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.

REPLY BRIEF ON THE MERITS

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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In this Reply Brief on the Merits, we cite to the following items thus:

The Appellant's Appendix, by volume and page, as "__AA/__."

The Respondents' Brief in the Court of Appeal, by page, as "RB/__."

The slip opinion of the majority in the Court of Appeal, by page, as "MajOpn/__."

The Opening Brief on the Merits, by page, as "OBM/__."

The Answer Brief on the Merits, by page, as "ABM/__."

I. INTRODUCTION

In its Opening Brief on the Merits, the American Diabetes Association (ADA) set out the issues on review:

1. Does the Nursing Practice Act (NPA), Bus. & Prof. Code § 2700 et seq., prohibit unlicensed persons from administering medication to anyone, including prohibiting unlicensed school personnel from administering insulin to students with diabetes?

2. Does Education Code section 49423 authorize unlicensed school personnel to administer insulin to students with diabetes?

3. If the first issue is resolved affirmatively and the second negatively, is the resulting prohibition in California law against unlicensed school personnel administering insulin to students with diabetes preempted, at least when a school nurse or other licensed person is unavailable, by Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. § 794, Title II of the Americans with Disabilities Act (the Americans with Disabilities Act), 42 U.S.C. § 12101 et seq., and the Individuals with Disabilities Education Act (the IDEA), 20 U.S.C. § 1400 et seq., which grant such students a right to a free appropriate public education and related health care services, including the administration of insulin, at no cost?

ADA showed that the issues on review arose in the context of a Legal Advisory issued by the California Department of Education

(CDE), which states, in pertinent part, that when a school nurse or other licensed person is unavailable to administer insulin to a student with diabetes, an unlicensed school employee may do so, provided that he or she has volunteered and has been adequately trained, in order to implement the student's rights under Section 504, the Americans with Disabilities Act, and the IDEA.

ADA also showed that the issues on review must be addressed against the background of a number of fundamental facts: Students with diabetes need insulin at both predictable and unpredictable times and places in the course of the school day in order to remain safe and to benefit from the free appropriate public education to which they are entitled. School nurses and other licensed persons, however, cannot be available whenever and wherever they are needed to administer insulin. In contrast, unlicensed school personnel can be available to administer insulin at such times and places. Innumerable unlicensed persons, of all backgrounds and ages, administer insulin safely innumerable times every day. Unlicensed school personnel can be trained to do so as well.

Finally, ADA showed that the issues on review must be resolved in its favor—or more properly, in favor of students with diabetes.

Against all of this, what do the American Nurses Association, the American Nurses Association/California, the California School Nurses Organization, and the California Nurses Association

(collectively the Nurses Associations) have to say in their Answer Brief on the Merits?

First, according to the Nurses Associations, ADA "misstate[d]" the issues on review. (ABM/1) Not so.

ADA was required to "quot[e]," at the outset, the "statement of issues in the petition for review." Cal. R. Ct. 8.520(b)(2)(B). That is what ADA did—nothing more, nothing less.

Second, according to the Nurses Associations, the "real" issues on review include the validity of the Legal Advisory's unlicensed-school-personnel provision under the Administrative Procedure Act (APA), Gov't Code § 11340 et seq. (ABM/1) Again, not so.

The APA issue has not been presented for review or is not fairly included in any that has been—nor do the Nurses Associations claim otherwise. (ABM/54) The issue is not new. The Nurses Associations had vigorously pressed the issue below. Nevertheless, they elected not to raise the issue, as they were entitled to, in an answer to ADA's petition for review. Cal. R. Ct. 8.500(a)(2). Indeed, they elected not to submit any answer at all.

Third, according to the Nurses Associations, the fundamental facts against which the issues on review must be addressed are not as stated by ADA. The Nurses Associations assert that the administration of insulin is far too "dangerous" and "complicated" for

unlicensed persons because insulin is a "high alert medication[ ]" and is subject to "special procedures" in hospitals. (ABM/5-6)

The Nurses Associations' assertion founders on the contrary determination by experts in the care and treatment of persons with diabetes—including the United States Department of Education; the United States Department of Health and Human Services and its Centers for Disease Control and Prevention and National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health; the American Medical Association; the American Academy of Pediatrics; the American Association of Clinical Endocrinologists; the American Association of Diabetes Educators; the American Dietetic Association; the Pediatric Endocrine Nurses Society; the Pediatric Endocrine Society; Children with Diabetes; and the Juvenile Diabetes Research Foundation. (3AA/720-23; 4AA/817-902, 908-12; 6AA/1647, 1649-50, 1652)[1]

That insulin is a high alert medication means only that both licensed and unlicensed persons who administer it run a higher risk of harm if they administer it improperly, *not* that unlicensed persons cannot be trained to administer it safely. (1AA/268) Further, that

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[1] *See generally* United States Department of Health and Human Services, National Diabetes Education Program, Helping the Student With Diabetes Succeed: A Guide for School Personnel (2010), *available at* http://ndep.nih.gov/publications/PublicationDetail.aspx?-PubId=97#main (as of Apr. 7, 2011).

insulin is subject to special procedures in hospitals has little to do with insulin and much to do with hospitals: In hospitals—unlike, for example, in schools—persons with diabetes are ill, are often more sensitive to variations in insulin dosage, and are unstable in their insulin needs. (3AA/722-23)

In any event, the Nurses Associations' assertion is contradicted by reality. As the members of this Court can confirm for themselves by considering the example of relatives, friends, and acquaintances with diabetes, the common reality is that innumerable unlicensed persons administer insulin safely innumerable times every day.

Fourth, according to the Nurses Associations, all of the issues on review must resolved in their favor, to the detriment of students with diabetes. Specifically, the Nurses Associations assert, as they have asserted previously, that Education Code section 49423 does not authorize unlicensed school personnel to administer insulin to students with diabetes, and that the NPA actually prohibits them from doing so. And for the first time, they now assert that, in spite of the right granted to such students by Section 504, the Americans with Disabilities Act, and the IDEA to a free appropriate public education and related health care services, including the administration of insulin, at no cost, school districts are nevertheless *not* required to administer insulin.

Fortunately, as the pages that follow prove, all of the issues on review must be resolved against the Nurses Associations and in favor of students with diabetes.

II. ARGUMENT

A. The Nurses Associations Do Not Defeat ADA's Showing That The NPA Does Not Prohibit Unlicensed Persons, Including Unlicensed School Personnel, From Administering Medication To Anyone, Including Insulin To Students With Diabetes

In its Opening Brief on the Merits, ADA demonstrated that the NPA does not prohibit unlicensed persons, including unlicensed school personnel, from administering medication to anyone, including insulin to students with diabetes. (OBM/15-29)

In its Answer Brief on the Merits, the Nurses Associations attempt to counter ADA's demonstration. (ABM/14-26)

The Nurses Associations first argue that the NPA prohibits unlicensed persons from rendering *any* services under *any* nursing function without more, and that the administration of medication, including insulin, is a nursing function *categorically*. (ABM/16)

Not so.

Although the NPA prohibits the unauthorized practice of nursing, it does *not* prohibit unlicensed persons from rendering any

particular services under any particular nursing function. Contrary to the Nurses Associations' implication, there is not a single word in the NPA that purports to prohibit the rendering of any services as such.

And although the NPA prohibits the unauthorized practice of nursing, it does *not* prohibit nurses from delegating to unlicensed persons any particular services under any particular nursing function.

Quite the contrary.

The Board of Registered Nursing (BRN), which is the only agency authorized by the Legislature to construe the NPA, Bus. & Prof. Code § 2725(e), has stated that, in authorizing nurses to provide "indirect" as well as "direct" patient care services, as in the "administration of medications," the NPA authorizes nurses to "delegat[e]" such services to "subordinates." BRN, An Explanation of the Scope of RN Practice, *available at* http://www.rn.ca.gov/pdfs/-regulations/npr-b-03.pdf (as of Apr. 7, 2011).

