossible, and which does not represent potential risk for any single individual or group of individuals. Such overly inflated dose ratios may cause the reader to incorrectly conclude that the SSFL poses an unacceptably high risk, when in reality the actual risk is much lower and in many cases may be at or near zero. Thus, the result is a study that will be prone to misinterpretation and constitute a disservice to the reader.*
>
> *"Second, the report fails to acknowledge numerous conclusions that state and federal agencies have made concerning SSFL and the surrounding communities...The UCLA report utilized essentially the same environmental data base used by the ATSDR study, yet it reached very different conclusions without explaining the basis for such a departure.*
>
> *"Third, the report bases its analysis on the maximum values of a small number of environmental positive detects for soil and water and ignores the totality of the environmental database that is comprised of mostly non-detects, thereby providing inaccurate and misleading portrayals of potential exposure issues. For example, Figure 4-3 of the report presents a map of morgenstern contaminants detected above health-based standards. The map shows the concentration of carbon tetrachloride at nine times the California Maximum Concentration Level. However, this representation is misleading because it fails to indicate that of the 895 offsite analyses conducted for this chemical, there were only 2 off-site detections. Identifying two detections, while failing to mention 893 non-detections, is not a fair and accurate portrayal of the groundwater data. The use of maximum detects to calculate dose ratios is a poor surrogate for estimating community exposures using the entire body of relevant data.*
>
> *"Fourth, the report also ignores crucial facts concerning the question of past exposures. For example, the study suggests that historical exposure to TCE emissions from rocket engine testing/degreasing is a potential concern for many lifelong residents living in eleven "receptor locales." Modeling results show that TCE concentrations rapidly decline with distance from the site (to approximately 2 µg/m^3 at just 1 mile). Approximately 89% of TCE emissions from rocket engine testing/degreasing occurred before 1967. Before 1967, less than twenty residents resided in the census tract encompassing most of the 1- mile area surrounding SSFL. Yet, the study inexplicably lists elevated dose ratios at eleven "receptor locales," some of which are located 5 to 10 miles from SSFL. The report also incorrectly uses the large exhaust rates for large LOX-kerosene engines to estimate emissions from the much smaller hydrazine engines. This has resulted in an over-estimate of hydrazine emissions by at least 100-fold.*
>
> *"Fifth, the report ignores the fact that background levels of some chemicals and radionuclides are found in all soils. The report fails to subtract background from off-site measurements prior to comparing to health based standards. Consequently, off-site measurements of background*

chemicals and radionuclides are incorrectly identified as contamination from SSFL.

"Sixth, the report does not adequately establish exposure pathways. Transport of specific contaminants should be traced from an identified SSFL source, through an air or water transport medium to a receptor (local resident). Specific effects on the food chain, if any, should be identified. Exposure modes should be established (e.g. inhalation, ingestion, dermal contact, etc.). Temporal changes in populated areas should be assessed. Finally, the likelihood of occurrence of the postulated exposure pathways needs to be quantified. Only, then can a realistic risk assessment be performed.

"Seventh, the report repeatedly claims that assessing health risk impacts was not possible and beyond the scope of the study. Yet the report presents dose ratios based on overly conservative estimates of exposures, and then draws conclusions about public health significance.

"Extensive environmental investigations have been ongoing for many years with regulatory agency review and approval. Until this report, the data have shown that neighboring communities have not been adversely impacted by SSFL operations. We have an extensive network of groundwater wells both on and offsite and have been monitoring these wells for 20 years. Based on our testing of known domestic wells in the vicinity of SSFL, we believe offsite receptors are not being exposed to contaminants in drinking water resulting from SSFL operations. Groundwater quality monitoring data show a few sporadic detections, all of which are either below health-based primary drinking water standards, are attributed to well owner activity, are naturally occurring, or are inconclusive as to source of contaminant."

Boeing provides over 50 pages of specific comments. One very important comment addresses the fact that the study ignored plume rise in evaluating air pathways. In Appendix I of the UCLA report, it is stated that sources modeled as point sources used the following parameters:

- "Stack Height: 0 m
- Stack Temperature: 273 K
- Stack diameter: 1 m
- Stack exit velocity: 0 m/s"

Boeing correctly states

"The parameters used do not correctly represent the type of emissions release. Using a stack temperature of 273K (32°F) is too low. Rocket engine testing is a turbulent activity and will cause a plume of pollutants. Depending on the size of the rocket, this plume can reach several hundred feet into the air resulting in significantly more dispersion in the atmosphere than modeled in the report. The exhaust from the engine is also at a significantly higher temperature than 273K. The higher exhaust temperature will also result in more dispersion in the atmosphere."

