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15 SUPERIOR COURT OF THE STATE OF CALIFORNIA
16 FOR THE COUNTY OF SACRAMENTO
17

18 AMERICAN NURSES ASSOCIATION;
AMERICAN NURSES ASSOCIATION/
19 CALIFORNIA, CALIFORNIA SCHOOL NURSES
ORGANIZATION, and CALIFORNIA NURSES
20 ASSOCIATION,

21 Plaintiffs/Petitioners,

22 vs.

23 JACK O'CONNELL, STATE SUPERINTENDENT
OF PUBLIC INSTRUCTION; and CALIFORNIA
24 DEPARTMENT OF EDUCATION,

25 Defendants/Respondents,

26 AMERICAN DIABETES ASSOCIATION, an
organization,
27

28 Intervenor.

No. 07AS04631

**DECLARATION OF LINDA SIMINERIO,
R.N., Ph.D., CDE IN OPPOSITION TO
PLAINTIFFS' PETITION FOR WRIT OF
MANDATE AND COMPLAINT FOR
DECLARATORY AND INJUNCTIVE
RELIEF**

Hearing Date: October 17, 2008
Hearing Time: 10:30 a.m.
Department: 33
Hon. Lloyd G. Connell

1 I, Linda Siminerio, declare as follows:

2 1. I make this declaration in support of Intervenor American Diabetes
3 Association's Opposition to Plaintiffs' Petition For Writ Of Mandate And Complaint For
4 Declaratory And Injunctive Relief. For the reasons stated in this declaration I have personal
5 knowledge of its contents and if called as a witness in this matter I could and would competently
6 testify to each of these facts. I am an associate professor of medicine, department of endocrinology
7 at the University of Pittsburgh School of Medicine, of nursing at the University of Pittsburgh School
8 of Nursing, a faculty member at the Pennsylvania State University School of Nursing and director of
9 the University of Pittsburgh Diabetes Institute. My primary research topics include diabetes
10 education, diabetes translation into community interventions, pediatric diabetes care and education,
11 and the psychosocial and behavioral aspects of diabetes. I have served as an investigator on
12 numerous diabetes studies and authored more than 50 scientific publications.

13 2. I am a registered nurse licensed in the state of Pennsylvania, and have been a
14 registered nurse since 1972.

15 3. I have been a certified diabetes educator (CDE) since 1980. A certified
16 diabetes educator is a health care professional who specializes in training individuals with diabetes
17 in managing and treating the disease and its complications. In order to be certified, an individual
18 must meet education, licensing and professional experience requirements and pass an examination
19 administered by the National Certification Board for Diabetes Examiners. Most CDEs work for
20 hospitals, clinics or medical practices where they have primary responsibility for training
21 individuals with diabetes in diabetes care tasks such as blood glucose monitoring, insulin
22 administration, and monitoring for signs and symptoms of hyperglycemia or hypoglycemia. In this
23 role, CDEs also frequently train other unlicensed individuals (such as parents, family members, and
24 school personnel) to perform these care tasks.

25 4. I am a past president, health care and education of the American Diabetes
26 Association, as well as the former editor of Diabetes Forecast, a magazine published by the
27 Association. I have also served as senior vice president for the International Diabetes Foundation

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1 (IDF), representing diabetes education worldwide and have been appointed as the organizing chair
2 of the next IDF world congress. A summary of my background, training and experience is attached
3 as Exhibit A.

4 5. My clinical experience includes treating and educating individuals with
5 diabetes and their families for more than 30 years. I was responsible for the diabetes education
6 program at the Children's Hospital of Pittsburgh for 27 years where I provided and supervised
7 pediatric diabetes services. Services included education for patients, professionals (pediatricians,
8 nurses and dietitians) and the community (schools and camps). I was responsible for organizing the
9 first diabetes camp for children with diabetes in western Pennsylvania and directed the camp for
10 over 20 years. As Director of the University of Pittsburgh Diabetes Institute, I am responsible for
11 the provision of quality diabetes services in the University of Pittsburgh Medical Center (UPMC)
12 that represents 19 hospitals, physician and diabetes educator services. I am also responsible for
13 overseeing a diabetes clinic and education service for the US Air Force at the Lackland Wilford Hall
14 Medical Center in San Antonio, Texas.

15 6. I am a co-chair of the American Diabetes Association's Safe at School
16 Working Group. The group was founded in 2005 to coordinate the Association's efforts to promote
17 the safe and adequate provision of diabetes care services at school so that children with diabetes
18 could attend school safely with confidence that their health care and educational needs would be
19 met.

