



December 8, 1999

TO: Members of the Senate Committee on Health, Utilities, Veterans and
Military Affairs

FROM: Jim Strachota, Chair JS
Wisconsin Council on Developmental Disabilities

RE: Support for Senate Bill 290, Birth Defects Surveillance and Prevention

The Wisconsin Council on Developmental Disabilities (WCDD) supports SB 290, the Birth Defects Surveillance and Prevention Bill.

The WCDD was actively involved in passing the original Birth and Developmental Outcome Monitoring program in 1988. At that time, and now, the WCDD believes that a birth monitoring program is needed both to further our knowledge of how to decrease the incidence of preventable disabilities, and to improve the delivery of services to children who are born with disabling conditions. Having respect for people who have a specific disability does not preclude our efforts to prevent the occurrence of the disability.

This bill improves upon the earlier program by expanding the reporters to hospitals and specialty clinics, limiting the children's age for reporting to two years, improving the referral of children with special needs to early intervention services, establishing an advisory council, and maintaining the right of the parents to confidentiality.

The following four examples are used to illustrate the importance of this legislation:

1. When a baby is born with a disability, one of the first questions the parent asks is "why did this happen?" For some disabilities, the causal factors are known, but for many they are not. In 1985 in two counties in east central Wisconsin, there was an apparent increase in the number of babies born with a neural tube defect. Both a tertiary care hospital and a county human service agency contacted state health officials to ask if the increase could be the result of environmental contamination.

The state responded by reviewing all the hospital discharge diagnoses for all live births in two counties from 1979 to 1984. The final report, published after a 18 month long investigation, proved that there was not a significant increase in birth defects. This was a tremendous relief to the health officials and to the families in the two counties, but the time and expense of such a retroactive study limit replication in other communities. If a good monitoring program had been in place, the state could have given a much quicker and less costly response.

2. A surveillance system in Texas led to the discovery that a maternal deficiency in folic acid can increase the risk of having a baby born with a neural tube defect. It is now known that taking the B-vitamin folic acid prior to conception can decrease the incidence of neural tube defect by 50%.
3. The Wisconsin Council on Developmental Disabilities has strongly supported efforts to decrease the incidence of fetal alcohol syndrome (FAS). FAS causes cognitive disabilities and is very difficult to diagnosis, especially in infants. It is unlikely that FAS will be reported on the birth certificate, since the certificate is filled out within the first few days of life. Although different prevention strategies have been implemented, which ones are effective? Should the state be applying more funds to the prevention of perinatal substance abuse? Should we follow the lead of other states and pass a warning that is posted in bars and restaurants? Without knowing the Wisconsin incidence of FAS, it is impossible to know if FAS prevention is a priority or whether or not a specific prevention strategy worked. This legislation will help us develop effective preventive strategies.
4. The Birth to Three Program offers early intervention services that can lessen the effect of a disabling condition. For infants who are cared for in a Neonatal Intensive Care Unit, there is already a referral system to the County based Birth to Three Program. This legislation extends the option of a referral to Birth to Three services to children with disabilities, such as Cerebral Palsy, that are not necessarily discovered at birth.

Thank you for your consideration of this important prevention legislation.



KIMBERLY M. PLACHE

STATE SENATOR • TWENTY FIRST SENATE DISTRICT
December 8, 1999

TO Members of the Senate Committee on Health,
Utilities, Veterans and Military Affairs

FR Sen. Kimberly Plache

RE Senate Bill 290, which relates to birth defects
monitoring and prevention

The Problem

Approximately 2,000 babies born in Wisconsin each year are born with at least one birth defect. While a Birth Defects Monitoring Program currently exists in the Dept. of Health and Family Services, it is inadequately staffed and in adequately funded. Accurate information is needed for research to determine the cause of birth defects and to determine prevention strategies. The State currently gathers insufficient data to monitor prevention strategies and provide children and families with information they need to obtain health, social and family services. The most recent state budget includes an additional \$200,000 for the Birth Defects Program. The policy changes sought by Governor Thompson were removed from the budget.

Senate Bill 290

Senate Bill 290 was introduced at the request of the March of Dimes and has been developed with the Department of Health and Family Services. This bill replaces the current program with one which requires physicians, hospitals, certain clinics and clinical labs to report birth defects identified in children under the age of 2 to the dept. of health and family services. As under CURRENT LAW, personally identifiable information that is contained in the reports is confidential and may not be released to any person, except under certain strictly regulated circumstances. SB 290 creates a council on birth defects to advise the department on the registry and protocol regarding the reporting of information.

Federal Research Dollars

Wisconsin is falling behind. There are 40 other states which are implementing their own Birth Development Outcome Monitoring program. If we pass SB 290, we will be able to obtain federal funds. An adequately funded and staffed program will help Wisconsin children and families and SAVE TAX DOLLARS in the long run.

Strong Bipartisan Support

There are 17 Democrats and 18 Republicans signed onto SB 290



Copy for distribution to Senate committee

Statement in Support of SB290

December 8, 1999

D. Gail McCarver, M.D. and Ronald N. Hines, Ph.D.

1 My name is Dr. Gail McCarver. I am one of the Co-Directors of the Birth Defects Research
2 Center (BDRC) recently established by the Children's Hospital of Wisconsin and the Medical College
3 of Wisconsin. The other Co-Director of the BDRC, Dr. Ron Hines, could not be here, but has given
4 me permission to speak on his behalf. In addition to our administrative responsibilities in the BDRC,
5 I am an Associate Professor and Dr. Hines a Professor of Pediatrics and Pharmacology/Toxicology
6 at the Medical College of Wisconsin. I also am an attending neonatologist at the neonatal intensive
7 care unit at Children's Hospital of Wisconsin and Waukesha Memorial Hospital. As a physician
8 scientist, my career has focused on the intersubject variation in disease risk, most recently that of birth
9 defects. In my clinical role within the neonatal intensive care nurseries, I provide care for infants with
10 life threatening birth defects. I have seen firsthand their suffering and that of their families.

11 I have a prepared statement about SB290 and then I would be pleased to entertain questions.
12 This statement reflects my view and those of Dr. Hines. In addition, I have been authorized by the
13 Children's Hospital of Wisconsin to serve as their spokesperson. This statement does not reflect an
14 official position by the Medical College of Wisconsin who will be sending a separate supporting
15 statement. I am also a member of the State Medical Society and the American Academy of
16 Pediatrics, Wisconsin Chapter, but this statement has not been authorized by either group.

17 As previously stated, birth defects are the leading cause of infant death. What does this mean
18 to real families and children in WI? Let me recount for you an example from the perspective of a
19 physician caring for babies.

20 The mother of Baby A has good prenatal care; she is happy to be pregnant and healthy. She
21 and her husband go to their local hospital expecting a normal delivery. They are happy with
22 anticipation. She has a boy, and the news is wonderful! But, horror unfolds quickly in the delivery
23 room...something is wrong with their baby, and it is serious. The cause is rapidly identified; he has
24 a hole in his diaphragm, the muscle that separates the lungs from the abdomen. The abdominal
25 contents have passed through the hole and into the chest. Because of this, the baby can not breathe
26 effectively. He is taken from mom and dad and transported to Children's Hospital. As the transport

27 team prepares to leave, the family is told he will need surgery. They ask "How serious is that?" They
28 must also be told, even with surgery, about half of the babies with his condition die. He is admitted
29 to the intensive care nursery at Children's Hospital where nurses, doctors and respiratory therapists
30 watch over him like a hawk. His lungs are severely affected; almost immediately he needs more
31 support than the standard ventilator can supply. He is changed to another ventilator, in hopes it will
32 work better. By this time, the parents are at the bedside, praying, crying and hoping. Baby A 's
33 blood pressure is marginal in spite of the many drugs he is receiving. The new ventilator works, for
34 a while, but over the next several hours, Baby A's condition begins a down hill slide. It becomes
35 apparent, without extraordinary means, Baby A will die. The parents are asked and give their consent
36 for cardiopulmonary bypass, as the only remaining hope to save his life. Baby A is maintained on
37 bypass for four days. His care by the physicians, the nurses, the respiratory therapists and the family
38 is vigilant. We pray and we hope. The parents are sweet people. We wonder, why did this happen
39 to them and to Baby A? He slowly stabilizes; bypass is discontinued. He is back on ventilator
40 support. Before he can safely go to surgery, he must improve somewhat, or the risk from surgery
41 is too great. Another three days pass - it seems like forever when every minute and every hour crawls
42 by in constant vigilance by family and care givers.. The family watches and waits in agony; he is still
43 life-threateningly sick. The decision is made. Baby A is going to the Operating Room. After several
44 hours, the family is told, "He has done well through the surgery." Back to the nursery safely, Baby
45 A still has a long way to go. What ultimately happens? Baby A survives, but he is in the hospital for
46 six more weeks. He has feeding problems and his long term developmental outcome will need close
47 evaluation. SB290 is not about databases and computers; it is about disease, death and suffering like
48 that of Baby A and his family.

