I				
1	James M. Wood (SBN 58679)			
2	Kenneth J. Philpot (SBN 62401) REED SMITH LLP			
3	1999 Harrison Street, Suite 2400 Oakland, CA 94612-3572			
4	Mailing Address:			
5	P.O. Box 2084 Oakland, CA 94604-2084			
6	Telephone: 510 763 2000 Facsimile: 510 273 8832			
7	Arlene Mayerson (SBN 79310)			
8	Larisa Cummings (SBN 131076) DISABILITY RIGHTS EDUCATION AND			
9	DEFENSE FUND, INC. 2212 Sixth Street			
10	Berkeley, CA 94710			
11	Telephone: 510 644 2555 Facsimile: 510 841 8645			
12	Attorneys for Intervenor American Diabetes			
13	Association			
14	SUPERIOR COURT OF THE STATE OF CALIFORNIA			
15	FOR THE COUNTY OF SACRAMENTO			
16				
17	AMERICAN NURSES ASSOCIATION; AMERICAN NURSES ASSOCIATION/	No. 07AS04631		
18	CALIFORNIA; CALIFORNIA SCHOOL NURSES ORGANIZATION; and CALIFORNIA NURSES	INTERVENOR AMERICAN DIABETES ASSOCIATION'S MEMORANDUM OF		
19	ASSOCIAITON, and CALIFORNIA NORSES	POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFFS'		
20	Plaintiffs,	VERIFIED SECOND AMENDED PETITION FOR WRIT OF MANDATE		
21	vs.	AND COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF,		
22	JACK O'CONNELL, STATE SUPERINTENDENT OF PUBLIC INSTRUCTION; and CALIFORNIA	OBJECTIONS TO EVIDENCE, REQUEST FOR JUDICIAL NOTICE, AND		
23	DEPARTMENT OF EDUCATION,	SUPPORTING DECLARATIONS		
24	Defendants,	Date: October 17, 2008 Time: 10:30 A.M.		
25	AMERICAN DIABETES ASSOCIATION, an	Dept.: 33		
26	organization,	Judge: Hon. Lloyd G. Connelly		
27	Intervenor.			
28				
	i			

# **Table of Contents**

		Page			
I. INTRODU	JCTION	1			
II. STATEM	ENT OF FACTS	2			
A.	Statement of Interest	2			
В.	Diabetes And Its Impact On School Children	3			
	1. An Overview of Diabetes	3			
	2. The Impact of Diabetes on Students	7			
C.	Non-medical School Personnel Are Trained to Administer Insulin	8			
D.	The Shortage of Nurses in California	9			
III. ARGUM	III. ARGUMENT				
A.	State Laws And Policies That Frustrate The Purposes Of Federal Education And Discrimination Laws Are Preempted	14			
	1. Federal Laws Require That Insulin Administration Be Provided	14			
	2. The Nursing Practice Act Is Preempted To The Extent It Would Frustrate The Purposes Of Federal Disability Laws	14			
	a. State Laws That Frustrate Federally Protected Rights Are Preempted	14			
	b. State Health And Safety Laws Can Be Preempted	16			
	c. Reliance On Unavailable Nurses Is Inadequate To Ensure Federal Rights	18			
В.	California State Laws Authorize School Personnel Who Are Not Licensed Health Care Professionals To Administer Insulin	20			
	1. The California Education Code Permits School Personnel To Administer Insulin.	21			
	2. The California Nursing Practice Act Permits School Personnel To Administer Insulin.	24			
	a. The Administration of Insulin by Trained Non-Licensed School Personnel Does Not Require A Substantial Amount of Scientific Knowledge or Technical Skill	25			
	- i -				

REED SMITH LLP
A limited liability partnership formed in the State of Delaware

C.	Non-Licensed Personnel To Provide Nursing Duties Un Specified Circumstances	
	Plaintiffs' APA and Constitutional Challenge Should Be Rejected	
D.	Plaintiffs Cannot Meet the Standard for Obtaining a Writ of Mandate	
CONCL	USION	•••••••

# A limited liability partnership formed in the State of Delaware

# **TABLE OF AUTHORITIES**

# **CASES**

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

# I. INTRODUCTION

Thousands of students with diabetes attending California public schools need insulin every day to survive and cannot attend school safely without it. Federal and state laws require California schools to provide these students diabetes care services, including insulin administration. Plaintiffs here do not, and indeed cannot, dispute these fundamental principles. What is very much in dispute, though, is whether California has established a legal regime that denies students access to insulin based solely on the unavailability of a licensed nurse or other health care professional at school and, if so, whether this violates both state and federal law.

Faced with compelling evidence that many California public schools were failing to provide legally mandated health care services--particularly insulin administration--to children with diabetes, the California Department of Education ("CDE") settled a federal lawsuit, K.C. v. O'Connell, brought by Intervenor American Diabetes Association against CDE and two school districts asserting violations of federal disability laws. Following the settlement, CDE issued a Legal Advisory<sup>2</sup> reminding school districts of their obligations--under federal law--to provide students with diabetes a free and appropriate public education, including help with insulin administration. The Advisory notes that this care can be provided by trained but unlicensed school personnel when licensed health care professionals are not available.

Plaintiffs seek to invalidate this part of the Legal Advisory and to forbid all unlicensed school personnel from administering insulin to students who need assistance, arguing that California state law prohibits such administration by unlicensed personnel. Plaintiffs' interpretation of state

K.C., et al. v. O'Connell, et al., No. C 05-4077 (N.D. Cal. filed Oct. 11, 2005).

Exhibit Z to Declaration of James M. Wood ("Wood Dec.").

law is incorrect. But even assuming *arguendo* it were not, such an interpretation, given the universally recognized shortage of nurses available in the school setting, unjustifiably interferes with the mandate of federal law that these students receive insulin in the school setting. Moreover, Plaintiffs' claim that insulin is a dangerous drug that cannot be safely administered by non-health care professionals is medically unsupportable and ignores the overwhelming consensus of medical professionals who direct care for individuals with diabetes and the fundamental reality that diabetes care is provided to children by unlicensed individuals. Every day at home, family members and other unlicensed personnel provide insulin to children. There are no legal or medical reasons why trained unlicensed personnel cannot do the same during the school day. Plaintiffs' interpretation of state and federal law will only guarantee that students with diabetes will not receive the care they are entitled to under these laws.<sup>3</sup>

Because Plaintiffs cannot meet their burden to show that writ relief is warranted, the Court should not accept their invitation to invalidate a key part of the Legal Advisory. Therefore this petition should be denied.

## II. STATEMENT OF FACTS

# A. Statement of Interest

Intervenor American Diabetes Association is a nationwide, nonprofit, voluntary health organization founded in 1940. It is comprised of persons with diabetes, health professionals who treat persons with diabetes, research scientists, and other concerned individuals. The mission of Intervenor is to prevent and cure diabetes and to improve the lives of all people affected by diabetes.

<sup>&</sup>lt;sup>3</sup> Plaintiffs have submitted the Declarations of Dale Parent and Jean Schumann, greatly overstating the complexity of insulin administration. Their statements are medically and scientifically unfounded. *See* Objections of James M. Wood as well as the Declaration of Francine Kaufman.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

It is the predominant non-governmental organization that deals with the treatment and impact of diabetes. With over 435,000 general members, nearly 18,000 health professional members, and over 1,000,000 volunteers, Intervenor is the largest voluntary health organization addressing diabetesrelated concerns. Members of the Intervenor organization will have their legal rights compromised and will be harmed by direct operation of a judgment in Plaintiffs' favor. In addition, Intervenor has rights under the settlement agreement in K.C. v. O'Connell, which are threatened by the relief Plaintiffs seek in the present action.

#### В. **Diabetes And Its Impact On School Children**

#### 1. **An Overview of Diabetes**

Diabetes is a serious, incurable disease that prevents the body from properly using food for energy. (Declaration of Francine Kaufman, M.D. ("Kaufman Dec.") at ¶ 5). Insulin, a hormone produced by the pancreas, moves glucose (a form of sugar) from the bloodstream into body cells where the glucose is needed to provide energy. (Id.) Without insulin, cells cannot get the energy they need for life and the body literally starves to death. (Id.) In people with diabetes, either the pancreas does not make enough insulin or the body cannot use insulin properly. (Id.) Without the ability to produce or properly use insulin, the body's main energy source--glucose--cannot be used as fuel but instead builds up in the bloodstream, causing severe and possibly fatal consequences. (Id.) Thus deprived of energy, a person with diabetes who does not receive insulin can die within a matter of days. (Id.)

There are two main types of diabetes, type 1 and type 2. (Kaufman Dec. at  $\P$  6) Type 1

This section summarizes those aspects of diabetes and its treatment essential for an understanding of the brief. A more detailed discussion of the disease can be found in Dr. Kaufman's accompanying Declaration.

