

**HEALTHY FROM THE START**  
***Why America Needs a Better System to Track and Understand Birth Defects and the Environment***

**FOREWORD BY COMMISSION CHAIRMAN LOWELL WEICKER, JR.**

*For more than a quarter-century, we have made enormous strides in protecting our air and water quality and preserving areas of natural beauty and biological diversity essential to a healthy environment.*

*Despite this progress, and many public health breakthroughs over the past 100 years, we have lost our focus on protecting our children from health hazards arising from exposure to environmental contaminants.*

*In the coming months, Pew Environmental Health Commission researchers will examine three serious health problems affecting thousands of American children: birth defects, asthma and childhood cancer. Unfortunately, one key finding will be the lack of health tracking information needed to understand and prevent these terrible killers and disablers.*

*These reports will not solve the problems of why too many American babies die each year of birth defects or why asthma among our children is at near-epidemic proportions or what causes childhood cancers. However they will raise scientifically valid questions aimed at redirecting our national will to solve this health crisis of chronic disease and disability.*

*As a longtime advocate for our public health institutes, I am dismayed that we only track pollutants in air and water, but not the levels of exposure in our bodies.*

*The time has come to renew our investment in a public health system that will prevent the chronic diseases and disabilities that today afflict millions of Americans, especially our children.*

## **INTRODUCTION**

Birth defects are the leading cause of infant mortality in the United States, about 6,500 deaths annually. For some groups in the United States, such as African Americans, preterm birth and low birthweight are the leading causes of infant mortality. Moreover, the reporting of certain birth defects and related conditions have increased over the past decade, according to an analysis of data collected from 29 states by the Centers for Disease Control and Prevention over the period from 1989-96.

The study analyzed a number of birth defects and several related conditions--preterm and low-weight births, and cerebral palsy, mental retardation and autism. While about 20 percent of birth defects have known causes, the causes of 80 percent of all birth defects and related conditions remain elusive, even as evidence mounts that environmental factors—including diet, personal behavior, and exposure to toxic substances and pollutants—play an important role in the development of these tragic and costly conditions.

What the analysis found is a wake-up call to strengthen and improve our nation's public health policy. The data show that despite much progress in clinical medicine, we know far too little about why rates of birth defects and related conditions remain stubbornly high and appear to be increasing in many

instances.

The good news is that much progress has been made in identifying environmental factors related to diet and personal behavior. For example, public health research helped to establish the detrimental effects of alcohol, caffeine and tobacco on a baby's development in the womb and the hazards posed by some medicines. Without public health research and education, American women might not have information about these threats, or the benefits of prenatal checkups, adequate diet, rest, exercise and avoidance of stress during pregnancy.

But despite all of these advances in medical knowledge and understanding---

- The U.S. has the worst infant mortality rate among the G-7 industrialized nations and ranks 25<sup>th</sup> internationally, principally as a result of birth defects and related conditions.
- The costs also are tragically high, both for families and the nation. Recent estimates place the cost to the economy at \$8 billion annually. In addition, the U.S. bears the burden of the direct costs of health care and disability and indirect loss of productivity related to low birthweight and preterm birth complications. Both contribute to infant deaths, and frequently accompany birth defects and such related conditions as cerebral palsy, mental retardation and autism.
- Despite the substantial gains that have been made in birth defects surveillance over the past two decades, public health researchers cannot pinpoint national trends because state tracking of birth defects remains inadequate. In fact, one-third of the states have no system for tracking birth defects at all.

The United States has an adequate network to capture important data on infectious disease in order to spot dangerous outbreaks before they spread. Certainly, we know how to build an effective mechanism that provides the consistency of reporting data and privacy protections. What is lacking is a national policy to guide state implementation of a comprehensive, modern tracking program that will help identify environmental and other preventable factors that contribute to birth defects and other disabilities and chronic diseases.

Addressing these tragic conditions and generating better information about environmental causes should be a national priority because birth defects and related conditions may be preventable.

## **NEW CHALLENGES FOR PUBLIC HEALTH**

The goal of the nation's public health system is to help people thrive by fostering conditions that lead to individual good health and healthy communities.

