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- I, Francine Kaufman, declare as follows:
- I am a physician licensed in the state of California and specialize in the treatment of children with diabetes. I am an endocrinologist and have been practicing as a pediatric endocrinologist since 1980. I make this declaration in support of Intervenor American Diabetes Association's Opposition to Plaintiffs' Petition For Writ Of Mandate And Complaint For Declaratory And Injunctive Relief. For the reasons stated in this declaration I have personal knowledge of its contents and if called as a witness in this matter I could and would competently testify to each of these facts. Each of these statements is based upon my background, training and experience as detailed below, and each is stated to a reasonable degree of medical and scientific certainty.
- 2. I am board certified in pediatric endocrinology and metabolism. I am currently the director of the Comprehensive Childhood Diabetes Center, and head of the Center for Endocrinology, Diabetes and Metabolism at Childrens Hospital Los Angeles. I am a Distinguished Professor of Pediatrics and Communications at the Keck School of Medicine and the Annenberg School of Communications of the University of Southern California. I have published more than 120 peer-reviewed publications, as well as more than 230 articles and abstracts, and am the author of more than 30 books or book chapters. I have been active on various committees of the National Institutes of Health, and have been a leader or principal investigator on a number of government funded studies on the prevention and treatment of diabetes. I am the incoming chair of the National Diabetes Education Program (NDEP) and an author of the NDEP publication Helping the Student with Diabetes Succeed: A Guide for School Personnel,. I am also a member of the Institute of Medicine of the National Academy of Sciences. A summary of my background, training and experience is attached as Exhibit A.
- 3. I am a member and former president of the American Diabetes Association. The Association is the nation's leading voluntary health organization working to cure diabetes and to improve the lives of people with diabetes. The Association publishes journals and position statements related to diabetes care that are widely respected in the diabetes community.

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- 4. My center currently has approximately 2200 children from the ages of newborn to 25 years as patients. Of these approximately 1900 have type 1 diabetes and 300 have type 2 diabetes.
- 5. Diabetes is a non-curable, serious, and chronic disease that prevents the body from properly using food for energy. The human body uses glucose (a form of sugar) from food to produce energy. In someone without diabetes, a sufficient amount of the hormone insulin is produced by the pancreas. Insulin is used to move glucose from the bloodstream into body cells where the glucose is needed to provide energy. Without insulin, cells cannot get the energy they need for life and the body literally starves to death. In people with diabetes, either the pancreas does not make enough insulin or the body cannot use insulin properly.
- 6. There are two main types of diabetes in children, type 1 and type 2. Type 1 diabetes (formerly called insulin-dependent diabetes or juvenile diabetes) is an autoimmune disease in which the body destroys insulin-producing beta cells in the pancreas. As a result of this destruction, the body produces very little or no insulin. Type 2 diabetes (formerly called non-insulin dependent diabetes or adult-onset diabetes) results when the body cannot make sufficient amounts of insulin or properly use insulin. Typically, the development of type 2 diabetes begins with the onset of insulin resistance, a condition in which the body produces insulin but no longer uses it as effectively, and so needs more insulin to meet its energy needs.
- 7. Without the ability to produce or properly use insulin, the body's main energy source—glucose—cannot be used as fuel. Rather, glucose builds up in the bloodstream, causing severe and possibly fatal consequences. Thus deprived of energy, a person with type 1 diabetes who does not receive insulin will die within a matter of days to months; in fact, this is what happened to all people with type 1 diabetes before the first insulin injections became available in 1921. Children and adults with type 1 diabetes must receive insulin through either injections or an insulin pump. People with type 2 diabetes may be able to control their disease through diet and exercise alone or may require oral medications and/or insulin injections. However, because often my patients with type 2 and their families do not recognize that they have diabetes until they have had the disease for a significant period of time and because type 2 diabetes in children may be associated with more

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severe insulin secretory defects, approximately 40% of my patients with type 2 diabetes initially use insulin.