The Nurses Associations assert that the NPA does not refer to "delegation" expressly. No matter. The BRN has construed the NPA to refer to "delegation" by implication by referring to "indirect" patient care services. Soundly so, because the only conceivable "indirect" patient care services are "delegated" patient care services. The Nurses Associations then assert that the " '[s]ubordinates' " to whom a nurse may delegate "typically include health care providers who work with or under" a nurse. (ABM/18 n.8) Even if a nurse's

subordinates are *typically* other licensed persons—an assertion not supported by any evidence—there is *no requirement* that they *must* be so. The Nurses Association finally assert that the BRN has construed the NPA to prohibit nurses from delegating to unlicensed persons services that "require a substantial amount of scientific knowledge and technical skills." BRN, Unlicensed Assistive Personnel, *available at* http://www.rn.ca.gov/pdfs/regulations/npr-b-16.pdf (as of Apr. 7, 2011). But what the Nurse Associations fail to mention, the BRN has construed the NPA to prohibit nurses from making such a delegation *only in health facilities*. *Ibid.*

Further, under the NPA the administration of medication is not a nursing function categorically, but only if it "require[s] a substantial amount of scientific knowledge or technical skill." Bus. & Prof. Code § 2725(b)(2).

The Nurses Associations claim that the Legislature has defined the administration of medication as necessarily requiring a substantial amount of scientific knowledge or technical skill, and that the Legislature has thereby made the administration of medication the exclusive domain of nurses.

The Nurses Associations' claim was effectively rejected decades ago. *See* Cal. Atty. Gen. Opinion No. 87-106, 71 Ops. Cal. Atty. Gen. 190, ___ [1988 WL 385204, at *7] (1988) (noting that the NPA expressly "qualified" its definition of nursing functions "by the clause: 'which require a substantial amount of scientific knowledge or

technical skill,' " which "would normally require an examination of the particular act in question to determine the amount of scientific knowledge and technical skill required to perform it in order to determine whether performance of the act constituted the practice of nursing").

In any event, the Legislature could not have defined the administration of medication as necessarily requiring a substantial amount of scientific knowledge or technical skill. If so, its definition would have extended to such services as "[d]irect and indirect patient care services that ensure the safety, comfort, personal hygiene, and protection of patients," *id.* § 2725(b)(1)—including extending a steadying hand, fluffing pillows, helping with bathing, and switching on a light in a dark room. That would be absurd: None of those services necessarily requires a substantial amount of scientific knowledge or technical skill. Moreover, in the Vocational Nursing Practice Act (VNPA), Bus. & Prof. Code § 2840 et seq., the Legislature has established that the administration of medication does not necessarily require a substantial amount of scientific knowledge or technical skill: Vocational nurses, who need *not* possess such knowledge or skill, *id.* § 2859, are nevertheless authorized to "[a]dminister medications," *id.* § 2860.5(a).

The Nurses Associations go on to claim that, if the administration of medication were a nursing function only if it required a substantial amount of scientific knowledge or technical skill, the result would "eliminate" the language in the NPA referring

to the "administration of medications," *id.* § 2725(b)(2). (ABM/21) Quite the contrary. To define the nursing function, one needs not only the *modifying* clause, "that require[s] a substantial amount of scientific knowledge or technical skill," but also the *modified* phrase, the "administration of medications." The reference to "medications" defines the *potential* scope of the nursing function; the reference to "medications" that "require a substantial amount of scientific knowledge or technical skill" defines its *actual* scope.

In addition, under the NPA the administration of insulin *specifically* is not a nursing function because it does not require a substantial amount of scientific knowledge or technical skill.

First, as stated, innumerable unlicensed persons administer insulin safely innumerable times every day. That fact proves that the administration of insulin does not require a substantial amount of scientific knowledge or technical skill.

Second, the VNPA provides that vocational nurses are authorized to administer medication, including "by hypodermic injection," *id.* § 2860.5(a), which is one of the methods for administering insulin. As noted, vocational nurses need not possess a substantial amount of scientific knowledge or technical skill. That means that the administration of insulin does not require a substantial amount of scientific knowledge or technical skill. The Nurses Associations assert that vocational nurses may administer insulin and other medication by hypodermic injection "only under the direct

supervision of [a] physician or a registered nurse." (ABM/22) They cite no support for their assertion. There is none.

The Nurses Associations effectively admit that, as a general matter, unlicensed persons can administer insulin safely—and without violating the NPA. For they admit that the unlicensed parents and guardians of students with diabetes, and unlicensed designees of parents and guardians, can do so. (ABM/4) The only unlicensed persons who supposedly cannot are persons who happened to be school employees. What then does the Nurses Associations' position boil down to: That one group of unlicensed persons alone may not do what innumerable other unlicensed persons do innumerable times every day. That is absurd.

Falling back, the Nurses Associations next argue that, in prohibiting the unauthorized practice of nursing, the NPA does not prohibit only the practice of nursing *for remuneration.* (ABM/17-18)

ADA has never suggested otherwise. The practice of nursing entails the rendering of certain services to the general public as a means of livelihood. (OBM/17-18) That does not mean that, to practice nursing, a person must charge for the rendering of any particular service. Instead, to practice a profession, a person, whether or not he or she charges for the rendering of any service, must present him- or herself to the general public as rendering such services constantly, habitually, usually, or customarily. Oxford English Dictionary, "Practice" (3d ed. July 2010; online version Nov. 2010),

available at http://www.oed.com/search?searchType=dictionary&q=-practice (as of Apr. 7, 2011). In administering insulin to students with diabetes, unlicensed school personnel do *not* present themselves to the general public as rendering any such service in any such fashion, but instead act solely and openly as volunteers for particular students, carrying out the specific written orders of each student's physician. In administering insulin to students with diabetes, they remain what they are—teachers, counselors, coaches, secretaries, etc.; they do not take on any other role, nor could anyone conclude otherwise.

The Nurses Associations then argue that, in administering insulin to students with diabetes, unlicensed school personnel do not come within the NPA's orders-of-physician exception to the prohibition against the unauthorized practice of nursing. (ABM/23-26)

Under the orders-of-physician exception, the NPA "does not prohibit" the "performance by any person of such duties as required in ... carrying out medical orders prescribed by a licensed physician," so long as such a person does not "assume to practice as a ... nurse." Bus. & Prof. Code § 2727(e).

In administering insulin to students with diabetes, unlicensed school personnel, as stated, necessarily act solely and openly as volunteers for particular students. In doing so, they carry out the specific written orders of each student's physician, which "detail[ ]

the ... method, amount, and time schedules by which" insulin is to be administered." Ed. Code § 49423(b)(1).

The Nurses Associations construe the NPA's orders-of-physician exception *not* to apply to *any* unlicensed person who renders *any* service under any nursing function—including, they assert, unlicensed school personnel who administer insulin to students with diabetes—because, "by definition," any such unlicensed person is "engaged in the practice of nursing." (ABM/24)

The Nurses Associations' construction of the NPA's orders-of-physician exception would render the exception nugatory. Under their construction, the exception would apply *only if* an unlicensed person were *not* engaged in the practice of nursing. But if an unlicensed person were not engaged in the practice of nursing, he or she could not be engaged in the *unauthorized* practice of nursing—and hence would have no need for any exception.

The Nurses Association claim that *Kolnick v. Board of Medical Quality Assurance*, 101 Cal.App.3d 80 (1980), supports their construction of the NPA's orders-of-physician exception. (ABM/24-25) The question in *Kolnick*, however, was *not* whether an unlicensed person came within the orders-of-physician exception when he or she performed duties required in carrying out the orders of a physician—there, the "giving of injections." *Id.* at 84. Instead, it was whether a physician could engage in unprofessional conduct in violation of the Medical Practice Act, Bus. & Prof. Code § 2000 et seq., by aiding or

abetting an unlicensed person in engaging in the unauthorized practice of *medicine*. 101 Cal.App.3d at 84. *Kolnick* discloses nothing about what injections the unlicensed person there gave or the nature of the accompanying physician's orders, if any. Therefore, it has no bearing on the application of the orders-of-physician exception to unlicensed school personnel administering insulin to students with diabetes: Unlicensed school personnel would do only what innumerable other unlicensed persons do innumerable times every day, and in doing so would carry out specific written orders of a physician "detailing the ... method, amount, and time schedules by which" insulin is to be administered. Ed. Code § 49423(b)(1).