Boeing also notes *"Stripping towers use an aeration technique. This also results in emissions being released with some vertical velocity resulting in more dispersion in the atmosphere."*

Other documents have noted the presence of temperature inversions as a frequent weather pattern in the vicinity of SSFL. During inversions, with any SSFL airborne emissions being above the inversion, there would be no way for any contaminants to reach the valley floor and the human receptors.

There are numerous factual errors in the UCLA report, such as stating that the cobalt-60 half-life is 5.3 days rather than the correct 5.3 years. It is a long-lived radionuclide, not short-lived. The lack of rigor in

the study and the documentation is particularly troublesome because of the very alarming conclusions reached by UCLA. It should be noted that Professor Cohen never responded to the comments or corrected his document.

Also in 2006, Dr. Alan Warren, Program Director, Environmental Health Science, University of South Carolina Beaufort, was retained by The Boeing Company to comment on the above UCLA study. His comments, which are taken as direct quotations, provide a thorough and thoughtful assessment. [Warren, 2006]

> *"…First, I wish to acknowledge the study's authors who expended considerable effort to conduct "A more in-depth evaluation of exposure pathways…," as recommended in ATSDR's Draft Preliminary Site Evaluation released in 1999. ATSDR's evaluation failed to identify a public health hazard to the communities surrounding SSFL and stated that exposures via all pathways (i.e., air, water and soil) were likely of insufficient magnitude to result in adverse human health effects. It further indicated future exposures of any health consequence were unlikely. The following statements were excerpted from the ATSDR evaluation:*
>
> *"Air Pathway: Based on the distance from the onsite release sources to offsite residential areas, the predominant wind directions, the meteorological conditions at the site, and the rapid dispersion and degradation of oxidants in air, it is unlikely that offsite residents have been, or currently are being exposed to chemicals and radionuclides at concentrations that would result in adverse human health effects.*
>
> *"Ground and Surface Water Pathway: Based on our preliminary review of the available data, there is no indication that residents living near the SSFL have been exposed, or are currently being exposed to chemicals or radionuclides in ground water or surface water at levels that would result in adverse human health effects. Based on the discontinuation of TCE use and the effectiveness of the ground water treatment system, it is unlikely that future exposure to chemicals or radionuclides will occur.*
>
> *"Soil and Sediment Pathway: Based on our preliminary review of the available data, ATSDR has no indication that persons in the community surrounding the SSFL have been, or are currently being exposed to chemicals or radionuclides in soil or sediment from the SSFL at levels that would result in adverse human health effects.*
>
> *"Conclusions: In this preliminary evaluation of available data and information, ATSDR has not identified an apparent public health hazard to the surrounding communities because people have not been, and are currently not being exposed to chemicals and radionuclides from the site at levels that are likely to result in adverse health effects.*
>
> *"Changes in site operations, such as reduced frequency of rocket engine testing, discontinuation of trichloroethylene use, and shut down of nuclear operations make it unlikely that future exposures to the offsite community will occur.*
>
> *"Because the conduct of the present study was a recommendation of ATSDR's evaluation, it is noteworthy that it leaves the reader with quite the opposite impression – that completed exposure pathways exist for numerous chemical and radiological contaminants found offsite in sufficient concentrations to pose an unacceptable health risk. Regardless of the study's intent, this is the message it conveys. Unfortunately, no effort is made in the present study to reconcile*

it with that published by ATSDR just 6 years earlier. This raises an obvious question – what data have been collected or modeled to invalidate the above excerpted statements made by a government agency that consistently applies the precautionary principle and whose self-described mission is to "…serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and diseases related to toxic substances"? In this regard, it is noteworthy that the overwhelming majority of monitoring data compiled and evaluated in the present study was collected prior to 1999 and was thus available to ATSDR when formulating its conclusions. Seemingly, the authors of the present study would be obliged to discuss their study in the context of that of ATSDR, especially considering that it was conducted in response to recommendations made in ATSDR's preliminary evaluation and is an ATSDR-funded initiative.