49 The etiology of about 70% of birth defects is unknown. We know that some defects run in
50 families and yet simple inheritance does not explain risk. We know that some environmental
51 exposures contribute. However, much of the data supporting the latter statement comes from animal
52 data. In many cases, the relevance to human risk remains untested. What are the causes of birth
53 defects? More importantly, what are the cause of birth defects in Wisconsin? Are there certain
54 defects for which we, or more specifically, our unborn children are at increased risk?

55 There is a sense among pediatric cardiologists in this state that Wisconsin has a greater than
56 expected number of cases of certain congenital cardiac defects. Are they right? We don't know.

57 There is a sense that these cardiac defects occur in geographic "pockets". Is this true? We don't
58 know for sure. If true, what is the mechanism for these clusters of risk? Is there something in the
59 environment that puts certain Wisconsin families at increased risk? Perhaps, but more likely, it is a
60 combination of genetic risk factors and environmental exposures. However, this remains a
61 hypothesis. We do not have definitive answers to these questions.

62 Most importantly, the research tools are now available to effectively address these types of
63 questions. By assessing the geographic location of birth defects using sophisticated computer
64 software, we can not only look for clusters, we can, using data from the EPA on the environment,
65 evaluate links between the geographical location of defects and environmental exposure. We can test
66 whether defects known to occur in animals exposed to certain chemicals occur at an increased
67 frequency in areas that have higher exposures. For example, we know that a group of compounds
68 called halogenated hydrocarbons repeatedly have been shown to be associated with congenital heart
69 defects in animal studies. We also know that two human populations, one in California and one in
70 Arizona, have demonstrated an increased risk from halogenated hydrocarbon exposure. What does
71 this mean to Wisconsin? One of the compounds known to cause cardiac defects is one of the top ten
72 chemicals emitted in Wisconsin. Is that a risk? We have the tools to answer that question, if only
73 we had the data.

74 Senate Bill 290 provides the means of gathering that all important data so crucial to answering
75 these and similar questions. Importantly, to draw correct conclusions, the data must be complete and
76 it must include specific geographic identification of cases. For completeness, the addition of hospitals
77 as reporting entities is a pivotal part of this legislation. All infants with significant defects will be seen
78 within a major hospital within the state. Some may object that this is too great a burden on hospital.
79 However, the entity with the greatest reporting burden, the Children's Hospital of Wisconsin, accepts
80 this burden and supports this bill as good for the families of Wisconsin.

81 There have been valid concerns expressed regarding privacy and abuse of information. I
82 understand these concerns, but our families want and deserve answers. How can we do both? In this
83 regard, I believe the provision within SB290 for a council which would have oversight of this
84 program is an essential piece of the bill. Such a council should be empowered to decide and be held
85 accountable for what data are collected, what queries are made of the data and by whom; that is,
86 what credentials and what process should be followed for individuals to have access to these data.

87 In this regard, I believe the power of the Council to determine the release of data should have one
88 additional statutory limitation. I believe the greatest confidentiality concern families have is that their
89 health status may be used against them by employers and insurance companies. I believe it should
90 be unlawful for the data collected under SB290 to assist in such discrimination. As such, access to
91 these data by employers and insurance companies should never be allowed; an Amendment to this bill
92 should legislate this protection explicitly.

93 We have heard other proposals for enhancing confidentiality. One proposal suggests parents
94 be offered the option of not having their child's data submitted. This "solution" will create other
95 problems. If the data are incomplete, which they will be if parents are allowed to opt out of
96 reporting, false conclusions will likely be reached regarding the specific frequency and the presence
97 of clusters of defects. These false results will lead to public outcry and studies of the possible causes.
98 Ultimately, this may lead to litigation against those thought to be responsible for causing a cluster.

99 The other solution that has been offered is only to collect non-identifying data. That is,
100 children would only be identified by their diagnosis and their birth date. This solution has at least two
101 problems. 1) Inclusion of only birth date and diagnosis will not suffice for legitimate identification,
102 such that duplicate reporting can be addressed. It is not uncommon to have two babies born in the
103 same day with the same defect. Thus, a birth date as the only identifier would, *a priori*, add error to
104 the data collected and to the conclusions drawn from the data. I believe to set up a collection
105 process that *a priori* we know will lead to false information, is unethical. Those offering this solution
106 have an additional concern that I believe can be addressed. That is, if health care providers submit
107 data without consent and the data is used in a way that a subsequent valid objection is raised, the
108 reporters may be held liable because no consent was obtained. This concern about reporters liability
109 should be protected by statute. 2) Failure to include at least geographic identifiers would eliminate
110 the ability to identify clusters of defects and may also impact the ability to provide quality local
111 services.

112 We can move forward in the fight to prevent birth defects in Wisconsin. But, we must know
113 exactly what it is we are fighting. We must understand "the where" in order to understand "the
114 why". We must understand "the why" before we can prevent. The process starts with well collected,
115 rigorously analyzed data. We believe that SB290 is a major step forward in that process.

PRO-LIFE WISCONSIN

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November 30, 1999

TO: State Legislators
FROM: Mary Matuska, Legislative Director
RE: AB579/SB290—Birth Defect Registry

Pro-Life Wisconsin would like to take the opportunity to share our concerns with Assembly Bill 579/ Senate Bill 290 (AB579/SB290) relating to birth defects prevention surveillance.

It is important to protect and help children with disabilities as much as possible. While we do not doubt the sincerity of the concerns that compelled the authors to initiate this legislative proposal, **we believe it is necessary to consider the potentially serious long-term harm this proposal may inflict on the children of Wisconsin.** Specifically, Pro-Life Wisconsin is concerned with the following items:

1) **Creation of a Council on Birth Defect Prevention and Surveillance.**

The concern that this Council, or members of the Council, may view abortion as a means of birth defect prevention is a serious one. Even with the explicit language in AB 579/SB290 requiring the Department of Health and Family Services (DHFS) to develop preventive strategies “without increasing abortions”, the potential for the Council or state officials to create an atmosphere where parents carrying disabled children may feel undue pressure—via genetic testing or specific diagnoses—to abort their children is real. While few birth defect prevention organizations advocate abortion as a preventive strategy, many do advocate genetic testing and subsequent counseling which can increase abortion rates.

We are also concerned that this Council, if created, may advocate other anti-life measures as a means of “preventing birth defects”. Sadly, some organizations advocating research into the cause of birth defects have advocated the use of research on human embryos (referred to as “stem cell research”). There is nothing in AB 579/SB290 that prohibits the Council from advocating research that destroys or manipulates human embryos.

2) **“Preventive Strategies”**

While AB 579 instructs DHFS to develop preventive strategies to decrease the occurrence of birth defects without increasing abortions, other possible preventive strategies are not prohibited. For example, if DHFS officials discover a trend of birth defects in a given geographic area, will the state begin an effort to convince parents to subject their preborn child to genetic tests that are sometimes dangerous and not always definitive? While genetic testing in and of itself is not unethical, the use of such tests to identify preborn children with disabilities can implicitly create an atmosphere where abortion is viewed as a humane and acceptable option.

The potential long-term ramifications of this legislation are dangerous for Wisconsin children and their families. We believe it is important for the State of Wisconsin to send a clear message that those with disabilities, no matter their age, are valued members of this society. Despite the honorable intentions of the authors, AB 579/SB290 does not validate that life-affirming message.

We urge you to oppose AB 579/SB290.

Date: 12/08/99

Written testimony of Marsha Malloy, 2030 S West Lane, New Berlin, Wisconsin
12 year resident of New Berlin
Mother of a 9 year-old daughter with a birth defect known as Down syndrome
In Support of 1999 Senate Bill 290, in the State of Wisconsin

Chairperson Moen and Representatives of the Committee on Health, Utilities, Veterans and Military Affairs:

I feel it both a privilege and a duty to speak to you for a few minutes to encourage you to support Senate Bill 290.

On April 28th, 1990 after having what I was told was a normal 9 month pregnancy, I delivered a 6lb 12 oz baby girl. She was my first child. My husband and I should have been ecstatic! We had planned for this moment for several years. I had never smoked, did not drink alcohol or use drugs before or during pregnancy. I even gave up caffeine and took prenatal vitamins religiously. Moments after birth I noticed the baby's eyes were a little slanted and her ears low set. She didn't appear to have the normal muscle tone of a newborn. I thought, "Marsha, you must be crazy to think such things, after all 25 year old healthy women with proper prenatal care and no family history don't have babies with Down syndrome"! I remember asking my husband to turn off the video camera, so I could bravely ask the dreaded question "Does the baby have Down's?" The obstetrician, said he was wondering the same thing. . . but he didn't know for certain . . . there were some tests that could be done . . and then he said "you didn't do anything to cause this".