The Nurses Associations also claim that the Legislature's enactment of what they call "express statutory exceptions" to the NPA's prohibition against the unauthorized practice of nursing addressing epinephrine and glucagon, in Education Code sections 49414 and 49414.5, respectively, support their construction of the NPA's orders-of-physician exception: If the orders-of-physician exception "allow[ed] unlicensed school personnel to administer glucagon and epinephrine, then those legislative enactments would not have been necessary." (ABM/25)

Education Code sections 49414 and 49414.5, however, are not exceptions to the NPA's prohibition against the unauthorized practice of nursing. Rather, they subject unlicensed school personnel who administer epinephrine and glucagon, respectively, to conditions specific to the administration of the specific medication, including

training standards. They remain necessary, notwithstanding the fact that the NPA's orders-of-physician exception allows unlicensed school personnel to administer insulin to students with diabetes, to impose the epinephrine- and glucagon-specific conditions.[2]

B. The Nurses Associations Do Not Defeat ADA's Showing That Education Code Section 49423 Authorizes Unlicensed School Personnel To Administer Insulin To Students With Diabetes

In its Opening Brief on the Merits, ADA demonstrated that Education Code section 49423 authorizes unlicensed school personnel to administer medication to students, including insulin to students with diabetes. (OBM/29-48)

In its Answer Brief on the Merits, the Nurses Associations attempt to counter ADA's demonstration. (ABM/26-32)

This Court need not reach the issue whether Education Code section 49423 authorizes unlicensed school personnel to administer insulin to students with diabetes if it construes the NPA, as it should,

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[2] The NPA's orders-of-physician exception is hardly unique. The VNPA provides even more broadly that it "does not prohibit the performance of nursing services by any person not licensed ... [as a vocational nurse]; provided, that such person shall not in any way assume to practice as a licensed vocational nurse." Bus. & Prof. Code § 2861.

not to prohibit them from doing so in the first place. But if the Court should reach the Education Code section 49423 issue, it would have to resolve it in ADA's favor.

Education Code section 49423 authorizes unlicensed school personnel as well as school nurses to "assist" students with medication. In so doing, as the Court of Appeal recognized, the provision is broad enough to authorize unlicensed school personnel as well as school nurses to *administer medication* as well as *help with self-administration.* (MajOpn/22-23)

The Nurses Associations first argue that Education Code section 49423 distinguishes between the authority of school nurses, on the one side, and of unlicensed school personnel, on the other, to "assist" students with medication. (ABM/27) Wrong. Although the provision distinguishes between *school nurses* and *unlicensed school personnel* by referring to "school nurse[s]" and "other ... school personnel," Ed. Code § 49423(a), it does *not* distinguish between the *authority* of either to "assist" students with medication by administration or by help with self-administration.

The Nurses Associations then argue that, in authorizing unlicensed school personnel as well as school nurses to "assist" students with medication, Education Code section 49423 authorizes each to "assist" only in whatever way it is legally permitted *under some other provision.* (ABM/27-32)

In making their argument, the Nurses Associations initially rely on the language of Education Code section 49423. (ABM/27-28)

But construed in accordance with its terms, Education Code section 49423's language grants authority to unlicensed school personnel in the very same way as it grants authority to school nurses—it grants both the authority to "assist" students with medication. Construed otherwise, the provision's language would be empty, merely authorizing unlicensed school personnel as well as school nurses to do what some *other* provision had *already authorized* them to do.

In making their argument, the Nurses Associations also rely on the Education Code section 49423 regulations, 5 Cal. Code Regs. § 600 et seq. (ABM/28-29)

It is true that the Education Code section 49423 regulations provide that unlicensed school personnel may administer medication to students "as allowed by law." 5 Cal. Code Regs. § 604(b). But they make identical provision for school nurses, *id.* § 604(a), for designees of parents and guardians, *id.* § 604(d), and even for parents and guardians themselves, *id.* § 604(c). The long and short of it is that *anyone and everyone* who administers medication to *any* student must do so "as allowed by law." By providing that anyone and everyone may administer medication to students "as allowed by law," the regulations do nothing more than accommodate any *specific* conditions that may be applicable to the administration of any *specific*

medication. Such conditions, as noted, are applicable to the administration of epinephrine and glucagon under Education Code sections 49414 and 49414.5, respectively. No such conditions, however, are applicable to the administration of insulin.

It is also true that the Education Code section 49423 regulations provide that "[n]othing" in the regulations "may be interpreted ... as affecting in any way" the "statutes," including the NPA, "governing any health care professional licensed by the State of California," including a nurse, "in the carrying out of activities authorized by the license." 5 Cal. Code Regs. § 610(a). But to "interpret" the Education Code section 49423 regulations, in accordance with Education Code section 49423's grant of authority to unlicensed school personnel to administer medication to students, would not affect in any way the NPA as it governs nurses in the carrying out of their authorized activities. The NPA remains the statute that governs nurses and nursing generally throughout California. Education Code section 49423 simply authorizes unlicensed school personnel to administer medication to students specifically in California public schools. *Cf. Ordlock v. Franchise Tax Bd.*, 38 Cal.4th 897, 910 (2006) (It is " ' "well settled ... that a general provision is controlled by one that is special, the latter being treated as an exception to the former." ' ")

Therefore, just as it is reasonable to construe the Education Code section 49423 regulations to provide that unlicensed parents and guardians of students, and unlicensed designees of parents and

guardians, may administer medication to students, it would be unreasonable to construe them to provide unlicensed school personnel *alone* from doing so.

In making their argument, the Nurses Associations finally rely on two documents issued by CDE. (ABM/29-32)

In its "Program Advisory on Medication Administration" ("Program Advisory"), issued in 2005, CDE provided "nonbinding recommendations on administering medication to students." (2AA/483) "On the basis of ... laws" including Education Code section 49423, CDE stated that it was "recommended" that unlicensed school personnel should not administer medication to students if the method of administration is by "injection," which could include insulin. (2AA/488-89) Notwithstanding its nonbinding recommendation, the document did not state that such personnel were without authority to do so.

In its "Medication Administration Assistance in California: Frequently Asked Questions" ("Frequently Asked Questions"), issued in 2006, CDE departed from its then-recent "Program Advisory." CDE now stated that Education Code section 49423 did not "clearly" authorize unlicensed school personnel to administer insulin to students with diabetes. (7AA/1709) The basis of CDE's statement was its view that the "terms 'assist' and 'administer' are plainly not synonymous," but instead mutually exclusive. (7AA/1709) Although not synonymous, "assist" and "administer" are not mutually

exclusive: As recognized by the Court of Appeal, "assist" is the *including* term and "administer" is the *included* term. (MajOpn/22-23) Since even a regulation would be "void" if it purported to "alter" a statute or "impair its scope," *Morris v. Williams*, 67 Cal.2d 733, 748 (1967), a document like "Frequently Asked Questions," which did not even rise to the dignity of a regulation, could fare no better. In any event, CDE soon withdrew "Frequently Asked Questions" (7AA/1707) and went on to issue the Legal Advisory, in which it acknowledged the authority of unlicensed school personnel to administer insulin (5AA/1109).

Although this Court would have to "respect" any construction of Education Code section 49423 adopted by CDE—perhaps even one as short-lived as that in its "Frequently Asked Questions"—it would nevertheless have to construe the provision "independently" for itself. *Yamaha Corp. of America v. State Bd. of Equalization*, 19 Cal.4th 1, 7 (1998).

Giving Education Code section 49423 such an independent construction, this Court, for the reasons stated above, should conclude that the provision authorizes unlicensed school personnel to administer medication to students, including insulin to students with diabetes.

C. The Nurses Associations Do Not Defeat ADA's Showing That Any Prohibition In California Law Against Unlicensed School Personnel Administering Insulin To Students With Diabetes Would Be Preempted By Section 504, The Americans With Disabilities Act, And The IDEA, At Least When A School Nurse Or Other Licensed Person Is Unavailable

In its Opening Brief on the Merits, ADA demonstrated that any prohibition in California law against unlicensed school personnel administering insulin to students with diabetes would be preempted by Section 504, the Americans with Disabilities Act, and the IDEA, at least when a school nurse or other licensed person is unavailable. (OBM/48-58)

In its Answer Brief on the Merits, the Nurses Associations attempt to counter ADA's demonstration. (ABM/32-49)

1. Section 504, The Americans With Disabilities Act, And The IDEA Require School Districts To Administer Insulin To Students With Diabetes, Not Merely Provide Some "Reasonable Accommodation" Of Their Own Choosing

At the threshold—and for the first time—the Nurses Associations argue that Section 504, the Americans with Disabilities Act, and the IDEA do not require school districts to administer insulin to students with diabetes, but merely provide some "reasonable accommodation" of their own choosing. (ABM/33-43) Not only is the argument new. It is also baseless.

