REPORT ON THE STUDY OF VERNON TOWNSHIP, NJ

December 1988

NEW JERSEY DEPARTMENT OF HEALTH

A BETTER STATE OF HEALTH

STUDY OF THE OCCURRENCE OF CHROMOSOMAL ANOMALIES IN VERNON TOWNSHIP BETWEEN JANUARY 1, 1985 AND JUNE 30, 1987

State of New Jersey
Department of Health

Trenton, New Jersey

December, 1988

INDEX

LIST OF TABLES

LIST OF TABLES, CONTINUED

LIST OF FIGURES

STUDY OF THE OCCURRENCE OF CHROMOSOMAL ANOMALIES IN VERNON TOWNSHIP BETWEEN JANUARY 1, 1985 AND JUNE 30, 1987

SUMMARY

The New Jersey State Department of Health (NJDOH) has been actively studying the occurrence of birth defects and adverse outcomes of pregnancy in Vernon Township, New Jersey since 1982. These studies were initiated in response to concerns about adverse health effects that might be associated with microwave radiation from satellite communication towers.

The following report reviews the results of these years of study and includes references to reports, data, and consultation from other governmental agencies and private citizens. The report covers the period from January 1, 1975 through June 30, 1987.

Vernon Township is located about 40 miles northwest of New York City and borders New York state. According to the 1980 U.S. Census, its population had grown rapidly to 16,302 persons and is dispersed over a large area of 67.25 square miles. In 1974, the communications industry began building and operating earth satellite communications stations there. During the time of the study, three stations operated within a few miles of each other in Vernon.

The NJDOH released a report of its first study in September 1984. This study was challenged by the community group Citizens Against the Towers (CAT), claiming that it did not clearly identify some of the cases of Down Syndrome then known to CAT. The Office of the NJ Public Advocate urged the NJDOH to expand

its study to include any additional cases which might exist. NJDOH called upon the New Jersey Department of Environmental Protection (NJDEP) to assess the radiofrequency radiation environment in Vernon and also requested consultation from the Division of Birth Defects and Developmental Disabilities of the federal Centers for Disease Control (CDC).

The staff of the Division of Birth Defects and Developmental Disabilities of the CDC visited Vernon Township, met with all concerned groups, and reviewed all materials on the situation. After careful review and study, CDC found no evidence that rates of all categories of birth defects and cancers were increased in Vernon. However, the rate of a single type of birth defect, Down Syndrome, was elevated from 1975 through 1981. The CDC report pointed out that there was an "absence of strong evidence that the exposure in question (microwave radiation) can cause cancer or birth defects in humans". In its report issued in November of 1985, CDC made the following recommendations to the NJDOH:

1. Describe the incidence of Down Syndrome from 1982 to 1985.

2. Conduct a case-control study of cytogenetically confirmed infants with Down Syndrome for the years 1975 through 1985, including an in-depth family interview.

3. Measure the range of microwave/radio frequency radiation in Vernon Township.

4. Regularly review cancer and birth defects data from on-going surveillance programs.

5. Establish an advisory panel to review planned activities.

The NJDOH proceeded to act upon the CDC Report recommendations as is described here. In order to determine if

the rate of Down Syndrome and other chromosomal anomalies remained higher than expected, the time period for the study was extended to 6/30/87.

Recommendation #1. Under ordinary circumstances, the accurate ascertainment of cases through the review of medical records and vital statistics information would be a time-consuming process. However, the mobility of the population, the long study period, the large number of Vernon births occurring in New York hospitals, and concerns about confidentiality further complicated the process. The NJDOH pursued several alternative approaches, including direct contacts with physicians and schools as well as newspaper ads, and devoted extensive resources to locating all children fitting the case definition. Copies of the results of chromosomal testing were forwarded to CDC <u>without individual identifiers</u> for independent confirmation of diagnoses.

The occurrence of Down Syndrome was documented from 1975 through 1981, the time period which first caused the community concern. For that period, the NJDOH identified seven (7) cases of Down Syndrome and one (1) case of Trisomy 18 and one (1) case of another chromosomal birth defect, for a total of nine (9) cases, which was the same number ascertained by CDC.

Similarly, the occurrence of Down Syndrome was also documented for the period from 1982 through June 30, 1987. During this latter time period, two (2) cases of Down Syndrome, one (1) case of Trisomy 13, and two (2) cases of other chromosomal birth defects, for a total of five (5) cases, were identified by NJDOH.

In the 1975 to 1981 time period, the observed number of

seven Down Syndrome cases exceeded the number of such cases expected, based on the application of two independent, external sources of rates. This statistically significant elevation confirms the earlier observation of a cluster of Down Syndrome cases in Vernon over that time period.

However, the two observed cases of Down Syndrome in the time period from 1982 to 6/30/87 fall within the range expected. Therefore, there is not a continuing statistically significant excess of Down Syndrome cases occurring in Vernon Township. The absence of significant elevations in rates also extends to other chromosomal defects during that time period.

Recommendation #2. In anticipation of the ability to link estimates of potential exposures to individuals, a case-control study was designed. A case was defined as a live birth to a resident of Vernon Township with the diagnosis of Down Syndrome or another chromosomal anomaly confirmed by karyotype. Four controls were matched to every case based on the year of birth and the age of the mother. During the period from December, 1987 to March, 1988, telephone interviews were conducted with participating cases and their controls. A total of 14 cases qualified for inclusion in the interview portion of the study. However, because of non-participation by three of the mothers and the difficulty of one mother in discussing previous pregnancy losses, data from only 10 cases could be considered for analysis.

In order to determine whether there was a difference in exposure to microwave radiation between the cases and the controls around the time of conception, an estimated value of microwave exposurement would have to be assigned to each case and

each control on a retrospective basis. As explained below, such retrospective estimates could not be determined with any reasonable degree of certainty.

Recommendation #3. In May 1985, the Bureau of Radiation Protection, NJDEP, conducted radiofrequency radiation measurements at each of the site boundaries of the earth satellite facilities in Vernon Township. No conditions of non-compliance with the NJ standards of microwave radiation were found. However, in order to quantify low levels of radiofrequency that were below the dectectability of the instruments used by the NJDEP, the federal Environmental Protection Agency (EPA) was requested to survey the area.

In November 1985, EPA measured microwave radiation at the three earth station facilities and at 25 sites in the community. These data were gathered from satellite uplink and terrestrial microwave communication links. All measurements were very low and did not exceed standards of exposure for the U.S. population.

Despite the low measurements of actual values observed at each of the locations selected and with the advice of the Advisory Panel, NJDOH set out to derive estimates of retrospective values for individuals from computer modeling of the exposure patterns in an effort to complete that aspect of the case-control study. When the panel members disagreed as to the most appropriate model to be used, NJDOH issued a Request for Methodologies to Measure the Exposure to Microwaves in Vernon Township (RFM). Two responses to the RFM were received. NJDOH then requested the National Bureau of Standards (NBS) to review these responses and report to the NJDOH on their technical merit

and validity.

The NBS advised the NJDOH in 1988 that the computed microwave power densities would have large uncertainties. They also affirmed that "the EPA Report is quite thorough, and the reported microwave power density levels appear to be valid." In summary, the NBS advised the NJDOH that the large uncertainties in these calculated values of microwave power density made the value of computerized models for estimating retrospective microwave exposure questionable.

Recommendation #4. A review indicates no elevations in the rates of cancers or in the rates of other reproductive outcomes such as low birthweight. In fact, those infants born recently in Vernon Township appear to have lower rates of birth defects than their counterparts throughout the state.

Recommendation #5. In 1986, a scientific advisory panel was convened with representation from the NJ Public Advocate, the NJ Department of Environmental Protection (NJDEP), the Mayor's Blue Ribbon Panel, and the Citizens Against the Towers (CAT). Six meetings of the panel took place. At the meetings, the diverse expertise of the individual members and the need to bring forth the point of view of the group which each panelist represented, frequently made consensus difficult.

Conclusion. NJDOH has documented that there is no continuation of the earlier increased rate of Down Syndrome in babies born to residents of Vernon Township. Recent measurements of actual levels of microwave radiation found by EPA are all within established standards. Furthermore, there appears to be no method with known reliability for computing past exposures to

microwave energy using retrospective information. Even if there were an adequate number of cases and control to be able to detect differences between the groups, the levels of possible exposures to individuals could not be estimated with any known certainty.

Therefore, NJDOH concludes that the most responsible course is to suspend further work on the the collection and analysis of data from the case-control study. Information gathered from the interview portion of the case-control study cannot serve as suitable substitutes for reliable estimates of exposures on a retrospective basis. Thus, any analysis of interview items could not be used to answer the fundamental question about the possible role of potential microwave exposures. Instead, the NJDOH will continue to monitor the health of babies born to residents of Vernon Township through the State Birth Defects Registry. It will reinstitute active surveillance should any unusual rates of abnormalities occur. In view of the apparent impossibility of retrospective modeling of microwave exposures to any known degree of accuracy, periodic prospective measurements may help in providing baseline values, if needed in the future.

STUDY OF THE OCCURRENCE OF CHROMOSOMAL ANOMALIES IN VERNON TOWNSHIP BETWEEN JANUARY 1, 1985 AND JUNE 30, 1987

I. INTRODUCTION AND BACKGROUND

The New Jersey State Department of Health (NJDOH) has been actively studying the occurrence of birth defects and adverse reproductive outcomes in Vernon Township, New Jersey since 1982. These studies were initially pursued in response to community concerns about adverse health effects that might possibly be associated with any exposures to microwave radiation from satellite communications towers.

This report summarizes the results of these efforts and includes references to reports from other federal, state, and local groups/agencies who contributed data, made measurements, or otherwise provided consultation. The study time frame, a twelve and a half year period from January 1, 1975 through June 30, 1987, encompasses a period of rapid population and industrial growth in the township. Vernon Township is located about 40 miles northwest of New York City and shares a common border with New York State. The township is large, both in terms of its land area of 67.25 square miles and its population of over 16,000 when compared to other municipalities in New Jersey. Table 1 shows some demographic characteristics of Vernon from the U.S. Census. Among variables included in that table, it is important to note the large percentage of its population under 5 years of age (10.46%), which is among the highest in the state.

TABLE 1

SELECTED DEMOGRAPHIC CHARACTERISTICS FROM THE 1980 US CENSUS FOR VERNON TOWNSHIP AND FOR 561 OF NEW JERSEY'S MUNICIPALITIES

VARIABLE	VERNON VALUE	STATE AVERAGE	STATE MINIMUM	STATE MAXIMUM	VERNON RANK*
AREA IN SQUARE MILES	67.25	13.26	.09	113.40	547 +
1980 POPULATION	16302.00	13127.17	192.00	329248.00	436
PERSONS PER SQUARE MILE? POPULATION DENSITY	242.41	3239.33	7.53	43548.89	102
1970 POPULATION	6059.00	12809.88	204.00	381930.00	266
% CHANGE: 1970-1980 POPULATION	169.05	14.77	-89.86	465.43	551 +
% LIVING IN RURAL AREAS	82.28	28.82	.00	100.00	425
MEDIAN HOUSEHOLD INCOME	22085.00	22082.31	9285.00	49484.00	324
MEDIAN FAMILY INCOME	22775.00	24622.96	10010.00	51101.00	261
MEAN HOUSEHOLD INCOME	23840.00	25266.25	11756.00	78956.00	312
MEAN FAMILY INCOME	24560.00	27823.94	11792.00	77812.00	240
PER CAPITA INCOME	7192.00	8651.39	3692.00	25185.00	170
% HIGH SCHOOL GRADUATES OR GREATER	81.30	72.29	25.57	94.37	433
% HOUSING UNITS BUILT BEFORE 1960	22.59	62.57	4.22	100.00	20 -
% OCCUPIED HOUSING UNITS	93.16	94.10	32.68	100.00	137
% OWNER-OCCUPIED HOUSING UNITS	90.36	72.39	12.89	96.73	497
% CROWDED HOUSING UNITS	1.74	2.23	.00	12.32	283
% FEMALES	49.79	51.47	24.29	57.25	63
% NON-WHITES	.80	8.12	.00	98.65	66
% POPULATION UNDER 5 YEARS OF AGE	10.46	6.05	.46	19.30	557 +
% FAMILIES WITH YOUNG CHILDREN & POVERTY	.14	.96	.00	10.82	128

* RANKS ARE IN ASCENDING ORDER, FROM LOWEST TO HIGHEST.

+ RANKS IN THE HIGHEST 5% OF NEW JERSEY'S MUNICIPALITIES.
- RANKS IN THE LOWEST 5% OF NEW JERSEY'S MUNICIPALITIES.

During the same time that many families were moving into Vernon, the communications industry began building and operating earth satellite communications stations there. According to the U.S. Environmental Protection Agency (EPA, 1986), the Vernon Valley is a radio quiet area with respect to radiofrequency and microwave electromagnetic radiation levels. This quietness coupled with its closeness to New York City are the principal reasons making Vernon a good location for such communications facilities. Lower electromagnetic radiation levels result in less interference with the reception of weak signals from satellites. There are presently three stations operating within a few miles of each other in Vernon.

In September of 1982 a community group, Citizens Against the Towers or CAT, was formed to protest the expansion of one of the earth satellite stations in Vernon Township. The group alleged that microwave radiation coming from the satellite stations was causing adverse health effects, including cancer and a variety of birth defects. Of particular concern were possible assocations between exposures of pregnant women to low levels of microwave radiation and the occurrence of birth defects.