While medical science has advanced to conquer many infectious and chronic diseases, preventing chronic illness through public health programs has failed to keep pace. After a vigorous start early in this century, we have not continued strong progress against life threatening, debilitating chronic diseases. In 1995, health studies estimated that of the 30 years added to Americans' life expectancy since 1900, only five years on average are due to improvements in clinical medicine. The majority, 25 years, are attributable to public health programs. The steepest decline in mortality resulted from improvements to environmental conditions that prevented the spread of infectious disease, such as treatment of drinking water and removal of wastes, and better nutrition and food handling practices. All were encouraged by public health efforts.

While infectious disease remains important, chronic disease is now the no. 1 killer, responsible for three of every four deaths in the U.S. annually (about 1.8 million) and a yearly economic cost of

\$325 billion. About 100 million Americans, more than a third of the population, suffer from some form of chronic disease. And the numbers are rising. By 2020, chronic disease is expected to afflict 134 million people and cost \$1 trillion. The list includes cancer, lung disease, multiple sclerosis and mental retardation, and has been called an epidemic unlike any in the nation's history.

While it is important to remain vigilant in protecting against infectious disease, on the eve of the 21<sup>st</sup> century our public health system should focus on causes and prevention of chronic disease and disability. These health problems might be preventable if only we knew more about the complex interactions among the social, biological and environmental factors that affect us.

Social factors include behavior, poverty, and community issues such as availability of health care and public health services. Biological factors include genetics, gender and age. Environmental factors include diet, smoking and drinking; conditions that cause injury; and the presence of toxicants such as radiation, chemicals and metals. These factors are closely intertwined. For example, disadvantaged communities are stressed in many ways, including higher levels of environmental exposures.

While we as a nation have conducted considerable research on the role of social and biological factors, the adverse health effects of exposures to environmental toxicants are not receiving the attention they need. Against this backdrop, the Pew Environmental Health Commission urges a national review to reinvigorate the ability of our public health system to understand and prevent chronic disease and disability. Upgrading the system, with a special emphasis on improving and expanding what information is tracked on a nationwide basis, is crucial to meeting environmental challenges to a healthy society.

## **BIRTH DEFECTS STUDY**

*A birth defect is "any anomaly, functional or structural, that presents in infancy or later in life and is caused by events preceding birth, whether inherited, or acquired."*

*--March of Dimes*

The Pew Environmental Health Commission report on birth defects and related conditions covers low birthweight and preterm births, 20 different structural birth defects, and three developmental disabilities—cerebral palsy, mental retardation and autism. It has three objectives:

- Examine the quality and comprehensiveness of state tracking systems in order to assess the ability of researchers to answer questions about causes and prevention strategies;
- Examine existing data on state registries on births and birth defects to learn more about the rates and variations among states;
- Investigate the connection between exposure to environmental toxicants and birth defects and related conditions.

## **DATA COLLECTION SYSTEMS LEAVE US IN THE DARK**

The study found that less than half the nation's population is covered in state birth defects registries. One-third of all states have no system for tracking birth defects. Two-thirds collect basic information about structural birth defects, but there are wide variations in how the data are collected. With the exception of some parts of California and metropolitan Atlanta, where a Centers for Disease Control

pilot tracking program is under way, no state tracks related conditions such as mental retardation and cerebral palsy. Such disparities leave public health researchers in the dark in efforts to understand and prevent these tragic conditions.

A total of 33 states have some form of tracking system, but many use the “passive” method that relies on reporting by doctors and hospitals. Only 26 of the 33 had registry data available to review, principally because the data are not compiled. Of the 26 states, 16 rely on “passive” reporting by hospitals and doctors, which frequently underestimates cases.

Only 10 states use “active” methods, applying state resources to search out information about birth defects and related conditions in the general population. And finally, a total of 17 states, the District of Columbia, and Puerto Rico have no system at all.

## FEW STATES MAKE THE GRADE

In order to highlight the seriousness of the problem, Commission researchers also evaluated each state’s system against the Commission’s model criteria, and gave each a letter grade from “A” to “F” to present a snapshot of the current situation.

- **Grade A:** Eight states came close enough to model criteria to achieve the top grade. All 8 are active systems that extend through the first 12 months of life, assess fetal deaths as well as births, and have analytic capacity. They are not perfect; for example, several do not yet cover the entire state (California, Georgia and Texas).
- **Grade B-C:** A total of 25 states have achieved some of the needed criteria to be effective. However, they fall short because of such shortcomings as: passive collection systems, failure to assess fetal deaths, and lack of analytical capability.
- **Grade F:** A total of 17 states, the District of Columbia and Puerto Rico have no birth defects registries at all. However, several states recently received federal funds and report that tracking systems are being developed.