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

diabetes (formerly called insulin-dependent diabetes or juvenile diabetes) is an autoimmune disease in which the body destroys insulin-producing beta cells in the pancreas. (Id.) As a result, the body produces very little or no insulin. (*Id.*) Type 2 diabetes (formerly called non-insulin dependent diabetes or adult-onset diabetes) results when the body cannot make sufficient amounts of insulin or properly use insulin. (Id. at  $\P$  4) Children and adults with type 1 diabetes must receive insulin either through multiple daily injections or an insulin pump. (Id. at  $\P$  7) People with type 2 diabetes may be able to control their disease through diet and exercise alone or may require oral medications and/or insulin injections. (Id.)

According to the Centers for Disease Control and Prevention, approximately 186,300 people under 20 years of age (0.22 percent of the population, or about 1 in 400-600) have diabetes (type 1 or type 2) and it is estimated that each year an additional 15,000 pediatric patients are diagnosed with type 1 diabetes and 3,700 pediatric patients are diagnosed with type 2 diabetes.<sup>5</sup> Using this ratio and the fact that there are 6.312.102 public school students in this state. vields an estimate of 13.886 children with diabetes in public school in California.

In people who do not have diabetes, the body naturally regulates the amount of insulin present in the blood so that the blood glucose level remains almost constant. (Kaufman Dec. at ¶ 17) However, a person with diabetes cannot naturally regulate the amount of insulin or the amount of

Centers for Disease Control and Prevention, National Diabetes Fact Sheet (2007), http://www.cdc.gov/diabetes/pubs/pdf/ndfs\_2007.pdf (last visited Sep. 11, 2008). Attached as Exhibit HH to Wood Dec. American Diabetes Association, Total Prevalence of Diabetes & Pre-*Diabetes* (2007),

http://www.diabetes.org/diabetes-statistics/prevalence.jsp (last visited Sep. 11, 2008). Attached as Exhibit II to Wood Dec.

California Department of Education, Public School Summary Statistics 2005-2006, http://www.cde.ca.gov/ds/sd/cb/sums05.asp (last visited Sep. 11, 2008). Attached as Exhibit B to Wood Dec.

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

glucose in the blood in the same way. (Id.) Therefore, people with diabetes who use insulin (as well as some oral medications) are subject to both high and low blood glucose levels. (Id.)

High blood glucose (hyperglycemia) occurs when the body gets too little insulin, too much food, or too little exercise. (Id. at ¶ 20) It may also be caused by stress or an illness such as a cold. (Id.) Symptoms of mild to moderate hyperglycemia include thirst, frequent urination, blurry vision, fatigue, hunger, stomach pain, flushed skin, inability to concentrate, dry mouth, nausea and vomiting. (Id.) Even mild hyperglycemia can cause a student to have difficulty concentrating and learning because of the effect it can have on brain functioning and cognitive ability. (Id.) In addition, untreated hyperglycemia can cause a serious and life-threatening condition called diabetic ketoacidosis (DKA), characterized by labored breathing, weakness, confusion and possibly unconsciousness. (Id. at ¶ 21) Normally DKA will not occur if blood glucose levels are regularly monitored and milder forms of hyperglycemia are treated, since DKA is preceded by a period of higher-than-normal blood glucose levels. (*Id.*)

The buildup of glucose in a student's blood not only deprives the body's cells of energy, it also can damage body systems. (Id. at  $\P$  10) Diabetes is the seventh leading cause of death by disease in the United States. Over time, high blood glucose levels can cause damage to the eyes, kidneys, nerves, heart, blood vessels and other body systems. (Kaufman Dec. at ¶ 10) People with diabetes are at significantly increased risk of heart attack and stroke, and diabetes is the leading cause of adult blindness in the United States. Other serious complications include kidney disease. neuropathy (damage to nerves that can cause pain or numbness and loss of function in certain parts

See Centers for Disease Control and Prevention, National Diabetes Fact Sheet, supra at fn 5. <sup>8</sup> *Id*.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

of the body), and foot problems that can lead to amputation of the foot or leg.

Low blood glucose (hypoglycemia) occurs when the body gets too much insulin, too little food, a delayed meal, or more than the usual amount of exercise. (Kaufman Dec. at ¶ 18) Symptoms of mild to moderate hypoglycemia include tremors, sweating, light-headedness, irritability, confusion, difficulty concentrating and learning, drowsiness, hunger, shakiness, weakness, paleness, anxiety, dizziness, headaches, poor coordination, blurry vision, weakness, and slurred speech. (Id.) A student with this degree of hypoglycemia will need to ingest carbohydrates promptly and may require immediate assistance from another person. (Id.) Severe hypoglycemia, which can develop if more moderate hypoglycemia is not promptly and effectively treated, may lead to unconsciousness and convulsions and can be life-threatening if not treated promptly. (Id.) Severe hypoglycemia should be treated immediately with an injection of glucagon, a hormone that raises blood glucose levels by causing the release of glycogen (a form of stored carbohydrate) from the liver. (*Id*. at  $\P$  19)

Thus, even when a person with diabetes gets enough insulin to survive, he or she still faces the risk of both long and short term complications by blood glucose levels that are either too high or too low. These complications can be delayed or prevented by keeping the student's blood glucose level on a relatively even keel. Accordingly, the primarily goal of diabetes management is to keep blood glucose levels as close to target range as possible. (Kaufman Dec. at ¶ 10)

Fortunately, advancements in the science and management of diabetes have made great strides in the ability to keep blood glucose within that safe range. However, these modern regimens

- 6 -

<sup>&</sup>lt;sup>9</sup> *Id*.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

require checking blood glucose numerous times a day 10 and (for all children with type 1 diabetes as well as many with type 2) administering insulin multiple times a day.

#### 2. The Impact of Diabetes on Students

Insulin is often needed at set times each school day, typically just before or after lunch as well as at other times when a student eats. Failing to time the dose of insulin correctly with the food increases the risk of both hypoglycemia and hyperglycemia, placing the student in immediate danger, making learning more difficult, and increasing the likelihood of long-term complications. (Kaufman Dec. at ¶ 25.) In addition, students will need additional insulin in response to blood glucose levels that are too high, which can occur at any time during the day. (Id. at  $\P$  15) Accordingly, for a student to be safe, healthy, and able to learn at his or her full potential there must be someone who can administer insulin to the child with diabetes at school, on field trips, and during extracurricular activities. (Id. at  $\P$  24) When insulin is needed, it must be given as quickly as possible. (Id. at ¶ 23) Insulin can be given by injection (through a syringe or an insulin pen) or through an insulin pump.  $^{11}$  (Id. at ¶ 7) Many children, particularly older children, regularly manage their disease and are able to administer insulin without assistance or supervision. (Id. at  $\P 22$ ) However, some children need supervision in administering insulin, and others need an adult to administer insulin to them. (*Id.*)

<sup>&</sup>lt;sup>10</sup> Measurements of blood glucose levels can be taken using a blood glucose finger-stick test, in which a drop of blood is obtained and placed on a test strip. Kaufman Dec. at ¶ 11. The test strip is then read by a blood glucose meter, which measures the blood glucose level. *Id.* 

Plaintiffs' declarants appear to believe that use of a hypodermic syringe is the only way to administer insulin, see Schumann Dec. at ¶ 15; Parent Dec. at ¶ 14, and may be unaware of other insulin delivery methods. Kaufman Dec. at ¶ 7.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

#### C. Non-medical School Personnel Are Trained to Administer Insulin

Non-medical personnel—including school personnel--routinely have been trained to safely administer insulin. 12 Indeed, it is the position of the experts who have devoted their professional and personal lives to the care of people with diabetes that trained non-medical school personnel can – and should – administer insulin to students with diabetes in the absence of a school nurse. The American Diabetes Association has issued a peer-reviewed position statement from specialists in the area of pediatric endocrinology supporting this practice (attached as Exhibit B to Siminerio Dec.). A statement of principles taking the same position has been signed by groups representing diabetes health care professionals, individuals with diabetes and others, including the American Academy of Pediatrics, American Association of Clinical Endocrinologists, American Association of Diabetes Educators, American Dietetic Association, Lawson Wilkins Pediatric Endocrine Society, Pediatric Endocrine Nurses Society, Children with Diabetes, and Juvenile Diabetes Research Foundation. (Siminerio Dec. at ¶ 19) The National Diabetes Education Program (NDEP)<sup>13</sup> also supports insulin administration by unlicensed personnel in Helping the Student with Diabetes Succeed: A Guide for School Personnel. 14 This guide states that unlicensed school personnel can and should be trained to

 $<sup>^{12}</sup>$  See Kaufman Dec. at  $\P$  29; Declaration of Linda Siminerio ("Siminerio Dec.") at  $\P\P$  10-11, 16, 20, 23; Declaration of Kathleen Breen ("Breen Dec.") at ¶ 5, 7, 13-14; Declaration of Kathy Spain ("Spain Dec.") at ¶¶ 23-26, 28; Declaration of Louise D. at ¶¶ 25-27 ("Louise D. Dec."); Declaration of James A. Stone ("Stone Dec.") at ¶ 21, attached as Exhibit MM to Wood Dec.; Declaration of Barbara W. ("Barbara W. Dec.") ¶¶ 11-16, attached as Exhibit VV to Wood Dec.).