"Due to insufficient data, neither ATSDR's evaluation nor the present study conducted quantitative, site-specific exposure and risk assessments for offsite receptors. In the case of the present study, however, the absence of data does not justify giving credence to an array of potential exposure scenarios regardless of their probability of occurrence, or in the event they did occur, how insignificant the added health risks might be. In fact, the study does so despite what amounts to a lack of empirical evidence for any fully completed exposure pathway for any of the numerous "chemicals of concern." Nonetheless, dose ratios (DRs) were calculated in what can only be described as a screening-level risk assessment apt to mislead those not technically astute enough to differentiate hypothetical from real risk or recognize the study represents the application of the precautionary principle run amuck. Indeed, much of the problem stems from the numerous worst-case assumptions freely integrated into dosage calculations that when examined relative to inherently conservative toxicity factors, result in grossly inflated DRs. Such DRs create the false impression that a particular exposure scenario may pose an unacceptably high risk, when in reality, the actual risk is much lower and in many cases at or near zero. In other words, multiple conservative assumptions, when compounded, result not in a worst-case scenario but one that is highly improbable, if not impossible, and pertains to no single individual or group of individuals. Therefore, the implementation of a worst-case strategy has resulted in a study that can be likened to "throwing stuff at a wall to see what sticks," rather than an attempt to determine those exposure pathways that are complete and the real risk, if any, associated with them. We are thus left with a study prone to misinterpretation that will be cited in support of the argument that chemicals and/or radionuclides emanating from SSFL are a plausible explanation for every past, present and future illness and untimely death of unknown etiology.

"The present study makes no attempt to hide its extreme conservatism, though in this case admitting to the problem is not the first step in its solution. What is done is done and the best approach now is to minimize the potential for the report to misrepresent the risk posed by SSFL before its finalization. To this end, an additional section should be drafted and added to Chapter 8.0 that fully discusses the conservatism that pervades the study and the implications that compounded conservatism has on the relevance of the report for any one individual or group of individuals. The study should also consider the possibility that overly inflated DRs are an ill-conceived means of providing a relative ranking of potential doses for various receptor locations of concern. In this regard, it is important that the study acknowledge the likelihood of health effects occurring with a DR greater than one depends in large part on the margin of safety inherent in the toxicity constant used in its derivation. This necessitates that great care be taken in ranking or prioritizing based on DR comparisons since differences may stem from varying degrees of certainty with which a toxicity constant can be accurately derived rather than

any real difference in the inherent toxicity of the chemicals being compared. This is one reason why one can not necessarily equate the extent to which a DR exceeds one with the level of risk the chemical might pose. This point is particularly relevant given that DRs were derived with an upper-bound as high as 21,000 (i.e., inhalation route for TCE in groundwater), a DR which might be alarming less one realizes the unlikelihood of the exposure scenario and the many unvalidated assumptions on which it is based. Such problems can be avoided in the future if similar studies are treated less like academic exercises and more as a means of allaying the fears of those least likely to incur unusually high risks and focusing concern on those who warrant it.

"With these goals in mind, the study should have attempted to characterize the full distribution of exposure levels in the population as accurately as possible, rather than defaulting to the worst case. Doing so would admittedly have been more difficult, but also more informative. For example, the study suggests that historical exposure to TCE emissions from rocket engine testing/degreasing is a potential concern for many lifelong residents living in eleven "receptor locales." However, 89% of TCE emissions from rocket engine testing/degreasing occurred pre-1967 at a time when less than twenty residents resided in the census tract encompassing most of the 1 mile area surrounding SSFL. Given the precipitous decline in modeled TCE air concentrations with increasing distance from SSFL (concentrations were ~ 2 $\mu g/m^3$ just 1 mile from the site), chronic exposure to TCE emissions would not theoretically result in even one excess cancer based on population estimates and California's TCE inhalation unit risk factor of 2E-6 $(\mu g/m^3)^{-1}$. Nonetheless, the study lists an average DR associated with TCE emissions from rocket engine testing/degreasing of 308 (range: 30 to 1942) for the eleven "receptor locales," some of which are located 5 to 10 miles from SSFL. As such, the study is likely to be unnecessarily alarmist to residents of those "receptor locales" for which a worst-case scenario suggests elevated risks. Another example of the study's bent to portraying exposure issues in a bad light is found in Figure 4-3, which presents a map of groundwater contaminants detected above health-based standards. The map reports that the concentration of carbon tetrachloride was nine times the California MCL, but fails to indicate that of the 895 offsite analyses conducted for the chemical, there were only 2 offsite detections (see Table 7 of ATSDR's 1999 evaluation).

