

No. S184583

In The Supreme Court of the State of California

AMERICAN NURSES ASSOCIATION, et al.,
Plaintiffs and Respondents,

vs.

JACK O'CONNELL, as Superintendent of Public
Instruction, etc., et al.,
Defendants and Appellants,

AMERICAN DIABETES ASSOCIATION
Intervener and Appellant.

**APPLICATION OF CALIFORNIA SCHOOL BOARDS
ASSOCIATION FOR PERMISSION TO FILE AMICUS CURIAE
BRIEF IN SUPPORT OF INTERVENER/APPELLANT
AMERICAN DIABETES ASSOCIATION;
BRIEF ATTACHED HEREWITH**

On Review From A Published Decision Affirming A Judgment Including
Issuance of A Peremptory Writ of Mandate
Court of Appeal, Third Appellate District, Appeal No. C061150

On Appeal From A Judgment On A Complaint And A Petition For Writ Of Mandate
Sacramento County Superior Court, No. 07AS04631
Honorable Lloyd G. Connelly

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TO THE HONORABLE TANI CANTIL-SAKAUYE, CHIEF JUSTICE
OF THE SUPREME COURT OF CALIFORNIA:

Pursuant to Rule 8.520(f) of the California Rules of Court, the California School Boards Association ("CSBA") and its Education Legal Alliance ("Alliance") respectfully requests permission to file the attached brief as amicus curiae in the above-captioned case. No party or counsel for a party in the pending appeal authored any part of the proposed amicus brief or made a monetary contribution intended to fund the preparation or submission of said brief. Nor has any other party or entity made any monetary contribution funding the proposed brief. The proposed brief supports intervener/appellant, the American Diabetes Association.

CSBA is a California non-profit corporation. CSBA is a member-driven association composed of nearly 1,000 K-12 school district governing boards and county boards of education throughout California. CSBA supports local school board governance and advocates on behalf of school districts and county offices of education. As part of CSBA, the Alliance helps to ensure that local school boards retain the authority to fully exercise the responsibilities vested in them by law to make appropriate policy and fiscal decisions for their local educational agencies. The Alliance represents its members, just under 800 of the state's 1,000 school districts and county offices of education, by addressing legal issues of statewide

concern to school districts. The Alliance's activities include joining in litigation where the interests of public education are at stake.

The Alliance views the present matter as integral in protecting both the public policy and fiscal interests of its school district members. Should the Nursing Practice Act (Bus. & Prof. Code § 2700 *et seq.*) be construed as barring unlicensed persons from administering medication to students, the flood gates may open to support the notion that nurses are the only employees who may administer other medications which require minimal to no supervision. In addition, school districts will suffer a deep fiscal impact should unlicensed school personnel be barred from administering such medication, as school districts will be required to employ a nurse at every school site and during every school-sponsored event, such as field trips and sporting events. Diverting precious school funding to employ a nurse, whose services would only be utilized for minutes per day in administering insulin, constitutes a waste of public resources. Further, the logistical impossibility of having a nurse available at all times should a student require medication, and the lower courts' prohibition of allowing unlicensed, trained school personnel to perform such duties, contravenes with the school districts' obligations to provide a safe and healthy environment for their students under the federal Individuals with Disabilities Education Act and Section 504 of the Rehabilitation Act.

The Alliance is familiar with the present case and has reviewed the briefs by the parties involved. The Alliance does not intend to reiterate arguments already submitted by the parties, but rather wishes to provide policy arguments which demonstrate that unlicensed school personnel may administer insulin medication in a safe and accurate manner, in compliance with state and federal law.

STATEMENT OF THE CASE

In 2007, the ADA and several public school students with diabetes entered into a settlement agreement with Jack O'Connell, as Superintendent of Public Instruction, and the California Department of Education ("CDE"), among others, after filing a class action lawsuit claiming that Superintendent O'Connell and CDE violated the federal rights of students with diabetes under the Individuals with Disabilities Act, the American with Disabilities Act, and Section 504 of the Rehabilitation Act, by denying them access to a free appropriate public education and related health care services for failure to provide them insulin medication as needed. As part of the settlement, CDE issued a Legal Advisory, which declared that an unlicensed, voluntary school employee who has received appropriate training may administer insulin pursuant to the student's prescribing physician's orders.

The present dispute stems from a lawsuit filed subsequent to the issuance of CDE's Legal Advisory by the American Nurses Association, the

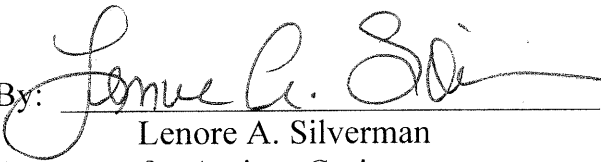
American Nurses Association/California, the California School Nurses Organization, and the California Nurses Association (collectively "Nurses Association"). The Nurses Association contends that the CDE advisory permitting unlicensed school personnel to administer insulin was inconsistent with the Nurses Practice Act ("NPA"; Bus. & Prof. Code § 2720 *et seq.*), which purportedly prohibits unlicensed individuals from administering medication categorically. The Nurses Association further contends that Education Code section 49423 does not authorize unlicensed school personnel to perform such duties. The ADA, an authorized intervener, claims that CDE's unlicensed school personnel provision was valid because it was consistent with the NPA, supported by Education Code section 49423, and that any prohibition would be preempted by requirements under Section 504, the American with Disabilities Act, and the IDEA.

The superior court found in favor of the Nurses' Association position, and determined that the CDE legal advisory was invalid because the NPA prohibited unlicensed persons from administering medication categorically, that Education Code section 49423 did not provide for any exemption to this rule, and that Section 504, the American with Disabilities Act, and the IDEA did not preempt the prohibition of unlicensed school personnel from administering medication. The superior court, however, also acknowledged that public policy reasons supported the ADA's

position, but that it was not under any authority to make such determinations. The Court of Appeal, upon review, affirmed the superior court's decision. ADA thereafter petitioned this Court for review, which was granted unanimously.

DATED: May 10, 2011.

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I. SCHOOL DISTRICTS HAVE AN OBLIGATION TO PROVIDE MEDICATION ADMINISTRATION, INCLUDING INSULIN, TO STUDENTS WITH DISABILITIES AND HEALTH NEEDS.

The argument set forth by the American Nurses Association ("ANA") that federal education laws do not require school districts to ensure the administration of insulin to students with diabetes is stunning. Public agencies such as school districts are obligated to provide students with disabilities including diabetes with a free appropriate public education ("FAPE") in the form of equal access to an education to the same extent as their non-disabled peers, which may include accommodating or modifying a program or activity to enable such participation. The Individuals with Disabilities Education Act ("IDEA"; 20 U.S.C. § 1400 *et seq.*) provides that students with disabilities are entitled to FAPE and related services designed to meet their individual needs in the least restrictive environment to receive educational benefit.¹ Section 504 of the Rehabilitation Act of 1973 ("Section 504"; 29 U.S.C. § 794) and the American with Disabilities Act (42 U.S.C. § 12101 *et seq.*) prohibit discrimination in federal programs and services, including education, on the basis of disability.

¹ For purposes of this amicus brief, the California School Boards Association ("CSBA") need not go into detail into the legal analysis already well-stated by intervener/appellant the American Diabetes Association ("ADA") in their opening and reply briefs, and concurred by the Alliance.

Together, these federal laws require public school districts to provide students with disabilities including students with diabetes, with an appropriate education that ensures access to the same activities and programs as their non-disabled peers. CSBA believes that the lower courts' overbroad interpretation of the California Nursing Practices Act (Cal.Bus&Prof.Code §2700 *et seq.*; "NPA") barring unlicensed school personnel from administering insulin, including when a school nurse is unavailable, will cause school districts to restrict the rights of students with disabilities, severely limiting their access to an equal education and participation with their non-disabled peers.

A. School Districts Must Adhere to Requirements Under the IDEA and Section 504 In Order to Protect Students.

As was well-stated in the ADA's opening and reply briefs, the lower courts' interpretation of California state law as barring unlicensed school personnel from administering insulin to students with diabetes directly contravenes and frustrates the purpose of the IDEA and Section 504. Accordingly, under federal preemption principles, this Court must reverse the lower courts' decisions. *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981) ("[i]t is basic to this constitutional command that all conflicting state provisions be without effect").

The purpose of the IDEA and Section 504 is to ensure that students with disabilities have access to the same educational opportunities as non-

disabled students and that these students can attend school in a safe and healthy environment to receive educational benefit, at no cost to them or their parents. *Cedar Rapids Community Sch. Dist. v. Garret F.*, 526 U.S. 66, 73 (1999); *Irving Independent Sch. Dist. v. Tatro ("Tatro")*, 468 U.S. 883, 891 (1984). The United States Supreme Court has highlighted the duties of school districts to provide necessary medical services for students with disabilities as a requirement for FAPE.

In *Tatro*, the Supreme Court considered whether a school district was required to perform clean intermittent catheterization ("CIC") services for a student during school hours. In determining that the child did, in fact, have a right to such services, the Court focused on the federal regulations which mandate the provision of necessary health care services to assist a disabled student during the school day, at no cost to the student or parents, if such services may be performed by a nurse or a qualified lay person. *Tatro*, 468 U.S. at 894. In the particular case of the CIC procedure, the Court noted the courts below found it to be a safe procedure even when performed by a 9-year-old girl. *Id.*, n. 12. "It bears mentioning that here not even the services of a nurse are required; as is conceded, a layperson with minimal training is qualified to provide CIC." *Id.* Indeed, in *Department of Education of Hawaii v. Katherine D.* ("Katherine D."), 727 F.2d 809 (9th Cir. 1983), cited in *Tatro*, 468 U.S. at 894, the Ninth Circuit held that a school district's providing a layperson to suction a tracheostomy

tube was not a medical service, because parents had been trained to provide the services at home, and, presumably, school personnel could do so. "It is indisputable that even a lay person could have been trained to provide the services Katherine required. Indeed, Katherine's mother, who had had no medical training, had performed them for some time." *Id.* at 815 n. 6.