The New Jersey State Department of Health (NJDOH) responded to CAT's concerns by initiating its first study. The report of the findings of this effort released in September of 1984 showed that the rate of all birth defects in Vernon Township from 1975 to 1981 did not differ significantly from the rate of all birth defects in the remainder of Sussex County (Halpin and Lawson, 1984). Only in the rate of Down Syndrome was there a difference between Vernon and the rest of Sussex County that approached

statistical significance. However, the report did not stress this single difference among all of the variables compared because the county rate for Down Syndrome was considered to be unusually low.

CAT quickly challenged the results of NJDOH's first report, noting discrepancies between the number of cases with chromosomal anomalies identified by the Department (3 Down Syndrome, 1 Trisomy 18) and the number of cases they had ascertained (8 Down Syndrome, 1 Trisomy 18) for the same time interval. Because of this discrepancy, CAT requested that the Office of Citizens Complaints (OCC) of the Public Advocate review the study. The OCC and NJDOH agreed that further investigation was warranted and a request for assistance from the Centers of Disease Control (CDC) was issued.

In April of 1985, NJDOH contacted the Division of Birth Defects and Developmental Disabilities of the Center for Environmental Health (CEH) of CDC to request a review of the Vernon Township study. At the same time, the Department also requested assistance from the New Jersey Department of Environmental Protection (NJDEP) to assess radiofrequency radiation exposure as a possible health hazard, especially to characterize the ambient radiofrequency radiation environment in Vernon.

In May of 1985, NJDEP's Bureau of Radiation Protection made radiofrequency radiation measurements at each of the site boundaries of the earth-satellite facilities in Vernon. In the course of obtaining those measurements using the two different

types of monitoring instruments described in their report, no conditions of non-compliance with the New Jersey Administrative Code governing exposure to radiofrequency radiation (N.J.A.C. 7:28-42.4, which sets the standard for such exposure at $5mW/cm^2$) were found. Using instrumentation capable of detecting exposures down to $0.01mW/cm^2$, no readings exceeding this level of sensitivity were observed anywhere in Vernon Township. Although NJDEP was confident that additional measurements made around the earth satellite facilities would not exceed New Jersey's Radiofrequency Protection Guidelines, the U.S. Environmental Protection Agency (EPA) was requested to quantify the low levels of radiofrequency that might fall below the detectability of NJDEP's instrumentation.

Representatives of CDC's Division of Birth Defects and Developmental Disabilities came to New Jersey on July 17 and 18, 1985. During that visit, meetings were held with NJDOH, NJDEP, and the Public Advocate. In addition, the representatives of CDC and staff members of NJDOH traveled to Vernon Township, where they toured the residential areas and the earth satellite stations as well as met with public officials and concerned citizens.

During the summer of 1985, the NJDEP arranged for technical assistance from the EPA's Office of Radiation Programs and Region II Office to investigate electromagnetic field levels in the Vernon area; CDC also urged EPA to aid in this study. The agreement between the NJDEP and EPA called for measurements at the perimeter of the satellite earth stations and at 8 or more locations in the community using an expanded set of monitoring

equipment described in the subsequent EPA report (EPA, 1986). EPA solicited suggestions concerning measurement locations from NJDEP, who contacted the Mayor's Blue Ribbon Panel and the Public Advocate for suggestions. In turn, the Public Advocate contacted CAT which elected not to provide a list of sites. Based on the suggestions made by the Mayor's panel and on the judgment of the EPA team, the set of measurement sites were then chosen (see Table 2). The principal rationale in the particular choice of sites was to obtain exposure readings for most of the residential areas in the township and at most of its schools. A secondary goal was to locate points that were topographically elevated, close to the earth stations, and along the transmission azimuth angles from the antennas, in order to allow measurements as close to the axes of the microwave beams as possible. EPA measurements in Vernon Township were conducted from November 10 to 16, 1985.

TABLE 2

LOCATIONS OF MEASUREMENT SITES USED IN THE EPA STUDY

Measurement Sites	Microwave Measurement	Broadcast Measurement	Blue Ribbon Panel Choices
Glenmeadow Primary School	X		X
Rolling Hills Primary School	X		X
Loundsberry Hollow Middle School	X	X	X
Walnut Ridge School	X		X
Vernon Township High School	X	X	X
Luthern Church (Kindergarten)	X		X
Multilearning Ctr. (Kindergarten)			X
Vernon Meth. Church (Kindergarten)	X		X
Highland Lakes Firehouse (Kindergarten) (count 2 sites)	X	X	X
RCA fenceline	X		X
Where RCA's Satcom V beam passes over the nearest ridge	X	X	X
Sussex Hills development	X		X
Memorial field	X	X	X
Stone Hill Condominiums	X		X
Lake Panorama development	X		X
Lake Conway development	X	X	X
Rt. 517 between McPeek & Edsall Rd.	X		X
Barry Lakes development	X	X	X
Scenic Lakes development	X	X	X
Cliffwood Lakes development	X		X
Parking lot in Hidden Valley (ski resort), Curtis Drive	X		
Vanderhoof Court	X		
200 ft. south of Kimberly Lane & Ivy Place	X		
Evergreen Heights development	X		
Upsala College, Wirth Campus	X		
Edsall Road	X	X	

On November 12, 1985 CDC released the written report of their findings and recommendations (Edmonds et al., 1985). CDC did not find any evidence that rates of all categories of birth defects and cancers were increased in Vernon Township. However, the rate of one defect, Down Syndrome, was elevated from 1975 through 1981 though there was an "absence of strong evidence that the exposure in question (microwave radiation) can cause cancer or birth defects in humans" (loc. cit., p. 7). After reviewing the existing data and after considering the existing public health concerns, the CDC report suggested the following plan (loc. cit., p. 12):

1. Describe the incidence of Down Syndrome from 1982 to the present.
2. Conduct a case-control study of cytogenetically confirmed infants with Down Syndrome for the years 1975 through 1985, including an in-depth family interview.
3. Measure the range of microwave/radio frequency radiation in Vernon Township.
4. Regularly review cancer and birth defects data from on-going surveillance programs.
5. Establish an advisory panel to review planned activities.

The EPA report, released in June, 1986, documented that each of the three earth station facilities was surveyed with broad band equipment and frequency-specific data were collected at 25 sites in the surrounding community. EPA gathered data in satellite uplink, terrestrial microwave, and broadcast band frequencies. The most restrictive power density limit in the New Jersey regulations is 1000uW/cm^2. The highest power density found in any publicly accessible area in Vernon was 60uW/cm^2 on

the property of one of the earth stations. In the surrounding community, the highest peak power density found was approximately 0.003uW/cm^2 in a frequency band that is not used for satellite uplink transmissions. Typical power density values found by EPA over all the frequency bands studied were below 0.001uW/cm^2, which is also far below the 0.005uW/cm^2 median power density to which most of the U.S. urban population is exposed.

Later in 1986, a review of all studies of the situation in Vernon Township, including those done by CAT, NJDOH, NJDEP, CDC, and EPA, was published (Becker and Becker, 1986). That review, critical of all the studies except for the one done by CAT, stated that the observed excesses of genetic defects (along with the alleged clustering of other birth defects and malignancies) were not randomly distributed throughout the township and also challenged the EPA analysis of microwave power density measurements.

In 1987, at the request of the representative of CAT on the advisory panel that was established (described in a later section), a written critique of the Beckers' article was prepared by the representative of NJDEP on panel. The lengthy critique that resulted (Petersen, 1987A) pointed out a number of technical flaws in the Beckers' article and challenged their analyses and interpretations of the results in the EPA study. In a similarly lengthy re-rebuttal to Petersen's critique (found in Morton, 1987), the Becker's repeated their earlier allegations about clustering.

The Beckers' review did not address some obvious flaws in the CAT study. First, as made clear in the CDC report, one of

the Down Syndrome cases identified by CAT was not a resident of Vernon. This mistake was apparently repeated in a more recent letter discussing the "cluster" issue (Becker, 1988). Second and more important, the CDC report pointed out that the ascertainment methods used by CAT identified fewer cases of other birth defects than would have been expected from applying external rates. Thus, despite CAT's claims of "clustering" of various outcomes, there was no evidence of elevation in health outcomes outside of the original identification of the excessive number of Down Syndrome cases.

The remaining portions of this report detail NJDOH's responses to the recommendations made in the report by the Centers for Disease Control (Edmonds et al., 1985).

II. IMPLEMENTATION OF THE COMPONENTS OF THE CDC PLAN

This section describes the activities that NJDOH undertook to implement each component of the plan recommended by CDC. In large part, the sequence in which the recommendations are presented reflects the temporal order of NJDOH's attempts to address the major points raised in the CDC report. In order to determine if the rate of Down Syndrome and other chromosomal anomalies remained higher than expected, the time period for the study was extended to 6/30/87. Thus, the discussions of the implementation of some of the CDC recommendations will refer to the expanded interval.

A. Describe the incidence of Down Syndrome from 1982 to the present.

Because of the discrepancies in case ascertainment previously noted by CAT and because of ongoing concerns about the possibility of continuing adverse health effects due to exposures of microwave radiation from the earth satellite stations, NJDOH emphasized the description of the incidence of Down Syndrome in Vernon Township since 1982. As part of the description of current incidence rates, CDC also recommended that the definition of cases be expanded to include all births to residents of Vernon Township with the diagnosis of Down Syndrome or any other chromosomal anomaly confirmed by karyotype, even though non-Down Syndrome anomalies were not involved in the identification of the original cluster. It was recommended that such confirmation extend to all cases ascertained, including both those previously noted from the 1975 to 1981 time period as well as those born

more recently (i.e., a clinical diagnosis of Down Syndrome was not sufficient).

Listed in Figure 1 below are the ICD-9 codes and the specific chromosomal anomalies satisfying the case definition criterion (codes in the 758.0 to 758.9 range). ICD-9 codes in the range of 759.7 to 759.9 are also included here to ensure that chromosomal anomalies are not obscured in other, less well-defined diagnostic categories.

FIGURE 1

Diagnostic Categories Included in the Definition of Cases

758.0 - Down's syndrome, Trisomy 21 or 22.

758.1 - Patau's syndrome, Trisomy 13.

758.2 - Edward's syndrome, Trisomy 18.

758.3 - Autosomal deletion syndromes.

758.4 - Balanced autosomal translocation in normal individuals.

758.5 - Other conditions due to autosomal anomalies.

758.6 - Gonadal dysgenesis.

758.7 - Klinefelter's syndrome.

758.8 - Other conditions due to sex chromosome anomalies.

758.9 - Conditions due to anomaly of unspecified chromosome.

759.7 - Multiple congenital anomalies, so described.

759.8 - Other specified anomalies.

759.9 - Congenital anomaly, unspecified.

---

1. Case Ascertainment.

Under ordinary circumstances, the accurate ascertainment of

children fitting the case definition given above would be a time-consuming process. However, the mobility of the population due to the long study period, the large number of Vernon births occurring in New York hospitals, and concerns about confidentiality further complicated the process of case finding in the present study. As a consequence, NJDOH pursued several alternative approaches and devoted extensive resources to locating all children fitting the case definition. Furthermore, changes in NJDOH computerized system for vital records made it necessary to divide case ascertainment in two time frames: (1) children born from 1975 to 1984; and (2) children born from 1985 to June 30, 1987.

For all births to residents of Vernon Township occurring in the time period from 1975 to 1984, a computerized line-listing was produced from Vital Statistics information. From this list, all New Jersey hospitals where these births took place were identified. Depending on whether or not a given hospital accounted for 2 per cent or more of the births to Vernon residents, two types of record reviews were undertaken.

The first type of record review took place in those hospitals where at least 2 per cent of the Vernon births occurred. In these facilities NJDOH personnel reviewed the medical records using line-listings of discharge diagnoses. When a diagnostic code reflected one of the qualifying chromosomal anomalies, the entire medical chart was pulled. The residence of the infant was then checked against the line-listing from Vital Statistics to determine if the baby was, in fact, born to a

resident of Vernon Township. For those infants that fit the case definition, the following information was pulled from the medical chart: (a) a copy of the chart's facesheet; (b) maternal prenatal history; (c) pathology reports; (d) chromosomal studies; and (e) the discharge summary. Small samples of medical records of other infants were also pulled to verify that the discharge listings accurately reflected diagnoses found in the charts. Access to medical records was obtained through the law establishing the New Jersey Birth Defects Registry (Public Law 1983, Chapter 291), which authorizes NJDOH to collect and review medical information on live born infants affected by congenital abnormalities. The 1983 law requires the confidential reporting to NJDOH by physicians of all children with birth defects diagnosed from birth through one year of age. Since the registry is connected with an active service delivery network, parents are informed when their children are registered.

In the second type of record review, personnel in the hospitals were utilized because of the small number of births. Thus, for those births in the 1975-1984 time period that occurred in other New Jersey facilities accounting for less than 2 per cent of the Vernon live births, each hospital was sent a list of its births from Vernon residents and asked to pull those medical records which had a discharge diagnosis of a chromosomal anomaly (ICD-9 codes 758.0 - 758.9 and 759.7 - 759.9). Furthermore, because of the smaller number of births in the second time frame, this second type of record review procedure was also followed for all births, in-state as well as out-of-state, from 1985 to June 30, 1987.

For births to Vernon residents that occurred in New York facilities, the New York Biostatistics Department was asked to provide line-listings of Vernon residents for each hospital. These hospitals were contacted and requested to review the discharge diagnoses of the Vernon births. Again, if an infant had a diagnosis within the ICD-9 codes specified, a copy of the medical record was requested. Unfortunately, since New York is not mandated to follow New Jersey Law, not all New York hospitals complied with NJDOH's request. Finally, the New York Birth Defects Registry was also contacted, but because of their laws on confidentiality, was unable to provide any useful information on Vernon births.