Conclusion: A national approach to build consistent, modern state tracking systems is essential if we are to develop prevention strategies that will alleviate suffering and deaths from birth defects and chronic disease and disability.

## KEY FINDINGS ON BIRTH DEFECTS

- U.S. rates for a number of major birth defects are on the rise, and although these rates vary among the 29 states whose rates could be compared, there are some dramatic increases that deserve further study.
- Certain conditions in the analysis were increasing over time. We do not believe the reporting systems are reliable enough to conclude whether these increases are real or just changes in diagnosis over time. For example:
  - The increased rate in infants born with atrial septal defect, ASD (a hole in the wall between the two upper chambers of the heart) deserves further study. The analysis found that ASD rose from 14.1 cases per 10,000 births in 1989 to 34.9 per 10,000 in 1996, an increase of 2 \_ times in eight years for states that track this defect.

- The increased rate in infants born with obstructive genitourinary defects (complete or partial blockages in the opening of the urinary tract) also warrants more study. The analysis found that these defects rose from 9.7 cases per 10,000 births to 15.5 cases in the same time period, a 1.6-fold increase, for states that track this defect.
- States with more comprehensive tracking systems had significantly higher birth defect rates, most likely because better resources allowed for better data collection. For instance:
  - The average for states with the best tracking systems showed the rate of tricuspid valve atresia (an absent or restricted heart valve) was 870 percent higher than the average of states with less-effective tracking systems, over the period from 1989-96.
- Low birthweight and preterm births have been rising steadily since the mid-1980s despite increased prevention efforts. This trend is even found in single births to mothers ages 20-34. From 1990-97, 6 percent more babies born to these mothers were very low weight at birth (less than 1,500 grams). Even white single births showed the same trend, with a 4.6 percent increase in preterm births from 1989-96.

## **WHAT IS THE ROLE OF ENVIRONMENTAL EXPOSURE TO TOXICANTS?**

Public health research has continued to identify factors in the environment that can affect children's health. Some of these factors involve personal behavior, such as consumption of tobacco and alcohol during pregnancy. But there are environmental factors, such as exposure to toxicants in the air, water or soil, over which individuals have limited or no control and which must be attacked on a community-wide basis.

There is little information on human exposure to the wide array of toxicants released into the environment in the U.S. every year. Most of the available information on exposure risks is based on results of animal testing. However, taken as a whole, the evidence suggests that exposures to these toxicants may play an important role in birth defects and related conditions.

Many of the chemical compounds in use in agriculture and in our homes and gardens have been found in animal studies to cause birth defects, but there is little research on safe human exposure levels or adverse human health effects. Human studies are the most challenging by far, in part because they require adequate tracking of diseases and exposures, and adequate funding of epidemiologic research.

There are a number of well-known environmental agents associated with harmful effects on a developing baby. These range from the mercury fish poisoning that led to Japan's outbreak of congenital disabilities and mental retardation known as "Minimata" disease, to the connection between folic acid deficiency and such neural tube defects as spina bifida in the United States. But much more information is needed if researchers are to identify other potential threats to children's health.

- Little is known about the human health effects of the estimated 15,000 chemical compounds produced in quantities of at least 10,000 pounds annually. Even more alarming, nothing is known about the human health effects of two-thirds of the chemicals produced in the U.S. in high volume (1 million or more pounds each year). However, based on animal and other studies, many of these chemicals are capable of causing developmental toxicity if exposure to sufficient dose occurs at a critical time.
- Gaps in tracking and research for both birth defects and exposures to developmental toxicants make

it difficult to answer the questions raised by animal testing. Inconsistent state and national tracking data limit research into whether increases in birth defects are related to changes in environmental exposures, diagnostic improvements or other factors. It is very likely some increases are due to changes in diagnostic technology. But it is important to our children's future—and society's—to know for certain.

A national opinion survey conducted among registered voters by The Pew Charitable Trusts earlier this year found there is strong support among Americans to track health problems and environmental exposures, including birth defects. Other surveys found Americans understand there are many factors in the environment under personal control, such as maternal diet and use of drugs.

But nearly nine of 10 Americans surveyed for Pew also believe environmental factors are a major cause of health problems. Two-thirds said more should be done to protect public health, and by more than three to one, respondents favored increased federal spending on public health over tax cuts.

More than 90 percent of Americans believe we should do more research to learn about the health effects of environmental problems. Americans understand this approach represents our best opportunity for prevention.