"In addition to the suggestion that a section devoted solely to the study's conservatism be added, it would be helpful if the theoretical risks inferred by numerous DRs well in excess of one were discussed in a broader context using a comparative risk analysis approach whenever possible. For example, a slide was presented at a February 2006 SSFL Workgroup Meeting showing annual average SSFL emissions (1955-2000) relative to those of Los Angeles and Ventura counties in 1990-1993. The slide indicated that with the exception of hydrazine, SSFL was responsible for a miniscule fraction of the hazardous air pollutants emitted (< 5% in the case of TCE). Therefore, any association between air emissions from SSFL and disease rates would be confounded by other sources impacting the "receptor locales" surrounding the site. Such information would suggest that SSFL emissions are at best, a minimal contributor to one's overall risk, thereby allowing the study's results to be placed into proper perspective. This is important given the pending release of a report [Morgenstern, H., et.al., 2007] on cancer incidence surrounding SSFL. Given its worst-case approach, the present study is incapable of providing realistic exposure data to explain differences in cancer incidence rates. The absence of such data explains the epidemiological study's reliance on residential distance from SSFL as a surrogate measure of exposure. The use of such a surrogate will result in almost certain exposure misclassification that can lead to a substantial overestimation or underestimation of the association of the exposure with the cancers under study. As such, it is alone sufficient to cast doubt upon the study as a reliable indicator as to whether SSFL has posed a cancer risk to

nearby residents. If the February 2006 presentation on cancer incidence near SSFL is indicative of the soon-to-be-released epidemiological study, findings suggest historical exposures from SSFL have not posed a considerable cancer risk. Based on the February presentation, very few of the 36 risk ratios (RRs) graphically presented appeared significantly elevated. Furthermore, only three of the 36 reported RRs were in excess of two and all three occurred among Hispanics, very few of whom lived near SSFL when emissions were at their highest. Thus, it appears as though the results of the soon-to-be-released epidemiological study will be largely consistent with the conclusions of ATSDR's preliminary evaluation and fail to support the level of concern for past exposures conveyed by the present study."

Also in 2006, the Groundwater Advisory Panel (Panel) provided the following comments based on a preliminary review of the UCLA Pathway Report, primarily Chapter 7 entitled "TCE Contamination." [Groundwater Advisory Panel, 2006] The report describes in Section 7.2 "A Simplified Conceptual Model of TCE Distribution in SSFL Groundwater." There are both conceptual and factual errors in this section which result in erroneous inferences and conclusions.

1) **UCLA*: "This means that the infiltrating TCE penetrated to depths below the water table and continued to sink until the resistances posed by friction against the fracture walls and buoyancy forces halted its progress".***
   Panel: "*Friction is force that acts only when there is motion. It affects the rate of DNAPL motion, but has no influence on when DNAPL ceases to move. Buoyancy is a driving force always acting to promote downward migration; it can never act to halt the progress of downward migration of DNAPL. Downward motion of DNAPL ceases only when all driving forces are balanced*."
2) **UCLA*: "At SSFL, where fractured flow dominates, DNAPL dissolution is expected to be slow and most of the DNAPL that reaches groundwater may still be harbored in fractures"*.**
   Panel: "*Thousands of measurements of TCE mass present in cores provide overwhelming evidence that no significant DNAPL is now present in the SSFL groundwater. The conclusions drawn from these data are supported by widely accepted calculations of the time required for DNAPL in fractures to dissolve into contiguous waters*."
3) **UCLA: *"Thus, the MW model's estimates of diffusive penetration into sandstone are much higher than would be suggested by the team's estimate of the diffusion coefficient of TCE".***
   Panel: "*This statement in Section 7.3.1 summarizes an inference made at several places that Boeing and its consultants have overestimated the effect of diffusive mass transfer of TCE into the sandstone matrix because sorption may be greater than used by Boeing. However, it is a well known fact that sorption, as characterized by the retardation factor, actually increases the rate of mass transfer from the fracture to the matrix, instead of decreasing it as claimed in the subject report. The reasoning and mathematical support for this fact are described in detail in Chapter 12, "Dense Chlorinated Solvents and Other DNAPLs in Groundwater, Pankow and Cherry, editors. This chapter references and summarizes several papers that are relevant to this issue. Also, it is shown in this chapter that the dependence of mass transfer from fracture to matrix upon tortuosity is not nearly as strong as implied by the authors. In fact, if one uses the values for retardation and tortuosity presented in Section 7.3.1, it is concluded that more TCE has transferred to the matrix than is calculated using typical parameters for SSFL."*