20 7. I have high regard for the role of school nurses and advocate for them;
21 however, the reality is that while there is a growing number of children developing diabetes there is
22 also a growing shortage of nurses. Therefore there is a critical need for identifying resources to
23 support the role of the school nurse in the care of children with diabetes in the school.

24 8. Managing diabetes requires careful monitoring of the disease, including
25 testing blood glucose levels and providing appropriate treatment, 24 hours a day, 7 days a week,
26 including during school hours. For most students with diabetes, management of the disease includes
27 multiple daily doses of insulin. For individuals with type 1 diabetes, insulin is necessary for
28 survival. For all individuals with diabetes who need insulin, failing to get insulin when needed can

1 lead to severe short-term and long-term complications. Therefore, it is critical that students with
2 diabetes who need insulin have access to insulin administration whenever they are at school or
3 participating in school-related activities.

4 9. Today, most older children and adults perform diabetes care tasks, including
5 insulin administration, themselves. Children who are not yet able to self-administer insulin almost
6 always receive it from parents, family members, or other unlicensed persons (such as friends or
7 babysitters). Once trained (a process that is neither time-consuming nor difficult), unlicensed
8 persons can safely and easily determine the proper dose of insulin to be given to a child (based on
9 the medical orders from the child's treating physician) and then dispense that dose through
10 injections by syringe, an insulin pen, or an insulin pump. This is what happens all the time when
11 children with diabetes are at home, and there is no reason why the same cannot happen at school.

12 10. Insulin can be safely administered by unlicensed personnel; in fact, such
13 persons (including parents, family members and caregivers) do so every day for thousands of
14 children with diabetes. In my professional opinion, such an individual, when properly trained and
15 following the detailed orders of a physician, is no more likely to make a mistake in administering
16 insulin than a nurse or other health care professional. Moreover, the possibility of an incorrect dose
17 does not change my opinion that unlicensed personnel can safely administer insulin, given that an
18 incorrect dose can be corrected so long as school staff are appropriately trained and appropriate
19 follow-up care (which should be specified in the physician's orders) is available and readily
20 provided.

21 11. In my professional opinion, administering a prescribed insulin dose to a
22 student based on detailed instructions from a child's treating physician does not require professional
23 skill or nursing judgment. Similarly, it does not require substantial scientific knowledge or technical
24 skill. There are two distinct steps involved in administering insulin: assessing the correct dose to be
25 given at a particular time and actually giving that dose (either by injection, using an insulin pen, or
26 pressing buttons on an insulin pump). In the school setting, the task that the person administering
27 the insulin to a student is being asked to do, whether it is a nurse or a trained unlicensed school
28 employee, is the same. That person is supposed to determine the amount of insulin based upon

1 orders from the experts in diabetes management, the child's treating diabetes care team, and the only
2 information this will require is knowing the amount of carbohydrates the child is about to consume
3 and/or the child's current blood glucose level. As a member of the treating team, when it comes
4 time to administer insulin I do not believe that it is necessary for that person to assess the student's
5 medical history or perform any other sort of physical assessment. The next step, getting the insulin
6 into the child by syringe, pen, or insulin pump, involves delivering an injection or pressing a button.
7 I have successfully – and routinely – taught all of these tasks to people of all educational
8 backgrounds, and even to children. On several occasions, I have trained parents with severe mental
9 challenges to safely administer insulin to their child.

10 12. The process for giving insulin by injection with a syringe is simple and
11 routine. Rarely is it necessary to mix one type of insulin with another in order to form the proper
12 dose. Most children today will take only one type of insulin at a given time (at school this is
13 generally rapid-acting insulin to cover meals or treat hyperglycemia). While older regimens
14 sometimes required a mixture of different types of insulin to be given in one dose, common
15 combinations of insulin types are commercially available in pre-mixed vials. If a child does require
16 a mixture, this particular mixed dose would almost always be given in the early morning before the
17 child goes to school. Therefore, the individual giving the shot outside of the home environment need
18 only deal with one vial of insulin. If in the very rare event two types of insulin are needed, the
19 insulin could easily be administered in 2 separate injections. With the advent of extremely short,
20 thin needles and insulin pens, it has been my experience that children with diabetes do not perceive
21 multiple injections to be frightening or painful.