April 28th 1990 was the day my life and my perspective about birth defects was forever changed. I soon learned that the odds of having a Down syndrome baby at my age were one in 1,500. . . and I was the "one"! While still in the hospital, I thought to myself, I will shelter her from public stares, not take her out in public. Well that idea soon changed! She is very friendly, outgoing and wouldn't want to miss out on anything! She is in gymnastics, soccer, and has had a picture of herself and her non-disabled friends displayed in Times Square in New York for National Down Syndrome Awareness Month (October). I would have brought her to meet all of you today, but she really enjoys being in a full-inclusion classroom at Orchard Lane Elementary School in New Berlin and is progressing well in reading and math. So I brought pictures to share with you instead. She wanted me to show you a picture of her younger sister Melissa too!

My story isn't unique. As a founding member of the Down syndrome Association of Wisconsin, which we organized the year Alexis was born, and as a parent advocate for families with children a wide range of birth defects I have heard several hundred parents recount a similar experience. They had thought that birth defects only happened when the pregnant mother abused drugs or alcohol. Some even said they were reluctant to go

to support groups initially because they thought the other parents would be drug abusers, and the fact that they were not was a rare case. In talking with other parents there is another common thought expressed. We love our children with genetic defects for who they are. We do not wish that they had not been born, for in their special way they have enriched our lives. Most of us didn't even consider abortion, even if we found out the diagnosis before birth. However, we all wish our child had not been born with the defect, and we all wish that there was a cure or a way to prevent the defect from happening.

SB 290 ← I and many other parents I know who have children with birth defects are in favor of Assembly bill 579 because we want the state of Wisconsin to do as much as possible to find out the causes of birth defects in our state and to prevent birth defects from occurring. There have been scientific studies that have suggested that some birth defects may be caused by toxicants in our diets, our water, our air, and in other elements of our environment. I understand that the department of Natural Resources requires companies to monitor and report toxic emissions of chemicals into the air and water. Companies in violation of these requirements receive citations. What good is collecting information about toxic chemicals if we don't require the same standards of reporting and accountability for reporting incidences of birth defects and cancer?

Parents of children with birth defects are always asking this question . . . "Why did this happen"? 80% of the time no one can tell them why the defect occurred. In Wisconsin, parents don't have the opportunity to fill out a statewide birth defects survey, as parents in many other states do. So many times I have heard parents say, "If there was something I could do to help prevent this from happening to another baby, I would do it." Filling out a birth defects survey soon after their baby is born is something that could help. It helped researchers find out that an absence of folic acid can cause neural tube defects. What I am holding up is a copy of the National Birth Defects Prevention Study Mother Questionnaire. I am told by the Centers for Disease Control that in some states it is even administered this survey over the web. I was told it costs \$200.00 to administer and analyze one survey. I think that would be money well spent if it resulted in finding the cause of even 1 type of birth defect in Wisconsin.

I have one last comment, and that is about confidentiality. There is a perception that many parents are worried that reporting a birth defect will cause them or their child to be punished in some way. I am not aware of an actual opinion poll being conducted in Wisconsin on this issue, so I don't know if the perception is actually true. But I do know that if the statute is written carefully, and the public educated, then these fears, if they are real, will be removed. As parents of special needs children, we want our children to be protected from harm that comes in any form. We don't want our child to be denied health insurance, medical treatment, or a public education at the school of our choice. We don't want our families to be discriminated against because of our child's birth defect and we don't want to be pressured or even encouraged to abort our babies with anomalies. Therefore it is important that any statute passed protect us and our children from these discriminations. On the other hand we are aware that our local school district already have authorization to find out about children in their districts that have birth defects. The statute says that this information is provided for planning purposes. In a

similar manner, we want state and academic researchers to have access to information that will help them find the cause of my child's birth defect. If there is a cluster of similar birth defects in my neighborhood, I want researchers to investigate this phenomenon in methodical way using a written protocol approved by the council formed by Assembly Bill 579. I am holding up a copy of a birth defect cluster investigation protocol that is used throughout the state of Texas. The investigation would require the researchers to have identifying information about me such as my street address, and maybe they will want me to fill out a confidential survey. I think the language in Assembly Bill 579 about confidentiality adequately protects my privacy rights, yet allows for necessary public health surveillance. I strongly encourage you to support improving birth defects surveillance and research in Wisconsin.

Thankyou.



1999 Senate Bill 290 Wisconsin Birth Defects Surveillance System

Testimony of Chris Cronk, D.Sc.

Program for Children with Special Health Care Needs
Birth Defects Surveillance

Background on Birth Defects

- A birth defect is a condition (i.e. single or multiple alterations in anatomical structures, organ systems, metabolism) present at birth that renders that infant different in some way from most other newborns.
- Conditions that cause death or that substantially change the opportunity for a normal life are of greatest concern. An example of such a condition is *Spina bifida*. A baby with Spina bifida is born with the top part of some of the vertebrae in the back improperly formed. Some of these children die; others are paralyzed, have mental retardation, and additional major organ problems. Between 1990 and 1997, more than 300 infants with spina bifida were born in Wisconsin.
- We understand some of the reasons these conditions occur. For example, folate intake is related to the occurrence of spina bifida. However, causes of the majority of these conditions are unknown. *The Pew Environmental Health Trust Report* (released November 12th) (1) warns that recent increases in some birth defects might be linked to environmental causes.

“The data show that despite much progress in clinical medicine, we know far too little about why rates of birth defects . . . remain stubbornly high and appear to be increasing in many instances. 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.”

The Pew Environmental Health Trust Report identified birth defect surveillance registries as the first step in solving this problem.

- Wisconsin’s current program is inadequate. *The Pew Report* gave Wisconsin’s registry (the Birth and Developmental Outcome Monitoring Program, BDOMP) a ‘C’ for its performance because it does not allow useful analysis of the data. With an estimated 3,500 birth defects occurring each year, for the past three years, the BDOMP has received about 50 reports per year.
- SB 270 tries to correct some of the problems with the Wisconsin BDOMP that prevent us from identifying the causes of birth defects in Wisconsin.

Why are birth defects important for children’s health in Wisconsin?

Birth defects are important to Wisconsin families because they often kill infants and children:

- Over the past 20 years, 17 %, (more than 4,000) of the 24,000 Wisconsin children who died had a birth defect listed as the underlying cause.

- By far the greatest number of these 4,000 children (3,000 or about 75%) were Wisconsin babies less than one year of age, and three quarters of these infants died in the first seven days of life. Chart 1 shows percent of children dying from birth defects by age group.
- Studies have found that even non-lethal anomalies increase mortality overall 9 fold and are listed as a contributing cause of death in over 60% of babies weighing more than 3 and a half pounds.
- The biggest killers among birth defects are heart defects. In Wisconsin, between 1980 to 1997, more than 1,200 babies died of heart defects. Central nervous system defects like spina bifida, anencephaly and hydrocephalus have resulted in 500 deaths. Other major categories of birth defects that kill are: structural defects (major alterations of various organs); chromosomal anomalies (e.g. Down syndrome); cerebral palsy not related to birth injury. This is shown in Chart 2.
- **Wisconsin does not do well compared with many other states.**
 - ◆ According to the March of Dimes (2), Wisconsin ranks 30th of all states in its infant mortality rate due to birth defects.
 - ◆ Combined data for the years 1988 to 1991 shows that Wisconsin's infant death rate due to birth defects was higher than that for the whole US, and higher than all other Midwest states except Indiana (Chart 3).
 - ◆ More recent information reported by the CDC show that Wisconsin is one of only 15 states with infant deaths due to birth defects greater than 190 per 100,000 births (Chart 4).
- **Wisconsin infant death rates due to birth defects have not fallen as fast as those for other causes of death.** While the rate of deaths due to birth defects has dropped from 2 per 1,000 to 1 in 1,000 births since the early 1970's, the decline in rates of deaths due to all other causes is much greater (from 8 in a 1,000 to 5 in a 1,000 births).
 - ◆ A specific example is shown in the accompanying chart (#5). The change in death rates of Wisconsin babies (<1 year of age) due to Sudden Infant Death Syndrome (SIDS) and birth defects is shown. In 1997, there were 119 fewer deaths per 100,000 births due to SIDS than in 1984. This is a 3 fold reduction. For birth defects, there was only a 1.5 fold reduction (from 246 to 149 deaths in 100,000 births). SIDS deaths went down partly due to the fact that one preventable cause (sleeping position) was identified, and an education campaign mounted to promote placement of infants on their backs during sleep.
- The impact of birth defects on mortality is their most devastating consequence. However, many babies born with birth anomalies go on to live full, active lives. For these children and their families, there are challenges, rewards and heartaches. Some of them are:
 - ◆ Increased lifetime medical costs. It is estimated that over his/her lifetime, an infant born with spina bifida requires \$300,000 more to care for than a child unaffected by a disability.
 - ◆ 12% of non-newborn pediatric hospitalizations in Wisconsin had diagnoses of birth defects mentioned in the discharge summary. This is more than any other type of illness, including asthma.
 - ◆ The average cost of Wisconsin newborn hospitalizations of infants with birth defects was 5 x higher than for other infants.
 - ◆ Wisconsin newborns with birth defects stayed an average of three times longer in the hospital than other infants.
 - ◆ Very often there is increased emotional strain and family disruption involved in caring for an infant with birth defects.