Section 504, the Americans with Disabilities Act, and the IDEA grant students with diabetes the right to a free appropriate public education, with the complementary right to health care services, including the administration of insulin, at no cost, in order to enable them to remain safe and to benefit from a free appropriate public education. *See, e.g., Cedar Rapids Community School Dist. v. Garret F. ex rel. Charlene F.*, 526 U.S. 66, 73-79 (1999); *Irving Independent School Dist. v. Tatro*, 468 U.S. 883, 891 (1984); *Smith v. Robinson*, 468 U.S. 992, 1017-18 n.20 (1984); *Board of Educ. of Hendrick Hudson Central School Dist., Westchester County v. Rowley*, 458 U.S. 176, 192 (1982); *Nieves-Marquez v. Puerto Rico*, 353 F.3d 108, 125 (1st Cir. 2003); *Ridgewood Bd. of Educ. v. N.E. ex rel. M.E.*, 172 F.3d 238, 253 (3rd Cir. 1999); 20 U.S.C. §§ 1400(d), 1401(26)(A), 1414(d); 34 C.F.R. §§ 104.33(b)(1), 104.33(c)(1).

In so doing, Section 504, the Americans with Disabilities Act, and the IDEA require school districts to administer insulin to students with diabetes, not merely to provide them with some "reasonable accommodation" of their own choosing.

It is too late in the day for the Nurses Associations to dispute what Section 504, the Americans with Disabilities Act, and the IDEA do. For they have already admitted that these federal statutes grant students with diabetes the right to a free appropriate public education, with the complementary right to health care services, including the administration of insulin, at no cost, and that they accordingly require school districts to administer insulin to them. (ABM/34

(acknowledging the right of students with diabetes to a "free, appropriate, discrimination-free education"); RB/1 n.1 (stating that the "real issue" in this case is not "whether students with diabetes will receive their insulin" but "from whom" (underscoring original))

The Nurses Associations cite several authorities to support their new argument that Section 504, the Americans with Disabilities Act, and the IDEA do not require school districts to administer insulin to students with diabetes, but merely to provide some "reasonable accommodation"—*Alexander v. Choate*, 469 U.S. 287 (1985); *Southeastern Community College v. Davis*, 442 U.S. 397 (1979); *Davis v. Francis Howell School Dist.*, 138 F.3d 754 (8th Cir. 1998); *DeBord v. Board of Educ. of Ferguson-Florissant School Dist.*, 126 F.3d 1102 (8th Cir. 1997); *Cercpac v. Health and Hospitals Corp.*, 147 F.3d 165 (2d Cir. 1998); *Fink v. New York City Dept. of Personnel*, 53 F.3d 565 (2d Cir. 1995); *R.K. v. Board of Education of Scott County*, No. 5:09-344, 2010 U.S. Dist. LEXIS 132930 (E.D. Ky. Dec. 15, 2010); *B.M. v. Board of Education of Scott County*, No. 5:07-153, 2008 U.S. Dist. LEXIS 66645 (E.D. Ky. Aug. 29, 2008); *McDavid v. Arthur*, 437 F.Supp.2d 425 (D. Md. 2006); 28 C.F.R. §§ 35.130 and 41.53.

As will appear, none of these authorities cited by the Nurses Associations support their new argument.

Specifically, sections 35.130 and 41.53 of title 28 of the Code of Federal Regulations have nothing to do with the rights of students

with diabetes under Section 504, the Americans with Disabilities Act, or the IDEA. Section 35.130 applies to all public entities, including public schools, but makes no reference to education or "reasonable accommodations." Although section 41.53 does indeed refer to "reasonable accommodations," it does so only with respect to federally-assisted employment programs.

Similarly, *Alexander*, *Cercpac*, *Fink*, and *McDavid* have nothing to do with the rights of students with diabetes under Section 504, the Americans with Disabilities Act, or the IDEA. *Alexander* involves Medicaid benefits for hospital care; *Cercpac* involves health care in medical facilities; *Fink* involves employment; and *McDavid* involves a recreation program.

Likewise, *Southeastern Community College v. Davis* has nothing to do with the rights of students with diabetes under Section 504, the Americans with Disabilities Act, or the IDEA. There, the United States Supreme Court held that a professional school did not violate Section 504 when it denied a woman with a serious hearing disability admission to its nursing program because she could not participate safely and hence did not qualify. 442 U.S. at 405-14. In so holding, the Court stated that it was "undisputed" that the woman could not participate safely unless the professional school "substantially lowered" its educational "standards," and that the professional school was not required to do so. *Id.* at 413. Of course, students with diabetes do not have to "qualify" for admission to public school; they have a right to attend. Neither do school districts have to

lower their educational standards to administer insulin; they need only respect the right of such students to health care services, at no cost, in order to remain safe and to benefit from the free appropriate public education to which they are entitled.

Davis and *DeBord* also have nothing to do with the rights of students with diabetes under Section 504, the Americans with Disabilities Act, or the IDEA. Rather, in each decision, the court held only that a student with attention deficit hyperactivity disorder (ADHD) was not entitled to have a school district administer Ritalin in an amount that was substantially in excess of the recommended dosage and, as such, potentially harmful. *Davis*, 138 F.3d at 756-57; *DeBord*, 126 F.3d at 1104-07. True, in each decision, the court concluded that the school district in question offered the parents of the student with ADHD the "reasonable accommodation" of allowing them to administer Ritalin themselves. *Davis*, 138 F.3d at 757; *DeBord*, 126 F.3d at 1106. Even if either decision could be read to stand for the proposition any such supposedly "reasonable accommodation" would not violate the right to health care services at no cost, it would no longer be good law. In *Cedar Rapids Community School Dist. v. Garret F. ex rel. Charlene F.*, 526 U.S. at 73-79, the United States Supreme Court subsequently held that the right to health care services at no cost is indeed guaranteed.

R.K. and *B.M.*, however, are different. In each decision, the court concluded that a school district that offered a student with diabetes a free appropriate public education, with health care services,

including the administration of insulin, at no cost, was not "require[d] ... to modify school programs" as proposed by the student's parent or parents to make what the parent or parents desired as a "reasonable accommodation." *R.K.*, 2010 U.S. Dist. LEXIS 132930, at *11-*21 & esp. *17); *B.M.*, 2008 U.S. Dist. LEXIS 66645, at *17-*28 & esp. *25. These decisions do not advance the Nurses Associations' position, inasmuch as the school district in question—unlike many in California—actually administered insulin.[3]

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[3] Contrary to the Nurses Associations' implication, it is immaterial in this case whether Section 504, the Americans with Disabilities Act, and the IDEA require school districts to *require* unlicensed school personnel to administer insulin to students with diabetes. That is because ADA has argued only that these federal statutes require school districts to *allow* them to do so, at least when a school nurse or other licensed person is unavailable. Because that is so, *McDavid*, on which the Nurses Associations rely, is doubly inapposite. First, *McDavid* dealt with participation by a child with diabetes in a public recreation program; it did *not* deal with attendance at a public school or with the right to a free appropriate public education and the complementary right to health care services, including the administration of insulin, at no cost. Second, *McDavid* addressed whether Section 504 and the Americans with Disabilities Act require school districts to *require* unlicensed recreation personnel to administer insulin; it did not address whether Section 504 or the Americans with Disabilities Act requires state law to *allow* them to do so.

2. The "Accommodation" That California Law Supposedly Makes For Students With Diabetes Would Not Be "Reasonable"

The Nurses Associations next argue that California law makes "reasonable accommodation" for students with diabetes by allowing school districts to administer insulin through seven categories of persons as enumerated in the Legal Advisory: (1) the student him- or herself; (2) a school nurse or school physician; (3) a licensed school employee other than a school nurse or school physician; (4) a licensed person other than a school employee; (5) a parent or guardian of the student; (6) a designee of the student's parent or guardian who is not a school employee; and (7) in an epidemic or public disaster only, an unlicensed school employee (5AA/1109). (ABM/33-39)

Even if Section 504, the Americans with Disabilities Act, and the IDEA required school districts merely to provide some "reasonable accommodation" of their own choosing, and not to administer insulin, to students with diabetes, the "accommodation" that the Nurses Associations claim that California law makes for such students would not be "reasonable."

To be "reasonable" under Section 504, the Americans with Disabilities Act, and the IDEA, any "accommodation" provided to students with diabetes would have to be effective in actually administering insulin whenever and wherever they needed it. That is because students with diabetes need insulin in order to remain safe

and to benefit from the free appropriate public education to which they are entitled.

What the Nurses Associations claim is the "accommodation" provided by California law to students with diabetes is hardly "reasonable."

First, it is not effective to entrust the administration of insulin to students with diabetes to a school nurse and other licensed person (including a school physician, another licensed school employee, or a licensed person other than a school employee).