<sup>&</sup>lt;sup>13</sup> NDEP is a federally sponsored partnership of the National Institutes of Health, the Centers for Disease Control, and more than 200 partner organizations, including medical, research, professional, educational, and other groups. Siminerio Dec. at ¶ 18.

Attached as Exhibit A to Wood Dec. Groups supporting the NDEP guide's use by school personnel include: American Academy of Pediatrics American Association for Health Education, American Association of Diabetes Educators, American Diabetes Association, American Dietetic Association, American Medical Association, Barbara Davis Center for Childhood Diabetes, Centers for Disease Control and Prevention, Indian Health Service, Juvenile Diabetes Research Foundation

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

provide diabetes health care services, including insulin administration. (Kaufman Dec. at ¶ 10) Broad-based medical organizations, including the American Academy of Pediatrics <sup>15</sup> and the American Medical Association <sup>16</sup> also support having trained non-medical school personnel administer insulin.

#### The Shortage of Nurses in California D.

The shortage of nurses in California generally, and in California schools in particular, is welldocumented in Defendants' brief. However, Intervenor wishes to direct the Court's attention to additional compelling evidence of the shortage that highlights the extent of the problem and its impact on students with diabetes.

Although Plaintiffs make no mention of the perilous shortage of nurses in their brief, they have acknowledged it elsewhere. <sup>17</sup> In 2002, California ranked 49<sup>th</sup> out of 50 states in its ratio of

International, Lawson-Wilkins Pediatric Endocrine Society, National Association of Elementary School Principals, National Association of School Nurses, National Association of Secondary School Principals, National Association of State Boards of Education, National Education Association Health Information Network, National Institute of Diabetes and Digestive and Kidney Diseases (National Institutes of Health) and the U.S. Department of Education. Siminerio Dec. at ¶ 18.

<sup>&</sup>lt;sup>15</sup> *Id*.

 $<sup>^{16}</sup>$  The AMA Council on Science and Public Health stated, "The ideal situation is for a school nurse to provide diabetes care-related health services. However, even if a full-time nurse is present (and many schools lack sufficient nursing staff), additional personnel must be trained to provide routine and emergency diabetes care, including checking blood glucose levels and administering glucagon or insulin, if needed, during the school day and during extracurricular activities and field trips when a nurse is unavailable." American Medical Association, Report 4 of the Council on Science and Public Health (June 2008), http://www.ama-assn.org/ama/pub/category/18643.html (last visited Sep. 11, 2008). Attached as Exhibit C to Wood Dec.

See, e.g., Am. Nurses Assoc. of Ca, Resolution: Strategies to Address the Nursing Shortage Crisis (2005), http://www.anacalifornia.org/resolutions05.pdf (last visited Sep. 11, 2008)(2005) ANA/C resolution saying nursing shortage is a "crisis"), attached as Exhibit D-1 to Wood Dec.; Orlovsky, Christina, Nursing Shortage Leaves Schoolchildren Stranded (2006),

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

registered nurses to population. This shortage is not likely to improve in the near future as the population of California is expected to increase 52% by 2025 while the supply of new nurses is not increasing at comparable rates, due in part to a lack of baccalaureate nursing programs. <sup>18</sup> In 2002, California allocated \$60 million to establish the three year Nurse Workforce Initiative (NWI) to develop and implement proposals to recruit, train, and retain nurses. 19

The nursing shortage has had a substantial effect in public schools. Plaintiff ANA admits that currently, the nurse-to-student ratio in California schools is 1 nurse per 2,700 students, far higher than the recommended 1:750 ratio. 20 Also, nearly half of all school districts in California

http://www.nursezone.com/Nursing-News-Events/more-news.aspx?ID=14765 (last visited Sep. 11, 2008) (2006 Nursing News article: Nancy Spradling discusses "hopes" for increased school nursing, admits shortage is scary and one root is shortage of nurses in general; states that some districts, including small, rural and large urban districts, have no nurses at all), attached as Exhibit E to Wood Dec.); Hollister, Julia, No Quick Cure for Nursing Shortage (December 2, 2007), http://www.jobjournal.com/article\_full\_text.asp?artid=2198 (last visited Sep. 11, 2008) (Dec 2007) California Job Journal article: "The bottom line is that there is a critical need for nurses, and the state's programs are not able to meet the need," declares Liz Jacobs, spokeswoman for the California Nurses Association), attached as Exhibit F to Wood Dec.

California Healthcare Association, California's Nursing Shortage (September 30, 2002), http://www.calhealth.org/public/press/article%5C113%5Cca%20nursing%20shortage%20backgroun der.pdf (last visited Sep. 11, 2008) (noting that in the mid-1990s the University of California system terminated its baccalaureate nursing program, in 2001 the University of Southern California closed its program, and most of California's nursing schools with associate degree programs are filled to capacity with students on waiting lists). Attached as Exhibit H to Wood Dec.

California Economic Development Department, Nurse Workforce Initiative, (June 2, 2008), http://www.labormarketinfo.edd.ca.gov/article.asp?articleid=437 (last visited Sep. 11, 2008). Attached as Exhibit G to Wood Dec.

<sup>&</sup>lt;sup>20</sup> American Nurses Association, *The American Nurses Association, ANA/California File Lawsuit Against the California Department of Education* (October 10, 2007) http://www.safestaffingsaveslives.org/WhatisANADoing/LegalAction/CaliforniaLawsuit.aspx (last visited Sep. 11, 2008) (ANA press release announcing lawsuit to challenge settlement of case to provide care to children with diabetes). Attached as Exhibit M-1 to Wood Dec.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

have no school nurse at all. <sup>21</sup> This shortage establishes why sole reliance on licensed school personnel to provide insulin administration to students poses a serious health crisis.

A specific example of the crisis in school nursing can be found in Orange County, one of the most populous counties in the state. In response to request by Intervenor, the Orange County Department of Education produced a document entitled "Orange County Department of Education Health & Wellness Program–2007–2008 Nurse and Health Clerks Ratio by District."<sup>22</sup> The report documents the number of students and the number of nurses and health clerks in 29 school districts throughout the county. The report shows that there were 160.58 full-time equivalent nurses serving more than 493,000 students or a ratio of 1 for every 3,064 students. Some individual districts fared much worse. Eight school districts had more than 5,000 students for each nurse, and six districts had only one nurse for the entire district, including Huntington Beach City School District (6,655 students) and Brea-Olinda Unified School District (6,141 students). Saddleback Valley Unified School District had only two school nurses to serve its 34,592 students. (*Id.*)

The reality of this shortage in California schools today is substantiated by the personal and professional experiences of those submitting declarations on behalf of Intervenor. <sup>23</sup> The shortage persists despite many legislative attempts over the past decade to address the problem.<sup>24</sup>

See California Department of Education, State of California Education Profile, FY 2005–2006. Attached as Exhibit N to Wood Dec.

<sup>&</sup>lt;sup>22</sup> See Orange County Department of Education, Orange County Department of Education Health & Wellness Program – 2007 – 2008 Nurse and Health Clerks Ratio by District (produced in response to a Public Records Act request). Attached as Exhibit O to Wood Dec.

<sup>&</sup>lt;sup>23</sup> See, e.g., Kaufman Dec. at ¶¶ 34-36; Siminerio Dec. at ¶ 7; Breen Dec. at ¶ 9; Spain Dec. at ¶¶ 14-17; Declaration of Nicole C. ("Nicole C. Dec.") at ¶ 9; Louise D. Dec. at ¶¶ 18-19; Stone Dec. at ¶ 23; Barbara W. Dec. at ¶ 15; Declaration of Lynn T. ("Lynn T. Dec.") at ¶¶ 11, 16-17, attached as Exhibit UU to Wood Dec.

<sup>&</sup>lt;sup>24</sup> Several recent bills supported by nursing organizations have tried (and failed) to address the

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

There is other compelling evidence as well. Counsel for Intervenor sent a Public Records Act request on November 27, 2007 to all 1,236 school districts in the state. <sup>25</sup> The following can be summarized for the 489 school districts that provided detailed information:

- 166 school districts (33%) have no registered nurses in their employ;
- 48 school districts have fewer than 1 full time equivalent nurse in their employ;
- 79 school districts have 1 full time equivalent nurse in their employ;
- Of the 166 school districts that have no registered nurses in their employ they also have no licensed vocational nurses in their employ;
- An additional 240 school districts do not have a licensed vocational nurse in their employ.

