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PROJECT RANCH HAND II

**A WHITE HOUSE DIRECTED EPIDEMIOLOGIC INVESTIGATION
OF POSSIBLE ADVERSE HEALTH EFFECTS ATTRIBUTABLE TO
HERBICIDE EXPOSURE AMONG OPERATION RANCH HAND
PERSONNEL**

STUDY DESIGN

IDENTIFY EXPOSED POPULATION

SELECT COMPARISON POPULATION

**DETERMINE BASELINE HEALTH STATUS OF THE TWO
GROUPS**

- **MORTALITY**

- **DISEASE OR ABNORMALITY (MORBIDITY)**

**COMPARE FINDINGS STATISTICALLY TO DELINEATE
POSSIBLE HERBICIDE EFFECTS**

ACCOMPLISH FOLLOW UP STUDIES OF POPULATIONS

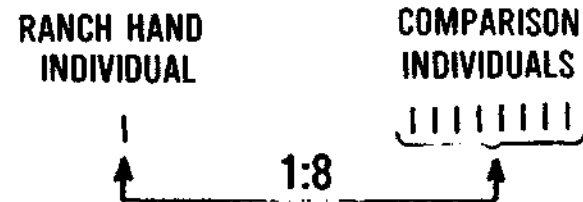
STUDY POPULATIONS

ALL RANCH HAND MEMBERS WHO SERVED IN VIETNAM DURING
1962-1971 IDENTIFIED (1,200+)

COMPARISON GROUP COMPOSED OF CARGO FLIGHT CREW MEMBERS AND
SUPPORT PERSONNEL IN SOUTHEAST ASIA DURING SAME PERIOD
BUT NOT OCCUPATIONALLY EXPOSED TO HERBICIDE (19,000+)

EIGHT COMPARISON SUBJECTS MATCHED TO EACH RANCH HANDER BY:

- JOB CATEGORY
- RACE
- AGE



EXPOSURE INDEX DEVELOPED FOR RANCH HAND POPULATION

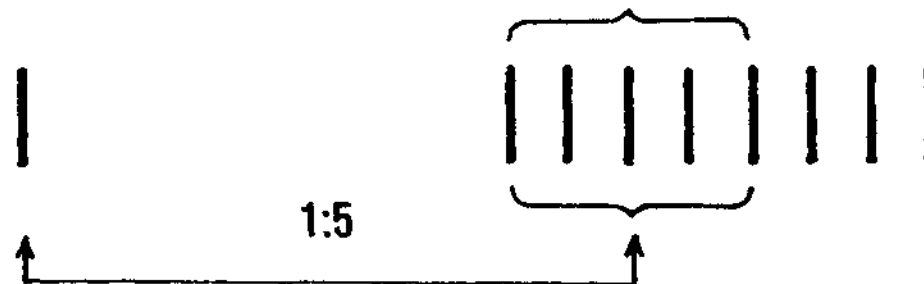
MORTALITY PORTION

FIVE INDIVIDUALS RANDOMLY ORDERED IN EACH COMPARISON SET
MORTALITY EXPERIENCE OF THE FIVE COMPARISON SUBJECTS
COMPARED TO A RANCH HANDER