## **THE CASE OF BRICK TOWNSHIP**

Tragically, there are many examples of reported clusters of birth defects and related conditions in communities around the country. So far, public health research has few answers to give us.

One of these is located in Brick Township, NJ. In 1993-97, concerned parents identified 53 cases of autism among 6,000 children between the ages of 3 and 10, and began asking questions about whether there is an increased risk in their community for autism due to environmental factors. Once believed to be a rare condition, autism is a complex developmental disorder that usually appears in the first three years of life. It is characterized by social aloofness, impaired verbal and nonverbal communication and imagination, and abnormal or limited activity. Some children with autism may function at below-normal intellectual levels, while others may do well in school but have severe social impairments.

Unfortunately, there are no answers at present as to the causes of autism, although research has identified suspected genetic and environmental factors. The unusual cluster of autism reported in Brick Township and in California, where the Department of Developmental Services recently issued a report showing a 210 percent increase in the number of autistic children entering its program over an 11-year period, must await the national baseline data that researchers need to answer such questions as:

Are these truly statistical excesses that should be studied further? Is evolution in the criteria used to diagnose autism responsible? Are more accurate diagnosis and reporting also factors? Are there environmental toxicants involved?

In Brick Township, investigators from the CDC and the state of New Jersey are examining a range of possibilities for environmental exposures, including air quality, a nearby landfill, and local drinking water supply. So far, there are no answers.

## **THE CASE OF BROWNSVILLE**

However, history has shown that public health research into such questions is rewarded with

advances in knowledge about health hazards and prevention techniques that work.

Just as Brick Township illustrates the human tragedy of unanswered questions, a preventive strategy that is now promoting healthy babies nationwide emerged from the study of another birth defect cluster in the Rio Grande Valley of Texas.

An unusually large number of cases of neural tube defects in Cameron County in the Brownsville area prompted state and CDC researchers to launch investigations into possible genetic and environmental factors. Although research was never able to answer the question of what had caused six babies to be born in a six-week period with a form of anencephaly, a neural tube defect in which all or part of the brain is missing, the effort led the State of Texas to begin a statewide program to monitor birth defects.

Texas is now one of the nation's leaders in developing a model system for tracking birth defects and related conditions. These cases, and the work of the Centers for Disease Control in assisting state health investigators, ultimately led to a preventive strategy that earlier research had identified as promising in protecting against this type of birth defect.

The role of the B vitamin folic acid as a protective factor against neural tube defects was initially suggested in the 1960s. In 1992, the U.S. Public Health Service recommended that all women of childbearing age take 400 micrograms of folic acid daily, starting before pregnancy. Folate, found in such foods as orange juice, is the naturally occurring form of folic acid. In 1998, the Food and Drug Administration determined that U.S. grain sold as 'enriched' be fortified with folic acid at a level thought by some to be less than optimum.

The Texas cases provide an excellent example of the value of public health research and tracking, and why it should be continued. As a footnote, now that folic acid is being added widely to the grains most Americans consume, research needs to continue to determine the impact of this supplementation on other potentially sensitive populations, including young children and the elderly. In addition, continued tracking is needed to evaluate the results.

## **STUDY CONCLUSIONS**

Birth defects are the no. 1 killer of infants in the United States, and certain birth defects and related conditions are increasing. The cost of these health problems is measured in family suffering and lifetimes of disability, as well as in higher health and educational costs.

Although exposures to environmental toxicants may play an important role, we have too little information at present on which to reach definitive conclusions. Addressing these tragic conditions and generating better information about environmental causes should be a national priority because birth defects and related conditions may be preventable.

There also are indications that certain birth defects, low birthweight and preterm births are increasing faster in some regions of the country than others. Yet we lack the information that consistent, nationwide tracking would provide to determine whether these variations are relevant and need more study, and if so, to develop prevention strategies.

The benefits to American society far outweigh the costs of improving our public health system and accelerating public health research to drive answers to the following questions:

- Why infant mortality rates due to birth defects and related conditions remain stubbornly high despite other improvements in the health of children and their mothers. There is much research suggesting

environmental triggers, but the causes of the majority of birth defects remain unknown.