Thus, whether it is commonplace for lay persons to perform the procedure at issue is highly relevant, and it is undisputed that insulin is safely, routinely and primarily administered by lay persons, requiring only the skills demonstrated by some children under the age of 10. (AA 00722 at ¶31.) Similarly, and beyond that, the Supreme Court found in *Cedar Rapids Community Sch. Dist. v. Garret F.* ("*Cedar Rapids*"), that a school district was obligated to provide a ventilator-dependent student with health care services (including manual pumping of his air bag, suctioning of a tracheotomy tube, and adjusting his ventilator in the event of a malfunction) during school hours because such "services that enable a disabled child to remain in school during the day provide the student with 'the meaningful access to education that Congress envisioned.'" *Cedar Rapids*, 526 U.S. at 997, quoting *Tatro*, 468 U.S. at 891.

There is no doubt that a school district is required to administer insulin for its students in accordance with their individualized plans under Section 504 and/or the IDEA in order to maintain an appropriate and equal educational program. However, in order to provide this access to equal

educational opportunities to students with diabetes in an environment where a school nurse is unavailable, school districts must be permitted to train unlicensed school personnel to meet the students' ongoing health needs. As discussed further below in Sections III and IV, hiring a full-time licensed nurse for each student with diabetes to provide a few minutes of daily medical care he or she may need is not feasible, due in part to the prohibitive costs of such staffing. The Court of Appeal's unprecedented interpretation of the NPA as requiring this kind of staffing would ultimately prevent school districts from performing their legally mandated duties and obligations under the IDEA, Section 504 and the ADA, potentially subjecting those districts to litigation for violation of those federal laws. Moreover, to deny a student his or her insulin due to the unavailability of a school nurse creates unnecessary risk for the student's health and well-being. Thus, the only resolution to ensure that students with diabetes receive an appropriate and equal access to their education under the IDEA and Section 504 is to allow trained unlicensed school personnel to administer insulin as needed in the event that a nurse is unavailable. As discussed in Section II below, such a holding does not contravene the NPA and upholds federal preemption principles.

B. If Non-Medical School Personnel are Not Permitted to Administer Insulin, Students with Diabetes Will Be Excluded and Have Limited Opportunities to Participate with Non-Disabled Peers in Conflict with the IDEA's and Section 504's Least Restrictive Environment Requirements.

As discussed above, school districts are required under the IDEA and Section 504 to provide their students with disabilities with meaningful and equal access to an education in the least restrictive environment.

"Least restrictive environment" is defined as:

- (1) That to the maximum extent appropriate, children with disabilities, including children in public or private institutions or other care facilities, *are educated with children who are non disabled*; and
- (2) That special classes, separate schooling or other removal of children with disabilities from the regular educational environment occurs only if the nature or severity of the disability is such that education in regular classes with the use of supplementary aids and services cannot be achieved satisfactorily.

20 U.S.C. § 1412, subd. (a)(5); 34 C.F.R. § 300.550, subd. (b); emphasis added.

Should this Court determine that nurses are indeed the only school personnel who may administer insulin to students with diabetes, this decision will contravene the intent of the IDEA and Section 504 to educate students with disabilities to the maximum extent possible *with their*

nondisabled peers. School districts will be forced to utilize alternative methods that would not be in the best interests of the student with diabetes.

As is clear from the record, students with diabetes will not require full-time nursing attention. The time necessary to check blood glucose levels, provide a snack (tasks unlicensed school personnel routinely perform), or administer insulin, would likely be just minutes a day. (AA 00716, 00721-00722 at ¶¶15, 29-31.) Barring an additional disabling condition, the student with diabetes should be otherwise be able to function independently during his or her school day. However, to be in a position to address the student's needs during the school day, taking into account student's varying schedules, classroom locations and potential school-sponsored trips off campus would require the nurse to accompany the student at all times. Further, the stigma attached with having a personal nurse may detrimentally affect the student's confidence and independence.

Additionally, as discussed in Section IV below, given the dire outlook of the State education budget presently, without any relief in sight, school districts will not be able to shoulder the costs associated with the Court of Appeal's ruling, assuming an available source of nurses.

Assigning individualized personal nursing care where not medically warranted constitutes a significant waste of public resources. Moreover if monies are spent in this manner, there would be an impact on other disabled students needing services to ensure FAPE.

School districts are in a quagmire - without the financial ability to provide for full-time personal nurses for their students with diabetes, school districts will be forced to exclude students with diabetes from their nondisabled peers by placing them in designated "diabetic" schools or classrooms. Neither option is in the best interests of the student requiring assistance.

Accordingly, this Court should not uphold the lower courts' decisions prohibiting unlicensed school personnel from administering insulin to students with diabetes due to the exclusionary effects such a decision will have on students with diabetes.

II. THE STATUTORY INTERPRETATION OF THE NPA AND EDUCATION CODE BY THE COURT OF APPEAL IS FLAWED.

The crux of the Court of Appeal decision which endangers school districts' ability to properly serve students with diabetes is its determination that the California Nursing Practice Act ("NPA") limits the administration of insulin to registered nurses. This holding fatally fails to reflect legislative intent of practical realities. The American Diabetes Association ("ADA") carefully and thoroughly addresses how the statutory analysis of the Court of Appeal is flawed and CSBA does not seek to repeat that here. However, CSBA would like to briefly touch on some of the points raised by

the ADA to the extent there is a specific impact on the day-to-day practices of school personnel.

A. **The BRN Policy Statement Should Not Provide the Basis for a Binding Interpretation of the NPA.**

No other court has interpreted the NPA as it applies in this setting. Thus, the Court of Appeal's consideration of whether a layperson's administration of medication is a violation of the NPA is a matter of first impression. In reaching this conclusion, the Court of Appeal not only finds that the NPA regulates laypersons but heavily and incorrectly relies on a policy statement of the California Board of Registered Nursing ("BRN") to interpret the statute.

The BRN is the state agency charged with the management of the profession of nursing.

The California Board of Registered Nursing (BRN) regulates the practice of registered nursing and certified advanced practice nurses in order to protect the public. The Board exists to protect the health and safety of consumers and promote quality registered nursing care in California.²

As stated by the BRN itself and as reflected in the NPA, the BRN's focus is the quality of nursing care provided by *nurses* and the protection of the public from incompetent nursing practices. This would include an

² <http://www.rn.ca.gov/index.shtml>

individual holding himself or herself out as a licensed nurse, when such license is not held. Bus.&Prof.Code. §§2727, 2732, 2742.

Similar to the relationships between bar associations and attorneys, the BRN is there to uphold standards within the profession and regulate licensing. It is not a judicial body. The ABA or California Bar Association, while they may have opinions or form positions regarding the law, cannot be substituted for the Courts in interpreting that law. The same is true of the BRN.

The Court of Appeal states that it can interpret the NPA based on the plain meaning of the statute. (MajOpn/15, n. 5.) Nevertheless, the Court of Appeal turns to a nonbinding agency policy statement and gives it "consideration and respect" to support its ultimate conclusion.

(MajOpn/15, n. 5.) Even if the NPA was ambiguous, this would be an improper approach.

As a policy statement adopted only after the filing of this litigation, rather than a properly adopted regulation, the BRN's position is entitled to no deference, and is hardly persuasive given the weight of legal and factual evidence to the contrary. The Court need not consider the BRN statement, especially with no prior court decisions interpreting the NPA. The Court of Appeal improperly relied on this statement as the support for its final holding that administering insulin is a "nursing function" that requires

substantial scientific knowledge or technical skill and which, under no circumstances, can be performed by unlicensed personnel.

B. There is Substantial Evidence in Other Statutes To Refute the Court of Appeal's Conclusion That Only Registered Nurses May Administer Insulin Because it Requires a Substantial Amount of Scientific Knowledge or Technical Skill.

The ADA has presented substantial authority which permits persons other than registered nurses to administer insulin by injection. This authority is inconsistent with the Court of Appeal holding that the NPA requires only registered nurses to administer insulin. In fact, the Court of Appeal simply states that it “rejects” this authority. (MajOpn/14.)

The Court of Appeal opines, without any authority from the legislative record, that the Legislature did not intend a specific inquiry into each “administration of medication” to determine if it required “a substantial amount of scientific knowledge or technical skill.” Thus, without any basis in the legislative record, the Court of Appeal concludes that nurses must perform all administration of medication, ignoring the multiple instances – both statutory and practical – which support the conclusion that the NPA does not prohibit the administration of insulin by patients, parents and other unlicensed third parties, as an impermissible

“practice of nursing.” CSBA wishes to emphasize just some of the legislative authority which directly contradicts this interpretation.

1. ***The Governor Vetoed Assembly Bill No. 481 For Redundancy.***

The Court of Appeal purportedly relies on Assembly Bill 481, which in 2002 would have added a section to the Education Code permitting "other designated school personnel"³ to administer assistance to students with diabetes in the absence of a school nurse, as evidence that this was not already permitted by law. The Court of Appeal correctly stated "the Governor's veto message suggests . . . that the Governor believed the legislation was unnecessary." (MajOpn/30.) Indeed, the Governor clearly confirmed this belief as follows:.