As for school nurses, the evidence introduced by ADA shows that there has been, and will continue to be, a severe shortage of school nurses and, more generally, a severe shortage of registered nurses, from whom school nurses are drawn. (6AA/1505) Indeed, the Legislature has itself so found. (6AA/1399) The present shortage of school nurses is severe: There are more than 6 million students in California public schools, including about 14,000 with diabetes, most of whom need insulin at unpredictable as well as predictable times and places in the course of the school day; there are only about 2,800 school nurses to care for all of these students, constituting only about 1 school nurse for every 2,200 students; only about 5 percent of schools have a full-time school nurse; about 69 percent have a part-time school nurse; and about 26 percent have no school nurse at all. (3AA/713, 718-19; 6AA/1399, 1410, 1415-19, 1428-29, 1493-94, 1500) The future shortage of school nurses will be more severe still.

(6AA/1505) As a matter of basic economics, the shortage of school nurses makes it costly—even prohibitively costly—for some school districts to hire school nurses and altogether impossible for others to do so. Sen. Com. on Health and Human Services, Analysis of Sen. Bill No. 1912 (2003-2004 Reg. Sess.) as amended May 3, 2004, at 3-4. As time passes, the number of school districts facing such a predicament is likely to grow larger and larger. *See* California Department of Education, News Release No. 11-05, *available at* http://www.cde.ca.gov/nr/ne/yr11/yr11rel05.asp (as of Apr. 7, 2011) (noting the "financial emergency facing California's schools").

As for licensed persons other than school nurses, the evidence introduced by ADA shows that such other licensed persons are unable, and will continue to be unable, to make up for the severe shortage of school nurses so far as students with diabetes are concerned: To arrange for the presence of a licensed person other than a school nurse requires advance scheduling, which by definition cannot anticipate the unpredictable times and places at which any given student may need insulin. (3AA/641, 718-19; 6AA/1428-29) And if, as the Nurses Associations have asserted, vocational nurses may not administer insulin except "under the direct supervision of [a] physician or a registered nurse" (ABM/22), they would not count for anything. For if a physician or registered nurse were present to directly supervise a vocational nurse, the vocational nurse would be unnecessary, since the physician or registered nurse could administer insulin. But if a physician or registered nurse were *not* present to directly supervise a vocational nurse, the vocational nurse would be

useless, since he or she could not administer insulin without the physician or registered nurse.

Second, it is even less effective to entrust the administration of insulin to students with diabetes, in an epidemic or public disaster only, to an unlicensed school employee. Thankfully, epidemics and public disasters occur very rarely. By contrast, the need for insulin arises every school day.

Third, it is not effective to entrust the administration of insulin to students with diabetes to the student him- or herself if the student is unable to perform the task. Although some students, particularly older ones, can administer insulin to themselves, others, particularly younger ones, cannot. (6AA/1418) Indeed, there are many students who cannot administer insulin to themselves. (3AA/627-28, 634-42, 669-79, 713, 718-19, 794, 796, 799; 5AA/1149-55, 1191-97, 1199-1211, 1248-56, 1237-46; 6AA/1415, 1428-29)

Fourth, even if effective, it is not lawful to entrust the administration of insulin to students with diabetes to the student's parent or guardian or to the designee of the student's parent or guardian. Section 504, the Americans with Disabilities Act, and the IDEA grant students with diabetes a right to health care services, including the administration of insulin, *at no cost.* To entrust a parent or guardian or designee with the administration of insulin when a school nurse or other licensed person is unavailable to do so is to *require* the parent or guardian or designee to administer insulin. To

require the parent or guardian or designee to administer insulin is impermissibly to shift the cost onto his or her shoulders. The cost would be substantial. Students with diabetes need someone constantly available who can administer insulin at all of unpredictable as well as predictable times and places at which they may need insulin. To require parents or guardians or designees to administer insulin would, in all likelihood, require them to forgo employment or to employ someone to take their place. Such a requirement would violate these federal statutes no less than a requirement to pay school nurses to administer insulin.

The Nurses Associations invoke, time and again, the seven categories of persons enumerated in the Legal Advisory as allowed to administer insulin to students with diabetes under California law as though they constituted a magic number. Under Section 504, the Americans with Disabilities Act, and the IDEA, the test is whether the categories, whatever their number, effectuate the right of students with diabetes to health care services, including the administration of insulin, at no cost. As shown, the categories fail the test.

The Nurses Associations go on to claim that evidence in the record shows that the "accommodation" supposedly provided by California law to students with diabetes is indeed "reasonable." (ABM/33-35) For support, they rely on declarations by Nicole C. and Louise D. (3AA/634-68, 669-710)

Nicole C. is the mother of a then six-year-old daughter, and Louise D. is the mother of a then nine-year-old son, each of whom is a child with diabetes who needed to have insulin administered at unpredictable as well as predictable times and places in the course of the school day. (3AA/635-42, 670-79)

The Nurses Associations assert that Nicole C.'s school district offered various "reasonable accommodations," including "training two teachers to check" her daughter's "blood glucose"; "giving" her daughter "certain snacks when needed"; providing a "nurse-developed health care plan"; arranging for a "phone call to" Nicole C. if her daughter "had high glucose levels"; "training" unlicensed school personnel in the "signs and symptoms of hypoglycemia and hypoglycemia [*sic*]"; "permitting" her daughter to "carry her own diabetes supplies"; "allowing for blood glucose testing whenever necessary, including in the classroom"; "storing emergency medications and extra supplies in the office or classroom"; and "providing a trained person to be with" her daughter "on off campus activities." (ABM/33-34) The Nurses Associations imply that Louise D.'s school district offered similar "reasonable accommodations." (ABM/34-35)

There is no dispute that the "accommodations" offered to Nicole C.'s and Louise D.'s children by their respective school districts were "reasonable," and indeed necessary, in light of the each child's right under Section 504, the Americans with Disabilities Act, and the IDEA to a free appropriate public education. But these

"accommodations" were altogether insufficient in light of each child's complementary right to health care services, including the administration of insulin, at no cost. Why? Because, notably, they did *not* include the administration of insulin.

Nicole C.'s daughter received the insulin she needed at school, when and where she needed it, only because Nicole C. herself administered it—at a substantial cost, since she was prevented from working and earning an income. (3AA/637-41) Likewise, Louise D.'s son received the insulin he needed at school, when and where he needed it, only because Louise D. herself administered it—at a substantial cost, since she too was prevented from working and earning an income. (3AA/672-78) Eventually, Louise D. was unable to continue administering insulin to her son at school, and had to remove him from school. (*Ibid.*)

Under Section 504, the Americans with Disabilities Act, and the IDEA, Nicole C.'s and Louise D.'s children had a right to health care services, including the administration of insulin, *at no cost*.

The Nurses Associations assert that Nicole C.'s and Louise D.'s declarations do not show that their children were denied their right to a free appropriate public education under Section 504, the Americans with Disabilities Act, and the IDEA, when they were denied their complementary right to health care services, including the administration of insulin, at no cost. (ABM/34-35, 44)

But how could Nicole C.'s and Louise D.'s children be said to have received a *free* appropriate public education when Nicole C. and Louise D. were compelled to pay for the administration of insulin by forgoing employment by the failure of their respective school districts to provide for the administration of insulin? Worse still, how could Louise D.'s son be said to have received any free appropriate public education *whatsoever* when Louise D. was compelled to remove him from school when her school district failed to provide for the administration of insulin?

With no answers to these questions, the Nurses Associations assert that school districts generally, including presumably Nicole C.'s and Louise D.'s, choose to make school nurses and other licensed persons "unavailable by refusing to hire or contract with them." (ABM/45 n.17) They do not cite any evidence in support. Nor can they, inasmuch as there is none. Quite the opposite. All the evidence shows that there has been, and will continue to be, a severe shortage of school nurses and, more generally, a severe shortage of registered nurses, from whom school nurses are drawn, and that other licensed persons are unable, and will continue to be unable, to make up for such a severe shortage because of the inherent difficulty of contracting for their availability at unpredictable times and places.

It is rather shocking that the Nurses Associations are now insinuating for the first time that parents like Nicole C. and Louise D. are asking too much for their children in light of all of the "accommodations" that they have supposedly been given. Surely, the

Nurses Associations recognize all such "accommodations" are meaningless without insulin, which is the lifeblood of these children.