Within NJDOH, the Birth Defects Registry was periodically accessed to obtain lists of children with chromosomal anomalies who were residents of Vernon Township. These lists were used to establish the minimum number of abnormalities and were always cross-referenced with the list of anomalies obtained by the medical record review. However, since 1985 when a completely new data collection and processing system was implemented, the registry has included all cases identified to date.

The public school administrator of Vernon Township was also contacted to provide a list of children enrolled in the public school system (from 1975 to 1986) that met the study's case definition. Although confidentiality laws forbade childrens' names from being released, NJDOH requested that the administrator forward letters to the parents asking for their cooperation in the study.

Selected New Jersey and New York health care professionals provided yet another source for potential cases. Among the types of individuals contacted and asked to submit any information they had on Vernon children with chromosomal defects were the following: (a) obstetricians; (b) pediatricians; (c) certified nurse midwives; (d) family practitioners; and (e) pediatric and obstetric subspecialists. The professionals selected for contact were those having a large number of Vernon residents in their practices.

In late May and early June of 1987, NJDOH ran an advertisement in newspapers serving Vernon Township. The advertisement was intended to solicit the participation of additional potential case-families in the study. This method of obtaining case participation was strongly urged by CAT. In an effort to comply the ad was assembled with the assistance of CAT, the Mayor's Blue Ribbon Panel, and the study's advisory panel. The resulting notice ran a total of 9 times in 4 different local newspapers in the Vernon area over a 13 day period of time.

Various state agencies charged with providing services to children with special needs were also contacted as part of the case ascertainment process. Among the agencies included in this part of the effort were the following: (a) purchase of service centers; (b) early intervention programs; (c) developmental centers; (d) day training programs; and (e) Sussex County Association for Retarded Citizens. Initially, these agencies were contacted by phone. Then, a follow-up letter was sent out. All agencies indicated a willingness to participate with the

study and submitted verification of any information they had on potential case children.

Another source of potential cases was the cytogenic laboratories where amniotic fluid testing and karyotyping for Vernon residents might have been done. The laboratories contacted included all of the cytogentic labs in New Jersey, along with referral centers in Pennsylvania and New York (one and two each, respectively). Unfortunately, in addition to the usual concerns about confidentiality, the paucity of available computerized data about recent test results meant that the labs were unable to be helpful in locating any potential cases.

Finally, on December 2, 1987 letters were sent to all participants on the study's advisory panel and to the groups they represented requesting their cooperation in locating all potential cases that might not have come to the attention of NJDOH. Due to the number of births to Vernon residents that occurred in New York State and to CAT's concern about confidentiality (see Becker and Becker, 1986, p. 234), NJDOH was also interested in ensuring that all children in Vernon, not just those affected by chromosomal anomalies, would have access to appropriate services. This letter was also unsuccessful in yielding any new leads to cases. However, the efforts in working with medical records enabled NJDOH to establish referrals to services for other children who did not qualify as cases in this study.

When a potential case-child was identified through the ascertainment process, a careful review of the medical records

was undertaken to ensure that the child met the case definition criterion. Once the chart review was complete and results of cytogenetic testing were available, copies of the karyotyping results were forwarded to CDC without individual identifiers for independent confirmation of the diagnosis.

Figure 2 below presents the final results of the exhaustive case ascertainment efforts conducted by NJDOH and includes the number of cases by diagnosis for the two time periods used in the study. A total of 14 cases were located, 9 in the period from 1975 to 1981, when the original cluster was initially identified and 5 in the later time period from 1/1/82 to 6/30/87. Diagnostic and other information for the entire group of 14 cases was presented to the study's advisory panel on 5/2/88, at which point no additional children were identified as meeting the case definition within the study period.

FIGURE 2

Final Results of Case Ascertainment Efforts

First Time Frame: 1/1/75 to 12/31/81

7 - Down Syndrome
1 - Trisomy 18
1 - Other Chromosomal Defect

Second Time Frame: 1/1/82 to 6/30/87

2 - Down Syndrome
1 - Trisomy 13
2 - Other Chromosomal Defect

Figure 3 below presents the number of contacts and the

number of cases identified from each source of potential cases. An inspection of this figure shows that the review of hospital records was the only source that was able to identify any cases not already known to NJDOH through the birth defects registry. Given the out-of-state reporting problems and restrictions mentioned previously, it is not surprising that New York hospitals accounted for 3 of the 4 newly-identified cases. The only New Jersey birth that was not captured by the birth defects registry occurred prior to 1/1/85, so that the case ascertainment process seems especially effective in locating in-state events. The ascertainment from the sources for potential cases were also presented at the meeting of the study's advisory panel on 5/2/88.

FIGURE 3

Results of Case Ascertainment by Source:*

NJ Hospitals
- Number of contacts = 45
- Number of potential cases = 6
  (5 known to NJDOH)

NY Hospitals
- Number of contacts = 19
- Number of potential cases = 3

Birth Defects Registry
- Number of potential cases = 10

School Administrator
- Number of potential cases = 0

Health Care Professionals
- Number of contacts = 86
- Number of potential cases = 7
  (5 known to NJDOH; 2 were not Vernon residents)

Newspaper Advertisement
- Number of potential cases = 3
  (2 known to NJDOH; 1 was not a chromosomal defect)

State Agencies
- Number of contacts = 37
- Number of potential cases = 5
  (5 known to NJDOH)

Cytogenetic Laboratories
- Number of contacts = 10
- Number of potential cases = 0

---

* Note that a potential case could be ascertained from several sources so that the sum of all potential cases identified contains duplicates.

Some Basic Summaries of the Cases. Using a small subset of the information available from the medical records as well as from the interviews of mothers and fathers who agreed to further participation, it is possible to augment the previous listing of diagnoses. The figures used to present these summaries will list separate results for the cases of Down Syndrome, Trisomies 13 and 18, and other chromosomal anomalies, along with results for all cases.

Figure 4 lists the minima, maxima, means, and standard deviations of the maternal ages. Two of the mothers of Down Syndrome children were of somewhat advanced maternal age (i.e., 35 years or above). The average ages of the mothers of the cases are similar to those for all mothers of Vernon births presented in the next section. Using the same format, Figure 5 presents results for the paternal ages of the cases.

FIGURE 4

Maternal Ages for Cases

Case Diagnosis	Number	Minimum	Maximum	Mean	Std.Dv.
Down Syndrome	9	19	43	29.33	7.12
Trisomy 13 or 18	2	24	27	25.50	2.12
Other Chromosomes	3	26	30	27.67	2.08
Total	14	19	43	28.43	5.85

FIGURE 5

Paternal Ages for Cases

Case Diagnosis	Number	Minimum	Maximum	Mean	Std.Dv.
Down Syndrome	9	23	39	30.44	5.29
Trisomy 13 or 18	2	26	27	26.50	.71
Other Chromosomes	3	30	42	35.67	6.03
Total	14	23	42	31.00	5.59

Figure 6 shows the results for maternal histories of miscarriages, abortions, or stillbirths in pregnancies prior to those of the cases. The per cents of cases having mothers with one or more such losses in a previous pregnancy do not include information from three mothers of Down Syndrome cases who refused to be interviewed and another mother who was unable to answer that section of the interview. The non-participation of some of the families will be discussed further in a later section. In addition, three other mothers could not be included in the per cents because they did not have any previous pregnancies. As can be seen in Figure 6, a majority of the participating mothers of cases with earlier pregnancies had experienced some such loss. However, the small number of mothers included in the per cents limits statistical power, illustrating one of the problems that can occur when information is lost because of non-participation or items not being appropriate to a particular subgroup of cases.

FIGURE 6

Prior Maternal History of Miscarriage, Abortion, or Stillbirth

Case Diagnosis	Number of Cases Interviewed	Number with an Earlier Pregnancy	Number with Previous Problems	Per Cent with Prev. Problems
Down Syndrome	5	3	2	66.67
Trisomy 13/18	2	2	1	50.00
Other Chromo.	3	2	1	50.00
Total	10	7	4	57.14

Using a similar format to Figure 6, Figure 7 displays results for family histories of pregnancy losses or birth defects. Although there were no Down Syndrome children reported among the relatives of these cases, 45.45 per cent of the

responding mothers had a family history of anomalies or reproductive losses. Again, however, there is still the issue of the small number of cases due to non-participation.

FIGURE 7

Family History of Pregnancy Losses or Birth Defects

Case Diagnosis	Number of Cases Interviewed	Number with a Family History	Per Cent with Family History
Down Syndrome	6	3	50.00
Trisomy 13/18	2	2	100.00
Other Chromo.	3	0	0.00
Total	11	5	45.45

Finally, Figure 8 summarizes the number of months that the mothers had resided in Vernon Township prior to the birth of the index cases. Based on interview information provided, four of the mothers (2 Down Syndrome, 1 Trisomy 13 and 18, and 1 Other Chromosomal Anomaly) did not appear to be residents of Vernon Township at conception (lengths of residence at birth were 9 or fewer months), making it extremely difficult to postulate any reasonable exposure to the microwave towers. With lengths of residence in Vernon ranging from 7 to 29 months, the Down Syndrome mothers had particularly short durations of stay in the community. In fact, across all of the diagnoses, the average is a surprisingly short 48.08 months. Moreover, the overall average is clearly driven by the only life-long resident among the responding case-mothers; if the average were recalculated with that single case removed, the mean for the remaining 11 cases drops to 22 months. The short durations in Vernon Township are

consistent with the earlier observation of a rapidly growing community. Furthermore, the dramatic lowering of the mean with the removal of a single case illustrates the importance of maximizing the number of cases so that the variability in estimates can be adequately assessed.

FIGURE 8

Months in Residence in Vernon Township Prior to Birth

Case Diagnosis	Number with Residence Histories	Minimum	Maximum	Mean	Std.Dv.
Down Syndrome	7	7	29	17.00	7.72
Trisomy 13 or 18	2	9	45	27.00	25.46
Other Chromosomes	3	4	332	134.67	173.87
Total	12	4	332	48.08	91.26

2. Developing Rates for Down Syndrome.

Some preliminary topics related to the development of rates for Down Syndrome need to be addressed before the occurrence of such anomalies in Vernon Township can be evaluated. Included among the topics presented in this section are: (1) the number of births by year; (2) the distribution of maternal ages for Vernon mothers and a discussion of the roles of some potential risk factors; and (3) "expected" rates of Down Syndrome from other independent, external reporting sources.

Number of Births. Table 3 shows the number of live births to Vernon Township residents over the entire study period. Because the out-of-state births have not yet been processed for 1987, the number of births for the first six months of 1987 is estimated from the yearly average of 1982 to 1986. Clearly, the average number of births per year increased from the first time period to the second, increasing from 233.14 per year for 1975 to 1981 to 274.91 per year from 1982 to 6/30/87. This increase in the number of live births in the later years of the study period indicates that the township's growth in overall population from 1970 to 1980 is likely to continue to the 1990 census as well, unless, of course, there is corresponding decrease in the other age groups.

TABLE 3

NUMBER OF LIVE BIRTHS BY YEAR IN VERNON TOWNSHIP

OVER THE TIME PERIOD FROM 1/1/75 TO 6/30/87

YEAR	BIRTHS
1975	187
1976	177
1977	234
1978	249
1979	258
1980	272
1981	255
1982	260
1983	297
1984	297
1985	338
1986	320
1987 (first half)*	151
TOTAL	3295

* ESTIMATED NUMBER FROM 1/1/87 to 6/30/87 BASED ON THE AVERAGE OF THE YEARS FROM 1982 TO 1986.

Maternal Age. Maternal age is the most widely researched risk factor known to be associated with for Down Syndrome (see Janerich and Bracken, 1986 for a recent review of available results). Therefore, as part of the later evaluation of the influence of maternal age in the present study, Table 4 gives the number of live births to Vernon residents by each year of maternal age. Frequencies are presented separately for the two time periods and only the years for which all out-of-state birth certificates are accounted for have been included (i.e., maternal ages for the first half of 1987 are not reflected in this table). There is a slight elevation in the average maternal ages (28.08 years) in the span from 1/1/82 to 12/31/86, especially evident in the older ages, when compared to the average maternal age (27.48 years) in the interval from 1975 to 1981.

TABLE 4

NUMBER OF LIVE BIRTHS IN VERNON TOWNSHIP BY EACH YEAR OF MATERNAL AGE FOR THE TIME PERIODS FROM 1/1/75 TO 12/31/81 AND FROM 1/1/82 TO 12/31/86

YEAR OF MATERNAL AGE	1/1/75 TO 12/31/81	1/1/82 TO 12/31/86
15	2	1
16	6	6
17	10	9
18	24	15
19	22	21
20	40	23
21	46	32
22	55	46
23	78	76
24	109	75
25	122	97
26	142	119
27	166	154
28	160	156
29	150	124
30	130	130
31	107	118
32	76	82
33	60	62
34	31	53
35	24	39
36	21	23
37	14	14
38	14	13
39	8	7
40	5	9
41	5	6
42	1	2
43	4	0
TOTAL	1632	1512

Other Risk Factors. Although its relationship to Down Syndrome has been widely-researched, maternal age is by no means the only risk factor that has been suggested in the literature. For example, a review by Lilienfeld and Benesch (1969) pointed out that recurrence risks could increase two to ten-fold for younger and other siblings of a Trisomy 21 patient. However, reports of associations with other risk factors, such as the study by Alfi et al. (1980) identifying a four-fold increase of Down Syndrome in consanguineous matings, need to be validated by subsequent studies.

Environmental Agents. While little is known of the specific roles of environmental agents, a recent study by Sheehan and Hillary (1983) suggests that exposures predating conception by years or decades may need to be explored to explain "clusters" of cases. Unfortunately, these other possible risk factors have not yet been systematically evaluated by any large, population-based reporting systems and, therefore, are of limited use to the present study.