Existing law already provides that any pupil who is required to take prescription medication during the regular school day may be assisted by school personnel if a written statement is obtained from a physician and a written request is made by the pupil's parent/guardian.⁴

³ In development of this bill, this was defined as "teachers who have volunteered and administrators of the school that are onsite fulltime and have received adequate training to provide assistance to pupils with diabetes." Assembly Bill No. 481 (2001-02 Reg.Sess.) Assembly Floor Bill Analysis (Sept. 6, 2002).

⁴ This message was stated after a discussion that the bill would permit designated non-medical school personnel to administer insulin in particular. Governor's Veto Message to Assem. on Assem. Bill No. 481 (2001-02 Reg.Sess.) (Sept. 26, 2002).

The Governor was not confused. He vetoed the bill because he saw it as unnecessary and redundant of existing law. CSBA contends that the Court of Appeal's interpretation of the NPA is therefore inapposite to existing law and ignores the clear authorization found in Education Code section 49423 that "other designated school personnel" may assist students with *all* "medication[s] prescribed for him or her by a physician...." Cal.Educ.Code §49423(a). This is the guidance the Court of Appeal should have taken from the veto message. *In re Marriage Cases*, 43 Cal.4th 757, 796 n. 17 (2008).

**2. *The California Legislature Has Repeatedly
Authorized Non-Medical Personnel to Administer
Insulin.***

The ADA has pointed to several valuable sources which demonstrate that other groups of persons can administer medication. First, there is a 1988 Attorney General Opinion which speaks to administration of medication by a home care companion. 71 Ops.Cal.Atty.Gen. 190 (1988). Second, federal Medicare regulations purposely excluded subcutaneous injections from a list of skilled nursing services. 42 C.F.R. § 409.33. Third, the law already allows students to self-administer insulin with physician authorization and parental consent. Ed.Code, § 49414.5(c). "Persons" can administer insulin to foster children. Health&Saf.Code, §

1507.25(b). Licensed vocational nurses can administer injections. Bus.& Prof.Code, § 2860.5, subd. (a).

There are several more statutory provisions that expressly or by implication permit nonlicensed school personnel to administer insulin, even in the NPA. Bus.& Prof.Code, § 2725(b)(1) (essentially authorizes delegation of registered nursing functions without qualification or limitation), § 2727(a) (provides an exception for friends and family members, which Respondents concede), § 2727(e) (provides an exception for any person caring for another by carrying out a physician's orders who does not "assume to practice as a professional, registered, graduate or trained nurse"). *See also*, Bus.& Prof.Code, § 2861 regarding licensed vocational nurses, which must be read to provide an exception for unlicensed persons to administer insulin because it has the same construction as § 2727(e).

III. THE RECORD IN THIS CASE PRESENTS SUBSTANTIAL EVIDENCE THAT NONLICENSED SCHOOL PERSONNEL CAN EFFECTIVELY AND SAFELY ADMINISTER INSULIN TO STUDENTS.

If the statutory language is ambiguous and susceptible of differing constructions, we may reasonably infer that the legislators intended an interpretation producing practical and workable results rather than one resulting in mischief or absurdity.

City of Santa Monica v. Gonzalez (2008) 43 Cal.4th 905, 919. CSBA does not contend that the NPA is ambiguous as to whether non-nurses can administer insulin in a school setting where necessary for the health of a child and where a nurse is not available. However, should the Court believe an ambiguity needs to be construed, CSBA asks that the Court consider the absurdity of accepting the Court of Appeal ruling that only nurses can administer insulin. Moreover, "the [C]ourt may consider the impact of an interpretation on public policy, for '[w]here uncertainty exists consideration should be given to the consequences that will flow from a particular interpretation.'" *Mejia v. Reed*, 31 Cal.4th 657, 663 (2003).

In balancing the practical realities of attending to the needs of students with diabetes against the true availability of nursing personnel, non-licensed school personnel must be permitted to assist students with the administration of insulin, and as stated above, that practice is authorized by state law. Such assistance occurs only with considerable precautions including physician direction, participation on a volunteer basis and training. There is sufficient evidence in the record to demonstrate that this will result in the safe and effective delivery of life-sustaining medical care for the protection of our students.

A. Medical Evidence Presented in the Record Establishes that Insulin Can Be Effectively and Safely Administered by Non-nursing Personnel.

CSBA makes particular note of the detailed and persuasive declaration of Dr. Francine Kaufman submitted in this case by the American Diabetes Association. (AA 00711-00785.) This declaration presents substantial medical evidence to support a fact which California school districts already know from practical experience – that non-nursing personnel, with the appropriate education and training, can effectively and safely attend to the insulin needs of students with diabetes.

Dr. Kaufman has been a board certified pediatric endocrinologist for over thirty years. (AA 00712 at ¶1-2.) She submitted her declaration as the head of Endocrinology, Diabetes and Metabolism at Children's Hospital Los Angeles ("Children's") and director of the Comprehensive Childhood Diabetes Center, a research unit at Children's. (AA 00712 at ¶2.) She is a professor of pediatrics and has written extensively on the subject of diabetes care for children. For instance, she chaired the writing group which produced the National Diabetes Education Program's publication *Helping the Student with Diabetes Succeed: A Guide for School Personnel*.⁵

⁵ This 2010 Guide, *available at* http://ndep.nih.gov/media/youth_ndepschoolguide.pdf, is an authoritative position statement on the care of students with diabetes, reflecting the views of diabetes, pediatric medicine, and educational organizations,

She also served as the national study chair of a multi-institutional study designed to compare diabetic treatment protocols for pediatric subjects.⁶ She is the former president of the American Diabetes Association, "the nation's leading voluntary health organization working to cure diabetes and to improve the lives of people with diabetes." (AA 00712 at ¶3.) A more proficient expert could not be found to provide the Court with the important medical information that affects this case.

As Dr. Kaufman notes, insulin is typically delivered via syringe, insulin pen or insulin pump. The insulin is injected or introduced via pump catheter just below the skin and not into a vein or deep into muscle. (AA 00714-00715 at ¶¶8, 14.) In fact, insulin needles are typically between .3 and .5 inches in length.⁷ Similarly, "insets," the connection used for an

including the Departments of Health and Human Services and Education. The Guide recognizes "that nonmedical personnel . . . can be trained and supervised to safely provide and assist with diabetes care tasks in the school setting, including . . . insulin . . . administration." *Id.* at 66. (The 2003 edition of this Guide can be located at AA 00817- AA 00902.)

⁶ Updated information on Dr. Kaufman's work with children can be found at <http://www.chla.org/site/c.ipINKTOAJsG/b.3579439/>.

⁷ Attached hereto as Exhibit 1 is the inventory list for syringes from Becton, Dickinson & Company, a leading medical supply company. There is one needle listed at 1 inch in length. All others range between .3 to .5 inches.

insulin pump, insert a catheter between $\frac{1}{4}$ and $\frac{1}{2}$ inches in length under the skin.⁸

Insulin is part of the treatment plan for many people with diabetes, which also includes monitoring of blood glucose levels and food intake and activity, the details of which are specific to each individual person. (AA 00714-00715 at ¶11.) While there may be many instances throughout a day that a student with diabetes would need to check blood sugar, administer insulin or have a snack, each task would require a fairly brief break in the student's activities for a school staff member to perform the necessary tasks, including referring to the physician's orders for the insulin and providing the injection or pressing a button on an insulin pump. (AA 00716, 00721-00722 at ¶¶15, 29-31.)

When an insulin dose is required, whether by syringe, pen or pump, the process is relatively simple. A physician, not the patient or the person administering insulin, determines the dosage for a particular student. (AA 00721 at ¶30.) Further, the mechanics of delivery require skills that physicians have found can be safely and effectively handled by children as young as ages 6 (for a pump) to 8 (for the syringe). (AA 00722 at ¶31.) While most older students can usually self-administer insulin, assistance may be required if they are not feeling well, have cognitive or motor

⁸ Attached hereto as Exhibit 2 is information on pump infusion sets from Animas, a leading pump manufacturer.

challenges or are implementing a new protocol. (AA 00718 at ¶21.) To keep students safe and address their insulin needs when they arise, students need someone who is readily available and properly trained. (AA 00718 at ¶22.) Availability is generally found through proximity. The ideal candidate for assistance is someone closest to the student's location, whether that is in the classroom or out on a field trip, and available at the precise time insulin should be taken. (AA 00718-00719 at ¶¶23-25.) Currently, in public schools, school nurses cannot be made available in this manner. (AA 00723-00724 at ¶¶34-36.) Delaying diabetes treatment because a nurse is not available can "put the child's short term and long term health at risk." (AA 00723 at ¶34.)

This person need not be a registered nurse. The medical judgment has already been made by the physician. (AA 00719-00720 at ¶26-27.) Rather, what is needed is someone who can understand how to work the equipment – equipment which some children as young as six years old can handle on their own. (AA 00722 at ¶31.) "It is not necessary for school personnel to decide independently how much insulin is needed in a given situation...they simply follow the instructions...." (AA 00720 at ¶27.)

Based on Dr. Kaufman's extensive expertise in the field of pediatric endocrinology, she opined "to a reasonable degree of medical and scientific certainty that non-medical personnel can, and routinely do, safely administer insulin." (AA 00720 at ¶29.) Dr. Kaufman points out that

"parents and family members of children newly diagnosed with diabetes are routinely and successfully trained to administer insulin within hours to days of diagnosis [and, in general] non-medical personnel can be trained to administer insulin through any method (syringe, insulin pen, pump) and can also safely supervise a child who is actually giving the dose to ensure the proper dose is given." (AA 00720 at ¶28.) Importantly, there is "[no] reason why a properly trained non-medical person would be more likely to make an error and give the incorrect dose of insulin than would a nurse or other health care professional." (AA 00720 at ¶29.)