22 13. To administer the dose via a syringe, the person giving the dose first pulls the
23 plunger on the syringe down to the appropriate number of units for the needed dose. Insulin will be
24 provided by the parent or caregiver, so, unlike in a hospital setting, the person administering the
25 insulin will not be choosing among types of insulin. Next, the person will remove the cap from the
26 syringe and insert the syringe needle into the insulin vial to draw out the correct dose. Syringes will
27 be provided by the parent, so there is no need to choose the type of syringe to be used. The person
28 is now ready to prepare the injection. Choosing the injection site is not difficult; children generally

1 pick the injection site themselves, and insulin can be given at many sites on the body (the most
2 commonly used are the upper arm, thigh, stomach, and buttocks). To deliver the injection, the
3 person will pinch the skin around the injection site, push the needle into the skin at a 90 degree
4 angle, push in the plunger on the syringe, count to 5, and withdraw the syringe. The syringe is then
5 disposed of per instructions in a safe container for sharps. The injection is given just under the skin;
6 there is no need to push the needle in deeply or to find a vein. This is all that is required. There is
7 no realistic danger of harming the child by performing the injection improperly, and training on how
8 to give injections is simple and routinely given.

9 14. Insulin pens are pen-shaped devices containing a supply of insulin and a
10 needle on the end. Some pens are pre-filled with a certain amount of insulin and are not reusable,
11 while others use cartridges of insulin that can be easily replaced. Injecting with a pen works much
12 the same as via syringe, except that the correct number of units is selected through a dial on the pen.

13 15. An insulin pump is an electronic device. The pump itself is worn on the body
14 and contains buttons that are used to specify the amount of insulin to be delivered; the pump is
15 connected by tubing to a needle which is inserted under the skin or attached directly to the skin.
16 The child will come to school with the pump already attached. Pumps deliver a constant supply of
17 insulin to cover activities throughout the day, and additional doses, or “boluses” are administered as
18 needed, often to cover meals or snacks. Use of the pump does not require an injection; it simply
19 requires pressing buttons to specify and then deliver the correct amount of insulin. With pumps
20 used today, all the person administering the insulin does is input some basic data and the pre-
21 programmed pump determines how much insulin to administer.

22 16. Determining the proper dose to be given is straightforward when the decision
23 is based on the detailed treatment orders of the child’s treating physician. At school, the dosage to
24 be administered in each situation will be specified in the treating physician’s orders. Non-licensed
25 school personnel, like a school nurse, would simply need to measure the student’s blood glucose
26 level and/or calculate the amount of carbohydrates to be compensated for, and refer to the
27 physician’s orders for the proper dose. No more assessment of the student’s condition than this is
28 required. In my opinion and experience, laypeople can, without a medical or nursing license,

1 follow the physician’s orders and safely give an insulin injection. I have trained hundreds of
2 children (those who have the maturity and cognitive skills, which is individually determined) and
3 their caregivers throughout my career and have never had a situation in which I was unable to train
4 safe administration of an insulin injection. Timing of training is dependent on a number of themes
5 like readiness, past experiences, willingness, etc. However on average, teaching a person to simply
6 administer a pre-determined amount of insulin, takes approximately one hour (with repeat
7 demonstration until the learner feels ready and confident). Insulin delivery methods have been
8 developed to make it as easy as possible for those without medical training to administer insulin.

9 17. While I certainly value the many roles that school nurses play to keep
10 students with diabetes – and all students – healthy and would strongly support there being more
11 school nurses in our nation’s schools, that does not mean that a trained unlicensed school employee
12 cannot safely administer insulin to a student with diabetes when a school nurse is not present. My
13 professional opinion is that unlicensed personnel can safely administer insulin when trained, and
14 this opinion is shared by the community of health care professionals who devote their lives to caring
15 for and treating individuals with diabetes. The American Diabetes Association’s official position
16 statement on diabetes care in the school and day care setting was adopted in 1998. A true and
17 correct copy of this statement is attached as Exhibit B.¹ The position statement was developed by a
18 group of leading health care professionals in the treatment of children with diabetes, and concludes
19 that unlicensed personnel may safely administer insulin. Specifically, the statement says: “An
20 adequate number of school personnel should be trained in the necessary diabetes procedures (e.g.,
21 blood glucose monitoring, insulin and glucagon administration) and in the appropriate response to
22 high and low blood glucose levels to ensure that at least one adult is present to perform these
23 procedures in a timely manner while the student is at school, on field trips, and during
24 extracurricular activities or other school-sponsored events. These school personnel need not be
25 health care professionals.”