Why Would the Proposed Registry Help?

- **Early Connection with Services:** The monitoring of birth anomalies has just been moved to the Program for Children with Special Health Care Needs (CSHCN). We in CSHCN are dedicated to the support of children and families with special needs, including babies born with birth defects. We see this registry as a point of referral (for parents choosing to be contacted) to the network of services for special needs children here in Wisconsin. Many families with special needs children are not provided with the resources, programs and support they need to provide for their child particularly when the diagnosis is first made. What we hope to accomplish with the proposed legislation is an improved,

timely linkage for all families with services through our central office and the newly created regional CSHCN centers.

- **Identification of Factors Causing Birth Defects**
 - ◆ **Many Birth Defects May be Preventable:** Though many birth anomalies occur without warning, studies have suggested causes for some of these conditions can be prevented.
 - **Spina bifida** has been linked to environmental causes by some epidemiological studies.
 - Some clusters of **Down syndrome** have been linked to environmental causes in combination with advanced maternal age. Currently, the only means of “preventing” Down syndrome is prenatal testing followed by therapeutic abortion. Primary prevention will depend on our understanding more about these cases (and indeed more about the causes of chromosome problems). This cannot be done without very good registry information.
 - **Fetal Alcohol Syndrome (FAS)** is thought to be one of the major preventable causes of mental retardation. Right now there is no way to count these children. It is thought that Wisconsin may have a larger number of FAS children because we have the highest rates of alcohol use and binge drinking among women of childbearing age in the country (4).
 - ◆ **More complete reporting of birth anomalies.** Rates of birth defects reported in states with the best kinds of registries suggest that there is a greater prevalence of many conditions than expected based on other registries.
 - ◆ **Ability to measure the effects of prevention programs.** Unless solid numbers for the occurrence of a particular condition are available before and after a prevention strategy is implemented, it will be impossible to know if that prevention worked.

What are the problems with the Current Reporting System

- The BDOMP was put into place in the early 1990’s. Its key features are:
 - ◆ Physician reporting
 - ◆ Required reporting for conditions arising birth to 6 years
 - ◆ Required reporting of 136 specific conditions, some arising after birth (for example spinal cord injury when associated with developmental problems).
- The problems with this system are:
 - ◆ **Physician reporting:** It is the physician’s first duty to care for patients, not fill out reports. This is partly responsible for the recent poor reporting record.
 - ◆ **Diffused outreach:** To maintain good reporting, ongoing outreach by the registry staff to reporters must be maintained. This is difficult to do with all individual physicians in Wisconsin.
 - ◆ **Broad age range:** Disorders arising later in life are harder to document
 - ◆ **Large number of monitored disorders:** Disorders arising after birth are included.

How would the new system improve this? SB270 does three things:

- **Identifies institutions (hospitals and specialty clinics) as the responsible reporters.** This allows us to do
 - ◆ Targeted, facility focused outreach
 - ◆ Build the reporting system from the ground up *in collaboration with these facilities*, so that the burden of reporting is minimized.
- **Narrows the age range** from 0-6 to 0-2, allowing greater focus.
- **Narrows the conditions** requiring a report to only those present at birth.

How confidentiality concerns will be addressed

- **Why does a registry have to have identifying information?:**
 - ◆ Avoid duplication of reports: We rely on multiple sources to get a complete idea of the occurrence of the various anomalies. Multiple reports that are not identified would result in overcounting of some conditions.

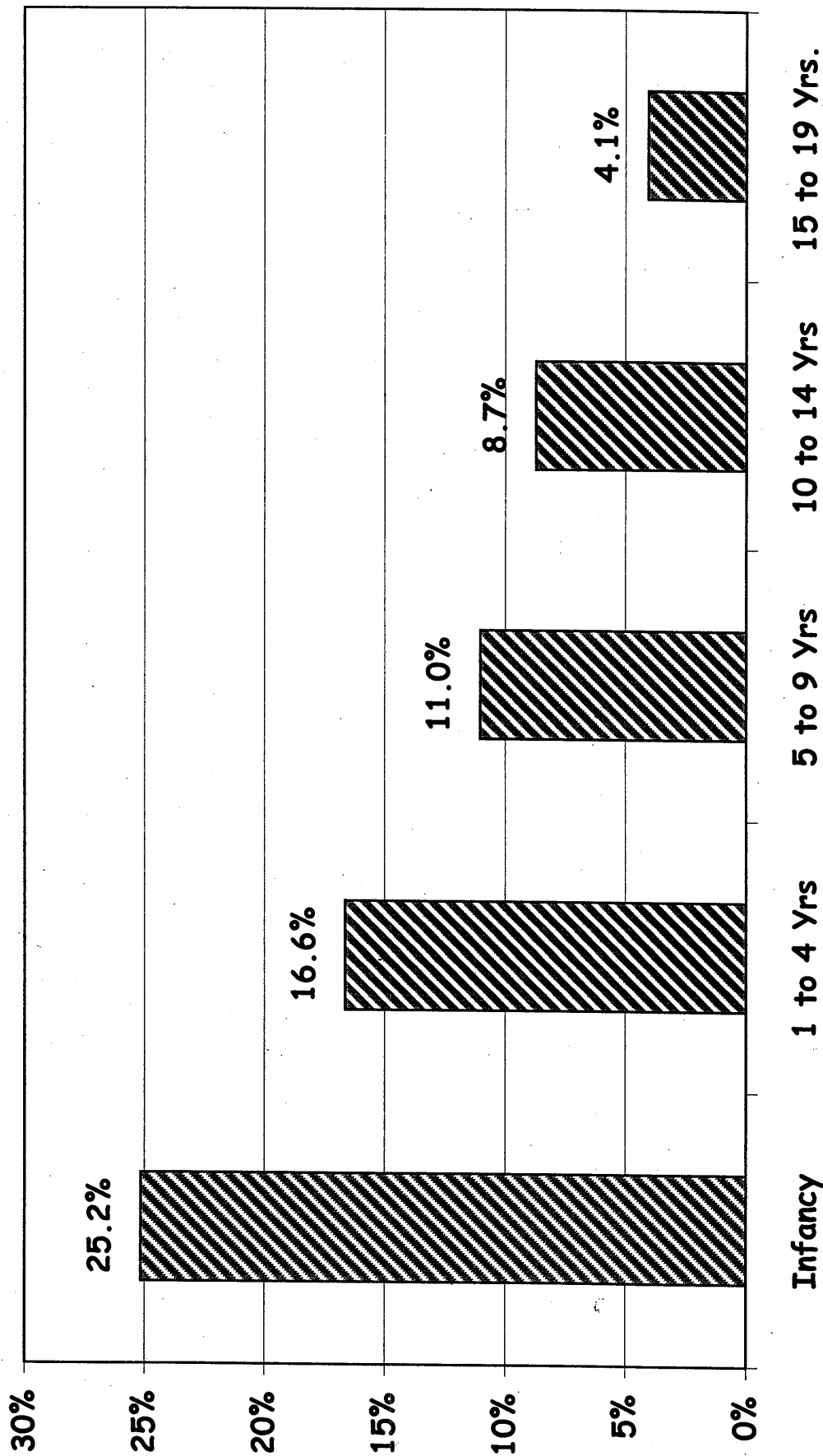
- ◆ Maintain limited information that may relate to the cause of a congenital anomaly (for example specific geographic information)
- *How we will protect information?*
 - ◆ The main registry data base uses an unique identifier to link with other records, but does not itself contain identifying information. Only one file links the name with the unique identifier. This file has special protections against unauthorized access.
 - ◆ Only registry staff will have access to the identifying information. Currently there are two people working in the registry. All registry staff sign a confidentiality agreement. Fines and criminal offenses are attached to breach of this agreement.
 - ◆ Identifying information from registry records **cannot be subpoenaed by courts, shared with other agencies of state or federal government, or used for research purposes without informed consent from the parents.**

Summary

The proposed birth defects surveillance system will allow Wisconsin to address a set of crucial health problems that result in death and negative health for many Wisconsin infants. Without this system in place, we are unlikely to identify causes of birth defects, particularly those specific to our area. We are also proposing a system that will connect families to services at the time of diagnosis, a time when families and infants need much support. Without this system in place, we will be depriving families of services and prevention programs that could significantly improve the health of Wisconsin children.