RANCH HAND INDIVIDUAL

COMPARISON INDIVIDUALS

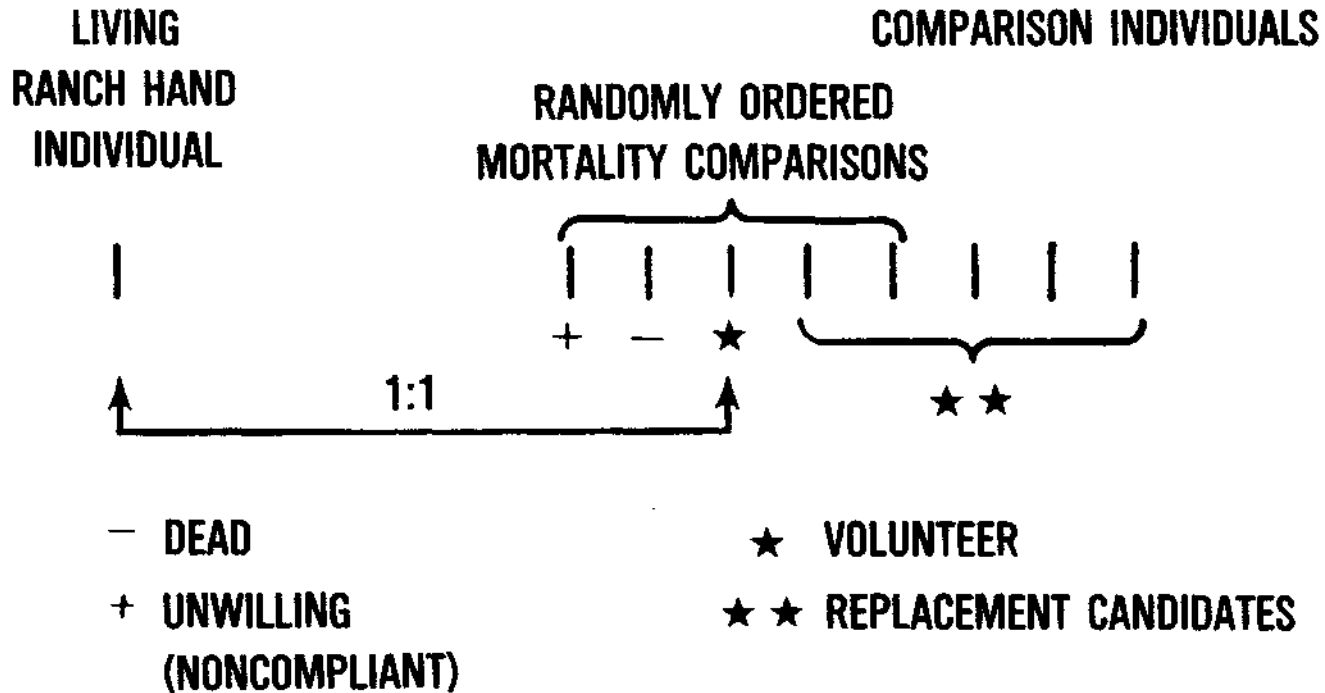
RANDOMLY ORDERED
MORTALITY COMPARISONS



MORBIDITY PORTION

FIRST INDIVIDUAL IN 5 MEMBER MORTALITY SET USED FOR COMPARISON STUDY

- IF COMPARISON SUBJECT DECEASED OR NON-COMPLIANT, NEXT COMPLIANT SUBJECT SELECTED



MATCHING PROCEDURES

INITIAL MATCH

RANCH HAND INDIVIDUAL



1 : 8

COMPARISON INDIVIDUALS



MATCH FOR MORTALITY PORTION

RANCH HAND INDIVIDUAL



1 : 5

COMPARISON INDIVIDUALS

RANDOMLY ORDERED

MORTALITY COMPARISON



MATCH FOR MORBIDITY PORTION

LIVING RANCH HAND INDIVIDUAL



1 : 1

COMPARISON INDIVIDUALS

RANDOMLY ORDERED

MORTALITY COMPARISONS



+ DEAD

★ VOLUNTEER

- UNWILLING

★ ★ REPLACEMENT CANDIDATES

QUESTIONNAIRES

DEVELOPED AND ADMINISTERED UNDER CONTRACT

- **INCORPORATED DATA FROM EXTENSIVE LITERATURE REVIEW AND VETERANS' COMPLAINTS AND CONCERNS**

QUESTIONNAIRES DEVELOPED FOR STUDY SUBJECTS, SPOUSES, AND NEXT OF KIN

ADMINISTERED FACE-TO-FACE IN HOME BY OVER 80 ESPECIALLY SELECTED AND TRAINED PERSONNEL

REQUIRED UP TO 3 HOURS TO COMPLETE

PROVIDED OVER 300 ITEMS FROM EACH STUDY SUBJECT FOR ANALYSES

OVER 5000 QUESTIONNAIRES ADMINISTERED

PHYSICAL EXAMINATION

ACCOMPLISHED BY CONTRACT

- **CIVILIAN ORGANIZATION OF NATIONAL STATURE**
- **EXAMINERS UNAWARE OF EXPOSURE HISTORY**

**PARTICULAR EMPHASIS ON DERMATOLOGIC, NEUROPSYCHIATRIC, HEPATIC,
IMMUNOLOGIC, REPRODUCTIVE, AND NEOPLASTIC ASPECTS**

- **BASED ON EXTENSIVE SCIENTIFIC LITERATURE REVIEW**

EXAMINATION REQUIRED THREE DAYS

PROVIDED OVER 1100 ITEMS FROM EACH STUDY SUBJECT FOR ANALYSES

OVER 2200 EXAMINATIONS ACCOMPLISHED

MORBIDITY PORTION PARTICIPATION

	RANCH HAND		COMPARISON	
	1206 POTENTIAL SUBJECTS		ORIGINAL	REPLACEMENTS
QUESTIONNAIRE	1174	(97%)	956 (93%)	576 (90%)
EXAMINATION	1045	(87%)	774 (76%)	450 (71%)