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27 ¹ This statement is published in the journal *Diabetes Care*, Volume 331, Suppl. 1 (January 2008) at pages S79-S86.
28

1 18. The National Diabetes Education Program (NDEP) is a federally sponsored
2 partnership of the National Institutes of Health, the Centers for Disease Control, and more than 200
3 partner organizations, including medical, research, professional, educational, and other groups.
4 NDEP also supports insulin administration by unlicensed school personnel as demonstrated in its
5 publication *Helping the Student with Diabetes Succeed: A Guide for School Personnel*.² This guide,
6 designed to help explain the needs of all students with diabetes, states that unlicensed school
7 personnel can and should be trained to provide diabetes health care services, including insulin
8 administration. Specifically, this publication states on page 10: “The diabetes medical community
9 has found that non-medical personnel ... can be trained and supervised to safely provide and assist
10 with diabetes care tasks in the school setting, including blood glucose monitoring, insulin and
11 glucagon administration, and urine ketone testing.” The *Guide* explains that “A few school staff
12 members should receive training from a qualified health care professional in student-specific and
13 routine and emergency diabetes care tasks so that at least one staff member is always available for
14 younger, less experienced students and for any student with diabetes in case of emergency.” This
15 guide represents the views of a wide range of other organizations, including medical, research,
16 professional, educational, and other groups.

17 19. In 2005, the American Diabetes Association adopted a statement of principles
18 as part of its Safe at School campaign (a true and correct copy of which is attached as Exhibit C),
19 which includes the following principle:

20
21 The school nurse holds a primary role of coordinating, monitoring, and supervising the care
22 of a student with diabetes. However, in addition to any full- or part-time school nurse, a
23 small group of school staff members should receive training from a qualified health care
24 professional in routine and emergency diabetes care so that a staff member is always
25 available for younger or less-experienced students who require assistance with their diabetes
26 management (e.g., administering insulin, checking their blood glucose, choosing appropriate
27 food) and for all students with diabetes in case of an emergency (including administration of
28 glucagon). These staff members should be school personnel who have volunteered to do
these tasks and do not need to be health care professionals.

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² Attached as Exhibit A to Declaration of James M. Wood.

1 24. I declare under penalty of perjury under the laws of the State of California
2 that the foregoing is true and correct.

3 Executed on _____, 2008 at _____, Pennsylvania
4

5
6 _____
7 Linda Siminerio, R.N., Ph.D., CDE
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9 DOCSOAK-9917934.1
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11 REED SMITH LLP
12 A limited liability partnership formed in the State of Delaware
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PROOF OF SERVICE

I am a resident of the State of California, over the age of eighteen years, and not a party to the within action. I am employed in the office of a member of the bar of this court at whose direction the service was made. My business address is REED SMITH LLP, 1999 Harrison Street, Suite 2400, Oakland, CA 94612-3572. September 12, 2008, I served the following document(s) by the method indicated below:

**DECLARATION OF LINDA SIMINERIO, R.N., Ph.D., CDE IN
OPPOSITION TO PLAINTIFFS' PETITION FOR WRIT OF
MANDATE AND COMPLAINT FOR DECLARATORY AND
INJUNCTIVE RELIEF**

- by transmitting via facsimile on this date from fax number 510.273.8832 the document(s) listed above to the fax number(s) set forth below. The transmission was completed before 5:00 PM and was reported complete and without error. The transmission report, which is attached to this proof of service, was properly issued by the transmitting fax machine. Service by fax was made by agreement of the parties, confirmed in writing. The transmitting fax machine complies with Cal.R.Ct 2003(3).
- by placing the document(s) listed above in a sealed envelope with postage thereon fully prepaid, in the United States mail at Oakland, California addressed as set forth below. I am readily familiar with the firm's practice of collection and processing of correspondence for mailing. Under that practice, it would be deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if the postal cancellation date or postage meter date is more than one day after the date of deposit for mailing in this Declaration.
- by placing the document(s) listed above in a sealed envelope(s) and by causing personal delivery of the envelope(s) to the person(s) at the address(es) set forth below. A signed proof of service by the process server or delivery service will be filed shortly.
- by personally delivering the document(s) listed above to the person(s) at the address(es) set forth below.
- by placing the document(s) listed above in a sealed envelope(s) and consigning it to an express mail service for guaranteed delivery on the next business day following the date of consignment to the address(es) set forth below.
- by transmitting via email to the parties at the email addresses listed below:

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I declare under penalty of perjury under the laws of the United States that the above is true and correct. Executed on September 12, 2008, at Oakland, California.

Trisha Suzette Hooper