There was - and still is - a widespread pattern of refusals and failures by schools to administer insulin and perform other necessary diabetes care services. These problems were clearly evident

state's nursing shortage. In 2001, Plaintiff CSNO sponsored S.B. 391, a bill that would have required every county office of education to employ a school nurse "to provide leadership and coordination of school health services." Assem. Com. on Education, Analysis of S.B. No. 391 (2001-2003 Reg. Sess.) as amended Jun. 29, 2001, p. 1. Attached as Exhibit S to Wood Dec. AB 1046 (2000) sought to employ tobacco settlement money to fund medical services grants. Assem. Com. on Health, Analysis of Assem. B. No. 1046 (1999-2000 Reg. Sess.) as amended Apr. 6, 1999 p. 1. Attached as Exhibit T to Wood Dec. AB 2171 (2001) sought to dispense money to school districts to increase nursing coverage and to credentialing programs to train more nurses. Assem. Com. on Appropriations, Analysis Assem. B. No. 2171 (1999-2000 Reg. Sess.) as amended Apr. 26, 2000, p. 1. Attached as Exhibit U to Wood Dec. AB 163 (2002) likewise sought to provide more funding for nurses due to the shortage. Assem. Com. on Appropriations, Analysis of Assem. B. No. 163 (2001-2002 Reg. Sess.) as amended Apr. 25, 2001, p. 1. Attached as Exhibit V to Wood Dec.. AB 68 sought to increase the number of school nurses in light of the state's low school nurse to pupil ratio. Assem. Com. On Education, Analysis Assem. B. No. 68 (2007-2008 Reg. Sess.) as amended Apr.17, 2007, pp. 3-4. Attached as Exhibit W to Wood Dec.

<sup>&</sup>lt;sup>25</sup> The letter requested information regarding district policies and the number of nurses and other health care professionals employed by the district. A copy of the letter is attached as Exhibit P to Wood Dec. and the spreadsheet summarizing findings is attached as Exhibit Q.

<sup>&</sup>lt;sup>26</sup> See, e.g., Breen Dec. at ¶¶ 6, 9-12; Spain Dec. at ¶¶ 11-13, 28; Nicole C. Dec. at ¶¶ 9, 11, 13, 15; Louise D. Dec. at ¶¶ 10-14, 16-18, 22; Lynn T. Dec. at ¶¶ 11, 16-17; Stone Dec. at ¶¶ 12,-13, 16-17.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

during the K.C. litigation, <sup>27</sup> and they continue today despite the settlement. The hardships caused to students and families by these failures are well-documented.<sup>28</sup> Deprived of adequate diabetes care required pursuant to treating physician's orders, students with diabetes (1) are forced to risk their short term and long term health to attend school; (2) cannot fully engage in learning; and (3) depend on their parents and other lay people to attend school on an on-call basis to administer insulin. The refusals and failures of schools to administer insulin have compromised the ability of parents and guardians to work or keep jobs necessary for their families' livelihood. This harms students by producing delays in necessary insulin administration, by virtue of the fact that these caregivers are not on site and are frequently summoned to the school site on an "on-call" basis. These realities have forced some parents and guardians to have to choose between their livelihood and the health of their children by requesting changes in insulin regimens to accommodate schools. (*Id.*)

The nursing shortage continues to be a crisis affecting children with diabetes – and other medical conditions – throughout the state.<sup>29</sup>

See also Declarations of the parents of individual plaintiffs in K.C., et al., v. O'Connell, et al., attached to Wood Dec.: Exhibit RR, Declaration of Laurie C. at ¶¶ 9, 14 ("Laurie C. Dec."); Exhibit PP, Declaration of Sheree F. at ¶¶ 11-14, 16 ("Sheree F. Dec."); Exhibit OO, Declaration of Stacey A. at ¶¶ 9, 14, 18 ("Stacey A. Dec."); Exhibit QQ, Declaration of Erica C. at ¶¶ 17-18, 21, 26 ("Erica C. Dec.").

See, e.g., Declaration of Anna Sandstrom, M.D., ("Sandstrom Dec.") at ¶¶ 8-14, attached as Exhibit SS to Wood Dec.; Breen Dec. at ¶¶ 8, 10-12; Spain Dec. at ¶¶ 10, 18-19; Nicole C. Dec. at ¶¶ 10, 12, 16-20; Louise D. Dec. at ¶¶ 15, 18-19, 24, 28; Sheree F. Dec. at ¶ 14-16, 20, 22-27, 34; Stacey A. Dec. at ¶ 10, 15, 18; Erica C. Dec. at ¶¶ 20-21; Lynn T. Dec. at ¶ 13; Stone Dec. at ¶ 14.

<sup>&</sup>lt;sup>29</sup> Intervenor requests the court to take judicial notice of the shortage of licensed nurses in California and in California's schools pursuant to California Evidence Code Section 452(h): "[Judicial notice may be taken of the following matters] . . . Facts and propositions that are not reasonably subject to dispute and are capable of immediate and accurate determination by resort to sources of reasonably indisputable accuracy."

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

# III. ARGUMENT

#### **State Laws And Policies That Frustrate The Purposes Of Federal Education** Α. **And Discrimination Laws Are Preempted**

Federal laws provide that students with diabetes are entitled to health related services at school and during school-sponsored activities.<sup>30</sup> If only nurses can administer insulin, the undisputed nursing shortage will result in the denial of these federal rights. The portion of the Advisory that permits trained unlicensed individuals to administer insulin when a nurse is not available does no more than recognize the well-established principle that the requirements of federal law override state laws (such as California's Nursing Practice Act) that would otherwise frustrate the purposes of those federal laws.

#### 1. Federal Laws Require That Insulin Administration Be Provided

As Defendant CDE has convincingly shown in its brief (Defendants' Br.), federal antidiscrimination and special education laws require that California public schools provide diabetes care services, including insulin administration, to eligible students. Plaintiffs concede as much. Intervenor joins with and adopts this section of CDE's brief, and need add nothing further on this point.

### The Nursing Practice Act Is Preempted To The Extent It Would 2. Frustrate The Purposes Of Federal Disability Laws

#### State Laws That Frustrate Federally Protected Rights Are Preempted a.

It is well established that state law is preempted, in whole or in part, where it conflicts with

<sup>&</sup>lt;sup>30</sup> Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. section 794 ("Section 504"), Title II of the Americans with Disabilities Act, 42 U.S.C. section 12131 et seq., ("ADA"), the Individuals with Disabilities Education Act, 20 U.S.C. section 1400, et seq. ("IDEA") and applicable federal regulations.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

or interferes with an applicable federal statute or regulation. The California Supreme Court recently discussed the basic framework underlying federal preemption claims. The court stated:

> The basic rules of preemption are not in dispute: Under the supremacy clause of the United States Constitution (art. VI, cl. 2), Congress has the power to preempt state law concerning matters that lie within the authority of Congress. In determining whether federal law preempts state law, a court's task is to discern congressional intent. Congress's express intent in this regard will be found when Congress explicitly states that it is preempting state authority. Congress's implied intent to preempt is found (i) when it is clear that Congress intended, by comprehensive legislation, to occupy the entire field of regulation, leaving no room for the states to supplement federal law; (ii) when compliance with both federal and state regulations is an impossibility; or (iii) when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Bronco Wine Co. v. Jolly, 33 Cal.4th 943, 955 (2004) (citations omitted). It is this third type of preemption, involving frustration of federal purpose, that is at issue in this case. The party arguing in favor of preemption bears the burden of demonstrating preemption. Id. at 956-957; McCall v. PacifiCare of Cal., Inc. 25 Cal.4th 412, 422 (2001). That burden has been satisfied in this case.

Courts have frequently found state statutes to be preempted by federal laws because they were an obstacle to the important purposes of the federal law.<sup>31</sup> Plaintiffs' legal position that only licensed health care professionals can administer insulin to students who cannot self-administer, even in situations where health care professionals are not available or cannot feasibly provide needed

For example, in Rim of the World Unified Sch. Dist. v. Super. Ct., 104 Cal. App. 4th 1393, 1399 (2002), the court held that the federal Family Educational Rights and Privacy Act (FERPA) preempted state public records laws because it prohibited disclosure of student expulsion records which the state statute required to be disclosed. The court held that the state disclosure requirement "is a direct obstacle to protecting parent and student rights to privacy in those records." See also People v. Edward D. Jones & Co., 154 Cal. App. 4th 627, 637 (2007) (analyzing claim that state laws regulating information to be disclosed to securities investors must be preempted by federal securities law because the purpose of the federal law was to free companies from the costs and burdens of duplicative and unnecessary regulations in different states, and rejecting claim because the federal statute specifically permitted the state to bring actions for fraud, deceit or unlawful conduct); cf. Union Sch. Dist. v. Smith, 15 F. 3d 1519, 1524 (9th Cir. 1994) (in order to be enforceable, state standards regarding education of students with disabilities must not be inconsistent with federal law).

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

insulin to students, would frustrate the express purpose of Section 504, the IDEA and the ADA. These laws were passed to ensure that people with disabilities, including students in public schools, had the same access and opportunities as their nondisabled peers. 32 Students with diabetes who need insulin during the school day cannot attend school safely if there is no one there to give it to them. They risk the long and short term complications of diabetes, and they cannot learn or participate in school as effectively as their peers.