BASELINE MORTALITY PORTION RESULTS

RELEASED JUNE 1983

**EVALUATED 50 RANCH HAND AND 250 COMPARISON SUBJECTS WHO
DIED FROM NONCOMBAT CAUSES**

SMALL NUMBER EMPHASIZES PRELIMINARY NATURE OF RESULTS

RESULTS

- **MORTALITY EXPERIENCE NEARLY IDENTICAL IN RANCH HAND
AND COMPARISON GROUPS**
- **CAUSE SPECIFIC ANALYSES NOT STATISTICALLY DIFFERENT**

MORBIDITY PORTION RESULTS

**LACK OF CLEAR CUT HALLMARKS REQUIRED COMPREHENSIVE
EVALUATION OF NUMEROUS SYSTEMS**

- **GENERAL PHYSICAL HEALTH**
- **MALIGNANCY**
- **FERTILITY/REPRODUCTIVE**
- **NEUROLOGY**
- **PSYCHOLOGY**
- **HEPATIC**
- **DERMATOLOGY**
- **CARDIOVASCULAR**
- **IMMUNOLOGY**
- **HEMATOLOGY**
- **PULMONARY**
- **RENAL**
- **ENDOCRINE**
- **INDIVIDUAL HEALTH**

GENERAL PHYSICAL HEALTH

- **SIGNIFICANT GROUP DIFFERENCE FOUND IN SELF-PERCEPTION OF HEALTH WITH MORE RANCH HANDERS PERCEIVING THEMSELVES TO BE IN FAIR OR POOR HEALTH**
 - **NOT SUPPORTED BY EXPOSURE INDEX ANALYSES**
- **BORDERLINE SIGNIFICANT GROUP DIFFERENCE IN THE EXAMINER'S ASSESSMENT OF ILLNESS OR DISTRESS (RH>C)**
 - **NOT SUPPORTED BY EXPOSURE INDEX ANALYSES**
- **NO SIGNIFICANT GROUP DIFFERENCES IN PERCENT BODY FAT OR HEMATOCRIT**
- **SIGNIFICANTLY MORE INDIVIDUALS WITH SEDIMENTATION RATE ABNORMALITIES IN THE YOUNGER COMPARISONS THAN IN THE RANCH HANDERS**
 - **NO OVERALL GROUP DIFFERENCES OBSERVED**

MALIGNANCY

- **NO SIGNIFICANT DIFFERENCE IN THE OCCURRENCE OF "SYSTEMIC" CANCER**
- **NO SOFT TISSUE SARCOMA FOUND RANCH HANDERS**
 - **ONE CASE FOUND IN COMPARISONS**
- **SIGNIFICANTLY MORE POST-SEA SKIN CANCER IN THE RANCH HAND GROUP THAN IN THE ORIGINAL COMPARISONS WHO COMPLETED PHYSICAL EXAMINATION**
 - **DIFFERENCE ONLY BORDERLINE WITH TOTAL COMPARISON GROUP**
 - **ANALYSES NOT FULLY ADJUSTED FOR SUN EXPOSURE (GEOGRAPHIC AREA OF RESIDENCE)**
 - **NON-MELANOMA CELL TYPE PREDOMINATES**
 - **FACE, HEAD AND NECK PREDOMINANT DISTRIBUTION**

MALIGNANCY (CONT'D)

- **ANALYSES DEMONSTRATED ASSOCIATION BETWEEN SMOKING AND "SYSTEMIC" CANCER AND INDUSTRIAL CHEMICAL EXPOSURE AND SKIN CANCER IN BOTH GROUPS**
- **SLIGHTLY MORE GENITOURINARY CANCER (6 TO 3), MORE OROPHARYNGEAL CANCER (4 TO 2), AND LESS GASTROINTESTINAL CANCER (0 TO 5) IN RANCH HAND GROUP, BUT DIFFERENCE NOT SIGNIFICANT**
- **EXPOSURE INDEX ANALYSES REVEALED NO STATISTICALLY SIGNIFICANT OR SUGGESTIVE ASSOCIATIONS BETWEEN HERBICIDE EXPOSURE AND EITHER SKIN OR "SYSTEMIC" MALIGNANCY**