Recently, there has been considerable public concern that exposures to radiofrequency radiation (RFP), including microwaves, may contribute to several undesirable health effects. Recent review articles by Roberts and Michaelson (1985), the National Council on Radiation Protection and Measurements (NCRP, 1986), Foster and Guy (1986), and Guy (1987), among others, point to questions about the potential roles of such exposures in congenital anomalies such as Down Syndrome. Unfortunately, the reports of health effects have not led to a definitive body of research findings such as that which exists for the relationship

between maternal age and the occurrence of Down Syndrome. Foster and Guy (loc. cit., p. 36) provide some comments that are helpful in understanding the inconsistency in the reports of such health effects.

> "Many studies have shown that exposure to high levels of microwaves is clearly hazardous, producing obvious heat stress in animals. Other studies, in which absorption levels are comparable to the rate of heat generated by the body, have observed changes that in part could be normal physiological responses to the added heat, although evidence for this inference is often less clear. Other effects have been reported at quite low power levels; no obvious explanation has been found."
>
> "There is also great diversity in the quality of the evidence. Although many studies reporting effects on living systems have apparently been well done, some have had obvious technical flaws (in particular, some have lacked adequate dosimetry) and others have been too briefly described to allow any judgement of their quality. Of the hundreds of biological effects of high or low levels of microwaves that have been reported, a surprising number are examples of the "Cheshire cat" phenomenon: they have not reappeared in follow-up studies."
>
> "Part of this disparity arises from the nature of the research itself. An investigator might report an "effect" on the basis of some difference found between control subjects and those exposed to microwaves. The reported effect might well arise from some specific biological activity of the energy. On the other hand, it might also result from a normal physiological response to added heat, from a statistical fluctuation or even from some experimental variable that was not adequately controlled by the investigators."

Despite tremendous advances in the measurement of radiation absorption in the laboratory, difficulties related to exposure assessment present severe obstacles to the study of health effects in humans. In this regard, Roberts and Michaelson (1985, p. 170) provide some helpful general comments about epidemiological studies of radiofrequency exposures in humans.

> "An outstanding problem of epidemiological studies of RFR exposure is related to exposure assessment. Many published

studies provide no documentation of the basic elements of exposures such as frequency, modulation, and power density. Often, populations are described merely as "exposed" or "non-exposed". Rigorous study designs, analyses, and discussions are often absent. Specifically, population selection criteria are usually not described and control groups are often not included or sufficiently identified. Control groups are occasionally described but inappropriate. Control of common confounding variables such as age or health status is commonly not considered. It is often necessary to study populations of many thousands in order to document or exclude significant results. The statistical methods applied are often not described, or may not be proper for the study design, failing to measure the strength of association via relative risk ratios. Many of the published studies are minimally descriptive or cross-sectional in nature. A major limitation of epidemiological studies of RFR exposures is the lack of generally recognizable pathophysiological manifestations at realistic levels of exposures."

"It is essential that multiple environmental factors, which can interact among themselves and with personal characteristics of the subjects, be evaluated. If reasonably controlled comparisons can be made for sufficiently long periods of time using groups that are comparable in important demographic, social and health characteristics, then possible health effects associated with exposure to RFR can be evaluated. In epidemiological studies, as in experimental or clinical investigation, there is rarely a single study, positive or negative, that can be accepted as definitive. Replication and validation are required, as well as recognition that inferences in regard to alternate conditions and exposures are unsubstantiated, although usually necessary because of the limits (cost or otherwise) upon investigation."

Rates of Down Syndrome. Table 5 displays the published rates for estimating the incidence of Down Syndrome from three different, major reporting systems for each year of maternal age. These three systems provide rates for births from: (a) Metropolitan Atlanta, administered by CDC; (b) Upstate New York (and widely cited in the literature); and (c) Sweden. The choice of these reporting systems was based on three considerations. First, because of the previously mentioned risk factor established in many different, independent studies, it was

important to have results for individual years of maternal age, especially given rapid increases in this risk for older mothers. Second, the number of live births upon which the rates are based should be sufficiently large to produce reasonably stable estimates. Third, the rates must exclude non-white so as to be comparable to the almost exclusively white population of Vernon.

In order to "smooth" results for ages having fewer live births, average values from the group of years were inserted for each individual year in 40-44 interval of the Metropolitan Atlanta figures and for the 15-19 span in the Upstate New York rates. Notice that, when compared to the other two systems, the Metropolitan Atlanta rates show less-rapidly increasing risks for older mothers, probably reflecting recent tendencies towards greater utilization of genetic counseling services for women of advancing age in that area.

TABLE 5

ESTIMATED RATES OF DOWN SYNDROME FROM THREE DIFFERENT REPORTING SYSTEMS: RATES PER 1000 LIVE BIRTHS BY EACH YEAR OF MATERNAL AGE

YEAR OF MATERNAL AGE	METRO-POLITAN ATLANTA	UPSTATE NEW YORK	SWEDEN
	[a]	[b]	[c]
16	1.36	0.59*	0.51
17	0.52	0.59*	0.57
18	0.72	0.59*	1.09
19	0.55	0.59*	0.30
20	0.48	0.52	0.64
21	0.43	0.59	0.67
22	0.29	0.65	0.71
23	0.19	0.71	0.75
24	1.41	0.77	0.79
25	0.66	0.83	0.83
26	0.64	0.89	0.87
27	0.47	0.95	0.92
28	0.87	1.01	0.97
29	0.93	1.07	1.02
30	1.70	1.13	1.08
31	1.10	1.21	1.14
32	1.24	1.38	1.25
33	1.80	1.69	1.47
34	1.96	2.15	1.92
35	0.86	2.74	2.51
36	2.88	3.49	3.28
37	1.20	4.45	4.28
38	2.62	5.67	5.60
39	1.50	7.21	7.32
40	7.69*	9.19	9.57
41	7.69*	11.71	12.51
42	7.69*	14.91	16.36
43	7.69*	19.00	21.39
44	7.69*	24.20	27.96

[a] Derived from MACDP data for white live births occurring from January, 1975 through December, 1985 (N = 180,153).

[b] Reported in Hook and Lindsjo (1978) and Hook (1978); based on white live births.

[c] Listed in Hook and Lindsjo (1978); based on 330,859 live births for 1968-1970.

* Average value over the time period is inserted for this year.

Table 6 presents the rates for Down Syndrome in five-year intervals of maternal age. To expand the range of possibly comparable rates for five-year maternal age intervals, that table also incorporates results from white births in Massachusetts along with those from the three reporting systems summarized in Table 5. An inspection of the rates in Table 6 reveals consistency across reporting systems through the 30-34 age interval. However, the grouping of the individual years into categories in Table 6 makes it more evident than Table 5 that the rates for Metropolitan Atlanta are substantially lower than the remaining three systems in both the 35-39 and the 40-44 intervals.

TABLE 6

RATES OF DOWN SYNDROME DERIVED FROM FOUR REPORTING SYSTEMS:

RATES PER 1000 LIVE BIRTHS BY MATERNAL AGE QUINQUENNIA

MATERNAL AGE GROUPING	METRO-POLITAN ATLANTA	UPSTATE NEW YORK	SWEDEN	MASS.
	[a]	[b]	[b,c]	[b,d]
15-19	0.69	0.63	0.59	0.68
20-24	0.58	0.65	0.74	0.66
25-29	0.71	0.96	0.88	0.79
30-34	1.51	1.38	1.45	1.26
35-39	1.70	4.37	3.74	3.72
40-44	7.69	13.45	14.96	13.16

[a] Derived from MACDP data for white live births occurring from January, 1975 through December, 1985 (N = 180,153).

[b] Listed in Hook (1978).

[c] Based on 330,859 live births for 1968-1970.

[d] Based on 832,531 white live births.

3. Evaluating the Occurrence of Down Syndrome in Vernon Township.

Two of the four reporting systems providing rates in the five-year intervals shown in Table 6 were used to evaluate the occurrence of Down Syndrome cases in Vernon Township. Although it provides the lowest rates for older mothers, the system used by CDC for Metropolitan Atlanta was selected because of the careful and comprehensive manner in which it collects information. In contrast, the second system chosen, covering births from Upstate New York, provides the higher rates of occurrence, but is from a geographically adjacent area with a population likely to have had similar patterns of utilization of genetic counseling services to residents of Vernon Township.

The evaluation of the rates from the two systems when applied to the maternal age distribution of Vernon births is based on the assumption of a Poisson distribution, a probability model especially appropriate to "rare" events occurring in a large number of independent trials (e.g., see Hays, 1973). For the time period from 1975 to 1981, the rates of Down Syndrome for the five-year intervals in Table 6 were applied to the maternal age distribution in Table 4 to calculate the "expected" number of cases. In turn, the expected values (1.6229 and 2.0772 from Metropolitan Atlanta and Upstate New York, respectively) served as the "intensity" parameter ($m = Np$) used to generate the Poisson probability distributions for the 1632 births in that time span. Table 7 shows the probability distribution for both models for the range from "0" to "10" cases. The 95% confidence intervals for the number of cases cover the values from 0 to 4

for the probabilities based on the rates from Metropolitan Atlanta and from 0 to 5 for those from Upstate New York. Clearly, the observed number of 7 cases falls outside of these two confidence intervals, so that the earlier identification of an excess number of Down Syndrome cases in Vernon Township in the 1975 to 1981 period is statistically significant beyond the .05 level.

TABLE 7

RESULTS OF TWO POISSON PROBABILITY DISTRIBUTIONS FOR DOWN SYNDROME FOR THE 1975-1981 TIME PERIOD (N=1632)

NUMBER OF CASES	MODEL I: METROPOLITAN ATLANTA		MODEL II: UPSTATE NEW YORK	
	PROBABILITY	CUMULATIVE PROBABILITY	PROBABILITY	CUMULATIVE PROBABILITY
0	.19733336	.19733336	.12527930	.12527930
1	.32024457	.51757793	.26023137	.38551068
2	.25985618	.77743412	.27027755	.65578823
3	.14057014	.91800425	.18714104	.84292927
4	.05703144	.97503569	.09718279	.94011207
5	.01851082	.99354651	.04037381	.98048587
6	.00500675	.99855326	.01397748	.99446335
7*	.00116075	.99971401	.00414774	.99861109
8	.00023547	.99994948	.00107696	.99968805
9	.00004246	.99999194	.00024856	.99993661
10	.00000689	.99999883	.00005163	.99998825

* NUMBER OF OBSERVED CASES BORN DURING THE TIME PERIOD.

The same two reporting systems were used to evaluate the occurrence of Down Syndrome infants in Vernon Township in the time period from 1/1/82 to 6/30/87. For that later span, the expected values are 1.7701 and 2.2908 cases for the Metropolitan Atlanta and Upstate New York systems, respectively. These expected values are greater than those for the earlier period and reflect the slightly greater ages of the more recent Vernon mothers. Table 8 gives the similar Poisson probability distributions for the 1663 births occurring in the second time period. Once again, the 95% confidence intervals cover the ranges from 0 to 4 and 0 to 5 cases, when rates from Metropolitan Atlanta and Upstate New York, respectively, are applied to the maternal ages in Vernon for the second period. However, in contrast to the earlier time period, the two observed Down Syndrome cases in the later time span fall within the confidence limits and are not statistically significant (at the .05 level) under either models. Therefore, there is not a continuing, statistically significant excess of Down Syndrome cases occurring in Vernon Township.

TABLE 8

RESULTS OF TWO POISSON PROBABILITY DISTRIBUTIONS FOR DOWN SYNDROME FOR THE 1982-1987 TIME PERIOD (N=1663)

NUMBER OF CASES	MODEL I: METROPOLITAN ATLANTA		MODEL II: UPSTATE NEW YORK	
	PROBABILITY	CUMULATIVE PROBABILITY	PROBABILITY	CUMULATIVE PROBABILITY
0	.17031643	.17031643	.10118725	.10118725
1	.30147664	.47179307	.23179799	.33298524
2*	.26682148	.73861455	.26549938	.59848462
3	.15743332	.89604787	.20273378	.80121840
4	.06966807	.96571594	.11610475	.91732315
5	.02466385	.99037979	.05319415	.97051730
6	.00727624	.99765603	.02030937	.99082667
7	.00183995	.99949598	.00664634	.99747300
8	.00040711	.99990309	.00190316	.99937617
9	.00008007	.99998316	.00048441	.99986058
10	.00001417	.99999733	.00011097	.99997155

* NUMBER OF OBSERVED CASES BORN DURING THE TIME PERIOD.

4. Evaluating the Occurrence of All Trisomies in Vernon Township.

This section evaluates the occurrence of chromosomal anomalies including any of the Trisomy conditions diagnosed in Vernon Township over the entire study period; that is, diagnoses of Trisomy 13 and 18 are added to those of Down Syndrome. In particular, there is the possibility that Trisomy 13 and 18 may have similar susceptibilities to environmental exposures that have been suggested for Down Syndrome. In addition, based on data available to him, Hook (1978) pointed out that, like Down Syndrome, Trisomies 13 and 18 also appear to have exponential risk relationships with maternal age.

Table 9 provides rates for Trisomies 13 and 18 from two different sources. The first reporting source is again from Metropolitan Atlanta (CDC). Hook's (1978) summarization of results from four studies of chromosomal abnormalities detected in live births to women of advanced maternal age (35+ years) provides the second source of rates for these two other Trisomies. Much like the rates for Down Syndrome presented earlier, it is apparent that Metropolitan Atlanta has the lower rates for older maternal ages.