- What chemical toxicants are present in the environment and what are the exposure levels.
- What exposure levels to various environmental toxicants place developing babies at risk.
- Why the apparent increases in rates of certain birth defects or variations by state and region. These differences may result from changes in diagnostic technology and reporting, or may be linked to environmental exposures or something else we don't yet know about.
- What is responsible for unusual clusters of birth defects at some local levels, and how can they be prevented.
- What is responsible for the reports of increases in such developmental disabilities as cerebral palsy, mental retardation, and autism. Children with birth defects or who are born preterm or low weight are more likely to suffer from these tragic conditions. Research has linked them to a number of environmental factors, but causes are largely unknown.

But to answer all these questions, we must have good state systems that do a significantly better job of gathering information on the incidence and prevalence of such children's health problems. Some states are managing to do a yeoman's job of carrying out this important task, while others have done very little. We can remedy this situation, and this report lays out recommendations for that improvement.

The Birth Defects Prevention Act of 1998 was intended to provide the impetus and support. For 1999, Congress appropriated less than a third of the money authorized to implement national standards for state tracking systems. To compare the scale of public expenditure, the additional \$22 million it would take to set up adequate databases on birth defects and related conditions would construct approximately 20 miles of a typical four lanes of interstate highway.

The federal government has failed to provide states with sufficient resources to track such health problems, and what is more, there is no policy framework to address exposures to environmental toxicants as a priority for public health investment.

## **COMMISSION RECOMMENDATIONS**

We know how to create the public investment priorities and build the tracking systems that public health professionals need to address the social, biological and environmental factors that are contributors to chronic disease and disability in America. If we do not look for answers, we will never know the causes, and thus, will be unable to prevent these costly and life-threatening conditions.

Despite gains in treatment and clinical science, we have not made equal gains in prevention. In fact, prevention and prevention-based science – the analysis and the tracking systems that are discussed in this report – have been neglected. Prevention-based science must become an effective partner with research on diagnosis, treatments and cures if we are to move forward in improving the health of our children.

Just as we have made much progress in combating infectious disease, we have the greatest single opportunity we have had in generations to achieve a new, higher standard for public health, and to launch another leap forward in Americans' quality of life.

The foundation for a national effort to revitalize our public health system is leadership at the federal, state and local levels to ensure the health of our children is monitored and defended against potential

environmental threats. With this national will, we can:

- *See to it that every state has the commitment and resources to watch and protect public health. Full funding of the National Birth Defects Prevention Act is an important first step.*
- *Require and provide the resources for analysis of existing data on birth defects and the studies to do follow-up and identify risk factors.*
- *Work toward a national reporting system that allows researchers, policymakers and the public access to all relevant information, including developmental disabilities, via public databases that protect confidentiality and privacy, while improving the American people's knowledge of the health of their communities.*
- *Develop a national approach for monitoring exposures linked to the environment. We should not be ignorant of exposure levels in our bodies to environmental contaminants that are likely to be in our food, water, and air.*
- *Re-evaluate the federal policy framework for the nation's public health system to ensure not only capacity but also appropriate strategies for monitoring, evaluating and preventing chronic disease and disability.*

The health of future generations of Americans depend on the choices we make today about the priority we give to attacking threats to public health. History has shown that a society's progress depends on its ability to maintain a healthy quality of life. Today we have more knowledge and tools to improve the determinants of health—biological, social and environmental—than ever before. The challenges are great, but so is our nation's ability to succeed.

### **ABOUT THE PEW ENVIRONMENTAL HEALTH COMMISSION**

*The Pew Environmental Health Commission was created by The Pew Charitable Trusts to develop recommendations designed to bolster the nation's ability to track and prevent health problems linked to conditions in the environment.*

*The Trusts, along with the Johns Hopkins University School of Public Health, determined it was important to focus on the often-overlooked role of environment as a means to prevent chronic disease, the leading cause of death and disability in the United States today. The Commission believes the role of environmental health cannot be underestimated if we are to be successful in combating these new health threats. In the Commission's words, environmental health is "those aspects of human health, including quality of life, that are determined by interactions with physical, chemical, biological and social factors in the environment. It also refers to the theory and practices of assessing, correcting, controlling and preventing those factors in the environment that may adversely affect the health of present and future generations."*

In the coming months, the Commission will be producing a series of reports on children's environmental health concerns—birth defects, asthma, and childhood cancer—that highlight the limitations of our present public health system in preventing chronic disease and disability, particularly those linked to the environment. This first report, on birth defects and related conditions, is intended to illustrate the gaps in our knowledge about birth defects and exposures to toxicants in the environment,

and why it is so urgent that we strengthen our public health system to address these challenges.