- 8. Insulin injections can be given either through a syringe or using an insulin pen (a device which delivers a predetermined amount of insulin stored in a cartridge). Insulin injections are given subcutaneously (just under the skin). Insulin does not need to be given through intravenous or intramuscular injection in routine diabetes care.
- 9. Even when a person with diabetes gets the insulin he or she needs to survive, long-term risks remain. The buildup of glucose in the blood not only deprives the body's cells of energy, it also itself can damage body systems. Over many years, high blood glucose levels can cause damage to the eyes, kidneys, nerves, heart, blood vessels and other body systems. The primary goal of diabetes management is to keep blood glucose levels as close to target levels as possible in order to prevent or delay the development of these long term complications. Advancements in the science and management of diabetes have made great strides in the ability to keep blood glucose within that safe range. These advances include blood glucose meters to allow self-testing of blood glucose levels, different types of insulin to allow more precise responses to fluctuations in blood glucose, and advanced insulin delivery systems such as insulin pumps.
- 10. Measurements of blood glucose levels are taken by a finger-stick blood glucose test, in which the finger is pricked with a lancet (needle) and a drop of blood is obtained and placed on a test strip. The test strip is then read by a blood glucose meter, which measures the blood glucose level. Recently, continuous glucose monitoring has become available. A person with diabetes wears a small catheter under their skin that continually measures the glucose content and relays the information to the insulin pump screen or a hand-held device. A person using this device must also check blood glucose through a finger-stick blood glucose test.
- 11. The Diabetes Control and Complications Trial (DCCT), a large-scale, rigorous and groundbreaking study of long-term diabetes care, showed a significant link between blood glucose control and the later development of diabetes complications, with improved glycemic control decreasing the risk of these complications. Since that time, the treatment regimen for many individuals with diabetes has focused on keeping blood glucose levels as close to the target range as

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possible through frequent blood glucose testing and insulin injections in order to minimize long term complications. The precise plan for managing blood glucose levels will vary based on the individual needs of the child, but for most children monitoring blood glucose levels frequently, monitoring the timing and content of meals and snacks, and taking insulin and/or other medications will be critical elements of this regimen.

- 12. The consequences of failing to control blood glucose levels through insulin administration or other appropriate therapies can be severe. Common complications of diabetes include cardiovascular disease caused by atherosclerosis (excess buildup on the inner wall of a large blood vessel, restricting the flow of blood), vision loss or blindness due to diabetic retinopathy, kidney disease due to diabetic nephropathy (often leading to end-stage renal disease or kidney failure), and neuropathy (damage to the nervous system causing numbness, pain or muscle weakness in the extremities or other symptoms).
- 13. Because maintaining tight control of blood glucose levels significantly lowers the risk of long-term complications, most children with diabetes today are most appropriately treated through a regimen which promotes tight control through multiple (often 4-6) insulin administrations per day and more frequent blood glucose monitoring. These more frequent insulin administration schedules generally require that insulin be given during school hours.
- 14. A common insulin regimen today is known as a "basal/bolus" regimen. When a person is on this kind of regimen, he or she maintains a relatively constant low level of insulin in the blood, either through injections of a long-acting type of insulin or through an insulin pump. This constant lower level of insulin is known as the basal rate. In addition, the person will take extra insulin (typically a rapid acting insulin) during the day in doses known as "boluses", typically given just before meals when the need for insulin is expected to rise and calculated to cover the anticipated amount of food. Additional doses of insulin are needed to treat abnormally high blood glucose levels, since all students, no matter how carefully their diabetes is managed, will experience high blood glucose levels from time to time. These are typically referred to as "correction doses", and can happen at unscheduled times at any time during the day.