1. Pew Environmental Health Commission (1999) Healthy from the Start: Why America Needs a Better system to Track and Understand Birth Defects and the Environment.
2. March of Dimes (1996) Birth Defects and Infant Mortality: A National Regional Profile (StatBook Technical Report Series).
3. CDC (1998) Trends in infant mortality attributable to birth defects—United States, 1980-1995. Morbidity and Mortality Weekly Review 47(37); 773-778.
4. CDC (1997) Alcohol consumption among pregnant women and women of child-bearing age-U.S. 1991 and 1995. Morbidity and Mortality Weekly Review 46(16); 346-350.

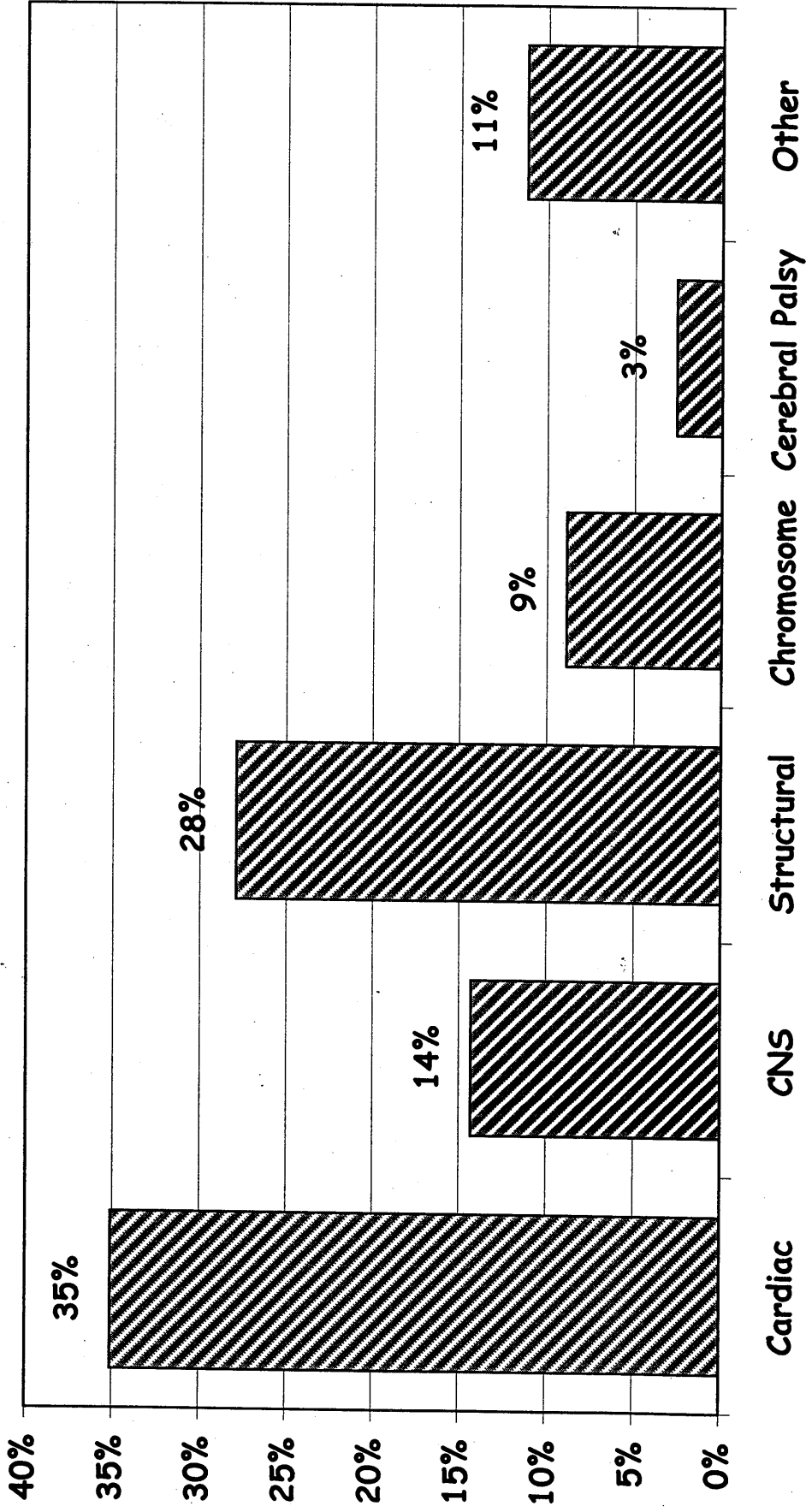
Chart 1: Percent of All Deaths of Wisconsin Children (0 to 19 Years) due to Congenital Disorders 1978-1997 by Age Group



Infancy 1 to 4 Yrs 5 to 9 Yrs 10 to 14 Yrs 15 to 19 Yrs.

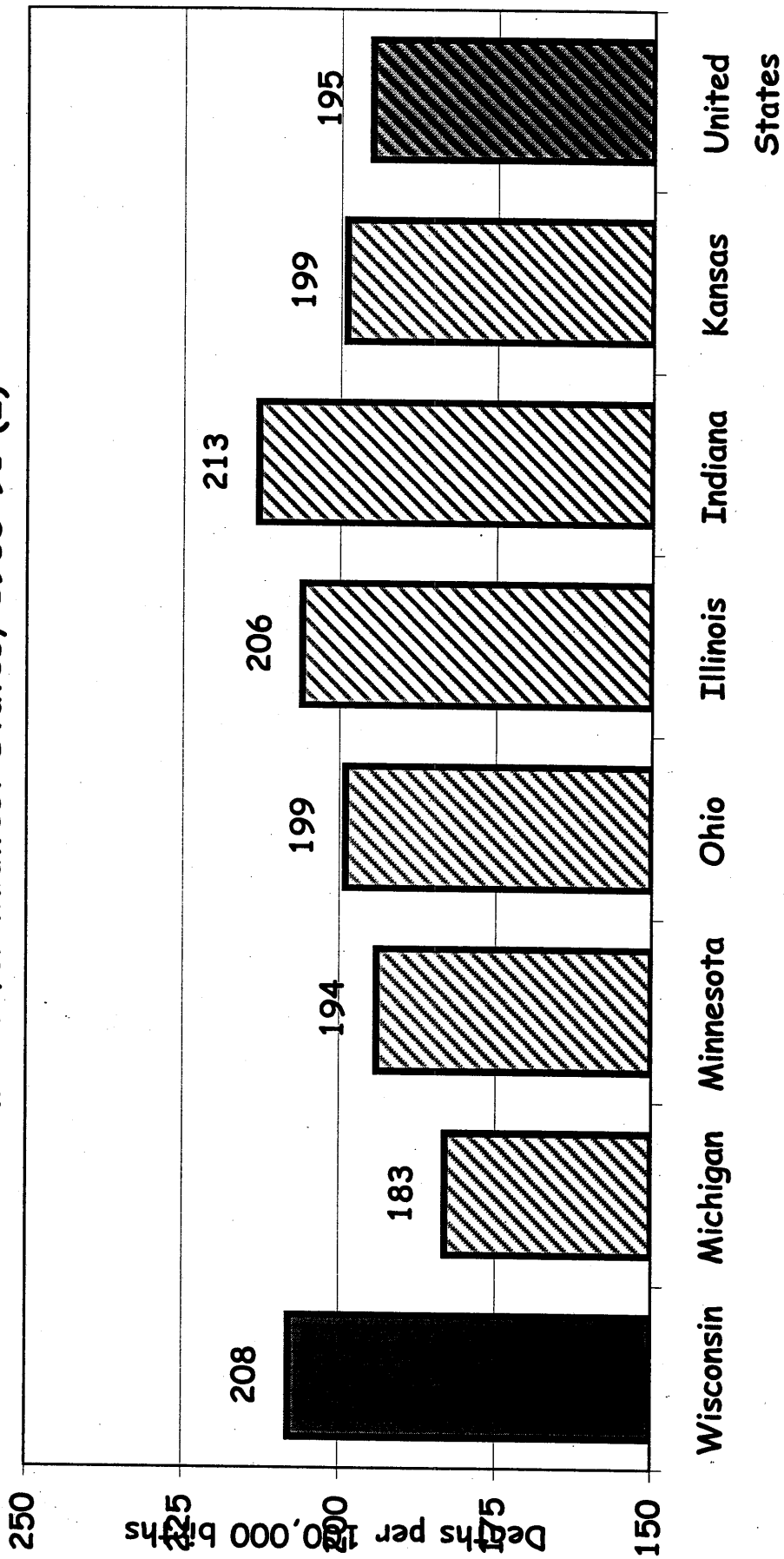
Source: Wisconsin Death Files

**Chart 2: Percent of Deaths to Wisconsin Children (0 to 19 Years)
from Congenital Anomalies 1978-1997 by Type of Condition**