TABLE 9

ESTIMATED RATES OF TRISOMIES 13 AND 18:

RATES PER 1000 LIVE BIRTHS BY MATERNAL AGE QUINQUENNIA

MATERNAL AGE GROUPING	METRO-POLITAN ATLANTA	FROM FOUR STUDIES
	[a]	[b]
15-19	0.11	---
20-24	0.14	---
25-29	0.16	---
30-34	0.19	---
35-39	0.53	3.77
40-44	2.20	3.77

[a] Derived from MACDP data for white live births occurring from January, 1975 through December, 1985 (N = 180,153).

[b] Summarized in Hook (1978); based on four studies of 1859 pregnancies.

Using the two sets of rates for Trisomy 13 and 18 shown in Table 9, the evaluation of the occurrence of all Trisomies in Vernon Township is based on two models for the Poisson distribution. The first model is based on the rates of the Trisomies as reported by the Metropolitan Atlanta (CDC) system; that is, the rates for Down Syndrome in the five-year intervals of maternal ages are combined with those for Trisomy 13 and 18. In the second model, the overall rate of all Trisomies is estimated by adding the Metropolitan Atlanta rates for Trisomy 13 and 18 for the age-intervals from 15 to 34 (where no other reporting source of rates is available) and the results for the four studies shown in Table 9 for the age-intervals from 35 to 44 to the Upstate New York rates for Down Syndrome found in Table 6.

Table 10 shows the probability distributions for all Trisomies under both models when applied to the maternal ages observed in Vernon Township for the time period from 1975 to 1981. Under the model based on rates from Metropolitan Atlanta, the expected value of 1.9470 leads to a 95% confidence interval covering the range from 0 to 5 cases. For the so-called "Upstate New York" model, the expected value is 2.6872, while the corresponding confidence interval goes from 0 to 6 cases. The observed number of 8 cases (with 1 Trisomy 13 case being added to the 7 Downs cases in that time period) falls outside of both confidence intervals. Therefore, there is a statistically significant (at the .05 level) elevation in the rate of all Trisomies observed in Vernon Township during the first time period, although this elevation is due almost entirely to the large number of Down Syndrome cases.

TABLE 10

RESULTS OF TWO POISSON PROBABILITY DISTRIBUTIONS FOR ALL TRISOMIES FOR THE 1975-1981 TIME PERIOD (N=1632)

NUMBER OF CASES	MODEL I: METROPOLITAN ATLANTA		MODEL II: UPSTATE NEW YORK**	
	PROBABILITY	CUMULATIVE PROBABILITY	PROBABILITY	CUMULATIVE PROBABILITY
0	.14270496	.14270496	.06806779	.06806779
1	.27784313	.42054809	.18291524	.25098303
2	.27047695	.69102505	.24576960	.49675263
3	.17553738	.86656242	.22014822	.71690085
4	.08544177	.95200419	.14789839	.86479925
5	.03327061	.98527480	.07948803	.94428727
6	.01079618	.99607099	.03560072	.97988799
7	.00300284	.99907383	.01366687	.99355485
8*	.00073081	.99980464	.00459079	.99814564
9	.00015810	.99996273	.00137073	.99951637
10	.00003078	.99999351	.00036835	.99988473

* NUMBER OF OBSERVED CASES BORN DURING THE TIME PERIOD.

** USES DOWN SYNDROME RATES FROM UPSTATE NEW YORK. FOR TRISOMIES 13 AND 18, INCORPORATES RATES FROM MACDP FOR AGES 15-34 AND FROM THE FOUR STUDIES OF 1859 PREGNANCIES FOR AGES 35-44 (SEE TABLE 6).

Table 11 lists the probability distributions of all Trisomies found by applying the two sets of rates to the maternal ages of Vernon births that occurred in the time period from 1982 to 6/30/87. Under the model based on Metropolitan Atlanta, the expected value is 2.1197 and the 95% confidence interval covers the range of 0 to 5 cases. For the "Upstate New York" model, the expected value is 3.0119 and the corresponding confidence interval ranges from 0 to 6 cases. Thus, when all Trisomies are considered together in the second time period, there is not an excessive number of cases occurring in Vernon Township. Unlike the earlier time period, there is not an elevation in the number of Down Syndrome cases in the interval from 1982 to 6/30/87, so that all Trisomies (2 Downs and 1 Trisomy 18) are well within the range of cases to be expected under either of the probability models. Thus, for those conditions which may possibly share some common potentials for exposure-related effects, there is not a continuing excess of Trisomy cases observed in Vernon Township. Furthermore, applying the observed rate for Vernon Township for 1975 to 1981 to the second time period leads to a 95% confidence interval ranging from 4 to 13 cases, so that, under such a model, there would be significantly <u>fewer</u> Trisomies than expected.

TABLE 11

RESULTS OF TWO POISSON PROBABILITY DISTRIBUTIONS FOR ALL TRISOMIES FOR THE 1982-1987 TIME PERIOD (N=1663)

NUMBER OF CASES	MODEL I: METROPOLITAN ATLANTA		MODEL II: UPSTATE NEW YORK**	
	PROBABILITY	CUMULATIVE PROBABILITY	PROBABILITY	CUMULATIVE PROBABILITY
0	.12007247	.12007247	.04920012	.04920012
1	.25451279	.37458526	.14818383	.19738394
2	.26974026	.64432552	.22315442	.42053836
3*	.19058586	.83491139	.22403657	.64457493
4	.10099430	.93590568	.16869166	.81326659
5	.04281471	.97872039	.10161511	.91488169
6	.01512544	.99384583	.05100840	.96589009
7	.00458011	.99842594	.02194716	.98783726
8	.00121353	.99963948	.00826272	.99609998
9	.00028581	.99992529	.00276513	.99886510
10	.00006058	.99998587	.00083282	.99969792

* NUMBER OF OBSERVED CASES BORN DURING THE TIME PERIOD.

** USES DOWN SYNDROME RATES FROM UPSTATE NEW YORK. FOR TRISOMIES 13 AND 18, INCORPORATES RATES FROM MACDP FOR AGES 15-34 AND FROM THE FOUR STUDIES OF 1859 PREGNANCIES FOR AGES 35-44 (SEE TABLE 6).

5. Evaluating the Occurrence of All Chromosomal Anomalies in Vernon Township.

This section attempts to evaluate the occurrence of all chromosomal anomalies in Vernon Township for the entire study period. In addition to the Trisomy conditions considered earlier, all other defects involving chromosomes are included here (e.g., extra X chromosomes). Table 12 gives a partial set of rates for these other defects by the five-year intervals of maternal age used in previous tables. Once again, Metropolitan Atlanta (CDC) provides the only complete set of rates, while the results from the four studies of chromosomal abnormalities cited in table 9 and summarized by Hook (1978) comprise the second set. It is apparent that the elevation in risks for mothers in Metropolitan Atlanta does not occur until the 35-39 and 40-44 age intervals. Furthermore, consistent with earlier observations about risks for older mothers, the Metropolitan Atlanta rates for other chromosomal defects are also lower than those derived from the four studies.

TABLE 12

ESTIMATED RATES OF OTHER CHROMOSOMAL ANOMALIES:

RATES PER 1000 LIVE BIRTHS BY MATERNAL AGE QUINQUENNIA

MATERNAL AGE GROUPING	METRO-POLITAN ATLANTA	FROM FOUR STUDIES
	[a]	[b]
15-19	0.16	---
20-24	0.26	---
25-29	0.23	---
30-34	0.13	---
35-39	0.85	5.38
40-44	2.20	5.38

[a] Derived from MACDP data for white live births occurring from January, 1975 through December, 1985 (N = 180,153).

[b] Summarized in Hook (1978); based on four studies of 1859 pregnancies.

Before evaluating the occurrence of all chromosomal anomalies in Vernon, a few cautions are needed. First, there are concerns about the completeness of the ascertainment of some of the non-Trisomy diagnoses with respect to the age of the fetuses or infants at which such conditions can be accurately determined. For example, if some of these defects are not readily discernible at birth or soon thereafter and, instead, require additional testing, this may deflate rates when such testing is not invoked. In part, this may explain why Metropolitan Atlanta's rates are so low for younger mothers (i.e., the more frequent use of prenatal diagnostic procedures among older mothers may lead to earlier identification of some chromosomal defects in their children). Second, some of the non-Trisomy conditions may be partially attributable to family histories which might need to be carefully pursued as possible explanations of some cases. Third, since Metropolitan Atlanta is the only large-scale source of rates for all maternal ages, there may be comparability issues (e.g., different patterns in the utilization of genetic testing and other medical care services) in applying those values to births in Vernon Township. Finally, none of the published research findings cited throughout this report address a possible microwave exposure basis underlying these other chromosomal defects.

Much like the earlier results for Down Syndrome and for all Trisomies, the evaluation of the occurrence of all chromosomal anomalies is based on two models for the Poisson distribution. Again, the first model is based on rates of all such defects as captured by the CDC system used in Metropolitan Atlanta; the

rates combine other defects with the values presented earlier for the Trisomy conditions. The second model is similar to its predecessor for all Trisomies; that is, the overall rate of chromosomal anomalies is estimated by adding the values for Metropolitan Atlanta for the age intervals from 15 to 34 (where no other reporting source is available) and the results for the four studies shown in Tables 9 and 12 for the age intervals from 35 to 44 to the Upstate New York rates for Down Syndrome given in Table 6.

Table 13 lists the probability distribution for all chromosomal anomalies under both models when applied to the maternal ages observed in Vernon Township for the time period from 1975 to 1981. For the Metropolitan Atlanta model, the expected value of 2.3671 leads to a 95% confidence interval from 0 to 5 cases. Under the so-called "Upstate New York" model, the expected value is 3.5219 and the corresponding confidence interval ranges from 0 to 7 cases. Not surprisingly given the earlier discussions on Down Syndrome cases for that time period, there is a statistically significant (at the .05 level) elevation; the 9 cases observed (7 Down Syndrome, 1 Trisomy 13, and 1 other chromosomal defect) fall outside of the limits of both intervals. However, it is clear that the large number of Downs cases contribute most heavily to this elevation.

TABLE 13

RESULTS OF TWO POISSON PROBABILITY DISTRIBUTIONS FOR ALL CHROMOSOMAL ANOMALIES FOR THE 1975-1981 TIME PERIOD (N=1632)

NUMBER OF CASES	MODEL I: METROPOLITAN ATLANTA		MODEL II: UPSTATE NEW YORK**	
	PROBABILITY	CUMULATIVE PROBABILITY	PROBABILITY	CUMULATIVE PROBABILITY
0	.09375664	.09375664	.02954455	.02954455
1	.22192692	.31568355	.10405165	.13359620
2	.26265636	.57833992	.18322746	.31682366
3	.20724049	.78558041	.21510025	.53192391
4	.12263730	.90821771	.18938802	.72131193
5	.05805779	.96627550	.13339947	.85471140
6	.02290431	.98917981	.07830229	.93301369
7	.00774510	.99692491	.03939563	.97240931
8	.00229163	.99921654	.01734321	.98975253
9*	.00060271	.99981926	.00678670	.99653923
10	.00014267	.99996192	.00239018	.99892941

* NUMBER OF OBSERVED CASES BORN DURING THE TIME PERIOD.

** USES DOWN SYNDROME RATES FROM UPSTATE NEW YORK. FOR TRISOMIES 13 AND 18 AND OTHER DEFECTS, INCORPORATES RATES FROM MACDP FOR AGES 15-34 AND FROM THE FOUR STUDIES OF 1859 PREGNANCIES FOR AGES 35-44 (SEE TABLE 6).

Table 14 shows the probability distributions of all chromosomal abnormalities found by applying the two sets of rates to the maternal ages of Vernon births that occurred in the time period from 1982 to 6/30/87. Under the model based on Metropolitan Atlanta, the expected value is 2.5599 and the 95% confidence interval covers the range from 0 to 5 cases. For the "Upstate New York" model, the expected value is 3.9897 and the corresponding confidence interval ranges from 1 to 8 cases. Similar to the earlier results for Down Syndrome and all Trisomy conditions in this later time period, there is not an excessive number of all chromosomal anomalies occurring in Vernon Township. The five observed cases (2 other chromosomal defects are added to the 3 Trisomy diagnoses) fall within the limits of both confidence intervals. Thus, while there is no research evidence to suggest why other chromosomal defects might possibly be related to microwave exposures and there are several cautions needed in even evaluating non-Trisomy conditions, the inclusion of other chromosomal defects does not alter the underlying finding of an absence of a continued excess of cases being observed in Vernon Township.

TABLE 14

RESULTS OF TWO POISSON PROBABILITY DISTRIBUTIONS FOR ALL CHROMOSOMAL ANOMALIES FOR THE 1982-1987 TIME PERIOD (N=1663)

NUMBER OF CASES	MODEL I: METROPOLITAN ATLANTA		MODEL II: UPSTATE NEW YORK**	
	PROBABILITY	CUMULATIVE PROBABILITY	PROBABILITY	CUMULATIVE PROBABILITY
0	.07731588	.07731588	.01850520	.01850520
1	.19791751	.27523339	.07383027	.09233548
2	.25332016	.52855355	.14728044	.23961592
3	.21615437	.74470792	.19586842	.43548434
4	.13833101	.88303893	.19536422	.63084856
5*	.07082149	.95386042	.15588906	.78673762
6	.03021547	.98407588	.10365851	.89039613
7	.01104961	.99512549	.05908096	.94947709
8	.00353567	.99866117	.02946444	.97894152
9	.00100565	.99966681	.01306160	.99200312
10	.00025743	.99992424	.00521119	.99721431

* NUMBER OF OBSERVED CASES BORN DURING THE TIME PERIOD.