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- 15. Some children with diabetes use an insulin pump. There are two types of insulin pumps – the pager type which is attached to the body with a catheter and the catheter is connected to the pump through tubing, and the pod type – that sits directly on the body and has a catheter inserted through the skin. Insulin pumps are electronic devices that send a variable preprogrammed amount of insulin into the body, known as the variable basal rates. In addition, the pump can be programmed to deliver bolus doses of insulin; bolus doses are given for meals and corrections of high blood glucose levels. The bolus dose must be given by the patient or, in the case of a child who is not yet able to perform this function, a caregiver such as a family member, babysitter or school personnel. Generally, a rapid-acting insulin is used in the pump. Because of this, any disruption in the flow of insulin for whatever reason -- from an empty reservoir to a kinked line to low batteries -- can cause blood glucose levels to quickly rise to what might become dangerously high levels. Children who use an insulin pump may require insulin injections and/or adult assistance if the pump malfunctions or problems develop.
- 16. In people who do not have diabetes, the body naturally regulates the amount of insulin present in the blood so that the blood glucose level remains almost constant. However, a person with diabetes who receives insulin through a syringe or pump cannot naturally regulate the amount of insulin or the amount of glucose in the blood in the same way. Therefore, people with diabetes who use insulin are subject to both high and low blood glucose levels.
- 17. Low blood glucose (hypoglycemia) is the most common short term health risk for students with diabetes. It occurs when the body gets too much insulin, too little food, a delayed meal, or more than the usual amount of exercise. Low blood glucose can also occur with illnesses, particularly those that affect oral intake. Symptoms of mild to moderate hypoglycemia include tremors, sweating, light-headedness, irritability, confusion, difficulty concentrating and learning, drowsiness, hunger, shakiness, weakness, paleness, anxiety, dizziness, headaches, poor coordination, blurry vision, weakness, and slurred speech,. A student with this degree of hypoglycemia will need to ingest carbohydrates promptly and may require immediate assistance from another person. Severe hypoglycemia, which can develop if more moderate hypoglycemia is /////

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not promptly and effectively treated, may lead to unconsciousness and convulsions and can be lifethreatening if not treated promptly.

- 18. When severe hypoglycemia causing seizures or loss of consciousness does occur, it is a medical emergency and must be immediately treated to prevent brain damage or death. Such a person will be unable to swallow and thus cannot take in glucose through food or liquids. The proper treatment in this circumstance is to immediately administer an injection of glucagon and to call 911. Glucagon is a hormone that raises blood glucose levels by causing the release of glycogen (a form of stored carbohydrate) from the liver. Because of the life-threatening nature of severe hypoglycemia, any delay in administering glucagon puts the student's health at unnecessary risk.
- 19. High blood glucose (hyperglycemia) is another complication of diabetes in children. Hyperglycemia occurs when the body gets too little insulin, too much food, or too little exercise; it may also be caused by stress or an illness such as a cold, the flu or something more serious. The symptoms of mild to moderate hyperglycemia are increased thirst, frequent urination, nausea, blurry vision, fatigue, hunger, stomach pain, flushed skin, inability to concentrate, dry mouth, and vomiting. Even mild hyperglycemia can cause a child to have difficulty concentrating and learning, because of the effect that it can have on brain functioning and cognitive ability. Thus, a student who is experiencing hyperglycemia and cannot get needed insulin on time will likely have difficulty learning and participating in educational activities until insulin can be administered and blood glucose levels return to the appropriate range.
- 20. In addition, if untreated over a period of time (usually several days but sometimes as little as a few hours), hyperglycemia can cause a serious condition called diabetic ketoacidosis (DKA), which is characterized by nausea, vomiting, labored breathing, weakness, confusion, possible unconsciousness and a high level of ketones in the blood and urine. DKA is a medical emergency and can result in death if not properly treated. For students using insulin pumps, lack of insulin supply may lead to DKA more rapidly. DKA can be life-threatening and thus requires immediate medical attention. Normally DKA will not occur if blood glucose levels are /////

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regularly monitored and milder forms of hyperglycemia are treated, since DKA is preceded by a period of higher-than-normal blood glucose levels.