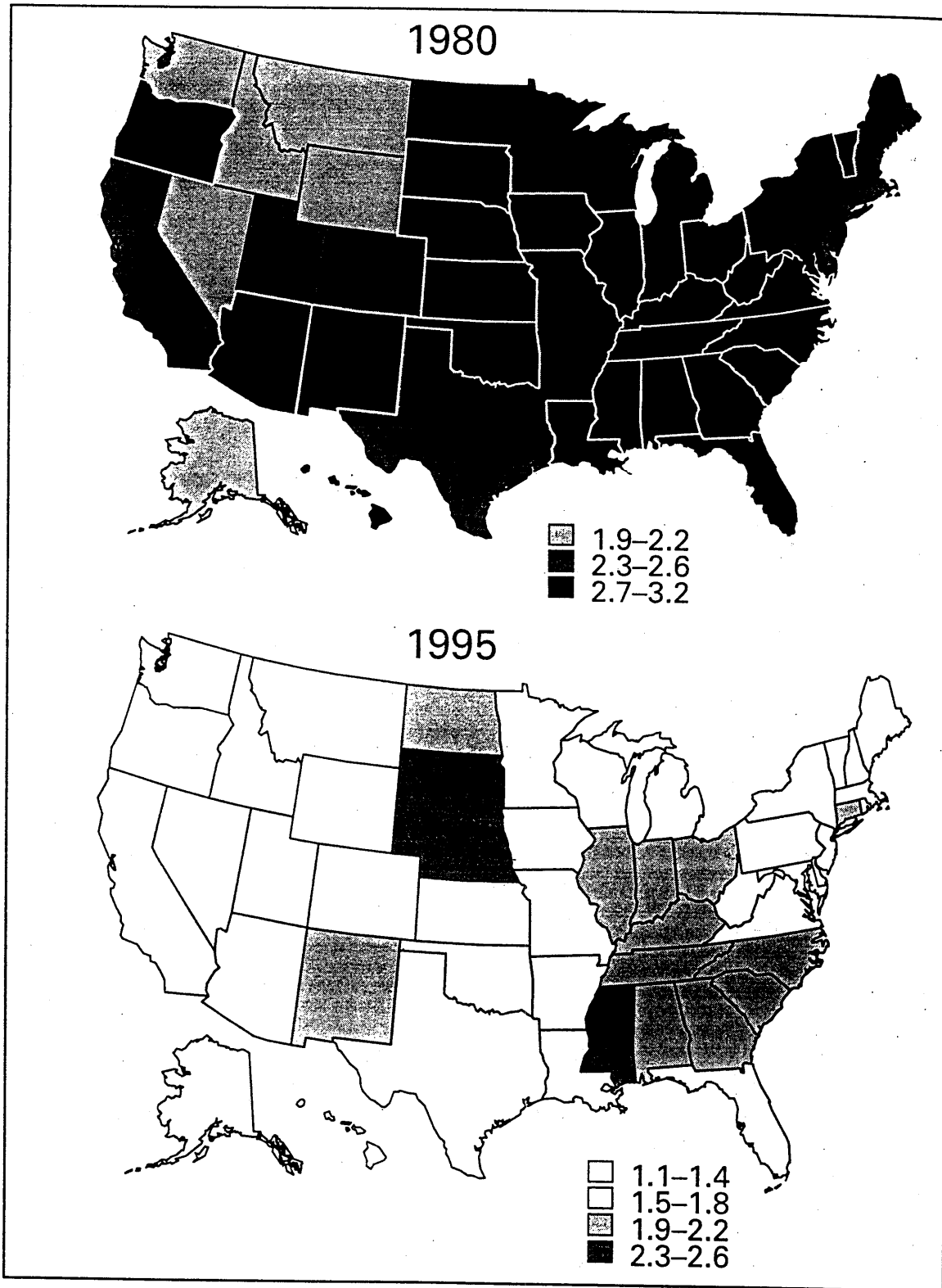
Source: Wisconsin Death Files

Chart 3 White Infant Mortality Rates from Birth Anomalies for Midwest States, 1988-91 (2)



Iowa is not shown because they had too few infant deaths due to congenital anomalies to compute a rate.

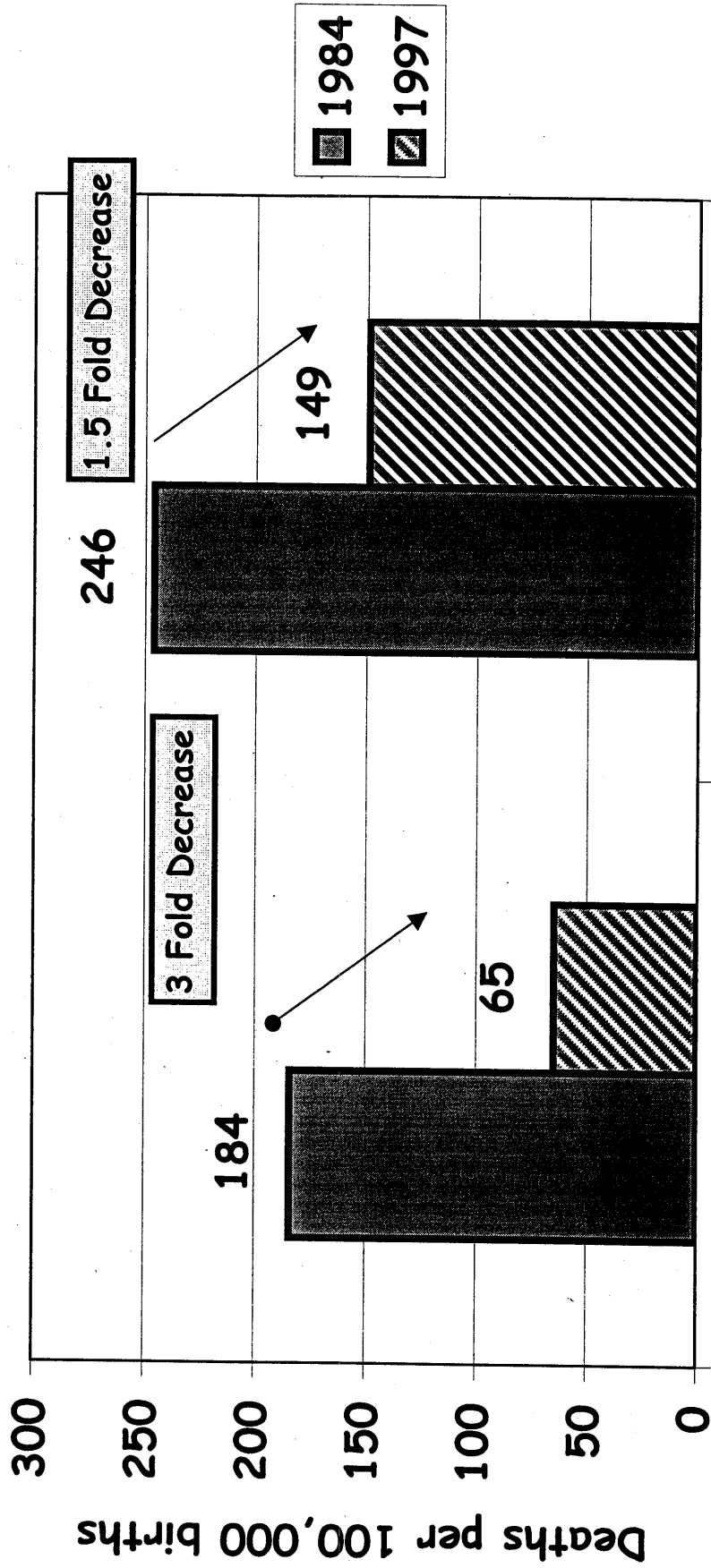
ility — Continued
Chart 4 Rate* of infant mortality attributable to birth defects, by state and year
 — United States, 1980 and 1995



*Per 1000 live-born infants.

From CDC (1998) Trends in infant mortality attributable to birth defects—United States, 1980-1995. *Morbidity and Mortality Weekly Review* 47(37): 773-778.