Congress could not have intended that critical services could be denied (and, in effect, students prevented from safely attending school) by a state choosing to limit who can perform those services. To hold otherwise would permit states to eviscerate the federal requirements to serve students with disabilities by severely restricting the personnel authorized to serve these students (or stating that no one is so authorized) such that in practice districts could not find service providers and could, on that basis, refuse to serve their students. Therefore, to the extent the Nursing Practice Act and/or other state laws prevent school districts from complying with Section 504, IDEA and/or the ADA, those state laws are preempted to the extent necessary to ensure that Congress' purpose is not frustrated.

#### State Health And Safety Laws Can Be Preempted b.

While states have broad power to protect the public health and establish licensing and practice standards for health care professionals including nurses, these interests do not insulate a law from a preemption challenge.<sup>33</sup> State laws, including those involving public safety and health, must

See Irving Indep. Sch. Dist. v.. Tatro, 468 U.S. 883, 891(1984) (in passing the IDEA, "Congress sought primarily to make public education available to handicapped children" and "to make such access meaningful") (quoting Board of Education v. Rowley, 458 U.S. 176, 192 (1982)).

<sup>&</sup>lt;sup>33</sup>See Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88 (1992) (court held state licensing scheme for haulers of hazardous materials preempted by federal Occupational Safety and Health Act because

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

yield to federal disability laws when their enforcement would deny individuals with disabilities their rights under such laws. In Crowder v. Kitagawa, 81 F. 3d 1480 (9th Cir. 1996), the Ninth Circuit sustained a challenge to Hawaii's requirement that all carnivorous animals entering the state, including guide dogs, must be quarantined for 120 days in order to prevent the introduction of rabies into the state. The court found that the quarantine system severely restricted the rights of blind and visually impaired plaintiffs' to access the state's programs and services because they depended on access to their guide dogs for mobility and safety. The court rejected the argument that the quarantine ordinance was a public health measure of general applicability. *Id.* at 1485. *Crowder* makes clear that state statutes must give way when they interfere with the rights of persons with disabilities under federal law. As in Crowder, Plaintiffs here argue that California has established a system, ostensibly based on protection of the public, that only permits licensed health care professionals to administer insulin to students. However, such a system would have the effect of excluding people with disabilities from full and equal participation in government programs and services and thus must be modified or eliminated when it stands in the way of clear federal rights.

Intervenor does not argue that the Nursing Practice Act must be completely preempted in order for federal law to achieve its purposes. Intervenor urges only that preemption applies in those situations where an actual conflict does exist between state and federal law because enforcing the state law would actually frustrate the purposes of federal law.<sup>34</sup> What the CDE did in its Advisory is

it frustrated the federal statute's goal of uniform national regulation of workplace safety). "[U]nder the Supremacy Clause, from which our pre-emption doctrine is derived, 'any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." Id. at 108 (internal quotations omitted).

<sup>&</sup>lt;sup>34</sup> See Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Ware, 414 U.S. 117, 127 (1973) ("Whenever possible, courts are to reconcile the operation of both statutory schemes with one another rather than holding [that state law has been] completely ousted.").

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

to acknowledge the principle that federal rights may trump state laws such as the Nursing Practice Act and to remind districts that where there is in fact conflict (where nurses are not in fact available) then federal law still requires that services be provided and allows them to be provided by trained unlicensed school personnel.

Frustration of federal purposes is not a hypothetical concern. The interpretation of state law advanced by Plaintiffs places severe obstacles in the way of districts attempting to provide insulin administration as a related service that must be provided to students with diabetes under federal law. The chronic, well-documented shortage of nurses in California means that there simply are not enough nurses available to work in all schools in the state.

#### c. Reliance On Unavailable Nurses Is Inadequate To Ensure Federal Rights

The statistics cited earlier make clear the extent of the nursing shortage in California and its schools, and many schools have nurses on site only a few hours a week, if at all. (See discussion supra at 10-14) Yet the problem is not merely related to the shortage of nurses in California. A system where only nurses may administer insulin to children with diabetes is impractical because nurses will not always be present when a student needs an insulin dose. Even in those rare schools that have a full-time nurse, there will be times when the nurse cannot provide insulin administration, such as during field trips and extra-curricular activities or when the nurse is otherwise unavailable, but the need for care will remain. The problem, of course, is much worse in schools without a full time nurse. Some districts attempt to address their school nurse shortage by having school nurses travel from school to school within a district to administer insulin to a student or hiring contract nurses to come to a school site when administration of insulin is needed.<sup>35</sup>

 $<sup>^{35}</sup>$  See Kaufman Dec. at  $\P\P$  34-36; Siminerio Dec. at  $\P\P$  7, 20-23; Breen Dec. at  $\P\P$  10, 17; Spain Dec. at ¶¶ 20-22; Nicole C. Dec. at ¶¶ 16, 19-20; Louise D. Dec. at ¶¶ 18-19.

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

These measures, however, do not take into account the practical realities of when insulin is needed at school.<sup>36</sup> Any system requiring a nurse to travel to a school to give the dose risks unacceptable and unpredictable delays in administration of insulin for several reasons. First, many students will need insulin at about the same time each day, around lunchtime; these children all need to receive the dose on time, otherwise a student will not be able to eat with his or her peers, or may not be able to eat at all. (Kaufman Dec. at ¶ 26) But if one nurse must serve multiple children with diabetes at multiple schools at about the same time, this inevitably leads to delays. Second, many students need to take additional insulin when they eat or drink (other than to treat a low blood glucose level) so someone is needed when there are snacks or school events with food. Third, insulin is often required to treat hyperglycemia at unexpected times. (Kaufman Dec. at ¶ 15) In this situation, time is of the essence because of the consequences of prolonged hyperglycemia (see discussion *supra* at 6; Kaufman Dec. at ¶ 20), but if there is no nurse on site delays will result. Nurses may also be delayed due to travel time to the school and due to other tasks the nurse may need to perform (such as attending to an emergency need of another student at another school). (See supra at fn 36) Problems with travel time are a particular concern in rural districts where the schools are separated by substantial geographic distances, and in urban areas where traffic can be unpredictable. Id. Thus, reliance solely on nurses leads to students with diabetes being unable to effectively manage their blood glucose level in a safe range, to maintain a normal schedule, and to learn.

In short, even accepting Plaintiffs' interpretation of the applicable state law, that law must give way to the obligations imposed on the state and on local districts by federal disability laws when licensed personnel are not available. The Advisory acknowledges the reality that, where <sup>36</sup> *Id*.

- 19 -

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

nurses are not available, insulin cannot be provided to students with diabetes, and thus federal law will be violated unless trained unlicensed personnel are also permitted to administer insulin. The Advisory does not set up a binary choice between insulin administration by nurses and administration by trained unlicensed personnel. Taking into account ongoing and also unpredictable needs of children with diabetes, the Advisory only clarifies that trained unlicensed personnel are authorized to administer insulin when a nurse is not available.<sup>37</sup> The Advisory is tailored to permit the use of trained unlicensed personnel only in situations where licensed personnel are actually unavailable.

# В. California State Laws Authorize School Personnel Who Are Not Licensed **Health Care Professionals To Administer Insulin**

Preemption need only be analyzed if state law does, as Plaintiffs assert, prohibit unlicensed personnel from administering insulin. But in fact there is no such prohibition in California state law, no conflict between the Advisory's provisions and the Nursing Practice Act, and therefore no basis for granting the writ.

The Education Code includes an express grant of authority for unlicensed personnel to administer medication, which includes insulin, at section 49423 (entitled "Administration of Prescribed Medication for Pupil"). In addition, the Nursing Practice Act (NPA), Bus. & Prof. Code section 2700 et seq. does not prohibit unlicensed personnel from administering insulin, because (1) the NPA does not prohibit delegation of medication administration by nurses to unlicensed

For example, some students may be able to get insulin from a nurse most days and may only need a trained unlicensed person as backup. In other situations, a nurse may administer insulin once or twice a week when on campus, while trained unlicensed personnel may do so on other days, pursuant to the Legal Advisory.

personnel; (2) insulin administration does not require the substantial knowledge or technical skill needed to fall within the scope of nursing practice; and (3) statutory exceptions to the NPA apply, as discussed below.

# 1. The California Education Code Permits School Personnel To Administer

# Insulin.

Section 49423 of the Education Code provides:

(a) Notwithstanding section 49422, any pupil who is required to take, during the regular school day, medication prescribed for him or her by a physician or surgeon, may be assisted by the school nurse *or other designated school personnel*... (Emphasis added).

As Defendants have clearly explained in their brief (CDE Br.), Cal. Educ. Code section 49423 and its implementing regulations<sup>39</sup> authorize unlicensed personnel to administer insulin to students who require it. Intervenor adds only a limited additional discussion of this issue including a focus on the particular needs of students with diabetes.