** USES DOWN SYNDROME RATES FROM UPSTATE NEW YORK. FOR TRISOMIES 13 AND 18 AND OTHER DEFECTS, INCORPORATES RATES FROM MACDP FOR AGES 15-34 AND FROM THE FOUR STUDIES OF 1859 PREGNANCIES FOR AGES 35-44 (SEE TABLE 6).

B. **Establish an advisory panel to review planned activities.**

Included among the five recommendations found in the CDC report was the establishment of an advisory panel for the review of scientific issues surrounding the study of the original cluster of Down Syndrome and other chromosomal abnormalities born to residents of Vernon Township. Although the critical work on the description of the incidence of Down Syndrome was clearly the most important activity to be conducted by NJDOH, the nature of the community's concerns made the assembling of an appropriate scientific review group extremely important. To ensure the adequate expression of divergent viewpoints, CDC recommended that this panel be composed of appointed representatives of (a) the New Jersey Public Advocate, (b) the New Jersey Department of Environmental Protection (NJDEP), (c) the Mayor's Blue Ribbon Panel, and (d) the Citizens Against the Towers (CAT). Each of these four groups had previously played a role in identifying the original cluster of cases in Vernon and/or had expressed an interest in finding explanations so as to prevent future occurrences of such events. This section describes the establishment of the study's advisory panel and summarizes its meetings held to-date.

In order to establish the advisory panel, NJDOH called a planning meeting on 2/23/85 and invited each of the four groups named above to send an appointed representative. As a result of that planning meeting, three criteria for membership on the panel were established:

(1) each member should have an advanced degree in medicine, epidemiology, medical physics, genetics, or a related field;

(2) each member should have at least 5 years experience working in the field of this degree; and

(3) each member should have publications in their field of expertise.

Each of the groups attending the planning meeting was asked to nominate two or three scientists and to submit the nominees' resumes to NJDOH. In turn, NJDOH forwarded all materials received to the Credentials Review Committee at the Robert Wood Johnson Medical School for independent verification and confirmation. After the review committee approved the qualifications of potential panel members, each group was asked to select a single, approved representative from among their list of nominees. The final group of nominees were then invited by NJDOH to constitute the scientific advisory panel.

First Meeting: 8/14/86. At this first meeting the panel members and NJDOH staff were introduced. A history of the Vernon Township Down Syndrome cluster problem was presented, along with the background information on how the panel was formed. Two reports were also distributed and discussed: (a) the June, 1986 report of the U.S. Environmental Protection Agency (EPA, 1986); and (b) the original CDC report of 11/12/85 (Edmonds et al., 1985). Drafts of a plan for the study design and for a parents' birth defects questionnaire were also given to the panel for their review. The need to ascertain all cases so as to maximize statistical power was also discussed.

Second Meeting: 11/25/86. Two representatives of NJDEP attended the second meeting and reported on other, non-microwave environmental concerns in Vernon Township. These other concerns

included high potentials for radon exposures because of Vernon's being located directly over the Reading Prong and the inspection of industrial sites for potential environmental contamination. The NJDEP representatives informed the panel that there was no evidence of exposures to environmental contamination from industrial sites in Vernon Township.

In addition to the report by the NJDEP representatives, the following issues concerning the study were discussed at the second meeting: (a) the public notice of the study for local newspapers; (b) the need to establish denominators for determining rates; and (c) the selection of controls for a case/control study. Topographical maps of the Vernon area, showing the locations of the earth satellite stations, were displayed for the panel members to inspect.

Third Meeting: 2/24/87. The meeting began with the introduction of the new representative of the CAT organization. NJDOH staff reported on the microwave transmission information from industries in Vernon Township. An update on the number of cases was presented (9 cases from 1975 through 1985 and 3 potential cases since 1986). Methods of case ascertainment and the study design, including interviews and the questionnaire to be used, were discussed. It was decided to proceed with newspaper ads as one of the approaches to discover potential cases.

Fourth Meeting: 4/20/87. NJDOH staff presented proposed procedures for interviewing cases and controls and methods for achieving the participation of cases in the study. The number of potential cases and their diagnoses were also updated, including

one recent birth who did not have any chromosomal abnormality and was, therefore, removed as a potential case. There was also a report of a field trip to the earth satellite stations to gather information on the microwave transmissions and a description of a proposed simple methodology for calculating the power exposure for each beam path (Petersen, 1987B) that was not accepted by the entire panel. A decision was reached on the guidelines for selecting controls; controls were to be selected from resident births of Vernon Township and matched to cases on maternal age, race, and year of birth.

Fifth Meeting: 9/15/87. NJDOH reported to the panel on several topics, including: (a) case ascertainment; (b) selection of controls; (c) contact of cases and their controls to elicit their participation in the study; (d) responses to the newspaper ad; (e) establishing a liaison relationship in the Vernon community; and (f) issues of the statistical power of the proposed study. The meeting also included a discussion of issues and approaches to the measurement of microwave exposures, including the need to distribute the Requests for Methodologies.

Sixth Meeting: 5/2/88. NJDOH staff reported on the rates of chromosomal anomalies found in Vernon Township during the time periods from 1975 through 1981 and from 1982 through 6/30/87. During the earlier time period, the number of cases with chromosomal anomalies was significantly greater than would have been expected using rates adjusted for maternal age derived from two large reporting systems. However, in the later time period, the earlier observation of an elevation of Down Syndrome cases

did not persist and the number of chromosomal abnormalities observed was not significantly different from that expected based on the ages of Vernon mothers. The methods used to ascertain and verify the diagnoses of the cases by karyotyping were also presented.

The panel was informed of the preliminary response from the Electromagnetic Fields Division of the National Bureau of Standards (NBS) which had reviewed two replies to the "Request for Methodologies to Ascertain Microwave Exposure." Although NBS was unable to send a representative, their preliminary report indicated that attempts at retrospective measurement of microwave exposures would have extremely high degrees of uncertainty.

Based on the lack of evidence of a continuing elevation of the rates of chromosomal anomalies and on the absence of a valid approach for assigning values to microwave exposures from retrospective data, NJDOH stated that it did not have sufficient justification or resources to complete the case-control study of Vernon Township. However, the department stated its intention to regularly review data from existing surveillance programs and to seek a method to monitor microwave exposures in Vernon. Panel members requested copies of the final NBS report when it became available and expressed their disappointment with the NJDOH's decision.

C. Regularly Review Cancer and Birth Defects Data from On-going Surveillance Programs.

The original CDC report (Edmonds et al., 1985) concluded that, except for Down Syndrome, there were no elevations in other health outcomes in Vernon Township that could be attributed to the earth satellite stations. Despite the absence of any other significant findings in the earlier study period it covered, the CDC report recommended regular reviews of health data from existing surveillance programs. In part, this recommendation was made to ensure that the entire range of outcomes that might be even remotely related to microwave exposures were included in any subsequent studies, even in the absence of clearly-established causal associations in the literature (e.g., environmental exposures are thought to have a partial role in explaining depressed birthweights). Because newborns are closer in time to possible, well-identified exposures, other health characteristics for infants are discussed first in this section.

Table 15 lists selected infant health characteristics for Vernon Township for the years from 1983 to 1986 based on an analysis of computerized records maintained by NJDOH's Bureau of Vital Statistics; over that four-year time period, there were 411,622 live births whose records were included in this analysis. For both Vernon and the state's 561 municipalities having 1 or more births in each of those four years (6 of New Jersey's 567 municipalities were deleted because of years with no births), that table presents rates per 1000 live births of the following outcomes: (a) very low birthweight (under 1500 grams); (b) low birthweight (under 2500 grams); (c) neonatal deaths (birth to 28

days); (d) post-neonatal deaths (29 days to 1 year); (e) total infant deaths (birth to 1 year); and (f) fetal deaths/stillbirths (20 or more weeks gestation). Except for calculating post-neonatal deaths as the difference between all infant deaths and neonatal deaths, the CDC report incorporated the same health outcomes for infants for the time period from 1975 to 1983.

The crude rates in Table 15 (i.e., unadjusted for any possible risk factors) indicate that those infants born more recently to mothers residing in Vernon Township do not differ significantly from the state averages. Furthermore, the overall finding of no differences between the Vernon rates and those for all of New Jersey in <u>each</u> of these outcomes agrees with that of the CDC report. Clearly, despite earlier concerns about the health effects of the microwave towers on adverse reproductive outcomes in Vernon Township, there continues to be no indication of a general problem.

TABLE 15

SELECTED INFANT HEALTH CHARATERISTICS FOR VERNON TOWNSHIP AND FOR AND FOR 561 OF NEW JERSEY'S MUNICIPALITIES FOR THE YEARS 1983 TO 1986:

RATES PER 1000 LIVE BIRTHS FOR 1252 VERNON BIRTHS AND FOR 411622 BIRTHS THROUGHOUT THE ENTIRE STATE

VARIABLE	VERNON VALUE	STATE AVERAGE	STATE MINIMUM	STATE MAXIMUM	VERNON RANK*
VERY LOW BIRTHWEIGHT (UNDER 1500 GRAMS)	4.07	10.75	.00	125.00	121
LOW BIRTHWEIGHT (UNDER 2500 GRAMS)	46.34	56.31	.00	146.67	177
NEONATAL DEATHS (BIRTH TO 28 DAYS)	6.39	6.22	.00	53.57	337
POST-NEONATAL DEATHS (29 DAYS TO 1 YEAR)	1.60	2.43	.00	51.28	288
TOTAL INFANT DEATHS (BIRTH TO 1 YEAR)	7.99	8.64	.00	53.57	287
FETAL DEATHS/ STILLBIRTHS (20 OR MORE WEEKS GESTATION)	1.59	7.16	.00	137.93	117

* RANKS ARE IN ASCENDING ORDER, FROM LOWEST TO HIGHEST.

+ RANKS IN THE HIGHEST 5% OF NEW JERSEY'S MUNICIPALITIES.
- RANKS IN THE LOWEST 5% OF NEW JERSEY'S MUNICIPALITIES.

Table 16 presents the Poisson probability distribution for all congenital abnormalities (ICD-9 codes in the 740 to 759 range), including chromosomal anomalies, to infants born in Vernon Township from 1/1/85 to 6/30/87. This time period encompasses the overlap between the beginning of the implementation of the new data collection and processing system of the birth defects registry and the end of the study period. The range of abnormalities is the same as that used in the CDC report.

TABLE 16

POISSON PROBABILITY DISTRIBUTION FOR CONGENITAL ANOMALIES IN VERNON TOWNSHIP FROM 1/1/85 TO 06/30/87 (N = 809 LIVE BIRTHS), BASED ON 2982 ANOMALIES AMONG 104,973 NEW JERSEY BIRTHS IN 1985

NUMBER OF CASES	PROBABILITY	CUMULATIVE PROBABILITY
0	.00000000	.00000000
1	.00000000	.00000000
2	.00000003	.00000003
3	.00000021	.00000024
4	.00000121	.00000146
5	.00000558	.00000704
6	.00002139	.00002843
7	.00007022	.00009865
8	.00020173	.00030038
9	.00051511	.00081549
10*	.00118381	.00199930
11	.00247324	.00447254
12	.00473657	.00920911
13	.00837334	.01758245
14	.01374514	.03132759
15	.02105894	.05238653
16	.03024788	.08263441
17	.04089070	.12352511
18	.05220721	.17573232
19	.06314739	.23887971
20	.07256110	.31144081
21	.07940778	.39084858
22	.08295047	.47379905
23	.08288377	.55668282
24	.07936641	.63604923
25	.07295838	.70900761
26	.06448821	.77349582
27	.05489023	.82838605
28	.04505215	.87343820
29	.03570228	.90914048
30	.02734974	.93649022
31	.02027543	.95676564
32	.01456124	.97132689
33	.01014059	.98146747
34	.00685429	.98832176
35	.00450063	.99282239
36	.00287309	.99569548
37	.00178454	.99748002
38	.00107925	.99855926
39	.00063597	.99919523
40	.00036539	.99956062

* NUMBER OF OBSERVED CASES BORN DURING THE TIME PERIOD.

Based on the overall rate of these anomalies throughout the state for 1985 and the estimated 809 Vernon births in that 2-1/2 year time period, the 10 observed cases displayed in Table 16 are significantly different (at the .05 level) than the number that would be expected from applying the model. That is, the observed number (representing a rate of 12.36 infants per 1000 live births) falls below the 95% confidence interval (14 and 32 cases are the lower and upper limits, respectively, of the two-tailed interval), using a state rate of 28.41 infants per 1000 live births. This significant result would not be altered if the rates for Vernon Township for the years 1975 to 1981 and for Metropolitan Atlanta cited in the CDC report (34.38 and 39.00 infants per 1000 live births, respectively) were applied to the 1/1/85 to 6/30/87 time period.

Thus, despite careful, proactive case ascertainment, those infants born recently in Vernon Township appear to have lower rates of birth defects than their counterparts throughout the state. Although future data will be required to confirm if this significant difference is part of a long-term trend toward healthier births, the lower observed birth defect rate among recent Vernon births is certainly consistent with the lack of elevations in other adverse reproductive outcomes, including chromosomal anomalies, for those infants.

Finally, a request was made of the state's cancer registry to provide a list of recently diagnosed cancer cases occurring in Vernon Township. This request was similar to that for the original CDC report and resulted in the initial identification of 279 cases diagnosed between 1/1/79 and 12/31/86. Since the CDC

report covered diagnoses in the four-year period from 1979 to 1983, there is an overlap of 167 cases with the latest request. Furthermore, the numbers of the diagnoses of the 112 new cases found in the three years from 1984 to 1986 do not appear to differ from those presented in the earlier report and there continues to be no evidence of any elevation in rates. Unfortunately, the most recent report from the Cancer Registry (NJDOH, 1985) covers the years 1981 and 1982 and does not have final, unduplicated figures for the later years of interest to this study. Thus, while awaiting the cancer registry's next report, NJDOH will continue to monitor their available data on a periodic basis.