Lastly, the Nurses Associations claim that the "accommodation" that ADA is supposedly seeking for students with diabetes—to "eliminate every 'burden' that [such] students face as a result of their condition"—is not "reasonable." (ABM/34, 35-39)

But ADA is not seeking to eliminate every burden that students with diabetes must face. Until there is a cure, all persons with diabetes will remain subject to a heavy burden that others are free of.

What ADA is actually seeking is far more modest, simply to allow unlicensed school personnel to administer insulin to students with diabetes, at least when a school nurse or other licensed person is unavailable. Although modest, it is nevertheless—and literally—essential. The administration of insulin is not one potential "accommodation" among others that a school district is free *not* to choose so long as it chooses another in its place. Students with diabetes need the administration of insulin, usually prior to eating and whenever and wherever their blood glucose levels rise unduly, in order to remain safe and to benefit from the free appropriate public education to which they are entitled.

At the very beginning of this proceeding, the Nurses Associations embraced the requirement of Section 504, the Americans with Disabilities Act, and the IDEA that school districts must

administer insulin to students with diabetes, stating that they "support[ed] proper implementation of federal anti-discrimination laws through administration of insulin to students who need such care," albeit by school nurses and other licensed persons, as "in the best interest of the children." (1AA/2)

Now, as this proceeding is approaching its conclusion, the Nurses Associations make a volte-face to reject the requirement and to sacrifice the best interest of children and attempt to hide behind the claim that it is ADA that is unreasonable.

By seeking to allow unlicensed school personnel to administer insulin to students with diabetes, at least when a school nurse or other licensed person is unavailable, ADA is seeking to substitute a new system for administering insulin, which works tolerably well even if not perfectly, in place of the old "system," which is disclosed in the declarations of Nicole C. and Louise D., and does not work at all. The new system would remove barriers arising from any prohibition in California law against unlicensed school personnel administering insulin that would prevent any realistic hope that someone would be available whenever and wherever a student with diabetes might need insulin. Of course, the new system, like any other, might break down on occasion, as when there is no unlicensed school employee ready, willing, or able to administer insulin. Such a breakdown would likely be rare. That said, whenever a breakdown did occur, it would not be caused by any prohibition in California law.

Although what ADA is seeking in this case is modest, the Nurses Associations claim that it is nevertheless "unreasonable."

Why?

On the one hand, the Nurses Associations say that it is *not* too dangerous for a student with diabetes to forgo the administration of insulin by an unlicensed school employee because the student might nonetheless escape death. (ABM/36) On this point, they cite opinion testimony by a physician in *McDavid* that it was "grossly inaccurate" to claim that, if the child with diabetes involved in that case did "not receiv[e] insulin" during a recreation program, he would "die." 437 F.Supp.2d at 428. That opinion testimony, of course, is not evidence in this proceeding. Moreover, it could not reasonably be understood to imply that students with diabetes do not need insulin in order to remain safe and to benefit from the free appropriate public education to which they are entitled. If it so implied, it would be have to be rejected as baseless. (3AA/717-18; 6AA/1426, 1429)

On the other hand, the Nurses Associations say that it *is* too dangerous for a student with diabetes to be administered insulin by an unlicensed school employee because the student might suffer some harm. (ABM/38 n.14, 44) On this point too, they cite opinion testimony by the same physician in *McDavid* that the "administration of insulin ... should not be undertaken by laypersons." 437 F.Supp.2d at 429. In so stating, that opinion testimony is contradicted both by the contrary determination by experts in the care and treatment of

persons with diabetes and also by the fact that innumerable unlicensed persons administer insulin safely innumerable times every day.

The possibility of harm, of course, is a fact of life. But it is also a fact of life that, as stated, innumerable unlicensed persons administer insulin safely innumerable times every day. Like other unlicensed persons, unlicensed school personnel can be trained to administer insulin safely.

The Nurses Associations assert that ADA "admits that students with diabetes would be *best* served" if they were administered insulin by a school nurse or other licensed person. (ABM/45 (italics added)) Not quite. ADA admits that such students would be *well* served by a licensed person like a school nurse. But in the absence of such a person, these students have a right under Section 504, the Americans with Disabilities Act, and the IDEA to be *safely* served *by someone else*. The choice is therefore not between an unlicensed school employee and a licensed person like a school nurse, but between an unlicensed school employee and no one at all.

It may well be that Section 504, the Americans with Disabilities Act, and the IDEA do not require states to do what they cannot. But they surely require them to do what they can—which entails putting in place a system for administering insulin that works, even if not perfectly, at least tolerably well.

3. Any Prohibition In California Law Against Unlicensed School Personnel Administering Insulin To Students With Diabetes Could Frustrate The Purpose Of Section 504, The Americans With Disabilities Act, And The IDEA, And Would Therefore Be Preempted

The Nurses Associations then argue that, whether or not California law makes any "reasonable accommodation," any prohibition in California law against unlicensed school personnel administering insulin to students with diabetes would not be preempted by Section 504, the Americans with Disabilities Act, or the IDEA. (ABM/33-35, 39-43)

The Nurses Associations first claim that any such prohibition in California law would not be preempted by Section 504, the Americans with Disabilities Act, or the IDEA, because it would not be impossible to comply with both.

The premise of the Nurses Associations' claim is that preemption requires an impossibility to comply with both federal and state law. That premise is unsound. Although impossibility of compliance with both federal and state law is a *sufficient* condition for preemption, it is *not* a *necessary* condition. In decisions including *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal.4th 910, 923 (2004), this Court has declared that, even when it is *not* impossible to comply with both federal and state law, state law is nevertheless preempted by federal law when it " ' "stands as an

obstacle to the accomplishment and execution of the full purposes and objectives of Congress." ' " Therefore, even when state law does not fall under impossibility preemption, it may nevertheless fall under obstacle preemption.[4]

The Nurses Associations then claim that any prohibition in California law against unlicensed school personnel administering insulin to students with diabetes would not be preempted by Section 504, the Americans with Disabilities Act, or the IDEA because any such state law prohibition could not frustrate the purpose of these federal statutes. (ABM/33-35, 39-43)

To be sure, as this Court acknowledged in *Dowhal*, there is a presumption that federal law does not preempt state law via obstacle preemption, the presumption is especially heavy in matters of health

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[4] In *Ginochio v. Surgikos, Inc.*, 864 F.Supp. 948 (N.D. Cal. 1994), on which the Nurses Associations rely, the court stated that, "if it is possible to comply with both federal and state law, there is neither a conflict [for impossibility preemption] *nor a frustrated purpose*" for obstacle preemption. *Id.* at 951 (italics added). *Ginochio*'s language is dictum. It is also wrong. In *Hines v. Davidowitz*, 312 U.S 52 (1941), the United States Supreme Court held that, even though it was possible to comply with both the Federal Alien Registration Act of 1940 and the Pennsylvania Alien Registration Act of 1939, the federal law preempted the state law because the state law frustrated the purpose of the federal law. 312 U.S. at 60-74 & esp. 65-68, 72-74. Hence, contrary to the *Ginochio* dictum, the possibility of complying with both federal and state law does *not* preclude obstacle preemption.

and safety, and the party claiming preemption has the burden of proving it. *Dowhal*, 32 Cal.4th at 923-24.

But as this Court made plain in *Dowhal*, the presumption, although heavy, is hardly irrebuttable. *See id.* at 923-29.

The question is: What must a party show to carry its burden to prove obstacle preemption?

The answer may be found, unsurprisingly, in *Dowhal* itself.

In *Dowhal*, a citizen filed an action against certain drug companies, alleging that the companies failed to warn consumers that nicotine replacement therapy (NRT) products that they offered for sale in California contained nicotine, "a chemical known to the State of California to cause reproductive harm," in violation of section 25249.6 of the Health and Safety Code, which was added by an initiative measure denominated as Proposition 65.

Under the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., the Food and Drug Administration (FDA) was authorized to regulate the labeling of products including NRT products. In accordance with its determination that the benefits flowing from use of NRT products to stop smoking would outweigh their costs, the FDA ruled that the label for NRT products had to state: "If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your

child. Try to stop smoking without any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known." In accordance with the same determination, the FDA also ruled that the label for NRT products could *not* state, as required by Proposition 65, that such products contained nicotine, "a chemical known to the State of California to cause reproductive harm."

Granting a motion by the drug companies for summary judgment on the ground that the FDCA, as implemented by the FDA, preempted Proposition 65, the superior court entered judgment in their favor. The Court of Appeal reversed the superior court's judgment. This Court in turn reversed the Court of Appeal's judgment.