Plaintiffs appear to claim that section 49423 somehow confers on school nurses the authority

<sup>&</sup>lt;sup>38</sup> Section 49423(b)(1) establishes requirements that must be met before school personnel may administer medication, including written parental consent and a prescription from the child's treating physician specifying the name of the medication, method, amount, and time schedules by which the medication is to be taken. The statute does not define or limit the types of medications that may be given, how they may be administered to the student, or limit which school personnel may be designated.

<sup>&</sup>lt;sup>39</sup> 5 Cal. Code Regs section 600 *et seq. See* Defendants' Br. These regulations followed an intensive process that included the Board of Registered Nursing, nurse organizations and other stakeholders who worked together to develop the regulations after researching and analyzing all aspects of children's needs for medication in school, noting reports of refusals by schools to administer medication and the fact that there are schools and school districts with no nurses available to administer medication. *See* Office of Administrative Law, *California Regulatory Notice Register*, (June 20, 2003), <a href="https://www.oal.ca.gov/pdfs/notice/25z-2003.pdf">http://www.oal.ca.gov/pdfs/notice/25z-2003.pdf</a> (see p. 921 *et seq.* regarding rulemaking on the regulations) (last visited Sep. 11, 2008). Attached as Exhibit GG to Wood Dec. Plaintiffs admit that they played a significant role in the development of these regulations. Plaintiffs' Br. at 8:24-9:9.

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

to do all of the tasks needed to administer insulin, but limits other school personnel to a lesser role. In fact, the express authority conferred here by the statute applies equally to school nurses and "other designated school personnel". Thus, Plaintiffs cannot prevail without effectively prohibiting even school nurses from administering medications, an absurd result supported by none of the parties.  $^{40}$ 

As Defendants' brief discusses, Plaintiffs' reliance on a legally significant distinction between the terms "administer" and "assist" is legally untenable. In addition, such a distinction would create an absurd result in the context of insulin administration. If assistance means taking actions short of putting the medication into the body, it still includes determining the amount of medication and preparing it to go into the body. Thus, it would allow drawing up the insulin into a syringe or dialing an insulin pen or inputting the numbers on an insulin pump, but then prohibit proceeding with the injection or pushing the buttons on the pump. Such a rule would be nonsensical as it would prevent school personnel from doing the very easiest part of the process, the part that children themselves learn to do at a very young age. (Kaufman Dec. at ¶¶ 29, 31) This absurd distinction would apply to a host of other medications as well. Thus, a school employee could measure cough syrup, but not put it in a child's mouth, and couldn't even put an eye drop in an eye. On the other hand, if Plaintiffs are arguing that even determining the amount of medication is beyond what is contemplated by "assist" then school personnel would be prohibited from even following a doctor's orders to determine if a student should have one or two Tylenol tablets – and it is hard to fathom what school employees would be allowed to do. That is, the statute would be meaningless.

In addition, to require that medication may only be administered by school nurses reads the phrase "other designated school personnel" out of the statute. Such an analysis is contrary to the governing principle that every word and clause is given effect so that no part or provision is useless, deprived of meaning or contradictory. Kleemann v. W.C.A.B. 127 Cal.App.4th 274 (2005).

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

In attempting to deny this clear statutory authorization, Plaintiffs misstate CDE's policy and past positions. 41 Contrary to Plaintiffs' assertions, CDE's Program Advisory on Medication does not expressly limit administration of insulin under Section 504 and the IDEA by unlicensed personnel to epidemics or public disasters.<sup>42</sup>

Education Code section 49414.5 and its legislative history do not support Plaintiffs' argument. The provisions of this bill involving administration of glucagon 43 to California students by unlicensed school personnel was an effort to clarify existing law, not change it. 44 Section 49414.5 and its legislative history confirm that existing law at the time of its passage in 2003 authorized the administration of medication by unlicensed school personnel; the glucagon legislation did not purport to establish such authorization. Rather, the specific legislative purpose for the law was to encourage the training and designating of unlicensed personnel to administer glucagon. As stated in

Plaintiffs are incorrect in arguing that the Legal Advisory is "a complete reversal of long-standing published policy." Plaintiffs' Br. at 2:6-8, 27; see Defendants' Br. (describing prior CDE guidance). CDE's long-standing policy recognizing the authority of unlicensed school personnel to administer medications and the preeminence of federal law is discussed in its brief at 12:7-17.

 $<sup>^{\</sup>rm 42}$  CDE's non-binding Medication Advisory (established in May 2005 - not 2002 as stated in Plaintiff's Br. at 2:23) recognizes the authority conferred by Education Code 49423 for administration of medication by unlicensed school personnel (CDE's Program Advisory on Medication, May 2005, Item IV), but recommends against unlicensed personnel administering medication by injection. Id. at Item IVB.2.d. However, the CDE recognized and acknowledged the supremacy of federal laws: "On the basis of these laws and regulations, it is recommended that the Title 5 regulations and this advisory serve as a guide to [local education agencies] in administering medications to students with IEPs and Section 504 plans as long as the regulations or the advisory do not conflict with the student's individually determined plan." CDE's Program Advisory on Medication, May 2005, Item XV. Plaintiffs also misstate the law with regard to emergencies. See infra at fn 57.

<sup>&</sup>lt;sup>43</sup> As discussed *supra* at 7, glucagon is a hormone that is injected when someone with diabetes is experiencing a hypoglycemia emergency.

<sup>&</sup>lt;sup>44</sup> See, e.g., City of Redlands v. Sorensen 176 Cal. App. 3d 202, 211 (1985) ("It is also well established that the enactment of a statute or an amendment to a statute for the purpose of clarifying preexisting law or making express the original legislative intent is not considered a change in the law.").

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

the Senate Rules Committee Analysis:

Current law permits a student who is required to take medication during the school day to be assisted by a school nurse or designated school personnel if the school district receives written statements from the pupil's parent or guardian and healthcare provider. . . . The purpose of this statute is to encourage training and remove fear of liability. (Emphasis added)

For all of the reasons stated in Defendants' brief, and the additional ones presented in this section, section 49423 authorizes unlicensed school personnel to administer insulin to students who require it. Given the authorization provided by section 49423, the Court need not address whether the Nursing Practice Act also permits insulin administration by unlicensed school personnel. As a specific enactment relating to education, section 49423 would supersede the more general provisions of the Nursing Practice Act. 46 The NPA does, however, provide independent authority for unlicensed school personnel to administer insulin, as described below.

# 2. The California Nursing Practice Act Permits School Personnel To Administer Insulin.

Nursing is defined in the California Nursing Practice Act to cover:

those functions, including basic health care, that help people cope with difficulties in daily

- 24 -

Sen. Rules Com. Off. Of Sen. Floor Analysis of Assem. B. No. 942 (2003-2004 Reg. Sess.) as amended Aug. 28, 2003, p. 2. Attached as Exhibit R to Wood Dec. Such legislative analyses are very commonly acknowledged as evidence of legislative intent "when the meaning of a statute is uncertain." See, e.g., Hutnick v. U.S. U.S. Fid. and Guar Co., 47 Cal.3d 456, 465 (n 7) (1988).

<sup>&</sup>lt;sup>46</sup> Also, since section 49423 was enacted prior to the current definition of nursing in the NPA, allowing a restrictive interpretation of the NPA to control in this situation would constitute a disfavored "implied repeal." San Joaquin Helicopters v. Dept. of Forestry, 110 Cal.App.4th 1549, 1564 (2003); Wirth v. State, 142 Cal.App.4th 131, 140 (2006) ("the presumption is ... against repeal by implication where express terms are not used and the statutes are not irreconcilable." (internal quotes and citations omitted). "The rule is that there must be no rational basis for harmonizing the potentially conflicting statutes, and the two must be so inconsistent that they cannot have concurrent operation." Nguyen v. Nguyen, 158 Cal.App.4th 1636, 1656 (2008). (citation omitted). In order to avoid such an outcome, courts have taken prior, specific laws to constitute an exception to subsequent, general laws. San Joaquin, supra at 1564.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

living that are associated with their actual or potential health or illness problems or the treatment thereof, and that require a substantial amount of scientific knowledge or technical skill ... including ...[d]irect and indirect patient care services, including, but not limited to, the administration of medications . . . . ". Bus. & Prof. Code section 2725(b)(2) as amended in 1974. (Emphasis added).

Despite these qualifiers, Plaintiffs urge that it is unlawful for anyone other than a nurse to administer any medication: "Clearly, the administration of medication is a function requiring a substantial amount of scientific knowledge and technical skill and constitutes the practice of nursing within the meaning of the NPA." Plaintiffs' Br. at 20:26-28. A proper reading of the NPA is that its reach is not endless and it does not purport to absolutely restrict the activities listed to nurses. 47 Rather, both the language in section 2725(b)(2) and other exceptions in the NPA provide for non-licensed school personnel to administer insulin.