D. Measure the range of microwave/radio frequency radiation in Vernon Township.

Because citizens were concerned that exposures to the earth satellite stations were the cause of chromosomal anomalies, birth defects, and other adverse health effects in Vernon Township, the CDC report recommended that the full range of microwave and radiofrequency radiation be measured. In addition to measurements around the earth stations' facility boundaries, special priority was given to sampling around and inside the schools located near the satellite dishes. It was also suggested that a priority list of 12 representative sites in the community be developed in consultation with community groups and included in the basic set of measurements. Beyond this basic set, it was recommended that as many of the remaining sites on the priority list be measured as resources would permit and that the advisory panel review all findings from the exposure assessments.

Prior to the CDC recommendation for microwave measurements, the NJDOH requested that NJDEP measure radiation levels in the community. On 5/22/85, NJDEP conducted a preliminary survey in residential areas of Vernon Township using two different types of broadband isotropic radiation monitors (the Narda and Holaday instruments). The major result of this survey was that all measurements taken were below the instruments' levels of detectability.

As a follow-up to the preliminary survey, both NJDEP and CDC agreed that the group most qualified to make more refined microwave measurements was the Nonionizing Radiation Protection Branch of EPA, located in Las Vegas, Nevada. The EPA group came

to Vernon Township and measured microwave and radiofreqeuncy radiation levels at selected sites throughout the community from 11/10/85 to 11/16/85. Their report (EPA, 1986) describes the study procedures, including the types of equipment used to obtain measurements at various locations. Listed below are the conclusions contained in the EPA report (loc. cit., p. 13)

1. "Earth station uplink transmissions cause very low power densities on the ground in the Vernon area. Contributions from other sources in the same frequency ranges, possibly terrestrial microwave communication links, add to the power densities that can be measured. The highest value at any of the community measurement locations in the Vernon Township area was about 3000 pW/cm^2. The source of this density was not a satellite uplink antenna but apparently terrestrial microwave relays. At some sites the power densities in the bands of interest were below the minimum detection limits of the equipment."
2. "Broadcast band measurements were unremarkable, the highest measured values being 220 pW/cm^2 in the AM band and 106 pW/cm^2 in the FM band."
3. "Typical community exposure levels measured in the Vernon area including broadcast and uplink frequencies are well below 1000 pW/cm^2 which is significantly lower than the values experienced by most of the U.S. population as measured by EPA in a 15 city study of broadcast band exposures."
4. "The highest value found during the study in a publicly

accessible area was 60 uW/cm^2 (60 million pW/cm^2) along the hill to the south of the RCA station. Data collected along this hillside at points which are not far from the axis of a beam with a low elevation angle, show that power densities fall to less than 10 uW/cm2 beyond 650 feet from the antenna."

Prior to their first meeting on 8/14/86, the advisory panel was given copies of the reports from the NJDEP preliminary survey and an executive summary excerpted from the EPA report. After a lengthy discussion, the panel concurred with CDC that a case/control study should be done, although there was considerable disagreement among the members as to a satisfactory methodology for assigning values to microwave exposures on a retrospective basis.

At a subsequent meeting of the advisory panel (4/20/87), it was suggested (Petersen, 1987B) that the power density associated with each beam path be calculated and, furthermore, that the upper bound based on the maximum power emitted from each earth station antenna in the direction predicted by the antenna radiation pattern envelope might serve as a reasonable method for determining retrospective microwave exposures. As part of this approach, it was recommended that exposures associated with terrestrial beams also be included in the assignment of exposure values.

However, there were strong objections by some panel members to using maximum power densities as the retrospective exposure surrogates; in particular, the point was made that, despite being

objectively determined, the maxima might mask effects of lower powers. Thus, in order to find a methodology that was satisfactory to all panel members, NJDOH prepared a Request for Methodologies to Measure the Exposure to Microwaves in Vernon Township (RFM). A draft of the proposed request was distributed to panel members and reviewed at their meeting of 9/15/87. Copies of the final version of the RFM were sent to panel members with a request that they forward these to appropriate consultants, universities, etc.

The NJDOH received two replies to the RFM (The consultant previously used by CAT was not one of the respondents.). With the concurrence of the advisory panel, the two proposals received were then forwarded to the Electromagnetic Fields Division of the National Bureau of Standards (NBS) for a review of their technical merit and validity. Listed below are the conclusions of the report from NBS (NBS, 1988, p. 5)

1. "We find that both proposals are sufficiently thorough to evaluate, and that they are both technically valid. The two major differences in the proposals are the result of attempts to reduce the large amount of data manipulation and computational effort required. The [one] proposal suggests using monthly averages for the transmitter powers, and thus, the computed power densities would be in terms of monthly averages. The [second] proposal suggests a worse-case analysis of path loss that assumes inphase addition of a direct and a ground-reflected ray. DOH will have to make the decisions whether monthly averages are adequate and

whether a worst-case analysis for path loss is as useful as a more accurate (but more time consuming analysis)."

2. "In any case DOH should realize that the computed microwave power densities will have large uncertainties on the order of 10 to 30 dB (a factor of 10 to 1000) and will be quite low. The large uncertainties are a result of a large uncertainty in path loss and in antenna sidelobe level. The lower power density level is a result of receptor sites always being the sidelobe region of the antennas, and this is consistent with the EPA measurements. The EPA report is quite thorough, and the reported microwave power density levels appear to be valid."

3. "Because of the large uncertainties in these calculated values of microwave power density, NBS believes that the value of the proposed study is questionable. Such large uncertainties could easily mask trends in the temporal and spatial variation of microwave power density that the study is attempting to reveal."

It is important to point out that the "large uncertainties" mentioned above all refer to <u>indirect</u> estimates of exposures to individuals that might be calculated using a number of assumptions. However, some assessment of the correlations of such indirect estimates with measurements of actual (i.e., <u>direct</u>) exposures to individuals (most importantly, the mothers of cases and controls around the time of conception) is needed. In traditional treatments of classical test theory (e.g., see

Lord and Novick, 1968), reliability is defined as the correlation between alternate forms of measuring the same underlying concept, while validity is the correlation between measurements of different concepts. Very early in the development of test theory it was recognized that reliability set a lower bound for validity, as indicated by the so-called Spearman-Brown "prophecy formula" [Spearman (1910) and Brown (1910)]; that is, unreliable tests will not lead to valid results in the long run.

In the present context, the implications of possibly unreliable indirect estimates of exposures is that they would have little opportunity to reveal significant validities (i.e., to detect differences between cases and controls), regardless of objectivity or costs. It is obvious from the review by Foster and Guy (1986) that the use of human subjects makes it exceedingly difficult to correlate indirect estimates with actual, direct measurements of individuals, given the state of dosimetry technology for microwaves. Moreover, even if the problem of directly measuring humans could be solved so that some assessment of reliability could be achieved, there are additional sources of potential unreliability in the indirect estimates. These other sources are principally due to the temporal variability in the operation of microwave transmission stations with respect to orientation, elevation, and power densities emitted. Still more sources of potential unreliability would come from problems of interference from such environmental characteristics as hills, valleys, trees, and structures. Then, in attempting to assess reliability, variability in the behavior and environments of the subjects involved would need to be

addressed. Among some of the questions about movements are differences in exposures between working and non-working mothers and locations most commonly used in their home (e.g., possible differences in exposures between the front and rear of subjects' homes). Further compounding the difficulty in attempting to account for behaviors and movements are the retrospective nature of much of the information and its possible susceptibility to serious recall errors. Finally, assuming that some type of reliable estimation strategy could be conducted within reasonable financial constraints, a decision would need to be made about how to use the resulting values to separate subjects into "exposed" and "unexposed" subgroups.

Unfortunately, we are aware of no previous research that addresses such reliability/validity concerns about estimating microwave exposures in a "real world" setting with human subjects. Perhaps the closest attempt is the long-term study of employees in the American Embassy buildings in Moscow from 1953 to 1976 (described in NCRP, 1986). In that study, prospective measurements of power densities were made on a regular basis and there was a sufficient number of cases to derive 18,000 years of observation for potential exposures. Even with that level of effort, that study could find no significant health effects attributable to such exposures.

In sharp contrast, the responding Down Syndrome mothers in Vernon appear to have a total of only about 5 years of residence in the community among them before conception and, except for the values obtained by NJDEP and EPA, all measurements would be

indirect and retrospective and, therefore, highly susceptible to recall errors and bias. Thus, it would appear that much more progress in solving measurement problems surrounding microwave exposures is needed before techniques can be generalized outside of the laboratory.

E. Conduct a case-control study of cytogenetically confirmed infants with Down Syndrome.

This section addresses the last of the recommendations of the CDC report (Edmonds et al., 1985) to be implemented. The original CDC recommendation for a case-control study of chromosomally affected infants born to Vernon residents was expanded to cover the entire time period from 01/01/75 to 6/30/87. The overall purpose of the case-control study was to test if the operation of the earth satellite stations in Vernon Township had led to microwave radiation exposures that could be associated with the occurrence of chromosomal abnormalities in the infants born to residents. In collaboration with the advisory panel, it was decided to use a standard case-control design.

From previous sections of this report it is clear that NJDOH and the advisory panel began to consider some aspects of the case-control study soon after the original CDC report was completed. For example, the interview questionnaire and the study design were among the topics discussed at the first meeting of the advisory panel. Furthermore, the efforts to ascertain all chromosomal defects and to elicit the agreement of their families to participate in the interviews were obviously critical to the success of a case-control study, especially in terms of increasing the sample size to maximize statistical power. The rest of this section highlights some of the major activities undertaken in conducting a case-control study.

Selection of Controls. As mentioned earlier, cases were defined as births to residents of Vernon Township with the

diagnosis of Down Syndrome or any other chromosomal anomaly confirmed by karyotype. Four controls, matched to cases by category of maternal age and year of birth, were selected for each identified case whose residence and diagnosis had been confirmed. Reflecting the almost complete absence of nonwhite residents in Vernon Township, all cases and controls were white. In general, the matching of maternal age categories occurred in five-year intervals (i.e., 15-19, 20-24, 25-29, 30-34, 35-39, and 40-44). All control infants were selected from births to residents of Vernon Township. Using resident births as controls avoided the selection bias of confounding group membership (exposed vs. not exposed) with outcome (abnormal vs. normal chromosome result) which would occur if controls were chosen from another location (e.g., within Sussex county, but outside of Vernon). Thus, selecting controls from among the resident births permits the testing of the central question of the possible relationship between levels of exposures to microwave radiation and the occurrence of chromosomal anomalies (i.e., comparing the differences in such exposures between the cases and their controls).

However, because of the small numbers of births in the youngest and oldest categories, the age categories were expanded to include all mothers under age twenty in the youngest group and those mothers aged 40 or more in the oldest category. For some of the cases, four controls could not be found which matched exactly with respect to the maternal age category or the year of birth. For example, there may not have been enough mothers in the maternal age category of a case to produce the number of

control infants needed. When such matching problems occurred, the pool of controls was expanded to include those infants born within one year of the case and then increasing and decreasing the maternal age category until a total of four matching control infants was reached.

Locating potential controls was accomplished by using line listings of information contained in the computerized records of birth certificates. Once appropriately matched control infants were selected for each case, a letter describing the study and an informed consent form was sent to the parents of both the case and control infants. Upon receipt of a signed consent form, telephone calls were made to schedule interviews for both the mother and father of each infant. Experienced interview staff were trained in procedures for conducting telephone interviews on this special topic.

Statistical Power. In addition to accurately determining the rates of chromosomal anomalies in Vernon Township over the entire study period, NJDOH's early and continued emphasis on case ascertainment was based primarily on considerations of statistical power.

> Power is the probability of correctly deciding that an observed test statistic comes from the sampling distribution generated by an alternative hypothesis (e.g., that cases of chromosomal anomalies in Vernon were exposed to greater levels of microwave radiation than their corresponding controls) when that hypothesis, in fact, is true. See Hays (1973) for an excellent treatment of power and other topics related to hypothesis testing. Usually, power is set at .80 as a minimum (e.g., see Cohen, 1969). When the alternative hypothesis is true but the decision rule fails to correctly assign an observed result, a **Type II Error** occurs with probability equal to **beta**. Thus, **"power"** is equal to 1 - **beta**.

In contrast to a Type II error, a Type I Error is the probability (equal to alpha) of rejecting the null hypothesis (e.g., that cases and controls in Vernon Township have the same levels of exposures to microwave radiation from the earth satellite stations) when that hypothesis, in fact, is true. Similarly, "confidence" (equal to 1 - alpha) is the probability of correctly failing to reject the null hypothesis.

Because the major focus of the case-control study was to test the alternative hypothesis of higher microwave exposures for the cases in Vernon, maximizing the ability to detect this hypothesis (e.g., increasing power) is of critical importance. Textbook treatments such as Hays (loc.cit.) point out the three parameters that can be increased to improve power: (1) alpha-level (i.e., permitting more Type I errors improves power); (2) sample size (i.e., studies with more cases have greater power); and (3) effect size (i.e., increasing the separation between the null and alternative hypotheses, sometimes referred to as the "noncentrality" parameter). For the study of exposure differences between cases and controls in Vernon, only the sample size parameter is free to vary; that is, both the alpha-level set by the researchers and the difference in levels of exposure are assumed to be known in advance. Therefore, the meticulous attempts to identify <u>all</u> cases of chromosomal anomalies were undertaken not only to offer services to those children and their families but also to make the study more sensitive by increasing its power.