In doing so, this Court addressed the argument that the FDA's ruling requiring its warning on NRT products and prohibiting Proposition 65's did not preempt Proposition 65 to the extent that it required a warning through point-of-sales posters or public advertising as opposed to product labeling, because the FDA's ruling applied to *only* product labels and *not* point-of-sale posters or public advertising.

Exercising its judgment without reliance on evidence, this Court rejected the argument:

> The FDA's ruling ... reflects the concern that Proposition 65 warnings on product labels might lead pregnant women to believe the NRT products were as dangerous as smoking, or nearly so, and thus discourage the women

> from stopping smoking. Warnings through point-of-sale posters or public advertising could have the same effect of frustrating the purpose of federal policy.... [P]reemption does not require a direct contradiction between state and federal law; the state law is preempted if state law " 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' "

32 Cal.4th at 929.

In light of *Dowhal*, the answer to the question, What must a party show to carry its burden to prove obstacle preemption, is simply, A reasonable basis for concluding that the state law in question could frustrate the federal law's purpose, without any need for evidence quantifying the existence or extent of any such frustrating effect.

In this case, it is plain that ADA carried its burden to prove obstacle preemption under Section 504, the Americans with Disabilities Act, and the IDEA for any prohibition in California law against unlicensed school personnel administering insulin to students with diabetes, at least when a school nurse or other licensed person is unavailable.

There is a reasonable basis—and more than a reasonable basis—for concluding that any such state law prohibition could frustrate the purpose of these federal statutes.

As stated, Section 504, the Americans with Disabilities Act, and the IDEA grant students with diabetes the right to a free

appropriate public education, with the complementary right to health care services, including the administration of insulin, at no cost, in order to enable them to remain safe and to benefit from a free appropriate public education. To do so, such students need insulin administered, usually prior to eating and whenever and wherever their blood glucose levels rise unduly. Consequently, these students need someone constantly available who can administer insulin at all of the unpredictable as well as predictable times and places at which they may need insulin. School nurses and other licensed persons cannot be constantly available because of the severe shortage of school nurses and the inherent difficulty of scheduling other licensed persons to be available at unpredictable times and places. Unlicensed school personnel, by contrast, are indeed constantly available.

It follows that any prohibition in California law against unlicensed school personnel administering insulin to students with diabetes could frustrate the purpose of Section 504, the Americans with Disabilities Act, and the IDEA, at least when a school nurse and other licensed person was unavailable. That is because such a state law prohibition would threaten to leave such students with no one to administer insulin to them, notwithstanding their need.

In arguing to the contrary, the Nurses Associations demand evidence quantifying the existence and extent of the frustrating effect of any prohibition in California law against unlicensed school personnel administering insulin to students with diabetes. ADA has indeed presented such evidence. (3AA/624-5AA/1320; 6AA/1526-

1680) The fact remains, however, that ADA had no need to present evidence in order to carry its burden to prove obstacle preemption when, as here, there was a reasonable basis for concluding that any such state law prohibition could frustrate the purpose of Section 504, the Americans with Disabilities Act, and the IDEA.

The Nurses Associations also claim that *Crowder v. Kitagawa*, 81 F.3d 1480 (9th Cir. 1996), is distinguishable. There, the court held that Hawaii law imposing a 120-day quarantine on all carnivorous animals entering the state could not stand as to guide dogs of visually-impaired persons who rely on such animals because it "effectively prevents such persons from enjoying the benefits of state services" in violation of the Americans with Disabilities Act. *Id.* at 1481, 1485. The court so held even though, during the quarantine period, the Hawaii quarantine law permitted a visually-impaired person to stay free of charge at an apartment or cottage at the quarantine station and, after an initial 10-day observation period, to train with his or her guide dog on and off the station grounds. *Id.* at 1482. The court concluded that, in spite of the fact that it allowed visually-impaired persons *some* access to state services, the Hawaii quarantine law was nevertheless violative of the Americans with Disabilities Act because it denied such persons "*meaningful*" access to state services, as when they "rely upon their guide dogs to assist them in negotiating public streets and using transportation systems." *Ibid.* (italics added). It is evident that the Hawaii quarantine law could frustrate the purpose of the Americans with Disabilities Act by denying visually-impaired persons meaningful access to state services by depriving them of needed guide

dogs. A fortiori, any prohibition in California law against unlicensed school personnel administering insulin to students with diabetes could frustrate the purpose of Section 504, the Americans with Disabilities Act, and the IDEA by depriving them of insulin, which they need in order to remain safe and to benefit from the free appropriate public education to which they are entitled.

The Nurses Associations finally complain that ADA "disagrees with the Legislature's policy" in supposedly prohibiting unlicensed school personnel from administering insulin to students with diabetes and "advocates for a lower standard of care provided by" such personnel. (ABM/45) Not at all. ADA simply agrees with *Congress's* policy, which is controlling for purposes of preemption, and advocates for such students to receive the care that they need in accordance with the specific written orders of their physicians, rather than no care at all.

D. Contrary To The Nurses Associations' Claim, To Authorize Unlicensed School Personnel To Administer Insulin To Students With Diabetes, At Least When A School Nurse Or Other Licensed Person In Unavailable, Is Both Good Law And Good Policy

In its Opening Brief on the Merits, ADA demonstrated that to authorize unlicensed school personnel to administer insulin to students with diabetes, at least when a school nurse or other licensed person is unavailable, is both good law and good policy. (OBM/15-26, 29-37, 48-58)

In its Answer Brief on the Merits, the Nurses Associations attempt to counter ADA's demonstration. (ABM/49-52)

First, according to the Nurses Associations, to allow unlicensed school personnel to administer insulin to students with diabetes would be "bad law" because it would supposedly create inconsistencies in the definition of the "administration" of medication in provisions of the Education Code over against provisions of other codes. Not true. In the Education Code as in other codes, the "administration" of medication means the delivery of medication onto or into a person. The Nurses Associations simply ignore the fact—which even the Court of Appeal recognized—that to "assist" with medication under Education Code section 49423 includes *administering medication* as well as *helping with self-administration.* (MajOpn/22-23)

Second, according to the Nurses Associations, to allow unlicensed school personnel to administer insulin to students with diabetes would "bad law" because it would supposedly render "unnecessary," "redundant," and "meaningless" Education Code sections 49414 and 49414.5 (ABM/52) Again, not true. As stated, Education Code sections 49414 and 49414.5 subject unlicensed school personnel who administer epinephrine and glucagon, respectively, to conditions specific to the administration of the specific medication, including training standards. To authorize such personnel to administer insulin does not subject them to the conditions of Education Code sections 49414 and 49414.5, and hence does not

render those provisions "unnecessary," "redundant," or "meaningless."

Third, according to the Nurses Associations, to allow unlicensed school personnel to administer insulin to students with diabetes would "bad law" because it would supposedly conflict with the Education Code section 49423 regulations, which provide that unlicensed school personnel may administer specific medication to students if they "[m]ay legally administer the medication" in question, 5 Cal. Code Regs. § 601(e)(2). Of course, in the case of any conflict, regulations must yield to statutes, not vice versa. *See, e.g., California Assn. of Psychology Providers v. Rank*, 51 Cal.3d 1, 11 (1990). In any event, there is no conflict. The Education Code section 49423 regulations do nothing more than accommodate any *specific* conditions that may be applicable to the administration of any *specific* medication, as in the case of epinephrine and glucagon under Education Code sections 49414 and 49414.5, respectively. Just as no provision subjects unlicensed school personnel to any conditions for administering cough syrup or eye drops, neither does any provision subject such personnel to any conditions for administering insulin.

Fourth, according to the Nurses Associations, to allow unlicensed school personnel to administer insulin to students with diabetes would be both "bad law" and "bad policy" because it would supposedly "expand the scope of CDE's rulemaking authority by granting it power that the Legislature has not seen fit to give it, in violation of Education Code § 33031." (ABM/52) Under Education

Code section 33031, CDE's rulemaking authority extends to "adopt[ing] rules and regulations not inconsistent with the laws of this state ... for the government of the ... elementary schools ... [and] secondary schools ... of the state." Authorizing unlicensed school personnel to administer insulin to students with diabetes under Education Code section 49423 does not expand or contract or affect in any way CDE's rulemaking authority. The fundamental question in this case has nothing to do with CDE's rulemaking authority, but everything to do with the meaning and interplay of Education Code section 49423, the NPA, and Section 504, the Americans with Disabilities Act, and the IDEA.