There is no evidence in the records which refutes these expert medical opinions. There is no evidence that supports a finding that the administration of insulin by non-medical personnel has presented an increased risk of harm to people with diabetes. In fact, the real world truth of diabetes management is that the vast majority of persons administering insulin are the patients themselves or unlicensed family members or caregivers who do not possess substantial scientific knowledge or technical skill. (AA 00721 at ¶29.) With the proper physician direction and training, non-medical school personnel can also provide this care. And, where the practice is not permitted, students' health has been harmed. (AA 00725 at ¶36.)

B. Many Safeguards Are in Place to Ensure that the Administration of Insulin by Non-Licensed School Personnel is Safe and Effective Care

The safety of students in California public schools remains a primary concern for school personnel at all times. The administration of medication, including insulin, to promote student health is integral to that interest. Moreover, the CDE Advisory pertaining to the administration of insulin by non-medical school employees and Education Code section 49423 itself contain key elements to ensure the process remains safe and effective: (1) administration pursuant to a physician's orders, (2) parental consent, (3) adequate training, and (4) voluntary participation by staff.

1. *Insulin Will Be Administered Pursuant to a Diabetes Medication Management Plan.*

As discussed in Dr. Kaufman's declaration, determining the dosage of insulin for an individual student requires the specialized skill of a medical doctor, and will therefore be determined by him or her. (AA 00720 ¶¶ 27.) School personnel (including school nurses when available) will not and cannot make such judgments which do, in fact, require advanced medical knowledge. Rather, school personnel will require that the physician provide sufficiently detailed information, typically in a document such as a Diabetes Medical Management Plan ("DMMP"), regarding the student's target blood glucose levels, insulin dosages,

treatment protocol for high or low blood sugars and instructions surrounding meals and/or exercise.⁹ (See, fn. 5, at pp. 21-26, a sample DMMP appears at p. 99-106.)

In Dr. Kaufman's publication she discusses how to use the DMMP and other tools for effective diabetes management.¹⁰ (See, fn. 5 at pp. 21-26, 98.) Once the school receives the DMMP from the physician's office, the information can be distilled into an easy to understand Individualized Health Care Plan ("IHP") for the student. (See, fn. 5, at pp. 107-108.) This plan would then be given to personnel who are truly available to the student at all times during his or her various school activities.

It is also important to note that the non-medical school personnel will be directly limited to the tasks permitted by the IHP or comparable orders provided to them. They will not be called upon to make independent medical judgments.

⁹ Education Code section 49423 generally requires this plan from parents prior to administering any prescription medication to students. The section provides that trained and qualified school personnel may perform such services if the student's physician, surgeon or physician assistant provides the details of the medication, the method, amount, and time schedules to be taken, and if the student's parents provide written consent.

¹⁰ There are many other comparable publications available to school districts that address these issues. The CDE has recommended that school personnel be trained to at least the standards found in the American Diabetes Association PowerPoint "Diabetes Care Tasks At School: What Key Personnel Need to know: Insulin Administration." (A copy of the forward for these materials is attached hereto as Exhibit 3.)

2. Administration by School Personnel Would Not Occur Without Parental Consent.

Nobody is suggesting that the administration of insulin to students be *required* without parental consent. Rather, where the parent is comfortable with the procedure, it should be permitted. Parents would be required to provide *written* consent to implementation of the physician's order. (See, e.g., Sample DMMP, fn. 5, p. 106.)

A decision that only school nurses are permitted to administer medication will directly circumvent what many parents want for their children. Parents, who are most intimately familiar with the healthcare needs of their children, generally want their students kept healthy and safe at school so they can attend to their education. When parents are comfortable with school personnel administering medication, but said personnel are prevented from doing so, parents may be prevented from being employed in order to stay near school to administer the medication themselves at school, or forced to make modifications to the management plan that may not be in the best interest of the child. This increases the risk of harm to the child which, again, is what parents seek to prevent. (AA 00724 at ¶36.)

3. Staff Will Be Trained.

Every person who must administer insulin to care for diabetes, whether it is the patient, a parent, a caregiver or a member of school staff,

requires training to administer by injection, pen or pump safely and efficiently. The training can be conducted fairly quickly, after which there is minimal risk of error. (AA 00720 at ¶28.) In her publication for school personnel, Dr. Kaufman outlines a typical training (which would include "periodic refresher training") that would be conducted to ensure staff are knowledgeable and prepared to assist the student. This training would include "step-by-step instruction on how to perform the task[s] using the student's equipment and supplies." (See fn. 5, at pp. 27-29.) This training would be conducted by a diabetes-trained health care professional. (See, fn. 5, at p. 29.)

4. *Staff Must Volunteer to Assist Students with Insulin Administration.*

Just as important as parental consent is a staff member's willingness take on the responsibility of assisting the student with medication administration. The safety and care of the child will be best ensured when all persons are willing and involved in the process. Thus, the CDE Advisory provides that only when the staff person volunteers to undergo the training and provide the assistance will it be permitted. When someone volunteers, it shows a commitment to the process and acknowledgment by that volunteer that he or she will take the matter seriously and adhere to the training provided.

IV. ADHERENCE TO THE NPA, AS INTERPRETED BY THE COURT OF APPEAL, WOULD BE A FISCAL AND PRACTICAL IMPOSSIBILITY FOR SCHOOL DISTRICTS.

A. School Districts in California are Facing an Unprecedented Financial Crisis.

In its decision, the Court of Appeal did not find persuasive the argument that the current fiscal crisis facing California public schools, or the shortage of nurses, could not be sufficiently overcome to ensure adequate numbers of licensed nurses are made available to administer insulin to students with diabetes. We disagree. The fiscal crisis facing California public schools is catastrophic.

On January 6, 2011, State Superintendent of Public Instruction Tom Torlakson declared a state of financial emergency in California's schools. He opined that the \$18 billion in cuts over the past three years have taken an unprecedented toll on public schools noting that there were 174 districts that were "teetering on the financial brink."¹¹ Currently, over 2 million students, approximately 30% of the students attending California public schools, are within a school district facing serious financial jeopardy. In the most recent semiannual Interim Status Report, the CDE produced bleak data on the financial status of the state's 1,032 school districts. The CDE

¹¹ See California Department of Education, News Release #11-04, (January 6, 2011). <http://www.cde.ca.gov/nr/ne/yr11/yr11rel04.asp>, attached hereto as Exhibit 4.

reported on March 13, 2011, that 37 school districts obtained "negative certifications" and 97 school districts were placed on the "qualified certification" list.¹²

Given the unresolved budget crisis, Superintendent Torlakson announced on March 9 2011, that further cuts of \$4.5 billion may be necessary and requested that districts throughout the state provide data on the impact of an "all-cuts" budget assumption.¹³ The response to the request has been alarming.¹⁴ In Alameda County alone, the ten reporting school districts indicate that they have issued lay-off notices to over 903 teachers and classified employees, proposed \$40.6 million in cuts and recommended the reduction and/or elimination of numerous academic and

¹² Certifications are classified as positive, qualified, or negative. A positive certification is assigned when a district has demonstrated the ability to meet its financial obligations for the current and two subsequent fiscal years. A qualified certification is assigned when the district may not meet its financial obligations for the current or two subsequent years and a negative certification represents that a district will be unable to meet its financial obligations for the remainder of the current year or for the subsequent fiscal year. See California Department of Education News Release #11-25, (March 21, 2011) *Nearly Two Million California Students Attend Financially Troubled Districts*, <http://www.cde.ca.gov/nr/ne/yr11/yr11rel25.asp>, attached hereto as Exhibit 5.

¹³ See California Department of Education, Letter to County Superintendents, (March 9, 2011). <http://www.cde.ca.gov/nr/el/le/yr11tr0309.asp>, attached hereto as Exhibit 6.

¹⁴ See California Department of Education, Budget Cuts by County, (updated April 12, 2011). <http://www.cde.ca.gov/nr/re/ht/bc1.asp#alameda>.

nonacademic programs, employee benefits, reduction of school days, increase in class size and elimination of positions. In rural Del Norte County, 32.9 teachers and 23 classified staff received layoff notices and the budget is being cut by \$1.3 million. In Los Angeles County, 21 school districts reported combined layoff notices to 9,090 teachers and classified staff with projected cuts of \$494.8 million and elimination of countless programs including summer school, academic and nonacademic programs, furlough days etc.¹⁵

B. Staffing School Nurses at the Ratio Recommended by the American Nurses Association and the National Association of School Nurses Would Cost California School Districts an Additional \$459,310,622.

The National Association of School Nurses (NASN) has advocated that school districts employ professionally prepared Registered Nurses to conduct and supervise school health programs which address the variety of health problems experienced by school children, including the administration of medications such as insulin. The NASN and American Nurses Association ("ANA") recommend a formula-based approach with minimum ratios of nurses-to-students depending on the needs of student populations as follows: 1:750 for students in the general population, and

¹⁵ *Id.*

1:225 in the student populations requiring daily professional school nursing services or interventions. The recommended ratio is further reduced for student populations with complex health care needs.¹⁶

Based on data obtained from Ed-Data, there were 6,252,031 students enrolled in California schools for the 2008-2009 school year.¹⁷ For the same period of time, 2,614 nurses were employed statewide.¹⁸ A simplistic calculation reveals that based on 2008-2009 enrollment figures and numbers of nurses employed in California schools, an additional 5,722 nurses would be necessary to reach a ratio of one nurse for every 750 students. Utilizing an estimated annual salary cost of \$80,271 per nurse, the projected additional cost for nursing services would be \$459,310,662.¹⁹ Even more conservative calculations underscore the dramatic fiscal impact of lowering nurse ratios. Based on a ratio of one nurse for every 1,000

¹⁶ American Nurses Association, *Position on Diabetes Care in Schools* (April 5, 2005). Exhibit 7.