# The Administration of Insulin by Trained Non-Licensed School a. Personnel Does Not Require A Substantial Amount of Scientific Knowledge or Technical Skill

Plaintiffs assert that the administration of insulin must be performed by nurses in a school setting because it requires "a substantial amount of scientific knowledge or technical skill." Relying almost exclusively on the testimony of two nurses, neither of whom is an expert in diabetes care, Plaintiffs dwell at length on the complexity of diabetes management and the supposedly dire consequences of errors in insulin administration. Plaintiffs discuss the many complicated steps that they allege are essential before anyone would dare to perform an insulin injection. Plaintiffs' Br. at

<sup>&</sup>lt;sup>47</sup> For example, given the specific authority conferred by Education Code section 49423 governing nursing practice regulations authorize registered nurses to delegate nursing tasks to unlicensed school personnel. The relevant provision identifies a competent nurse as one who "delegates tasks to subordinates based on the legal scopes of practice of the subordinates and on the preparation and capability needed in the task to be delegated." 16 Cal. Code of Regs. section 1443.5(4).

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

20:3-12. In Plaintiffs' worldview, every person with diabetes needs a nurse constantly hovering nearby to provide nursing assessment and treatment (since insulin could be needed at any time to correct for a high blood glucose level). This claim is not only wrong, impractical, and untenable, it is insulting to the millions of individuals and family members living with diabetes who manage the disease successfully every day, without benefit of a nursing degree.<sup>48</sup>

The flaw in Plaintiffs' logic is demonstrated most convincingly by the fact that every day across the state individuals with diabetes (including children as young as ten) administer insulin, as do their family members and caregivers. (Kaufman Dec. at ¶¶ 29-31; Siminerio Dec. at ¶¶ 9-10) Today, nearly all routine diabetes care is provided by lay-people, and insulin delivery methods have been developed with this in mind.<sup>49</sup> The training needed to do this task is neither difficult nor timeconsuming. (Kaufman Dec. at ¶ 29; see discussion supra at 8-10) Plaintiffs' continued insistence that adult school personnel cannot be trained to safely administer insulin, even though children routinely are, defies logic and common sense. 50

Plaintiffs characterize Intervenor's position supporting insulin administration by unlicensed

<sup>&</sup>lt;sup>48</sup> Plaintiffs even go so far as to quote from Intervenor's complaint in the *K.C.* litigation regarding the need for careful and timely monitoring and treatment of diabetes as supporting its allegation that insulin administration requires scientific knowledge and technical skill. Plaintiffs' Br. at 19:15-27. While Intervenor acknowledges that diabetes does require careful monitoring and adequate treatment, that in no way suggests that unlicensed personnel lack the skill to safely administer insulin.

<sup>&</sup>lt;sup>49</sup> As cited in Defendant's brief, courts have recognized that certain procedures may be safely performed by laypeople.

 $<sup>^{50}</sup>$  See, e.g., Siminerio Dec. at ¶ 11 ("I have successfully – and routinely – taught all of these tasks to people of all educational backgrounds, and even to children. On several occasions, I have been able to train parents with severe mental challenges to safely administer insulin to their child."); *Id.* at ¶ 16 ("I have trained hundreds of children (those who have the maturity and cognitive skills, which is individually determined) and their caregivers throughout my career and have never had a situation in which I was unable to train safe administration of an insulin injection."); Kaufman Dec. at ¶ 32.

personnel as well-intentioned but misguided. Plaintiffs' Br. at 17:24-26. If so, Intervenor is in good company. Intervenor's position, which is based on a peer-reviewed position statement developed by leaders in the field of pediatric endocrinology, is supported by the organizations made up of the doctors, nurses and other health care professionals who have devoted their lives to diabetes treatment and research, the organizations of the families who love these children, a host of educational organizations, the federal government agencies with expertise in both health care and education, and by broad-based medical groups such as the American Medical Association and the American Academy of Pediatrics. (*See* discussion *supra* at 9-10) Diabetes experts agree that the danger to be concerned about here is not that non-licensed school personnel cannot be trained to safely administer insulin; the danger is not having someone on site who can provide this vital medication when it is needed. (Kaufman Dec. at ¶ 24, 35; Siminerio Dec. at ¶ 21-23)

Here it is useful to distinguish between two aspects of administering insulin: assessing the correct dose to be given at a particular time and actually giving that dose (either by syringe, using an insulin pen, or pressing buttons on an insulin pump). Plaintiffs cannot seriously dispute that the latter does not involve a substantial amount of scientific knowledge or technical skill. <sup>51</sup> (Kaufman Dec. at ¶¶ 29-32; Siminerio Dec. at ¶¶ 11, 16) With respect to the former, Intervenor does not dispute that establishing insulin regimens including the method for calculating the dosage to be taken in response to various blood glucose levels and carbohydrate intake, does require such skill. However, in the school setting, the type and amount of insulin will be specified in the treating physician's orders on file with the school. Education Code section 49423(b)(1). Dr. Francine

Plaintiffs' Declarant Schumann acknowledges that "filling a syringe and pushing the plunger" are "rote tasks." Schumann Dec. at ¶ 14.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Kaufman, <sup>52</sup> one of the nation's foremost experts in pediatric diabetes care describes this process:

The child's treating physician and health care team should provide detailed specifications to the school as to what insulin dosage is proper under different circumstances. For example, in my practice I provide individualized information (in the form of a written health care plan) for each child showing the doses of insulin to be taken at regular intervals as well as dosages needed to treat given blood glucose levels that are outside the child's target range. . . it is not necessary for school personnel to decide independently how much insulin is needed in a given situation. Rather they simply follow the instructions that I, like all other health care personnel caring for children with diabetes, provide. (Kaufman Dec. at ¶ 27)

Whoever provides the care, whether a nurse or an unlicensed person, is to follow these physician's orders. According to Dr. Linda Siminerio, <sup>53</sup> an expert in diabetes care and in training lay people to provide this care:

In the school setting, the task that the person administering the insulin to a student is being asked to do, whether it is a nurse or a trained non-medical school employee, is the same. That person is supposed to determine the amount of insulin based upon orders from the experts in diabetes management, the child's treating diabetes care team, and the only information this will require is the amount of carbohydrates the child is about to consume and/or the child's current blood glucose level. As a member of the treating team, when it comes time to administer insulin it is not necessary for that person to assess the student's medical history or perform any other sort of physical assessment. (Siminerio Dec. at ¶11)

Contrary to Plaintiffs' assertion that if the Legal Advisory were upheld "California's public schools [would] no longer have any need for a school nurse," (Plaintiffs' Br. at 24:18-19), school nurses have many vital roles in caring for all students, including students with diabetes. Intervenor

Dr. Kaufman, a professor at the Keck School of Medicine at the University of Southern California, has been a pediatric endocrinologist since 1980. She has authored more than 120 peer-reviewed publications, and has been leader or principal investigator on numerous studies related to diabetes. She is the incoming chair of the National Diabetes Education Program and a member of the Institute of Medicine of the National Academy of Sciences.

<sup>&</sup>lt;sup>53</sup> Linda Siminerio has been a registered nurse for 36 years and is an associate professor of medicine in department of endocrinology at the University of Pittsburgh School of Medicine and an associate professor of nursing at the University of Pittsburgh School of Nursing. She is director of the University of Pittsburgh Diabetes Institute and has conducted extensive research on diabetes education, diabetes translation into community interventions, and pediatric diabetes care and education.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

strongly supports having more nurses in California's schools to benefit all children, to perform diabetes care tasks when available, and because school nurses are ideally suited to coordinate diabetes care and to provide training and guidance to non-licensed school personnel. That school nurses are vital, however, does not mean that a trained unlicensed school employee cannot safely administer insulin to a student with diabetes when a school nurse is not present. (Siminerio Dec. at ¶17)

Plaintiffs also err in arguing that only the Board of Registered Nursing has statutory authority to interpret and enforce the NPA. Plaintiffs' Br. at 18. Intervenor does not dispute that the BRN has a role to play in the interpretation and enforcement of the statute, but notes that the BRN, like any state agency, is bound to be faithful to the language of the statute that it interprets and enforces, and may not create requirements or rules at odds with that statutory language or in violation of the California Administrative Procedure Act (APA). The November 30, 2007 document issued by the BRN and cited by Plaintiffs is far from a conclusive statement regarding state law or agency action satisfying the requirements of the APA.<sup>54</sup>

Finally, the fact that hospitals utilize nurses to administer insulin sheds no light on whether that practice is legally required in the school setting. (Plaintiffs' Br. at 16-17) There are significant differences between the environment and the needs of individuals with diabetes in a hospital and a school. In particular, sick hospital patients have more unstable and unpredictable insulin needs, and

<sup>&</sup>lt;sup>54</sup> Board of Registered Nursing, Administration of Insulin in Schools by Unlicensed Personnel (Nov. 30, 2007). Attached as Exhibit C to Plaintiffs' Parent Dec. The document merely says that the "administration of medication, including insulin, is a nursing function that may not be performed by an unlicensed person unless expressly authorized by statute," but fails to address the impact of section 49423. It acknowledges that it is not the final word on this issue stating that it is providing guidance "[u]ntil the issue [referencing this lawsuit] is resolved." Furthermore, it is nothing more than a conclusory statement about the law without any factual support, and thus is not entitled to the deference that would be due to an agency acting in its area of scientific or medical expertise. Finally, it is not an interpretation or regulation adopted after public notice and comment.

are more sensitive to variations in insulin levels, than healthy children in the school setting.