Fifth, according to the Nurses Associations, to allow unlicensed school personnel to administer insulin to students with diabetes would be "bad law" because it would supposedly allow Section 504, the Americans with Disabilities Act, and the IDEA to " 'trump[ ]' state health care licensing laws." (ABM/52) For federal law to trump state law, however, is the necessary and proper consequence of preemption. In *Crowder*, the Hawaii quarantine law had to yield to the Americans with Disabilities Act, notwithstanding the importance of the law as a health-and-safety measure, because of the right granted to visually-impaired persons to enjoy the benefit of state services and to use guide dogs to do so. California health care licensing laws would similarly have to yield to Section 504, the Americans with Disabilities Act, and the IDEA, notwithstanding the importance of these laws as health-and-safety measures, because of the right granted to students with diabetes to a free appropriate public education, with the

complementary right to health care services, including the administration of insulin, at no cost.

Sixth, according to the Nurses Associations, to authorize unlicensed school personnel to administer insulin to students with diabetes would be "bad policy" because it would supposedly "lower the standard of care" for such students. (ABM/49-50) Hardly. It would increase the chances that these students would actually receive the care that they need in accordance with the specific written orders of their physician, rather than none at all, in the face of the severe shortage of school nurses and the inability of other licensed person to fill the gap. The care that these students would receive would not be deficient. As stated, unlicensed school personnel can be trained to administer insulin safely, joining the innumerable other unlicensed persons who do so innumerable times every day.

Seventh, according to the Nurses Associations, to allow unlicensed school personnel to administer insulin to students with diabetes would be "bad policy" because it would supposedly "[r]adically expand[ ] the responsibilities of unlicensed school personnel to provide health care services," including performing "traditional medical functions" and engaging in "psychotherapy" and "physical therapy." (ABM/50) Although the Nurses Associations purport to discern a "slippery slope" leading from the administration of insulin to, presumably, brain surgery, in truth there is no slope and it is not slippery. The "responsibilities" of unlicensed school personnel do not extend to providing *any* health care services,

including the administration of insulin. Unlicensed school personnel are *authorized* to administer medication to students, including insulin; they are not *required* to do so. There is no basis to speculate that the Legislature would authorize unlicensed school personnel to do more than they could do safely.

E. The Nurses Associations Have Forfeited The Issue Whether The Legal Advisory Is Invalid Under The APA And In Any Event The Issue Is Moot

For the first time, the Nurses Associations request that this Court consider and decide the issue whether the Legal Advisory's unlicensed-school-personnel provision was invalid because it was subject to but not compliant with the APA—or at least that this Court remand the issue to the Court of Appeal for its consideration and decision. (ABM/53-54)

This Court should dismiss the Nurses Associations' request out of hand.

Whether the Legal Advisory's unlicensed-school-personnel provision was invalid under the APA is not one of the issues that has been presented for review; neither is it fairly included in any of the issues that have been so presented.

Generally, this Court declines to consider or decide any issue that has not been presented for review or is not fairly included in one that has been. *See MW Erectors, Inc. v. Niederhauser Ornamental &*

Metal Works Co., Inc., 36 Cal.4th 412, 421 n.4 (2005); *Jimenez v. Super. Ct.*, 29 Cal.4th 473, 481 (2002); *PLCM Group, Inc. v. Drexler*, 22 Cal.4th 1084, 1094 n.3 (2000).

There is no reason for this Court to depart from its practice in this case. The APA issue is not new. The Nurses Associations had vigorously pressed it below. Nevertheless, they elected not to raise it, as they were entitled to, in an answer to ADA's petition for review. Cal. R. Ct. 8.500(a)(2). Indeed, they elected not to submit any answer at all.

Should this Court choose to consider and decide the APA issue nonetheless, it must "give[ ]" ADA "reasonable notice and an opportunity to brief and argue" it. Cal. R. Ct. 8.516(b)(2). ADA stands ready to avail itself of any such opportunity.

When all is said and done, however, it turns out that there is no practical reason for this Court to consider and decide the APA issue itself—or even to remand the issue to the Court of Appeal for its consideration and decision.

That is because, however this Court may decide the issues presented for review, its decision will moot the APA issue. *See Environmental Coalition of Orange County, Inc. v. Local Agency Formation Com.*, 110 Cal.App.3d 164, 170 (1980); *Hixon v. County of Los Angeles*, 38 Cal.App.3d 370, 378 (1974).

Assume that this Court were to end up agreeing with ADA and hold that Education Code section 49423 authorizes, and the NPA does not prohibit, unlicensed school personnel to administer insulin to students with diabetes, or that any such prohibition would be preempted by Section 504, the Americans with Disabilities Act, and the IDEA, at least when a school nurse or other licensed person is unavailable. On that assumption, the validity or invalidity of the Legal Advisory's unlicensed-school-personnel provision would prove to be " without practical effect' " because the provision itself would be without practical effect. *Environmental Coalition of Orange County*, 110 Cal.App.3d at 170. State and federal law would be as they were and, as such, would be controlling. If state law or federal law or both authorized unlicensed school personnel to administer insulin, what would it matter if the provision in question said the same thing?

In contrast, assume that this Court were to end up agreeing with the Nurses Associations and hold that Education Code section 49423 does not authorize, and that the NPA prohibits, unlicensed school personnel to administer insulin to students with diabetes and that such a prohibition is not preempted by Section 504, the Americans with Disabilities Act, and the IDEA, even when a school nurse or other licensed person is unavailable. On that assumption too, the validity or invalidity of the Legal Advisory's unlicensed-school-personnel provision would prove to be without practical effect because the provision itself would be without practical effect. Here too, state and federal law would be as they were and, as such, would be controlling.

If state law prohibited unlicensed school personnel from administering insulin, and federal law did not authorize them to do so, what would it matter if the provision in question said something different?

III. CONCLUSION

The Nurses Associations claim that the NPA prohibits unlicensed school personnel from administering any medication to any student who needs it, whether cough syrup or eye drops—or insulin in the case of a student with diabetes—and that Education Code section 49423 does not authorize them to do so. At the same time, they admit that unlicensed persons *other than school personnel* are allowed to administer medication without limitation. Such a result would be nonsensical.

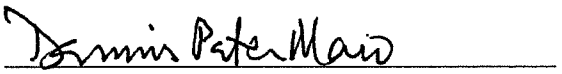
The Nurses Associations also claim that Section 504, the Americans with Disabilities Act, and the IDEA tolerate this nonsensical result for students with diabetes. They state that, under these federal statutes, it is altogether proper for a school district *not* to administer insulin, which such students need to remain safe and to benefit from the free appropriate public education to which they are entitled, if a school nurse or other licensed person is absent, even if an unlicensed school employee is ready, willing, and able to step into his or her place. Such a result would be intolerable.

To prevent such a nonsensical and intolerable result, this Court should reverse the judgment of the Court of Appeal with directions to reverse the judgment of the superior court.

DATED: April 11, 2011.

DISABILITY RIGHTS EDUCATION AND DEFENSE FUND, INC.

REED SMITH LLP

By 
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WORD COUNT CERTIFICATE

This Reply Brief on the Merits contains 12,458 words (including footnotes, but excluding cover, tables and this certificate). In preparing this certificate, I have relied on the word count generated by Microsoft Office Word 2003.

Executed on April 11, 2011, at San Francisco, California.

Dennis Peter Maio

PROOF OF SERVICE

American Nurses Association et al. v. O'Connell et al.,
Cal. Sup. Ct. No. S184583
(Cal. App. 3 No. C061150; Sacto. Super. Ct. 07AS04631)

I am a resident of the State of California, over the age of eighteen years, and not a party to the within action. I am employed in the office of a member of the bar of this court at whose direction the service was made. My business address is REED SMITH LLP, 101 Second Street, Suite 1800, San Francisco, CA 94105. On April 11, 2011, I served the following document(s) by the method indicated below:

REPLY BRIEF ON THE MERITS

☒ by placing the document(s) listed above in a sealed envelope with postage thereon fully prepaid, in the United States mail at San Francisco, California, addressed as set forth below. I am readily familiar with the firm's practice of collection and processing of correspondence for mailing. Under that practice, it would be deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if the postal cancellation date or postage meter date is more than one day after the date of deposit for mailing in this Declaration.

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I declare under penalty of perjury under the laws of the State of California that the above is true and correct. Executed on April 11, 2011, at San Francisco, California.

Myra R. Taylor

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