- 21. Many children, particularly older children, are experienced in managing the disease and are able to give themselves insulin and perform other routine diabetes care tasks without assistance or supervision. However, other children may need supervision in administering insulin, and some may not be able to do so at all. Many of the children needing assistance are young, but even older children may require assistance or supervision, particularly for a period right after diagnosis and until adjustment to the disease has been made. For some children, their cognitive abilities, motor coordination and/or maturity level may make self-management inappropriate. Also, all children with diabetes will require assistance with diabetes care in emergency situations.
- 22. When there are symptoms of hyperglycemia or hypoglycemia, it is important for the blood glucose level to be measured and treatment provided quickly. In particular, when insulin is needed, it must be given as quickly as possible. The more quickly a student (or an adult providing assistance to a student) can learn the blood glucose level and implement the needed treatment, the more quickly the student can return to normal and active participation in the learning process and avoid severe health consequences.
- 23. At a minimum, effective and safe diabetes care for most students would require that someone be trained and available on site to provide needed care whenever the student is at school, at lunch, on a field trip, participating in extracurricular activities, or being transported in a school vehicle. This includes providing or supervising insulin administration for those who cannot self-manage that part of their treatment regimen. It is safe and generally preferable for diabetes care tasks to take place in the classroom or wherever the student happens to be as part of school activities.
- 24. Delaying or missing a dose of insulin will cause blood glucose levels to be higher than necessary and will put the child at risk for both short-term and long term health problems, as discussed earlier. It is important that insulin be administered to children receiving multiple daily insulin injections at the prescribed time to avoid putting the child in immediate danger and increasing the risk of long-term complications. For example, many children are

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supposed to receive a "bolus" of insulin just before eating or right after eating, to cover the increased need for insulin that will be caused by the food to be eaten. Giving the dose of insulin at some other point in the day will cause blood glucose levels to be too high during and immediately after lunch, when the insulin is needed, and perhaps dangerously low at other points in the day.

- 25. For students who use insulin, the timing, amount and content of food eaten need to be carefully matched to the action of the insulin the student takes. The timing of a lunchtime bolus dose of insulin is particularly important because it must be coordinated with the timing of lunch and amount of food that the child eats. It is best for children who need a lunch bolus to take insulin a short time before lunch, so that the insulin will reach its peak effectiveness at the right time. However, it is sometimes necessary to have insulin administered to a child after eating, particularly where the child does not consistently eat all his or her food and so the amount of carbohydrates consumed cannot be estimated in advance. In either case, consistent timing of the dose is very important. Because insulin given as a bolus dose is rapid acting insulin, a dose given thirty minutes prior to lunch will not have the same effect as a dose given five minutes prior to eating, or one given after lunch. Insulin given too early can lead to dangerous hypoglycemia. Insulin boluses may also be needed when food is consumed at other times during the school day, such as for snacks or class parties or celebrations; here too, administering insulin on time is critical. Delays in insulin administration of even a few minutes beyond the intended time or administering insulin at inconsistent times from day to day (as often happens when a nurse or other individual must be summoned from an off site location to administer the insulin) impedes proper diabetes management and results in unnecessary hypoglycemia or hyperglycemia.
- 26. It is critical that the physician's orders regarding the student's treatment regimen be followed while the student is at school. These orders represent the treating physician's medical judgment about what treatment is appropriate and necessary for the student, and failing to follow these orders puts the student in danger.
- 27. The child's treating physician and health care team should provide detailed specifications to the school as to what insulin dosage is proper under different circumstances. For example, in my practice I provide individualized information (in the form of a written health care

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plan) for each child showing the doses of insulin to be taken at regular intervals as well as dosages needed to treat given blood glucose levels that are outside the child's target range. My staff is also generally available to assist parents and school personnel with questions about the diabetes care of the child. While many parents have the knowledge necessary to make minor dosage adjustments for their child (within broad parameters established by the treating physician), and some older and more mature children can make dosage adjustments themselves, it is not necessary for school personnel to decide independently how much insulin is needed in a given situation. Rather they simply follow the instructions that I, like all the other health care personnel caring for children with diabetes, provide. This is true whether a nurse or other health care professional is administering the insulin or whether administration is being done by a trained non-medical school employee. In either case, I want the person administering the insulin to follow my medical orders, not to make an independent judgment about how much insulin is needed or when it should be administered.