(Kaufman Dec. at ¶ 35) Second, at school, unlicensed personnel have the opportunity to become familiar with the insulin needs of a particular student, based on a treatment regimen that has been developed and tested by the treating physician and family. These differences make the likelihood of an incorrect dose, and the severity of its consequences, much less in the school setting no matter who administers the insulin. (Kaufman Dec. at ¶ 35) <sup>56</sup>

# b. The NPA Contains Exceptions That Explicitly Permit Non-Licensed Personnel To Provide Nursing Duties Under Specified Circumstances.

The NPA expressly confirms that various nursing tasks can be performed by non-licensed personnel in certain specified circumstances. *See, e.g.*, Cal. Bus. and Prof. Code sections 2727(a), (d), and (e). <sup>57</sup> Section 2727(e), wholly ignored by Plaintiffs, is directly applicable here if

Similarly, Plaintiffs' expressed concerns that the wrong type of insulin or syringe will be chosen are simply inapplicable to the school situation where all medications and supplies for the child are provided by the family for that specific child. Siminerio Dec. at ¶ 12.

For the same reason, Plaintiffs' reliance on the prohibition contained in Bus. & Prof. Code section 2725.3 (Plaintiffs' Br. at 16-17) is entirely unhelpful to its case because section 2725.3 specifically prohibits delegation of medication administration to unlicensed persons in health care facilities *only*. Indeed, the presence of the explicit prohibition in section 2725.3 makes clear that the general provisions of section 2725(b) do not prohibit delegation, since section 2725.3 would be surplusage if they did. In construing the language of a statute, courts must avoid an interpretation that would render a statute superfluous. *See Plumas County Child Support Servs. v. Rodriquez*, 161 Cal.App.4th 1021, 1029 (2008).

For example, section 2727(a) excludes "gratuitous nursing of the sick by friends or members of the family." Section 2727(d) permits persons other than nurses to provide nursing services in case of an emergency. Plaintiffs misstate Section 2727(d). Plaintiffs' Br. at 2:20-26, 21:4-5. This provision expressly does *not* limit the definition of "emergencies" to "epidemics or public disasters." Bus. & Pro. Code section 2727: "Exceptions in General. … This chapter does not prohibit . . . (d) Nursing services in case of an emergency. 'Emergency,' as used in this subdivision *includes* an epidemic or public disaster." (emphasis added) The list of general exceptions thus includes activities that are categorized as nursing but places them outside the requirement of exclusive provision by nurses.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

administration of insulin is otherwise found to be a nursing function (cf. preceding discussion). Section 2727(e) authorizes and generally excepts from the restrictions of the NPA:

The performance by any person of such duties as required in the physical care of a patient and/or carrying out medical orders prescribed by a licensed physician; provided, such person shall not in any way assume to practice as a professional, registered, graduate or trained nurse.

As discussed above, where personnel other than nurses administer insulin to students with diabetes in the school setting, they do so strictly carrying out medical orders provided by the student's physician. Any insulin dosage, whether administered by a nurse or by a trained volunteer, is given only in accordance with a detailed, written health care plan developed by the student's treating physician. Trained unlicensed school personnel are following the physician's orders and are not in any way holding themselves out as nurses. Therefore, section 2727(e) authorizes and provides an exception for the type of care Plaintiffs challenge here.

For all of the reasons discussed above, the NPA does not prohibit non-licensed school personnel from administering insulin, and the Education Code specifically permits it.

#### C. Plaintiffs' APA and Constitutional Challenge Should Be Rejected

Intervenor joins with and adopts the arguments of the CDE with regard to Plaintiffs' contentions that the Legal Advisory violates the APA and section 3.5 of the California Constitution.

#### D. Plaintiffs Cannot Meet the Standard for Obtaining a Writ of Mandate

Plaintiffs seek a writ of mandate under section 1085 (or in the alternative section 1094.5)<sup>58</sup> of the Code of Civil Procedure. A writ may only issue if the Plaintiffs prove either that the CDE failed

Although Plaintiffs refer to section 1094.5, this writ claim is not properly brought under that section, which only applies to agency proceedings "in which by law a hearing is required to be given [and] evidence is required to be taken". Code Civ. Proc. section 1094.5(a). As the issuance of the Legal advisory was not an agency action (such as an adjudicatory hearing) which met these requirements, this brief will consider only the requirements of section 1085.

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

to carry out a purely ministerial duty that it is required by law to perform, or that the CDE abused its discretion in carrying out its legal duties. A writ may not be employed to "control discretion as to a matter lawfully entrusted to the [agency]." Terminal Plaza Corp. v. City and County of San Francisco, 186 Cal. App. 3d 814, 830 (1986). Here, the CDE did not fail to perform a ministerial duty, and did not abuse its discretion in issuing the Advisory. Because the Advisory is not a regulation and reaffirmed long-accepted legal principles, the CDE had no ministerial duty to comply with the Administrative Procedure Act in its adoption. (Id.) Moreover, the CDE's issuance of the challenged portion of the Advisory neither violated a ministerial duty nor abused the agency's discretion to enforce compliance with the state and federal laws for which it is responsible. The challenged portion of the Advisory should also be upheld because unlicensed personnel may administer insulin under applicable state law, and because it is consistent with established principles governing the interaction between state and federal law. All of Plaintiffs' policy preferences, however fiercely held, cannot change the fact that no legal obstacle prevented the CDE from issuing the challenged provision of the Advisory, which represented a reasonable and wholly legal response to the crisis of diabetes care in California schools.

Despite the nature of this case as a writ proceeding (which generally involve legal questions), Plaintiffs' brief is filled with factual assertions, many of them unsupported (and unsupportable). Intervenor has refuted these assertions with support from health care professionals with expertise in diabetes and the parents of children who live with the disease every day. The facts relevant to the resolution of this case cannot reasonably be disputed; the Court must deny the request for a writ.

To the extent that the Court believes that there are factual disputes as to how much knowledge and skill is required for insulin administration or whether needed insulin administration can be provided in California schools using only nurses and other health care professionals,

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Intervenor urges that it is inappropriate to grant a writ when there are unresolved issues of fact and requests that the parties be permitted to develop the factual record further through additional discovery, and that remaining factual issues be resolved at an evidentiary hearing or other appropriate proceeding.<sup>59</sup>

Finally, the relief Plaintiffs seek in their memorandum in support of a writ is also not only far too broad, but is also inconsistent with their complaint in this matter, which must govern. In their memorandum, Plaintiffs apparently seek to have the entire Legal Advisory invalidated (see Plaintiffs' Br. at 4:8 and 26:19-20), despite the fact Plaintiffs actually challenge only one paragraph of the 13 page document in their complaint. Plaintiffs' complaint asks the Court for a writ of mandate "(i) setting aside, vacating and invalidating 'Legal Advisory' standard #8 60 [and] (ii) enjoining Defendants from taking any action in connection with 'Legal Advisory' standard #8." Plaintiffs' Second Amended Petition for Writ of Mandate and Complaint for Declaratory and Injunctive Relief ("Complaint") at 11:25-27. Thus, Plaintiffs have only asked this court to invalidate the specific provision permitting unlicensed school personnel to administer insulin when a nurse is not available, not the entire Legal Advisory.

<sup>&</sup>lt;sup>59</sup> Plaintiffs also seek declaratory and injunctive relief on much the same basis as their writ claim. Plaintiffs' Br. at 24-25. Intervenor believes that declaratory and injunctive relief is inappropriate and should be denied for generally the same reasons as have been articulated in this brief as to the writ claim. In addition, relief should not be granted on these claims without giving the parties an opportunity to address legal issues that are not relevant to the request for a writ now before this Court. For example, while Intervenor concedes for purposes of this opposition that Plaintiffs have standing to seek writ relief on at least some of their claims, Intervenor does not believe that Plaintiffs have, or can, demonstrate standing to seek declaratory or injunctive relief because Plaintiffs cannot show any injury in fact to themselves or their members. No cognizable interest of Plaintiff nursing organizations or their members has been threatened by the issuance of the Legal Advisory. These issues should be explored through discovery and appropriate motions before being resolved.

<sup>&</sup>lt;sup>60</sup> Legal Advisory standard #8 is the challenged provision of the Legal Advisory governing insulin administration by unlicensed personnel. See Plaintiffs' Complaint at 6:8-16.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

IV. CONCLUSION. For the reasons stated above, Plaintiffs' petition should be denied and their complaint dismissed. Dated: September 12, 2008 REED SMITH LLP By James M. Wood Kenneth J. Philpot Attorneys for Intervenor American Diabetes Association DISABILITY RIGHTS EDUCATION AND DEFENSE FUND, INC. By\_ Arlene Mayerson Larisa Cummings Attorneys for Intervenor American Diabetes Association - 34 -