Conclusions

From the epidemiological studies of cancer incidence in the vicinity of the Santa Susana Field Laboratory (SSFL) using cancer registry data, it is clear that there is no evidence of elevated off-site cancer rates resulting from operations at SSFL. The most pessimistic results, cited by Dr. Morgenstern, are within the

range of expected statistical variation and he has acknowledged the methodological limitations of his study.

Dr. Morgenstern also led two health studies of Rocketdyne workers. The first study identified an increased risk of dying from cancers of the blood and lymph system (such as leukemia and lymphoma), lung cancer, and upper aero-digestive tract cancers (mouth, throat, esophagus and stomach). The second study reported the observed positive association between presumptive exposures to hydrazine and the rates of dying from cancers of the lung.

The Agency for Toxic Substances and Disease Registry (ATSDR) of the U. S. Center for Disease Control (CDC) reviewed the above UCLA worker health studies and concluded that the studies were well designed and the data analysis was rigorous, but that the studies had some weaknesses. These included high uncertainty in internal radiation doses, and lack of knowledge of exposures received before employment at SSFL. Although the study attempted to control for the effect of other chemical exposures (i.e., hydrazine and asbestos), misclassification of the chemical exposures is highly likely. The use of the upper aerodigestive tract cancers group is somewhat unusual, although it is meant to take consideration the properties of internally deposited radionuclides. Another problem of the study is the small number of cancer deaths, particularly in the high dose group (e.g., >200 mSv). Most of these limitations are acknowledged appropriately in the report. Given the limitations, the most consistent and biologically plausible finding of the study is the hemato-lymphopoietic cancers. The observed positive relationship between external radiation and lung cancer mortality has not been reported consistently in other studies of nuclear workers.

Boeing sponsored a worker health study conducted by the International Epidemiological Institute which, when compared with the UCLA studies, covered many more workers over a longer period of time and estimated radiation doses from biokinetic models for 16 organs or tissues and combined external and internal dose measurements in their analyses of specific cancers. They also included radiation doses received before and after employment at Rocketdyne; using other databases, and to estimate radiation effects, they compared radiation-monitored workers with unmonitored workers assumed to be unexposed. While the less rigorous UCLA studies showed some possible health effects from worker chemical and radiation exposures, the IEI studies showed none, with the exceptions of cancer of the kidney (SMR 2.22) which was based on only 7 deaths.

The 1999 ATSDR pathway study concluded that it is unlikely that people living in communities near the site have been exposed to substances from the site at levels that would have resulted in adverse health effects, and although chemicals and radionuclides were released from the site, the likelihood of those releases resulting in human exposure is limited by a number of factors, including: the distance from the release sources to the offsite residential areas that results in rapid dispersion and degradation of oxidants and solvents in air; the predominant wind patterns that normally blow away from the nearest residential areas; other meteorological conditions at the site such as the atmospheric mixing height; and drawdown in ground water levels that reduce the rates of contaminant migration. ATSDR stated that considering these factors, it is unlikely that residents living near the site are, or were exposed to SSFL-related chemicals and radionuclides at levels that would result in adverse human health effects. Changes in site operations, such as reduced frequency of rocket engine testing, discontinuation of trichloroethylene use, and shut down of nuclear operations make it unlikely that future exposures to the offsite community will occur.