- 28. Based upon my background, training and experience with patients as well as with those who care for them it is my opinion to a reasonable degree of medical and scientific certainty that non-medical personnel can be and routinely are trained to administer diabetes medications, including insulin. In my experience, parents, family members, friends, and school personnel can be trained to safely administer insulin. In my practice, parents and family members of children newly diagnosed with diabetes are routinely and successfully trained to administer insulin within hours to days of diagnosis. Parents and family members also train others (such as friends or babysitters) to administer insulin, and I approve of this practice. Non-medical personnel can be trained to administer insulin through any method (syringe, insulin pen, or insulin pump) and can also safely supervise a child who is actually giving the dose to ensure that the proper dose is given.
- 29. Based upon my background, training and experience with patients as well as with those who care for them it is my opinion to a reasonable degree of medical and scientific certainty that non-medical personnel can, and routinely do, safely administer insulin to children. The technical aspects of delivering a dose of insulin are very easy to learn. I am not aware of any 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. Although it is

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possible for an incorrect dose to be given by anyone, blood glucose levels that are too high or too low as a result of an incorrect dose can be corrected with follow up care, such as giving an additional dose of insulin or providing a snack. In my professional opinion, administering a prescribed insulin dose based on detailed instructions from a child's treating physician, such as a scale relating carbohydrate counts or blood glucose levels to the number of insulin units to be given, does not require substantial scientific knowledge or technical skill. The vast majority of family members we train to administer insulin, as well as the children who learn to self-administer, are not licensed health care professionals, nor do they possess substantial scientific knowledge or technical skill. Some children as young as 10 to 11 years of age are trained to take on the full responsibility of self-administration, including calculating the proper dose and giving the insulin. There are two distinct steps involved in administering insulin: assessing the correct dose to be given at a particular time and actually giving that dose (either by injection, using an insulin pen, or pressing buttons on an insulin pump). Technically dispensing the dose does not require any specialized knowledge or skill, as this involves simply performing an injection or pressing a button. Young children are routinely taught to give themselves injections of insulin or operate their pumps, even before they have sufficient mathematical skills or maturity to determine the proper dose. There is no realistic danger of harming the child by performing the injection improperly, and training on how to give injections is simple and routinely given.

30. Likewise, determining the proper dose to be given is straightforward when the decision is based on the detailed treatment orders of the child's treating physician. While establishing insulin regimens (including the dosage to be taken in response to various blood glucose levels and carbohydrate intake) would require the skill of a health care professional, this is not what school personnel are asked to do. At school, the dosage to be given in each situation will be calculated and specified in the treating physician's orders. Non-licensed school personnel would simply need to measure the student's blood glucose level and/or calculate the amount of carbohydrates to be compensated for, and refer to the physician's orders for the proper dose. No more assessment of the student's condition than this is required. In my opinion, laypeople can, without a medical license, safely give an insulin injection under specified conditions provided by the

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treating physician or parent. Insulin delivery methods have been developed to make it as easy as possible for those without medical training to administer insulin. In fact, in the vast majority of circumstances those administering, be they parents or people with diabetes themselves, will not have medical training.