Chart 5: Rates of Death for Wisconsin Infants in 1984 and 1997 from SIDS and Congenital Anomalies*



*Source: Wisconsin Death Files

Statement in Support of SB 290 – Birth Defects Surveillance and Prevention
Russell S. Kirby, PhD, MS, FACE
December 8, 1999

My name is Russell Kirby. I am a perinatal epidemiologist and associate professor of clinical obstetrics and gynecology at the Milwaukee Clinical Campus, University of Wisconsin Medical School. I am the current president of the Wisconsin Association for Perinatal Care, and president of the National Birth Defects Prevention Network. When the existing legislation for BDOMP was enacted, I assisted in its development as an employee of the Center for Health Statistics at the Division of Health; I subsequently served as the director of the Arkansas Reproductive Health Monitoring System, a comprehensive birth defects registry for that state. My testimony this afternoon reflects my own views, and in no way represents an endorsement by the University of Wisconsin or any organization to which I belong.

I have chosen to focus on selected issues raised concerning the proposed legislation. After my brief remarks, I would be happy to serve as an 'expert witness' concerning any questions you may have.

A National Perspective on Birth Defects Surveillance and Prevention

While birth defects surveillance programs in this country can be traced to the 1920s, the impetus for surveillance as a public health function really began with the *thalidomide* scare in 1959-1961. This led to the creation of the Metropolitan Atlanta Congenital Defects Program in 1967 and the gradual spread of birth defects surveillance activities across the country. At present, more than 30 states have established registries for birth defects. Virtually all of these programs are grounded in legislative authority; with only one exception all collect personal identifiers of infants and/or their mothers for the purpose of maintaining the registry. The National Birth Defects Prevention Network, organized in 1997, has a membership of over 300 individuals working in state and regional birth defects surveillance programs or using these data for public health promotion and birth defects prevention activities. Congress passed the Birth Defects Prevention Act of 1998, authorizing birth defects surveillance programs and activities within the Public Health Service. This authorizing legislation may ultimately lead to increased availability of federal funds to support state and local birth defects prevention activities.

Why do we need comprehensive birth defects surveillance programs now? There are many reasons, but the most important is that the best strategy for prevention is to plan ahead. We don't know when or where the next public health concern will occur. Having a good data system in place will ensure that, if and when a calamity (such as the Weyauwega train derailment in 1996) occurs, the baseline data necessary to determine the public health impact will already be in place. It is also clear that biomedical research will identify many opportunities for primary prevention of birth defects in the future. Folic acid to prevent neural tube defects is undoubtedly only the first in a series of discoveries. Translating

knowledge into prevention requires data for program design, implementation, and evaluation – and a comprehensive birth defects surveillance program is essential to these activities.

Surveillance Methods and Approaches

There are three basic strategies for public health surveillance: (1) active case-finding (where trained staff personally visit clinics or hospitals and abstract records directly); (2) passive case-finding (where individuals, usually health care providers or staff of facilities, encounter patients or make diagnoses and file case reports); and (3) impassive case-finding (where cases are identified through automated record linkage from available administrative health databases). Impassive case-finding has been shown to be highly unsatisfactory as a surveillance methodology for birth defects registries and most states that initially used this methodology are attempting to transition to active or passive case-finding. Active case-finding is the gold standard approach; it is considerably more expensive than passive case-finding but yields a comprehensive registry that can support epidemiologic research, public health activities, and support for families with affected children.

The proposed legislation would create a passive case-find registry, with mandatory reporting by hospitals, selected clinics, and physicians.

The current BDOMP was modeled directly after the original legislation for the New York State Congenital Malformations Registry in the mid-1980s. That program required physicians to file case reports; it quickly became apparent that hospitals and clinics would not implement the necessary infrastructure to support physician reporting unless facilities also were mandated to report cases of birth defects to the registry. New York's legislation was therefore changed to require hospitals to file case reports. The current BDOMP identifies at most 3-10% of cases of birth defects diagnosed in the state of Wisconsin among infants each year through case reports filed by physicians. While I personally believe that it is possible to obtain reports on most cases without requiring health care facilities to file case reports, the experience in other states that use passive case-finding suggests that mandatory reporting will ultimately be needed in order to ensure that the registry results in complete enumeration of all cases of birth defects born to Wisconsin women.

Proposed Changes to BDOMP

The proposed legislation modifies the existing program in several ways. In addition to extending required reporting to hospitals and selected clinics, it significantly narrows the range of conditions for which reporting is required, and the age range within which cases must be reported. The restructured program will focus on birth defects, and will narrow the age for reporting from age 6 to age 2. Some have asked what the practical effects of this change will be, and especially whether some cases will be missed. The answer is that a few cases may be missed, but the gains in surveillance efficiency and cost-effectiveness from this change far outweigh the losses in potential cases. In other states, it has been shown that well over 95% of all cases that will ultimately be diagnosed by the age of 6 are identified by the

age of 2. On the other hand, failing to follow children into the toddler years can result in a significant loss of cases, perhaps as many as 20-25%. Many programs, including New York's, now use the age cutoff of the second birthday, as is proposed here. The current program requires reporting of a number of developmental disabilities and acquired conditions affecting child growth and development; the proposed legislation narrows the focus of the program to birth defects. This change is proposed to improve the efficiency of the program and also because mechanisms to support families in the quest for information and services using the BDOMP as a gateway have been difficult to implement. I believe that this remains a laudable goal, but that it is more important at this time to have a comprehensive, effective program for birth defects surveillance for the state of Wisconsin.

Privacy and Confidentiality Issues

The proposed legislation modifies an existing program of public health surveillance. All disease surveillance programs require the collection of personal identifiers in order to manage the registry, avoid double-counting, and interpret data in relation to other databases. It is essential to collect these identifiers; it is not essential that those conducting analyses of the database have access to personal identifiers once data management activities are completed.

With only one exception of which I am aware, all states with passive case-find birth defects registries require the collection of personal identifiers. The one exception is the state of Maryland, which enacted legislation in the early 1980s without much thought to the implications for the resultant program. In Maryland, parents have the option of including names and address information but not to prevent information about their child from being reported to the registry. In other programs, it has been shown that the average child with a birth defect generates 3-4 separate case reports. Unless all cases are reported, with sufficient identifiers to ensure that multiple reports on the same child are linked and counted only once, we will not have the quality surveillance program that Wisconsin needs.

The proposed legislation offered exceedingly stringent safeguards to prevent improper disclosure of data from the registry. In fact, the requirements for academic researchers to access the database are such that it is unlikely that I will be able to utilize the data for research projects myself. I believe that if the legislation is amended to restrict access to information on specific cases to insurance companies (both health and life insurance) and employers, that privacy advocates concerns are adequately handled.

For more information, feel free to contact Russell Kirby at 414-219-5610, or by email at <r-kirby@whin.net>.



Tommy G. Thompson
Governor

Joe Lekan
Secretary

State of Wisconsin
Department of Health and Family Services

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**Written Testimony – The Bureau of Developmental Disabilities
In Support of SB290
Birth Defects Surveillance and Prevention**

The Bureau of Developmental Disabilities has responsibility for the administration of a number of children's disability programs. These include the Birth to 3, Family Support and Katie Beckett (TEFRA Medicaid eligibility) Programs, as well as the Department of Health and Family Services Children's Long-term Support Initiative. The Birth Defects Surveillance and Prevention legislation will improve the ability for families to link to these critical services in a timely manner.

Specifically, the greatest impact that we can have on a child's development in the first three years of life. Many birth defects cause delays in physical, cognitive, and social emotional development. An early referral to the Birth to 3 Program provides families access to individuals who are experts in child development. The Birth to 3 Program can complete a comprehensive evaluation of the child's needs and work in partnership with the child's family to promote optimal development.

The Birth to 3 Program is required to have ongoing outreach efforts to parents, as well as community providers to ensure that we locate children who could benefit from early intervention. We are currently serving about two percent of the children between the ages of birth to 36 months. This approximates the number of children expected to meet the program's eligibility criteria. However, when state staff complete program reviews at the county level, we continue to hear from families that there were delays in their initial referral to the program.

These delays have a variety of causes, but the most frequent reason given for the delay in referral is that the parent raised concerns about their child's developmental progress to the child's physician, however, the physician encouraged a "wait and see" approach. For many families, this can add six months to a year prior to their child getting needed services and the parents getting needed support.

The Birth Defects Surveillance and Prevention legislation provides a mechanism for families to receive information about early intervention services from the Birth to 3 Program. The Birth to 3 Program is a voluntary program. This means that families retain their right to decline any further contact with the program at all times.

The Birth to 3 Programs are capable of handling any increase in referrals which may occur as a result of this legislation. In fact, we believe that the numbers of children receiving services will not significantly increase. Rather we will have the opportunity to link to children and their

families sooner. The child, who currently is referred at 18 months, may be referred at six months or earlier as a result of this legislation. The ability to provide services and supports to the child and family at an early age is cost effective.

An additional benefit of this legislation is the comprehensive epidemiological data that will be collected. This type of data will provide information on trends and incidence related to specific birth defects. This data is useful for long-range planning for the early intervention programs. Our office receives a number of requests from counties regarding the incidence of a specific disability. For example, many programs are reporting an increase in children with an autism spectrum diagnosis. We do not have statistics to determine whether there are any trends within the state. These types of statistics will help local Birth to 3 Programs to identify the staff and equipment resources they will need to meet the specific needs of infants and toddlers.