¹⁷ Ed-Data is an education data partnership with the California Department of Education, Ed-Source and the Fiscal Crisis Management and Assistance Team (FCMAT) <http://ed-data.k12.ca.us/>

¹⁸ California Department of Education Dataquest for Enrollment & Certificated Pupil Services Data (Nurse data represents FTE counts for School Site Nurses (code 404), County Office Nurses (code 206) and Special Education Nurses (code 281)).

¹⁹ The \$80,271 figure is premised on a salary of \$61,000 (estimated average obtained from postings for school nurses on Ed-Join.Org. <http://www.edjoin.org/>), the cost of statutory benefits of 11.92% and health and welfare benefits of \$12,000.

students, the cost for additional 3,638 nurses would be \$292,025,898. If the ratio were adjusted to one nurse for every 1,500 students, the additional cost for 1,554 nurses would be \$124,741,134.

This analysis provides only a partial illustration of the costs that would be incurred if only licensed nurses were permitted to administer insulin in the school. Tending to the needs of a student with diabetes is only one of the responsibilities for schools and districts fortunate enough to have a school nurse. Responsibilities of the school nurse include the provision, expertise and oversight of school health services, promotion of health education, provision of health care services to students, conducting health screenings and acting as a liaison between the school, families, community and health care providers. Even if school nurses were employed at a 1:750 ratio, this would not guarantee that a nurse would be consistently available for the student with diabetes during his or her school day, including extracurricular activities or field trips. As conceded by all parties, diabetes is unpredictable. Delaying or refusing to provide insulin to a child because the nurse is engaged in the performance of other duties or is not at a particular school site or field trip unreasonably and unnecessarily places a child with diabetes at risk.²⁰ Nothing less than individual full-time

²⁰ Declaration of Francine Kaufman (AA00723); National Diabetes Education Program's publication *Helping the Student with Diabetes Succeed: A Guide for School Personnel*, (AA00832).

staffing of a nurse for each student with diabetes would satisfy the Court of Appeal's reading of the NPA.

C. Hiring Contract Nurses or LVN's is not the answer.

As discussed in Section III, above, the specific needs of a student with diabetes throughout the school day are unpredictable and may only take a few minutes of assistance at a time. Further, for the student who self-administers insulin, this may mean that assistance is rarely required. Under these circumstances, it is not practical or economically feasible to have a nurse, whether a LVN or licensed school nurse, on the school site, every day solely to meet the needs for insulin administration.

Also, for these reasons, it is not a valid option for school districts to employ contract nurses in lieu of full-time staff. First, contract nurses are typically retained to work with a particular student who, for example, may require direct nursing assistance to ensure FAPE. Unless a student has specialized health care needs that require a full-time nurse, contract nurses typically perform monitoring duties on a set schedule. In cases of school sites with multiple students with diabetes, more than one contract nurse would be necessary, further driving up costs.

Second, the nature of diabetes management does not allow school districts to hire a contract nurse for less than a full day. Routine monitoring of blood glucose levels and administration of insulin at scheduled times is acceptable provided the student's blood glucose level remain stable.

However, fluid and ongoing management also requires that a trained person be available at other times such as when the student's blood sugar is too high or too low, a unique physical activity occurs or a snack is provided outside of the customary meal schedule. If school districts were to retain nurses on a less than full-time schedule, the safety of our students would be compromised.

Third, many contract nursing agencies still require a minimum number of hours per nurse, which would still exceed the actual time spent assisting the student with diabetes. For school districts located in remote or rural locations, which typically have smaller populations and budgets, nursing agencies are more likely to require minimum hours due to travel and nurses would typically be too far away to respond in a timely manner.

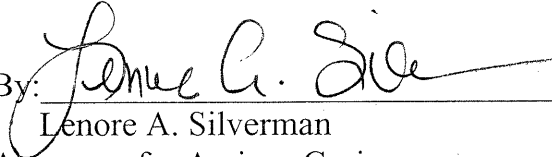
The decision by the Court of Appeal opined that the record did not contain data regarding the availability of licensed vocational nurses. (MajOpn/15.) While the Vocational Nursing Practice Act ("VNPA") provides that vocational nurses are authorized to administer medication, including administration by "hypodermic injection," (Bus.&Prof.Code §2840 *et seq.*), Respondents have asserted that vocational nurses may administer insulin and other medication, "only under the direct supervision of [a] physician or a registered nurse." (ABM/22) It would be impractical and fiscally irresponsible to hire vocational nurses if "direct" supervision by a licensed registered nurse were necessary in order to administer insulin.

Even if the vocational nurse were authorized to administer insulin while not under the direct supervision of a physician or registered nurse, the refrain would be the same. Students with diabetes require assistance at unpredictable times, while on field trips and during extracurricular activities. School districts would need to hire a separate class of employees to fill this need when it is not medically necessary or fiscally feasible.

V. CONCLUSION.

It is difficult to reconcile the position of the Respondents in light of either current fiscal realities or the realities of diabetes care. The school nurse provides vital services to school children. However, school districts in California simply cannot absorb the cost of adding a school nurses to assist in the daily care of each students with diabetes when the vast body of scientific evidence supports the safety and necessity of trained unlicensed personnel performing that function. (AA 00720 at ¶29.)

DATED: May 10, 2011. FAGEN FRIEDMAN & FULFROST, LLP

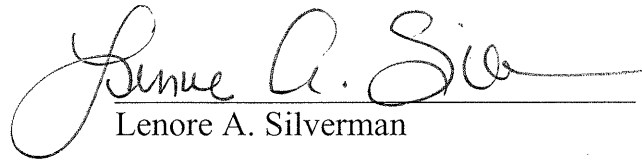
By: 
Lenore A. Silverman
Attorneys for Amicus Curiae
CALIFORNIA SCHOOL BOARDS
ASSOCIATION

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This AMICUS CURIAE BRIEF IN SUPPORT OF INTERVENER/
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Executed on May 10, 2011, at Oakland, California


Lenore A. Silverman

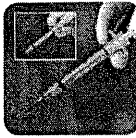
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EXHIBIT 1

Safety-Engineered Needles and Syringes

BD Integra™ Syringes

The BD Integra™ Retracting Syringe with detachable needle provides the benefit of low waste space, which is important in reducing medication waste and costs.



BD Cat No.	Description	Packaging
305310	25 G x 5/8 in. Retracting Needle	100/Box, 1000/Case
305311	25 G x 1 in. Retracting Needle	100/Box, 1000/Case
305312	25 G x 1 1/2 in. Retracting Needle	100/Box, 1000/Case
305313	22 G x 1 1/2 in. Retracting Needle	100/Box, 1000/Case
305275	18 G x 1 1/2 in. Blunt Fill Needle	100/Box, 1000/Case
305433	18 G x 1 1/2 in. Blunt Fill Needle with Filter	50/Box, 500/Case
305289	3 mL Syringe Only	100/Box, 400/Case
305276	3 mL Syringe with Detachable 25 G x 5/8 in. Needle	100/Box, 400/Case
305277	3 mL Syringe with Detachable 25 G x 1 in. Needle	100/Box, 400/Case
305278	3 mL Syringe with Detachable 22 G x 1 1/2 in. Needle	100/Box, 400/Case
305279	3 mL Syringe with Detachable 21 G x 1 1/2 in. Needle	100/Box, 400/Case

* 18 G Blunt Fill and Blunt Fill Needle have connecting needles

BD Eclipse™ Needles

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For use with BD Luer-Lok™ Syringes

BD Cat No.	Description	Packaging
305787	30 G x 1/2 in. Needle	100/Box, 1200/Case
305788	27 G x 1/2 in. Needle	100/Box, 1200/Case
305789	25 G x 5/8 in. Needle	100/Box, 1200/Case
305790	23 G x 1 1/2 in. Needle	100/Box, 1200/Case
305791	21 G x 1 in. Needle	100/Box, 1200/Case
305792	23 G x 1 1/4 in. Needle	100/Box, 1200/Case
305793	22 G x 1 1/2 in. Needle	100/Box, 1200/Case
305794	21 G x 1 1/2 in. Needle	100/Box, 1200/Case
305795	21 G x 1 in. Needle	100/Box, 1200/Case
305796	18 G x 1 1/2 in. Needle	100/Box, 1200/Case
305797	1 mL BD Luer-Lok Syringe with Detachable 30 G x 1/2 in. Needle	50/Box, 300/Case
305798	1 mL BD Luer-Lok Syringe with Detachable 27 G x 1/2 in. Needle	50/Box, 300/Case
305799	1 mL BD Luer-Lok Syringe with Detachable 25 G x 5/8 in. Needle	50/Box, 300/Case
305800	3 mL BD Luer-Lok Syringe with Detachable 25 G x 1 in. Needle	50/Box, 300/Case
305801	3 mL BD Luer-Lok Syringe with Detachable 22 G x 1 1/2 in. Needle	50/Box, 300/Case
305802	3 mL BD Luer-Lok Syringe with Detachable 21 G x 1 1/2 in. Needle	50/Box, 300/Case
305803	3 mL BD Luer-Lok Syringe with Detachable 21 G x 1 in. Needle	50/Box, 300/Case
305804	3 mL BD Luer-Lok Syringe with Detachable 22 G x 1 1/2 in. Needle	50/Box, 300/Case
305805	3 mL BD Luer-Lok Syringe with Detachable 21 G x 1 1/2 in. Needle	50/Box, 300/Case
305806	10 mL BD Luer-Lok Syringe with Detachable 22 G x 1 1/2 in. Needle	50/Box, 300/Case

For use with Luer Slip Syringes – Featuring SmartShip™ Technology

BD Cat No.	Description	Packaging
305771	30 G x 1/2 in. Needle	100/Box, 1200/Case
305772	27 G x 1/2 in. Needle	100/Box, 1200/Case
305773	25 G x 5/8 in. Needle	100/Box, 1200/Case
305774	1 mL Luer Slip Syringe with Detachable 30 G x 1/2 in. Needle	50/Box, 300/Case
305775	1 mL Luer Slip Syringe with Detachable 27 G x 1/2 in. Needle	50/Box, 300/Case
305776	1 mL Luer Slip Syringe with Detachable 25 G x 5/8 in. Needle	50/Box, 300/Case
305777	1 mL Luer Slip Syringe with Detachable 22 G x 1 1/2 in. Needle	50/Box, 300/Case

* Data on file at BD.