- 31. There are no involved processes required to give a dose of insulin by syringe, pen or pump. The person giving the insulin does not need to conduct a nursing assessment or any detailed assessment of the child's physical condition. All that is required is following the orders to arrive at the amount of insulin needed to correct the blood glucose level – if required – and the amount needed to cover the amount of carbohydrate in the meal. The amount of carbohydrate is either given on a label on the food brought from school or on the menu of the food purchased in school. That amount is drawn in the syringe – again a procedure that most 10 year old children can do, dialed in the insulin pen – a procedure that most 7 year olds can do, or dialed in the pump – a procedure that 6 year old children can do. For injections, the skin is cleansed with a swab of alcohol – the children do this themselves, and the dose is given. The places insulin can be given on the body are universal, and the selection and cleaning of an injection site are routine tasks that do not require technical skill. For a pump a button is pressed. That is the whole procedure.
- 32. Based upon my review of the declarations filed by Plaintiffs here, it is my understanding that plaintiffs in this lawsuit claim that it is not appropriate for unlicensed personnel to administer insulin at school in part because they are not permitted to administer insulin in hospitals. However, based upon my background, training and experience detailed above it is my professional opinion to a reasonable degree of medical and scientific certainty that the safety and appropriateness of administration by unlicensed school personnel is not affected by the practices in hospitals.
- 33. The bases for these opinions are: There are several key differences between hospitals and schools which render those concerns that might lead to requiring nurses to give insulin in the hospital setting inapplicable in the school context. First, patients in hospitals are by definition sick, and for this reason are often more sensitive to variations in insulin dosage than people with diabetes generally, and their insulin needs are universally unstable. Moreover, in a hospital, many

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different individuals on multiple shifts are likely to be involved in the care of a particular patient, rendering it more difficult for one unlicensed person to become familiar with the specific needs of a particular patient. In contrast, those giving care in the school setting are more likely to be familiar with the student's condition and treatment regimen, and are therefore much less likely to give an incorrect insulin dose (as they give the same or similar doses to that student every day). Also, the principle underlying diabetes care in the school setting is that each student with diabetes has a plan describing the kind of care needed, including precise dose information. Those administering insulin at school become familiar with the plan in advance, and have the opportunity to clarify with the treating physician or the family any parts of the plan that are unclear or confusing, before the insulin regimen is implemented.

- 34. It is also my opinion to a reasonable degree of medical and scientific certainty based upon my background, training and experience detailed above that it is appropriate for diabetes care to be provided by a school nurse where the nurse can provide that care in a way that minimizes disruption to the student in the school environment. However, in my experience, very few schools that my patients attend have a full time school nurse. Where a nurse is not on site, it is inappropriate to delay or refuse to provide insulin when a child needs it, as this may put the child's short term and long term health at risk. In this situation, the only way to provide adequate diabetes care is to have trained personnel on site who can administer insulin in a timely manner. In my professional opinion, it is better and safer to have trained non-licensed school personnel administer insulin to students than to subject those students to delays in insulin administration or missed doses while a nurse is found or summoned. I also note that schools routinely allow unlicensed siblings, friends of the family, grandparents, baby sitters, and parents to come to school to give insulin injections, thus it is clear that whether or not the person is licensed is not determinative with regard to student safety.
- 35. Even where a full time school nurse is available, care must be provided during field trips, extracurricular activities and at other times when the school nurse is not present on site. Therefore, merely having one school nurse present at a school, even full time, is not sufficient to provide adequate care.

36. I am aware from my	experience in treating patients that there are widespread
problems with the diabetes care being prov	vided in California schools. Based upon my experience
with my patients and their parents/guardian	ns I am aware that many schools currently are not
following physician's orders. When school	ols do not follow treating physician recommendations (by,
for example, failing to provide for needed	administration of insulin) students are being put at risk for
serious complications. I am aware of pare	nts who have requested that their child's treatment
regimen be changed, not because of the mo	edical needs of the child, but because of the refusal of
school personnel to administer insulin. I a	m also aware of parents being prevented from working
because of the burden placed on them to be	e constantly "on call" to administer insulin during the
school day. I am aware of students whose	health has been harmed because they did not receive
adequate diabetes care at school.	
I declare under penalty of perjury to	under the laws of the State of California that the foregoing
is true and correct.	
Executed on	008 at, California
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	Francine Kaufman, M.D.
	Francine Rauman, W.D.
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