The Birth to 3 Program was involved with the initial start up of the Birth and Developmental Outcome Monitoring Program, which had similar goals to this legislation. The focus on physicians reporting has not been effective. This legislation improves on this earlier attempt. The Birth to 3 Program is required by federal regulations to be actively seeking children who may be eligible for early intervention services. A Birth Defects Surveillance and Prevention system as described in the legislation would address this requirement effectively.



State of Wisconsin
Department of Health and Family Services

Tommy G. Thompson, Governor
Joe Leraan, Secretary

DHFS TESTIMONY IN SUPPORT OF SENATE BILL 290

BEFORE THE
SENATE COMMITTEE ON
HEALTH, UTILITIES, VETERANS & MILITARY AFFAIRS

DECEMBER 8, 1999

“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 are also 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.”

Healthy from the Start Companion Report
The Pew Environmental Health Commission
November 1999

Over the last 20 years, 4,000 children have died in Wisconsin as a direct result of a congenital anomaly. Birth defects continue to cause 20% of the infant deaths in the United States, a country that despite our wealth has the worst infant mortality rate of any of the largest industrial nations in the world. And in Wisconsin we rank worse than the national average in our infant mortality rate due to congenital anomalies. An effective and workable state tracking system is essential if we are to develop public health prevention strategies that reduce this burden of suffering and deaths as a result of birth defects and chronic disease and disability. And yet, in Wisconsin of the estimated 3,500 children born with congenital anomalies every year, only 50 were reported in the last year.

When the Birth Developmental Outcome Monitoring Program (BDOMP) was first established in the DHSS at the start of this decade, we had a much higher rate of compliance in reporting among physicians and nurses, the only mandated reporters under our current laws. This was primarily because we had four federal staff whose sole purpose was the necessary training and ongoing consultation with doctors and clinics to encourage the proper and timely filing of reports as directed by law.

SB 290 replaces the existing BDOMP under s. 253.12 with an improved prevention and surveillance system that will bring Wisconsin on a par with other good models of reporting from our sister states by broadening the reporting responsibility, providing a clear connection to services for those parents who desire assistance, increasing our confidentiality protections, and establishing an oversight council. The overhaul of existing law will recreate a program to enable the fulfillment of two primary purposes:

- I. Prevention, referral and planning purposes including measuring the effectiveness of current prevention efforts in reducing occurrence of defects; integrating the point of identification with the point of referral to service for these conditions; using surveillance information for program and service planning.
- II. Epidemiological purposes including determination of the accurate rates of occurrence of certain birth defects (e.g. heart defects, neural tube defects, Down syndrome); identification of potential causes and risk factors (e.g. maternal conditions, environmental exposures), time and space clustering of these defects; and establishing trends in the occurrence of these defects ALL WITH THE PURPOSE OF IDENTIFYING PUBLIC HEALTH PREVENTION STRATEGIES.

Key elements to this approach that policymakers need to understand:

- **Prevention is the Result of Research.** This legislation is intended to give health care professionals a good idea of the number of infants born in Wisconsin with certain conditions that are present at birth. Without these numbers, we cannot know whether prevention and treatment efforts are working. For example, there is an attempt now to help prevent neural tube defects (for example anencephaly, a condition where the upper brain is not present at birth). It has been proven that increased folic acid intake of mother's helps prevent these conditions. We will not know whether our way of trying to encourage an increase in folic acid intake is effective unless we can compare numbers of infants with neural tube defects that are born before and after the folic acid information campaign has taken place.
- **Treatment and Referral Services.** Like a number of the states with the most successful birth defects registries (e.g. New Jersey and Colorado) a major aim of this program will be to provide timely referral to service and family support for all infants registered. Responsibility for birth defects surveillance has moved from the Center for Health Statistics to the Children with Special Health Care Needs Program, which is devoted to service provision for children with special health care needs. The parents of an infant for whom a report is submitted may, if they choose, request information on the infant's condition and resources available in their area to assist them. They may also request to be referred to the local public health department for assistance and support. The people working in this unit have long experience with special needs children, and care deeply about the welfare of the children they serve.
- **Advisory Panel Oversight.** Oversight of the registry activities will be provided by an Advisory Panel constituted of medical experts, representatives from the State Medical Society, the Wisconsin Health and Hospital Association, the American Academy of Pediatrics, the Council on Developmental Disabilities, both state medical schools, local health departments, key state staff (maternal and child health, medical assistance and health statistics), nonprofit foundations that work to prevent birth defects, and parents of special needs children.

- **Reports are Confidential.** The conditions targeted by the proposed legislation ask for a report not from the parents of the infant, but from physicians, clinics, labs and hospitals providing treatment for the infant. All identifying information (for example, the infant's or family's names and addresses) is strictly confidential, and may not be given to anyone unless the parents sign a written release allowing it. The child's name is never used in any of the work that is done on the information collected. Explicit statutory measures in the bill affirm this confidentiality. (Please see the attachment for more detail.)
- **Research Concerns Numbers and Risks, not Individuals.** One of the goals is to identify the number of infants with a particular condition (e.g., infants with Down's syndrome) born in Wisconsin in a given year. This might help us discover how common this condition is in Wisconsin compared to other states, or what some of the factors (e.g., mother's age) associated with the condition are. This does not involve using an individual's name or other identifying information.

A tale of two opposing scenarios:

SOLUTION FOUND

A clustering of babies born with anencephaly in Cameron County, Texas, prompted investigations into possible genetic and environmental factors. Anencephaly is a neural tube defect in which all or part of the brain is missing. This tragedy prompted Texas to begin a statewide program to monitor birth defects, a program that is now heralded as one of the best in the nation. As a result of the work of the CDC with state investigators, a public health prevention strategy was developed that is now beginning to be common knowledge: B vitamin folic acid as a protective factor against neural tube defects. In fact, this prevention strategy has proven so effective in curbing devastating neural tube birth defects which afflict as many as one in 1,000 newborns that just last year the Food and Drug Administration ordered folic acid (a critical B vitamin) to join the list of vitamins and minerals added to the nation's food supply in an effort.

CASE UNRESOLVED

In Minnesota, public health officials have been trying to ascertain whether their lake water is contaminated with excessive amounts of retinoic acid. Retinoic acid is a vitamin A compound and a hormone that regulates key aspects of development in vertebrates but excess amounts of retinoic acid produce birth defects in humans. In responding to this grave potential for human health problems, an environmental health professor at the University of Minnesota said that Minnesota officials are missing a valuable tool:

"If we had in place some kind of an information system in Minnesota that recorded human birth defects, and we had some information status and trends over a few years, that would be immensely useful at this point – but we don't." (Ken Sexton, University of Minnesota)

An environmental epidemiologist for the Health Department, Marian Marbury, agreed that a registry of birth defects is needed and could be devised with confidential data similar to the state's registry for tracking cancer.

And so the question for Wisconsin is whether we can reinvigorate our reporting system of congenital anomalies in order to find effective public health prevention and intervention strategies that can stem the tide of unnecessary and avoidable disability and death. Please join in support of SB 290. Thank you.

Confidentiality of Birth Defect Data as it pertains to AB 579 and SB 290

- All information contained in a birth defect report made to DHFS is confidential. AB 579 and SB 290 prohibit DHFS from releasing this confidential information except to:
 - (a) the parent or guardian of an infant or child for whom a birth defect report is made;
 - (b) a local health officer, birth-to-3 coordinator, or children with special health care needs agency *upon receipt of a written request and informed consent from the parent or guardian of the infant or child*;
 - (c) a physician, hospital or pediatric specialty clinic for the purpose of information verification; and
 - (d) a representative of a federal or state agency, upon written request if the information is necessary to perform a legally authorized function of that agency, including investigation of causes, mortality, methods of prevention, treatment or care of birth defects, associated diseases or disabilities.
- Information released to a representative of a federal or state agency *cannot* contain the name or address of the infant or child. A state or federal agency may in turn disclose this information only as necessary to perform the legally authorized function of the agency for which the information was requested.
- If a local health officer is authorized to receive information (upon receipt of a written request and informed consent from the parent or guardian of the infant or child), it can only be used to the extent necessary to provide and coordinate follow-up care for the infant or child or to conduct a health, demographic or epidemiological investigation. A local health officer must destroy the information received within one year of receipt.
- DHFS is authorized to release information for the purposes of research only if a set of stringent guidelines set in the proposed legislation are met that provide safeguards to ensure confidentiality.
- The database of birth defect information is stored in a secured and protected environment that includes record encryption and physical room security (e.g., equipped with motion detectors).