Safety-Engineered Needles and Syringes

BD Safety-Lok™ Syringe

The only safety-engineered syringe of its type to offer clear visual confirmation of the lock position.*

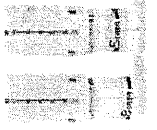


BD Cat No.	Description	Packaging
334644	1 mL Insulin Syringe with 29 G x 1/2 in. Permanently Attached Needle (U-100)	100/Box, 500/Case
305553	1 mL Tuberculin Syringe with 27 G x 1/2 in. Permanently Attached Needle	100/Box, 500/Case
305554	1 mL Tuberculin Syringe with 25 G x 5/8 in. Permanently Attached Needle	100/Box, 500/Case
309606	3 mL Syringe only	100/Box, 800/Case
309592	3 mL Syringe with Detachable 25 G x 5/8 in. Needle	100/Box, 800/Case
309594	3 mL Syringe with Detachable 22 G x 1 1/2 in. Needle	100/Box, 800/Case
309595	3 mL Syringe with Detachable 22 G x 1 in. Needle	100/Box, 800/Case
309596	3 mL Syringe with Detachable 21 G x 1 1/2 in. Needle	100/Box, 800/Case
309597	3 mL Syringe with Detachable 21 G x 1 in. Needle	100/Box, 800/Case
305551	5 mL Syringe only	50/Box, 400/Case
305552	5 mL Syringe with Detachable 21 G x 1 1/2 in. Needle	50/Box, 400/Case
305553	5 mL Syringe with Detachable 21 G x 1 in. Needle	50/Box, 400/Case
305554	10 mL Syringe with Detachable 21 G x 1 1/2 in. Needle	50/Box, 400/Case

* As of May 2008

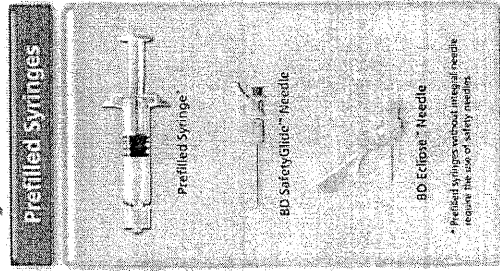
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Now you can bring the unique advantages of a pen to your facility with the BD AutoShield™ Pen Needle, a safety-engineered device for use with insulin pens and other delivery devices. Shield automatically locks after injection to help prevent accidental needlesticks. Fits all insulin pens with 8 mm and 5 mm needle length.



BD Cat No.	Description	AOC No.	Packaging
329308	29 G x 5/16 in. (6 mm)	08296-3293-08	200/Box
329305	29 G x 3/16 in. (5 mm)	08296-3293-05	200/Box

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* Prefilled syringes without integral needles require the use of safety needles

* Data on file at BD.

EXHIBIT 2

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Everybody is different and every body is different. That's why it's important to have a choice in infusion sets, so you can find the one that fits you best in every way.

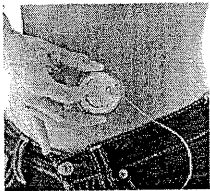
inset® and inset® 30: two great choices.

These all-in-one sets combine the inserter and infusion set in a single, portable unit, so they're a snap to change anytime, anywhere—in fact, you can insert them one handed.*

They work with any pump, too†.

Animas®, OneTouch®, Deltec Cozmo®, ACCU-CHEK®, or Medtronic MiniMed Paradigm® - you name it, you can attach the inset® or inset® 30 to it. (A special reservoir is required for use with the MiniMed Paradigm® series.)

Prefer a straight set? Choose inset®.



The first all-in-one straight set

90° insertion angle

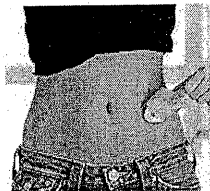
6 mm or 9 mm cannula length

Available in blue, pink, green and grey

[inset® product overview](#)

[inset® visual guide](#)

Prefer an angled set? Choose inset® 30.



The first and only all-in-one angled set

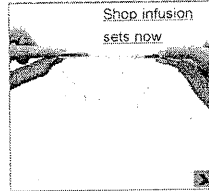
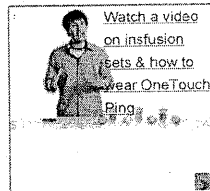
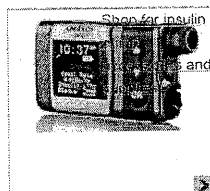
30° insertion angle

13 mm cannula length

Available in blue, pink, and grey

[inset® 30 product overview](#)

[inset® 30 visual guide](#)



*Placement and insertion for both inset® and inset® 30 can be done one-handed. When removing the introducer needle, inset® 30 requires holding the set in place with the other hand.

†Excludes pumps that do not use infusion sets. Special reservoir from Applied Diabetes Research (ADR) required for use with Medtronic MiniMed Paradigm® 511, 512, 515, 522, 712, 715 and 722 pumps

5 great things about the inset® infusion set family

1. No separate inserter (they're pre-loaded)
2. Insert them one-handed (more infusion site options)*
3. Built-in needle cover (for after use)
4. Friendly packaging (fits easily in pockets and purses)
5. Works with any insulin pump† (including yours)

EXHIBIT 3

Diabetes Care Tasks at School: What Key Personnel Need to Know

Third Edition (December 2008)

Forward

The American Diabetes Association is pleased to make available the third edition of our training modules for school personnel: *Diabetes Care Tasks at School: What Key Personnel Need to Know*. The modules have been updated to enhance usability and reflect new technologies that have evolved since the first publication in June 2003.

The most exciting change is the creation of a DVD with video segments to supplement the PowerPoint training modules that are packaged together in a two-disk set. Each training module has a corresponding video segment. The training modules and video segments are designed to be used together to demonstrate how diabetes care should be carried out in the school setting.

Children and youth with diabetes spend an enormous amount of time in school and must be able to achieve the same level of diabetes management in class and at school-related activities that they do during the rest of the day. This is critical in order for students with diabetes to be medically safe, to delay or prevent the short- and long-term complications of diabetes, and for students to be ready to learn and able to participate in all school activities. In order to manage diabetes at school, students need access to the tools for diabetes management and to school personnel who are knowledgeable about diabetes and able to assist them when needed.

A crucial step to diabetes management at school is educating school personnel about diabetes so that they understand how easily they can facilitate good diabetes care for their students with diabetes. With this in mind, the National Diabetes Education Program (NDEP) worked with key government agencies and diabetes and education organizations to develop written educational materials entitled *Helping the Student with Diabetes Succeed: A Guide for School Personnel* (www.ndep.nih.gov/diabetes/pubs/Youth_SchoolGuide.pdf). This guide provides school personnel with the basic information they need to facilitate diabetes management at school. It includes background information on diabetes and the tools for diabetes management at school, and sets out the roles and responsibilities of various school personnel at the district and school level.

A cornerstone of the NDEP guide is that there must be someone present at school and at all school functions who can assist those students who need help with blood glucose monitoring and insulin administration and help all students with diabetes in case of a high or low blood glucose emergency. This person can either be a school nurse or, in the absence of a nurse, another school employee who has received training in these tasks (referred to in the NDEP guide as “trained diabetes personnel”).

The NDEP guide sets out what diabetes care tasks must take place at school, but does not provide instruction on how to perform these tasks. That is the function of *Diabetes Care Tasks at School: What Key Personnel Need to Know*. Thus, these training modules will enable schools to fully implement the


NDEP approach to diabetes management at school. The training modules are:

- Diabetes Basics
- Diabetes Medical Management Plan
- Hypoglycemia
- Hyperglycemia
- Blood Glucose Monitoring
- Glucagon Administration
- Insulin Basics
- Insulin by Syringe and Vial
- Insulin by Pen
- Insulin by Pump
- Ketones
- Nutrition and Physical Activity
- Legal Considerations


The training modules and video should be used as part of a training that includes hands on instruction in diabetes care tasks. When either the training modules and/or video segments are used to train school nurses or other school staff members who will assist in diabetes care tasks, it is vitally important that the trainer is a school nurse or another qualified health care professional with expertise in diabetes care. Although the video is primarily intended to enhance the hands-on, experiential training of those who will directly perform or monitor diabetes care tasks, we also encourage using selected segments at school staff and parent meetings to increase general diabetes knowledge and awareness.