Professor Yoram Cohen of UCLA led a pathway study that used essentially the same data as ATSDR, yet reached the opposite conclusion that residents in many areas adjacent to SSFL were at substantial risk

from contamination resulting from SSFL operations. Both Boeing and Dr. Alan Warren provided extensive comments to Professor Cohen, but despite the acknowledged extreme conservatism of the assumptions and analyses of his study, he failed to respond to the comments. The comments document the reasons why Professor Cohen's conclusions lack sufficient technical basis.

It is interesting to note that Dr. Morgenstern and Professor Cohen were both members of the UCLA Santa Susana Field Laboratory (SSFL) Public Health Initiative and their work was sponsored and directed by the Santa Susana Advisory Panel, led by Dan Hirsch, and publicized by the SSFL Workgroup, also led by Dan Hirsch. The publicized conclusions of the UCLA investigators seem to be at variance with those of all of the other epidemiologists and toxicologists, whether in public or private service. It is disingenuous to claim that the UCLA investigators are more credible because they were independent, while the others were not. Dan Hirsch is an avowed antinuclear activist who has litigated against Boeing, DOE, and DTSC, and is certainly not independent. The close relationship between Professor Cohen and Dan Hirsch can be seen from the following excerpt from the UCLA Newsroom [UCLA, 2008]:

> *"The Rosenfield Prize recognizes innovative collaborations between faculty and regional nonprofits aimed at addressing critical issues affecting the community. This year's honorees have focused on issues involving the environment, health care, teen suicide prevention and theater. Each partnership will receive a $25,000 award.*
>
> *"Yoram Cohen / Committee to Bridge the Gap*
> *Cohen, a professor of chemical and biomolecular engineering, and the Committee to Bridge the Gap, a nuclear policy organization focused on nuclear safety, waste disposal, proliferation issues and disarmament, joined to help Simi Valley and its surrounding communities deal with environmental issues associated with the Santa Susana Field Laboratory, a site used until 1959 for the development of nuclear reactors and currently owned by Boeing. The partnership educated the public about the adverse environmental and health impacts associated with the release of chemical contaminants and radionuclides from various operations at the site and conducted a study that found that hazardous chemicals from the site had reached off-site locations. This four-year scientific and community effort contributed to the development and passage of a bill, authored by state Sen. Sheila Kuehl, to ensure the proper cleanup of the site and its designation as a state park when Boeing vacates the area."*

The completely opposite conclusions of the UCLA researchers and the others exactly mirror the polarization within the community. Both views cannot be correct. It would be extremely beneficial to the resolution of the issues relating to purported health effects from SSFL operations, to have a public workshop where the various authors of these health studies can meet and discuss the reports and the comments and see if there is a technically sound commonality. The SSFL cleanup discussion needs to move beyond partisan advocacy into the realm of science-based decision-making.

Table of Acronyms

Acronym/Abbreviation	Definition
1,1-DCE	Dichloroethene/Dichloroethylene
AEC	Areas of exposure concern
ANLL	Acute Non-Lymphocytic Leukemia
ATSDR	Agency for Toxic Substances and Disease Registry
CalEPA/DTSC	California Environmental Protection Agency/Department of Toxic Substances
CBG	Committee to Bridge the Gap
CDC	Centers for Disease Control
CDHS	California Department of Health Services
CI	Confidence Interval
CLL	Chronic lymphocytic leukemia
DHS	Department of Health Services
DNAPL	Dense non-aqueous phase liquid
DOE	Department of Energy
DRs	Dose Ratios
DTSC	Department of Toxic Substances Control
F	Fahrenheit
HML	Hazardous Materials Laboratory; part of the DTSC
IEI	International Epidemiology Institute
K	Kelvin
LA	Los Angeles
MCL	Maximum Concentration Level
mSv	milliSievert
n	number
NIOSH	National Institute for Occupational Safety and Health
p	probability
RB	retinoblastoma
RR	Relative risk
SIR	Standard Incidence Ratio
SMR	Standard Mortality Ratio
SSFL	Santa Susana Field Laboratory
TCE	Trichloroethylene/Trichloroethene
TCSP	Tri-Counties Cancer Surveillance Program
TRCR	Tri-County Regional Cancer Registry
UCLA	University of California at Los Angeles
VEN	Ventura
$\mu g/m^3$	microgram/cubic meter

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