VERIFIED SKIN AND SYSTEMIC CANCER

	<u>RANCH HAND</u>	<u>ORIGINAL</u> <u>COMPARISONS</u>	<u>ALL</u> <u>COMPARISONS</u>
	NUMBER (%)	NUMBER (%)	NUMBER (%)
<u>SKIN CANCER</u>	35 (3.3)	11 (1.4)	25 (2.1)
<u>SYSTEMIC SITE</u>			
LIP, MOUTH, THROAT	4	2	2
DIGESTIVE SYSTEM	0	4	5
RESPIRATORY	3	1	2
GENITOURINARY	6	2	3
BLOOD, LYMPH	0	0	1
OTHER	1	1	1
TOTAL	14 (1.3)	10 (1.3)	14 (1.2)

FERTILITY/REPRODUCTIVE

- OVER 7000 CONCEPTIONS EVALUATED
- NO SIGNIFICANT GROUP DIFFERENCES
 - SPERM COUNT, PERCENT ABNORMAL
 - FERTILITY/INFERTILITY
 - MISCARRIAGE, STILLBIRTH, LIVE BIRTH
- SIGNIFICANT GROUP DIFFERENCE (RH > C)
 - REPORTED BIRTH DEFECTS
 - NO SIGNIFICANT DIFFERENCE WHEN SKIN ANOMALIES (BIRTH MARKS, BLEMISHES, etc.) REMOVED
 - REPORTED PHYSICAL HANDICAPS
 - REPORTED NEONATAL DEATH
- MEDICAL RECORD VERIFICATION OF REPORTED EVENTS UNDER WAY
- NO CONSISTENT PATTERN WITH INCREASING EXPOSURE

REPORTED POST-SEA DEFECTS BY SEVERITY

RANCH HANDERS (RH) VERSUS ORIGINALS (O)

		<u>RH</u>	<u>O</u>	
SEVERE	Y	32	18	P 0.20
	N	885	726	
MODERATE	Y	22	20	P 0.71
	N	895	724	
LIMITED	Y	26	10	P 0.04
	N	891	734	

RANCH HANDERS (RH) VERSUS ALL COMPARISONS (A)

SEVERE	Y	32	34	P 0.22
	N	885	1,275	
MODERATE	Y	22	34	P 0.77
	N	895	1,275	
LIMITED	Y	26	18	P 0.01
	N	891	1,291	

INDIVIDUAL HEALTH (CONT'D)

- **NO SIGNIFICANT DIFFERENCE IN DISTRIBUTION OF ILL INDIVIDUALS**
- **GROUP DIFFERENCES ONLY FOR**
 - **SKIN CANCERS, NOT CORRECTED FOR SUN EXPOSURE**
 - **PULMONARY FUNCTION**
(MORE ABNORMALITIES IN COMPARISON)
- **BOTH GROUPS IN GOOD HEALTH FOR AGE**

NEUROLOGY

- **NO SIGNIFICANT GROUP DIFFERENCES IN CRANIAL NERVE FUNCTION**
- **NO SIGNIFICANT GROUP DIFFERENCES IN TESTS OF PERIPHERAL NERVES EXCEPT FOR A BORDERLINE DIFFERENCE IN BABINSKI REFLEX**
 - **EFFECTS OF ALCOHOL USE AND ABNORMAL GLUCOSE METABOLISM DEMONSTRATED IN BOTH GROUPS**
- **NO GROUP DIFFERENCES IN CENTRAL FUNCTION (TREMOR, COORDINATION, ROMBERG, GAIT)**
- **NO SIGNIFICANT GROUP DIFFERENCES IN NERVE CONDUCTION VELOCITY**
- **NO DOSE RESPONSE EFFECT OBSERVED FOR PERIPHERAL NERVES, CRANIAL NERVES, CONDUCTION VELOCITY, OR CENTRAL FUNCTION**