Together with the NDEP guide, the *Diabetes Care Tasks at School: What Key Personnel Need to Know* training modules and video segments will provide schools with the best and most practical means to ensure that their students with diabetes are not only medically safe at school, but also have the best possible opportunity to learn and to fully participate in all that school has to offer.

Sincerely,



Linda M. Siminerio, RN, PhD, CDE
Co-Chair, Safe at School Working Group
American Diabetes Association



Larry C. Deeb, MD
Co-Chair, Safe at School Working Group
American Diabetes Association

EXHIBIT 4



CALIFORNIA DEPARTMENT OF EDUCATION
NEWS RELEASE

TOM TORLAKSON
State Superintendent
of Public Instruction

Release: #11-04
January 6, 2011

Contact: Paul Hefner
E-mail: communications@cde.ca.gov
Phone: 916-319-0818

**Schools Chief Tom Torlakson Declares
Schools in State of Financial Emergency**

Begins Department-Wide Review, Urges Californians to Help

SACRAMENTO — State Superintendent of Public Instruction Tom Torlakson declared a state of financial emergency in California's schools today, launching a department-wide review and urging Californians to come to the aid of schools across the state.

"There's simply no other way to describe it: this is an emergency," Torlakson said. "Every day, teachers, school employees, and principals are performing miracles, but the \$18 billion in cuts over the last three years are taking their toll. We have 174 districts teetering on the financial brink. If this isn't an emergency, I don't know what is."

Torlakson acknowledged that his options for addressing the problem were limited, but pledged to do what he could within his own department while calling Californians to action to address the financial crisis facing schools.

"The law won't let me call out the National Guard," Torlakson said. "So I'm saying to every Californian: 'Your schools need your help. And they need it now.'"

At a news conference held today to discuss the economic challenges facing K-12 education, Torlakson was joined by representatives of the state's Education Coalition, including Barbara Nemko, Superintendent of the Napa County Office of Education; Dana Dillon, Member of the California Teachers Association Board of Directors; Jo Loss, California State PTA President; Dave Low, Executive Director of the California School Employees Association; Gary Ravani, Vice-President of the California Federation of Teachers, and Rick Pratt, Assistant Executive Director, Governmental Relations, the California School Boards Association.

Torlakson said the California Department of Education would do its part, including conducting an independent review to set priorities and find ways to lessen the burden of state requirements on county offices of education, districts, and schools.

"Like our schools themselves, the Department has suffered severe cuts over the last several years, and multiple rounds of downsizing," Torlakson said. "It's time to step back and reassess what we can and cannot do and what we should do with the resources that remain."

He noted that the Department was working to expand its free and online-resources for school districts, including its "CDE on I-Tunes U" that provides free professional development resources to districts.

Torlakson said he would also examine streamlining the school construction process, devote a part of the Department's Web site to help districts learn from one another about ways to work together and save money, and, when appropriate, work to provide districts more financial flexibility.

"Giving schools more control over how they spend limited funds is a poor substitute for providing them the resources they need and deserve, but we shouldn't make our schools spend time and money on unnecessary paperwork — especially now, when both are in such short supply," Torlakson said.

Torlakson called for Californians to get directly involved in helping their local schools and to support making the investments necessary to restore California's leadership in education, starting with an extension of current tax levels now set to expire, to prevent another round of devastating cuts to schools.

Torlakson noted that 58 percent of school districts have cut instructional materials; 35 percent have increased class size; 35 percent have reduced their teaching force; 48 percent have cut nurses, counselor, and psychologists; and almost half of local educational agencies have reduced the pay of their employees, according to a CDE survey conducted last year.

"Educators are making heart-wrenching decisions so they can meet their fiscal obligations, but these kinds of cuts endanger the quality of student learning today and our future economic competitiveness as a state tomorrow," Torlakson said. "It's time to treat this problem like the emergency that it is, and start working together to address it."

EXHIBIT 5



CALIFORNIA DEPARTMENT OF EDUCATION
NEWS RELEASE

TOM TORLAKSON
State Superintendent
of Public Instruction

Release: #11-25
March 21, 2011

Contact: Tina Jung
E-mail: communications@cde.ca.gov
Phone: 916-319-0818

**State Schools Chief Tom Torlakson: Nearly Two Million
California Students Attend Financially Troubled Districts**

SACRAMENTO—Nearly 2 million students—roughly 30 percent of pupils in California—now attend school in a district facing serious financial jeopardy, State Superintendent of Public Instruction Tom Torlakson announced today.

"The emergency confronting California's schools is widening and deepening," Torlakson said. "As disturbing as these numbers are, unless the Legislature moves to place the Governor's tax extension plan on the ballot, they are just the tip of the financial iceberg facing school districts up and down the state."

Torlakson's findings came as he released the results of the first semiannual Interim Status Report that represents budget certifications for California local educational agencies (LEAs) through the end of October 2010. The reports reflect a certification of whether an LEA is able to meet its financial obligations.

The number of LEAs on the negative certification list rose to 13 from 12 last year at this time. The number of LEAs on the qualified certification list dipped slightly to 97 from 114 last year at this time.

Torlakson noted that the certifications do not take into account the impact of the state failing to extend temporary tax increases adopted two years ago that are set to expire July 1 unless placed on the ballot by the Legislature and approved by voters in a special election.

The California Department of Education semiannually prepares Interim Status Reports for the Superintendent on the financial status of the state's 1,032 LEAs, comprised of school districts, county offices of education, and joint powers agencies.

The certifications are classified as positive, qualified, or negative. A positive certification is assigned when the district will meet its financial obligations for the current and two subsequent fiscal years.

A qualified certification is assigned when the district may not meet its financial obligations for the current or two subsequent fiscal years. This certification allows the LEA's county office of education to provide assistance to the LEA.

A negative certification—the most serious of the classifications—is assigned when a district will be unable to meet its financial obligations for the remainder of the current year or for the subsequent fiscal year. This certification means the LEA's county office of education may intervene in the LEA's finances.

The numbers used to arrive at the certifications preceded the Governor's Budget proposal, and therefore do not reflect the potential loss of temporary tax revenues, and the new proposed multi-billion dollar funding deferral.

"Schools face the daunting challenge of up to \$4.5 billion in additional cuts if tax extensions are not placed on the ballot by the Legislature and approved by voters in June, an additional cut of 10 percent," added Torlakson. "This would be devastating to an education system that has already sustained \$18 billion in state funding cuts over the last three years – a loss of one-third of the annual budget for schools."

After decades of recording relatively steady numbers of LEAs on the Interim Status Report list, the numbers moved up sharply in 2008-09 and again in 2009-10 as a result of deeper and deeper cuts to education. It is anticipated that the numbers will move up even more sharply in 2011-12 if the tax extensions are not placed on the ballot and approved by the voters.-

Fiscal Year	Negative Certification First Interim	Qualified Certification First Interim
1991-92	1	19
1992-93	2	18
1993-94	3	24
1994-95	2	57

1995-96	1	12
1996-97	0	11
1997-98	0	12
1998-99	1	13
1999-00	2	13
2000-01	2	24
2001-02	8	32
2002-03	5	39
2003-04	7	50
2004-05	10	54
2005-06	5	32
2006-07	3	19
2007-08	7	29
2008-09	16	74
2009-10	12	114
2010-11	13	97

For more information and a list of LEAs on the Interim Status Report, please visit [Interim Status - Fiscal Status](#). For information on LEA budget cuts, please visit [School Financial Emergency - Hot Topics](#).

###

Tom Torlakson — State Superintendent of Public Instruction
Communications Division, Room 5206, 916-319-0818, Fax 916-319-0100

EXHIBIT 6



CALIFORNIA
DEPARTMENT OF
EDUCATION

TOM TORLAKSON
STATE SUPERINTENDENT OF PUBLIC INSTRUCTION

March 9, 2011

Dear County Superintendent:

FISCAL EMERGENCY INFORMATION REQUEST

I am writing today to ask for your help with compiling information about the number of pink slips and lay-off notices being issued, and the program cuts being proposed, by the Local Education Agencies in your jurisdiction.

As you know, should the state budget resolution require an all-cuts solution, our schools could face an additional \$4.5 billion in cuts—a dire situation for our schools already facing a state of fiscal emergency. Are most of your districts producing layoff and program reduction plans based on the “all-cuts” budget assumption? I think it is vital for the public to know the full impacts of the worst-case budget scenario.

Given the urgency we face, I ask you to share the pink slip, layoff notice, and program cut information with me as soon as it becomes available to you. I am interested in learning specific information about the pinks slips issued to certificated staff and lay-off notices given to non-certificated staff. The program and funding details of the cuts being proposed will be more difficult to share, but I would appreciate any level of detail you may be able to provide.

Please send this information to me in care of Craig Cheslog, Principal Advisor to the State Superintendent of Public Instruction, Superintendent’s Initiatives Office, by e-mail at ccheslog@cde.ca.gov, by fax at 916-319-0100, or by phone at 916-319-0554. You may also contact Mr. Cheslog if you have any questions or require additional information about this request.

In addition, I am interested in learning more about how the school districts in your jurisdiction are responding to the funding deferrals that have already occurred, and what the potential impact may be from those included in the budget package proposal.

I am also deeply concerned about how the pattern of deferrals has, in effect, led to our schools being used as a bank to cover the state’s ongoing fiscal problems. I will be developing an estimate of the total cost of this borrowing to our school districts across the state. I want to share this information with the Governor, the Speaker of the Assembly, the President pro Tempore of the Senate, and the general public.