Based on the approach of Schlesselman (1982), Table 17 presents some statistical power results for case-control studies using several combinations of relative risks, exposures, and cases. An alpha-level of .10 and a case/control ratio of 1:4 are

employed throughout that table. Inspection of Table 17 reveals that large relative risks (of five or greater) are needed to reach acceptable levels of power (.80 or greater). For example, if the relative risk is 5 and the per cent of the study population exposed is 10, at least 11 cases are required to reach an acceptable power to detect the alternative hypothesis. Assuming that exposure values can be assigned objectively, as few as 9 cases would be needed, provided that the per cent exposed is between 20 and 30 per cent.

TABLE 17

STATISTICAL POWER BASED ON SCHLESSELMAN'S (1982) APPROACH FOR VARIOUS COMBINATIONS OF RELATIVE RISKS, EXPOSURES, AND CASES

[Alpha= .10 (one-tailed); Case/Control Ratio= 1:4]

Relative Risk	Per Cent Exposed	Number of Cases 7	8	9	10	11	12
2	5	.20	.22	.22	.23	.24	.25
2	10	.25	.27	.27	.29	.30	.32
2	15	.28	.30	.31	.33	.34	.36
2	20	.30	.32	.33	.35	.37	.39
2	25	.31	.34	.35	.37	.39	.41
2	30	.31	.34	.36	.38	.40	.42
2	40	.32	.34	.36	.38	.40	.42
2	50	.31	.34	.35	.37	.39	.41
3	5	.32	.34	.36	.38	.40	.42
3	10	.41	.44	.47	.49	.52	.54
3	15	.46	.50	.52	.56	.58	.61
3	20	.49	.53	.56	.59	.61	.65
3	25	.50	.54	.57	.60	.63	.66
3	30	.51	.55	.58	.61	.64	.67
3	40	.50	.54	.56	.60	.62	.65
3	50	.46	.50	.53	.56	.58	.61
5	5	.54	.58	.61	.64	.67	.70
5	10	.66	.70	.74	.77	.80	.83
5	15	.71	.76	.79	.82	.85	.87
5	20	.73	.77	.81	.84	.86	.89
5	25	.73	.78	.81	.84	.86	.89
5	30	.72	.76	.80	.83	.86	.88
5	40	.68	.73	.76	.79	.82	.85
5	50	.62	.67	.70	.73	.77	.79

Case Non-Participation. For the earlier description of the incidence of chromosomal anomalies, cases were defined as resident births of Vernon Township with diagnoses confirmed by karyotype. However, to be included in the case-control study of the possible effects of the towers, a case must also have consented to participate in the study (i.e., to provide critical items in an interview). Despite additional follow-up contacts by letter and telephone, two of the potential case-families refused to participate in the case-control study altogether. Furthermore, one of the remaining twelve potential case-mothers also refused to partipate, so there was no comparable information about problems with previous pregnancies and other potential confounders from the maternal perspective. In addition, two of the fathers could not be located and interviewed, although this loss of information was viewed as much less serious than any lack of participation by a case-mother since maternal sources of confounders were still available. Fortunately, through its exhaustive efforts to ascertain all cases, NJDOH was able to locate a potential case that had been previously lost to follow-up and a signed consent to participate was obtained. In summary, there was a total of 12 potential cases that could be considered for inclusion in most of the analysis of the case-control data, although some analyses involving maternal perspectives (e.g., previous pregnancy losses) would be reduced to 11 potential cases.

Development of the Interview Questionnaire. Work on the development of the interview questionnaire also began soon after the CDC report was issued. The questionnaire was developed by

NJDOH based on survey techniques employed in other related studies conducted by CDC and the National Institute for Occupational Safety and Health (NIOSH). Panel members also reviewed the proposed content of the interview questionnaire and made important contributions, especially to the retrospective exposure-surrogate items. Separate forms were developed for mothers and fathers, although most of the questions relevant to the case-control study were asked of the mothers; fathers were asked those items that pertained directly to them.

The final versions of the mothers' and fathers' interview questionnaires contained items in six major areas: (1) general background; (2) residence history; (3) family history; (4) pregnancy history; (5) environmental information; and (6) employment history (including occupational exposures to toxic substances).

Interviewing of Cases and Controls. The interviewing of cases and controls was undertaken in December, 1987. It was assumed that the interview data would be used to provide items to statistically control for a few critical variables (e.g., previous history of any problematic pregnancy, family history of chromosomal defects, etc.) before evaluating differences in exposures between the cases and controls. Interviews were conducted by trained staff not otherwise involved in the study. The interviewers had no information about the cases or controls prior to the study. Cases and controls were interviewed in the same general time frame, most within a 2-month interval. Each interviewer completed questionnaires for both cases and controls.

Interviews were conducted by telephone, at a pre-arranged time. Care was taken to ensure that cases and controls had no knowledge of specific questions to be asked prior to the conduct of the interview.

Discussion. While the inadequate statistical power that can result from a small number of cases was always recognized as a threat to validity, it was the lack of usable exposure values with demonstratable reliability that led to NJDOH's decision to not proceed in the analysis of the case-control data. The continued inability to arrive at a reliable and valid method for objectively assigning values of microwave exposures from the towers on a retrospective basis clearly prevents the items in the interview portion of the case-control study from being linked with such values. Thus, despite the tremendous effort taken in designing and executing the interview portion of the case-control study (in hope that the exposure measurement problem could be solved), the resulting information could not be used to answer the fundamental question of whether the cases had higher levels of actual, objectively-determined exposures to microwave radiation. Furthermore, both the high relative risks (5 or more) needed to obtain statistical powers in excess of .80 (given the potential number of cases) and possible differences in recall between cases and controls (e.g., parents of cases may have a "bias" toward attributing their childrens' conditions to the emissions from the earth satellite stations) make it unacceptable to substitute <u>any</u> of the subjective exposure-surrogate items of unknown reliability and validity for an objectively-assigned exposure value.

Problems associated with the inability to link actual measurements of exposures were further compounded by the loss of subjects in the interview portions of the case-control study. In addition to the two case-families who refused any participation in the study mentioned earlier, data from two other cases cannot be brought into the analysis of the fundamental question of exposure differences: (a) the first case was mentioned earlier with respect to non-participation and must be removed because the mother's refusal to be interviewed at all prevents the possibility of controlling for any confounders; and (b) the second case must be removed because the mother was unable to proceed with the portion of the interview that asked questions about problems with previous pregnancies. Therefore, the original group of 14 cases included in the description of the rates of chromosomal anomalies is reduced to only 10 cases that might qualify for inclusion in an analysis of case-control data, clearly limiting the power of any attempts to assess differences in exposures, even if the measurement problems could be solved. This reduction in sample size is particular damaging since at least three of the already scarce degrees of freedom are required to statistically control for maternal age, previous pregnancy losses, and an exposure measure. Moreover, the four cases that must thus be removed all have a diagnosis of Down Syndrome, so that any analysis of common etiologies is obviously not possible (i.e., only 2 degrees of freedom would remain, resulting in a situation perilously close to being indeterminant).

Despite clear evidence of a lack of elevation in the rates

of Down Syndrome and other Trisomies among recent births in Vernon Township, the low levels of statistical power mean that we cannot rule out the alternative hypothesis. In fact, even though the EPA report found that all measurements were within existing standards, the earlier cases may still individually have been exposed to higher levels of microwave radiation than the controls. However, without a reliable method to assign exposure values, this question cannot be addressed at all. Conversely, given the loss of four Down Syndrome cases and the reduction in power that results, analysis of the remaining data might lead to spurious or misleading findings (if a Type I error were committed), and even dangerously erroneous results (if a Type II error were made). For example, such inappropriate analyses might lead to a conclusion that cases (vs. controls) have more problems with previous pregnancies, when such a difference in a small group of cases of mixed etiologies might be attributable to recall bias. That is, because of possibly greater sensitivity of case-mothers to pregnancy outcomes, mothers of controls may under-report such problems and the "cluster" may be erroneously dismissed.

Therefore, the NJDOH concludes that the most responsible approach is to discontinue further analytic work with an inappropriate case-control study. The absence of a reliable method to assign values to the relevant exposures clearly prevents any analysis of differences between cases and controls. Furthermore, without any evidence of continued elevations of chromosomal anomalies among the recent births in Vernon Township, there is not sufficient justification to analyze data that cannot

answer the fundamental question. At the same time, we do not want to leave the impression that we can attribute the original "cluster" to some other cause - there are simply too few valid responses from the parents of Down Syndrome cases to permit that type of analysis. Unfortunately, small sample sizes and methodological issues in assigning exposure values are difficulties frequently encountered in the conduct of such cluster investigations (e.g., see Rothman, 1987).

Thus, as originally recommended by CDC, the NJDOH will continue to monitor health-outcome data for Vernon Township from existing surveillance programs on a regular basis. If there are unusual trends or elevations in adverse outcomes similar to those that led to the identification of the earlier cluster of cases, additional investigations could then be considered.

III. REFERENCES

1. Alfi, O.S., Chang, R., and Azen, S.P. Evidence for genetic control of nondisjunction in man. American Journal of Human Genetics, 1980, 32, 477-483.

2. Becker, R.O. Letter to the editors: Vernon, NJ cluster continues. Microwave News, 1988, page 10.

3. Becker, R.O. and Becker, A.J. An analysis of the effectiveness of regulatory agency responses to a situation involving perceived health effects from microwave radiation. Journal of Bioelectricity, 1986, 5, 229-251.

4. Brown, W. Some experimental results in the correlation of mental abilities. British Journal of Psychology, 1910, 3, 296-322.

5. Cohen, J (1969). Statistical Power Analysis for the Behavioral Sciences. New York: Academic Press.

6. Edmonds, L., Eheman, C., Freni-Titulaer, L., Cordero, J.F., and Adams, M.M. (1985). Report of Centers for Disease Control Consultation on Vernon Township, New Jersey. Division of Birth Defects and Developmental Disabilities, Center for Environmental Health, Centers for Disease Control, Atlanta, GA.

7. EPA (1986). An Investigation of Microwave and Radiofrequency Radiation Levels in Vernon Township, New Jersey, November 10-16, 1985. Electromagnetics Branch, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC.

8. Foster, K.R. and Guy, A.W. The microwave problem. Scientific American, 1986, 255, 32-39.

9. Guy. A.W. Dosimetry associated with exposure to non-ionizing radiation: very low frequency to microwaves. Health Physics, 1987, 53, 569-584.

10. Halpin, G.J. and Lawson, C. (1984). Birth Defects Study: Sussex County and Vernon Township, 1975-1981. Paternal and Child Health Services, State of New Jersey Department of Health, Trenton, NJ.

11. Hays, W.L. (1973). Statistics for the Social Sciences. New York: Holt, Rinehart and Winston.

12. Hook, E.B. Differences between rates of Trisomy 21 (Down Syndrome) and other chromosomal abnormalities diagnosed in livebirths and in cells cultured after second-trimester amniocentesis - suggested explanations and implications for genetic counseling and program planning. Birth Defects: Original Articles Series (The National Foundation - March of Dimes), 1978, 14, 249-267.

13. Hook, E.B. and Lindsjo, A. Down Syndrome in live births by single year maternal age interval in a Swedish study: comparison with results from a New York State study. American Journal of Human Genetics, 1978, 30, 19-27.

14. Janerich, D.T. and Bracken, M.B. Epidemiology of Trisomy 21: a review and theoretical analysis. Journal of Chronic Diseases, 1986, 89, 1079-1093.

15. Lilienfeld, A.M. and Benesch, C.H. (1969). Epidemiology of Mongolism. Baltimore, MD.: John Hopkins Press.

16. Lord, F.M. and Novick, M.R. (1968). Statistical Theories of Mental Test Scores. Reading, MA.: Addison-Wesley.

17. Morton, W.E. (1987). Letter to R.C. Petersen, distributed to members of the advisory panel, June 18, 1987.

18. NBS (1988). An evaluation of proposals for estimating microwave power densities. Electromagnetic Fields Division, Center for Electronics and Electrical Engineering, National Bureau of Standards, Boulder, CO.

19. NCRP (1986). NCRP Report No.86: Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields. Bethesda, MD.: National Council on Radiation Protection and Measurements.

20. NJDOH (1985). Cancer Incidence in New Jersey: 1981 and 1982. Report published by the Cancer Registry Program, Division of Epidemiology and Disease Control, State of New Jersey Department of Health, Trenton, NJ.

21. Petersen, R.C. (1987A). Review of "An analysis of the effectiveness of regulatory agency responses to a situation involving perceived health effects from microwave radiation". Memorandum distributed to members of the advisory panel, April 13, 1987.

22. Petersen, R.C. (1987B). Predicted upper bound for microwave exposure levels in Vernon Township. Memorandum distributed to members of the advisory panel, April 17, 1987.

23. Roberts, N.J. and Michaelson, S.M. Epidemiological studies of human exposures to radiofrequency radiation: a critical review. International Archives of Occupational and Environmental Health, 1985, 56, 169-178.

24. Rothman, K.J. Clustering of disease. American Journal of Public Health, 1987, 77, 13-15.

25. Schlesselman, J. (1982). Case-control studies. New York: Oxford University Press.

26. Sheehan, P.M. and Hillary, I.B. An unusual cluster of babies with Down's syndrome born to former pupils of an Irish boarding school. British Medical Journal (Clinical Research), 1983, 287, 1428-1429.

27. Spearman, C. Correlation calculated with faulty data. British Journal of Psychology, 1910, 3, 271-295.