PSYCHOLOGY

- **COMPREHENSIVE GROUP OF VALIDATED TESTS USED**
- **ANALYSES STRATIFIED BY EDUCATION**
 - **REFLECTED KNOWN SUBSTANTIAL EFFECT OF EDUCATION ON PSYCHOLOGICAL TESTING**
- **SUBJECTIVE MEASURES SHOWED SIGNIFICANT GROUP DIFFERENCES FOR HIGH SCHOOL EDUCATED PERSONNEL (QUESTIONNAIRE, CORNELL INDEX, MMPI)**
 - **NOT OBSERVED IN THE COLLEGE EDUCATED INDIVIDUALS**
- **NO DIFFERENCES IN IQ OR PERFORMANCE TESTING**
- **NO DOSE RESPONSE EFFECTS OBSERVED**

HEPATIC

- RANCH HANDERS REPORTED MORE LIVER SYMPTOMS IN PAST
 - NO CLINICAL EVIDENCE OF SIGNIFICANT GROUP DIFFERENCES AT EXAMINATION
- OVERALL BIOCHEMICAL GROUP DIFFERENCES:
GGPT (RH > C), LDH (RH > C), CHOLESTEROL (RH < C)
- NO OVERALL GROUP DIFFERENCES:
SGOT, SGPT, ALK. PHOS. T. BILI, D. BILI, TRIGLYCERIDES, UROPORPHYRIN,
COPROPORPHYRIN, D-ALA
- NO PORPHYRIA CUTANEA TARDA DETECTED
- NO DOSE RESPONSE EFFECT OBSERVED

DERMATOLOGY

- **QUESTIONNAIRE RESPONSES SHOWED NO GROUP DIFFERENCES FOR**
 - **OCCURRENCE OF PAST ACNE**
 - **OCCURRENCE OF PAST ACNE RELATIVE TO INDIVIDUAL'S SEA TOUR**
 - **SEVERITY OR DURATION OF PAST ACNE**
 - **ANATOMIC LOCATION OF PAST ACNE SUGGESTING CHLORACNE**

DERMATOLOGY (CONT'D)

- **PHYSICAL EXAMINATION SHOWED**
 - **NO CLINICAL DIAGNOSES OF CHLORACNE**
 - **NO POSITIVE BIOPSIES FOR CHLORACNE**
 - **NO GROUP DIFFERENCES IN THE PREVALENCE OF THE 5 MOST COMMON DERMATOLOGIC DIAGNOSES**
- **EXPOSURE INDEX ANALYSES WERE NEGATIVE**

CARDIOVASCULAR

- **PHYSICAL EXAMINATION SHOWED SIMILAR GROUP FINDINGS FOR**
 - **SYSTOLIC, DIASTOLIC BLOOD PRESSURES**
 - **ABNORMAL ECG'S**
 - **COMPARISON OF PAST ECG'S TO THE EXAM ECG**
 - **HEART SOUNDS**
 - **FUNDUSCOPIC ABNORMALITIES**
 - **CAROTID BRUITS**
- **NO PREMATURE HEART DISEASE IN THE RANCH HANDERS**

CARDIOVASCULAR (CONT'D)

- **SOME PERIPHERAL PULSES DECREASED IN RANCH HANDERS**
 - **SIGNIFICANCE UNCERTAIN**
- **ANALYSES DEMONSTRATED EFFECTS OF**
 - **AGE**
 - **SMOKING, PAST AND PRESENT**
- **HERBICIDE EXPOSURE ANALYSES WERE ESSENTIALLY NEGATIVE FOR
CARDIOVASCULAR ABNORMALITIES**

IMMUNOLOGY

- **NO GROUP DIFFERENCES**
- **SMOKING, ALCOHOL, AGE EFFECTS DEMONSTRATED IN BOTH GROUPS**

HEMATOLOGY

- **NO DIFFERENCE IN CLINICALLY SIGNIFICANT BLOOD ABNORMALITIES**
- **DIFFERENCES IN CELL HEMOGLOBIN CONCENTRATION PRESENT**
 - **MOST VALUES STILL WITHIN NORMAL LIMITS**

PULMONARY

- **NO GROUP DIFFERENCES IN REPORTED DISEASE, FORCED VITAL CAPACITY, FORCED EXPIRATORY VOLUME (1 SECOND) OR FEV₁/FVC RATIO**
- **NO CONSISTENT ASSOCIATIONS BETWEEN PULMONARY FUNCTION AND EXPOSURE LEVELS**
- **EXPECTED EFFECTS OF SMOKING HISTORY SEEN IN BOTH GROUPS**
- **NO INDICATION THAT CURRENT PULMONARY FUNCTION WAS AFFECTED BY EXPOSURE TO HERBICIDES**