Please ask the districts in your county to provide the latest information they can about how they are handling this situation—including interest costs, lost interest from use of reserve funds, time, cash-flow management, programs, etc.

You may also share the deferral information with Mr. Cheslog.

Thank you in advance for your help in compiling this information.

Sincerely,

Tom Torlakson

TT:ccc

cc: District Superintendents, Charter School Administrators

Last Reviewed: Thursday, March 10, 2011

EXHIBIT 7

ANA's Position on Diabetes Care in Schools

April 4, 2005

Schools are required by law to provide an environment that allows for the management and safe delivery of care for children with diabetes during the school day. Obstacles to effective diabetic care still exist in many schools and are of mutual concern to health care providers, parents, and educators. Legislative and regulatory initiatives are being promoted at the state level to address these barriers to care. ANA has been working with representatives from ANA's Constituent Member Associations (CMAs), the National Association of School Nurses, and the American Federation of Teachers to address this issue.

Background

ANA has also been involved in discussions with the American Diabetes Association (ADA), which represents individuals with diabetes and their families. ADA is promoting model legislation at the state level that emphasizes the central role of the school nurse, but authorizes the training of volunteer, non-medical personnel in the performance of diabetes care tasks and emergency care. ADA has developed a guide to support diabetic children in schools which is being enacted through school policy, regulations and legislation. ADA believes that in order to facilitate appropriate care of the diabetic student, school personnel must have an understanding of diabetes and be trained in its management and emergency treatments for students.

In October, 2004, ANA staff met with ADA representatives to discuss their model legislation, as well as concerns related to the delegation of nursing services. ANA agrees with the concept of providing broad support for diabetic students, but is concerned about details of the ADA plan related to delegation of nursing services and the training of non-medical school employees to address the health care needs of diabetic students. These plans include student assessments and the administration of Insulin and Glucagon. The lines of communication remain open between ADA and ANA. ADA continues to seek ANA support for their model legislation and to look for areas of agreement on the issue.

CMAs, particularly those in states targeted for legislative action in 2005, now find themselves needing to address issues related to safe, effective care for diabetic children in the school setting while also protecting their state's nurse practice act. During November 2004, ANA convened a conference call with representatives from the CMAs and the National Association of School Nurses (NASN) for a discussion about the components essential for inclusion in a policy statement on care of students with diabetes. ANA has also been working with the American Federation of Teachers (AFT) on this issue. Both NASN and AFT have developed positions that reflect the general principles identified by the CMAs as essential for safe diabetic care in the school setting.

ANA Board of Directors Action

At their March meeting, the ANA Board of Directors adopted policy to promote the management and safe delivery of diabetes care in schools and to facilitate advocacy on this issue. The policy includes the following:

* ANA supports delegation of routine management tasks for the care of students with diabetes only if state law permits delegation of nursing services and only when the registered nurse determines who will be trained and what aspects of the care shall be delegated. In addition, the registered nurse will conduct the training, oversight, and

evaluation of all care delivered by the nonmedical personnel; and

* ANA does not support delegation of those registered professional nursing services that require assessment and/or emergency care; and

* ANA advocates that, if a registered nurse is not available to attend to an emergency situation involving a child with diabetes, emergency services should be activated immediately by dialing 911 or the appropriate local emergency number for assessment and treatment by a qualified health care professional; and

* ANA will work collaboratively with the CMAs, the National School Nurses Association and the American Federation of Teachers to advocate for policy, legislation and/or regulation related to the safe delivery of care in schools for children with diabetes that protect both the children and the registered nurses in these settings; and

* ANA will continue to advocate for public policy and funding that provides for at least one full time licensed registered nurse in every school building.

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF ALAMEDA

At the time of service, I was over 18 years of age and **not a party to this action**. I am employed in the County of Alameda, State of California. My business address is 70 Washington Street, Suite 205, Oakland, California 94607.

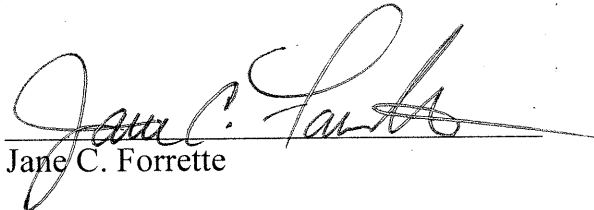
On May 11, 2011, I served the following document(s) described as **APPLICATION OF CALIFORNIA SCHOOL BOARDS ASSOCIATION FOR PERMISSION TO FILE AMICUS CURIAE BRIEF IN SUPPORT OF INTERVENER/ APPELLANT AMERICAN DIABETES ASSOCIATION; BRIEF ATTACHED HEREWITH** on the interested parties in this action as follows:

SEE ATTACHED SERVICE LIST

BY MAIL: I enclosed the document(s) in a sealed envelope or package addressed to the persons at the addresses listed in the Service List and placed the envelope for collection and mailing, following our ordinary business practices. I am readily familiar with Fagen Friedman & Fulfrost's practice for collecting and processing correspondence for mailing. On the same day that the correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service, in a sealed envelope with postage fully prepaid.

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

Executed on May 11, 2011, at Oakland, California.


Jane C. Forrette

SERVICE LIST

<p>John S. Poulos, Esq. Carrie Bonnington, Esq. Pillsbury Winthrop Shaw Pittman LLP 2600 Capitol Ave., Ste. 300 Sacramento, CA 95816-5930</p> <p>Telephone: 916-329-4700 Facsimile: 916-329-4700 e-mail: carrie.bonnington@pillsburylaw.com</p>	<p>Attorneys for Respondents American Nurses Association, American Nurses Association/California, California School Nurses Organization, and California Nurses Association</p>
<p>James M. Wood Dennis Peter Maio Reed Smith LLP 101 Second St., Ste. 1800 San Francisco, CA 94105</p> <p>Telephone: 415-543-8700 Facsimile: 415-391-8269</p>	<p>Attorneys for Intervener and Appellant American Diabetes Association</p>
<p>Arlene Mayerson Larisa Cummings Disability Rights Education and Defense Fund, Inc. 3075 Adeline Street, Suite 210 Berkeley, CA 94703</p> <p>Telephone: 510-644-2555 Facsimile: 510-841-8645 e-mail: amayerson@dredf.org lcummings@dredf.org clanvers@dredf.org</p>	<p>Attorneys for Intervener and Appellant American Diabetes Association</p>

<p>Alilce L. Bodley, Esq. Jocelyn Winston, Esq. Maureen E. Cones, Esq. American Nurses Association 8515 Georgia Avenue., N.W. Suite 400 Silver Spring, MD 20910</p> <p>Telephone: 301-628-5127 Facsimile: 301-628-5345 e-mail: alice.bodley@ana.org</p>	<p>Attorneys for Respondents American Nurses Association, American Nurses Association/California, and California School Nurses Organization</p>
<p>Pamela S. Allen, Esq. Linda M. Shipley, Esq. California Nurses Association Legal Department 2000 Franklin St., Ste. 300 Oakland, CA 94612</p> <p>Telephone: 510-273-2271 Facsimile: 510-663-4822 e-mail: pallen@calnurses.org</p>	<p>Attorneys for Respondent California Nurses Association</p>
<p>Ava C. Yajima, Esq. Marsha A. Bedwell, Esq. Michael E. Hersher, Esq. California Department of Education Legal Department 1430 N. Street, Room 5319 Sacramento, CA 95814</p> <p>Telephone: 916-319-0860 Facsimile: 916-319-0155 e-mail: ayajima@cde.ca.gov mbedwell@cde.ca.gov mhersher@cde.ca.gov</p>	<p>Attorneys for Appellants Jack O'Connell and California Department of Education, the Board of Education and its members</p>

<p>Robin B. Johansen, Esq. Kari Krogseng, Esq. Remcho, Johansen and Purcell, LLP 201 Dolores Avenue San Leandro, CA 94577</p> <p>Telephone: 510-346-6200 Facsimile: 510-346-6201 e-mail: rjohansen@rjp.com</p>	<p>Attorneys for Appellants Jack O'Connell, Superintendent of Public Instruction; California Department of Education</p>
<p>Eve R. Hershkopf, Esq. Interim Directing Attorney Child Care Law Center 100 McAllister Street San Francisco, CA 94102</p> <p>Telephone: 415-558-8005</p>	<p>Attorney for Child Care Law Center, Disability Rights California, Child Care Inclusion Challenge project, and BANANAS (Amici curiae in support of Petition for Review)</p>
<p>Patricia Cleary Dukes, Esq. Epilepsy Foundation of America 8301 Professional Place Landover, MD 20785-2353</p>	<p>Attorney for Epilepsy Foundation of America (Amicus curiae in support of Petition for Review)</p>
<p>Daniel Einhorn, MD, FACP, FACE President American Association of Clinical Endocrinologists 245 Riverside Avenue, Suite 200 Jacksonville, FL 32202</p>	<p>American Association of Clinical Endocrinologists (Amicus curiae in support of Petition for Review)</p>
<p>Myles Abbott, MD District Chair American Academy of Pediatrics, California District 107 S. Fair Oaks Ave., Ste. 318 Pasadena, CA 91105</p>	<p>American Academy of Pediatrics, California District (Amicus curiae in support of Petition for Review)</p>
<p>Clerk of the Superior Court Sacramento County Attn: Hon. Lloyd G. Connelly, Judge Gordon D. Schaber Sacramento County Courthouse 720 Ninth Street Sacramento, CA 95814-1398</p>	

Clerk of the Court of Appeal Third Appellate District 621 Capitol Mall, 10 th Floor Sacramento, CA 95814-4734	
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