RENAL

- **NO SIGNIFICANT DIFFERENCES IN TESTS OF RENAL FUNCTION**
- **NO CLINICAL EVIDENCE OF HERBICIDE EFFECT**
- **EXPOSURE INDEX ANALYSES ESSENTIALLY NEGATIVE**

ENDOCRINE

- **SOME THYROID HORMONE GROUP DIFFERENCES**
 - **MOST VALUES STILL WITHIN NORMAL LIMITS**
- **TESTOSTERONE LEVELS INCREASED IN RANCH HANDERS**
 - **MOST VALUES STILL WITHIN NORMAL LIMITS**
- **BLOOD GLUCOSE LEVELS NOT SIGNIFICANTLY DIFFERENT**

INDIVIDUAL HEALTH

- **BOTH GROUPS SIMILAR IN**
 - **RISK TAKING ACTIVITIES**
 - **RELIGIOUS PREFERENCE**
 - **EDUCATION**
 - **PERSONAL AND FAMILY INCOME**
 - **MILITARY STATUS**
 - **REPORTED INJURIES AND POISONINGS**
 - **CURRENT AND PAST USE OF ALCOHOL**
 - **PAST HISTORY OF CIGARETTE, PIPE, CIGAR, USAGE**
- **MORE RANCH HANDERS CURRENTLY SMOKE THAN COMPARISONS**

INTERPRETIVE COMPLEXITIES

- **STATISTICAL ASSOCIATIONS DO NOT MEAN CAUSATION**
- **NO ANALOGOUS HUMAN STUDIES**
- **MANY STATISTICALLY SIGNIFICANT RANCH HAND-COMPARISON GROUP DIFFERENCES ARE NOT OF CLINICAL RELEVANCE**
- **EXPOSURE INDEX ANALYSES ARE UNREFINED**
- **POSITIVE AND NEGATIVE FINDINGS REQUIRE FOLLOW-UP**

SUMMARY

BASELINE MORBIDITY PORTION

**DID NOT DEMONSTRATE DEFINITIVE CLINICAL END POINTS
CONCLUSIVELY ATTRIBUTABLE TO HERBICIDE EXPOSURE**

NO STS, PCT, CHLORACNE DIAGNOSED IN RANCH HANDERS

**DID FIND A NUMBER OF CLINICAL AND SUBCLINICAL
DIFFERENCES**

- **DEFINING SIGNIFICANCE OF SOME DEPENDENT ON
ANALYSES OF DATA NOT YET COLLECTED
(SUN EXPOSURE, BIRTH RECORDS)**
- **MOST VALUES STILL WITHIN NORMAL RANGES**

**SCHEDULED FOLLOW UP EXAMINATIONS WILL PROVIDE
ESSENTIAL DATA NECESSARY TO DEFINE BOTH FALSE
POSITIVES AND ANY FALSE NEGATIVES**

PROJECT RANCH HAND II

BASELINE MORTALITY AND MORBIDITY STUDIES ACCOMPLISHED

**RESULTS CONFIRM EFFECTIVENESS OF PROTOCOL DESIGN AND
IMPLEMENTATION**

INITIAL FINDINGS UNDERSCORE NEED FOR FOLLOW UP OVER TIME

**EXTENSIVE DATA BASE ALREADY OBTAINED WILL ALLOW CONTINUING
DATA ANALYSES**

CONCLUSIONS

- **STUDY MEASURED TRUE HEALTH STATUS TO MAXIMUM EXTENT POSSIBLE**
- **ALL SIGNIFICANT FINDINGS ARE BEING FOLLOWED UP**
- **INSUFFICIENT EVIDENCE TO SUPPORT HERBICIDE CAUSALITY AT THIS TIME**
- **FINDINGS TO DATE SHOULD BE REASSURING TO RANCH HANDERS**
 - **NO CHLORACNE MEANS LOW EXPOSURE VERSUS CHEMICAL WORKER POPULATIONS**
 - **NO MAJOR CLINICAL HEALTH PROBLEMS**
 - **OVERALL GOOD GENERAL HEALTH FOR AGE**

STUDY COMPLEXITIES

- **ENORMOUS DATA BASE (4 MILLION ITEMS)**
- **VALIDITY OF SELF REPORTING IN ABSENCE OF COMPLETE MEDICAL RECORD VERIFICATION**
- **EFFECTS OF MULTIPLE RISK FACTORS (AGE, SMOKING, etc.)**
- **POTENTIAL BIASES**
- **STUDY SCHEDULE**