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“Mommy, my head hurts.”

That’s how it all started. Alex, whose nickname was Smiles, never complained. If he said his head hurt then it must really hurt, and it was hurting every single day. Four weeks and three doctors later, a simple blood test immediately revealed everything. Alex was having headaches because his red blood cell count was depleted so his brain swelled and hurt from hypoxia (low oxygen saturation). The simple test also revealed Alex had insufficient normal white blood cells, replaced by a population of BLAST cells (leukemic cancer cells). Alex would become the boy in the plastic bubble but without the bubble. The bruises we thought were from playing soccer were from Alex’s lack of platelets.

Alex’s bone marrow was no longer producing healthy red blood cells, white blood cells or platelets. It was producing cancer cells. Although he appeared healthy, he was in an extremely fragile state and had to be hospitalized immediately. The pediatrician called to notify us of the blood test results and to tell us to immediately travel to Savannah, Ga (an hour away) to the children’s hospital where a team would be waiting for us. When we arrived, the childhood cancer rollercoaster ride began. Alex immediately received a blood transfusion and, within minutes of arriving, we were told that our 9-year old son had cancer - AML (Acute Myeloid Leukemia), a very aggressive form of Leukemia. We were advised that he was too fragile and unstable to move anywhere for a second opinion and no visitors other than parents were permitted – not even his siblings.

How was this possible? He looked great. He was at school the day before, running around with his friends. A clinical trial composed of a combination of old adult drugs was the best treatment option they had for Alex. Through the Children’s Oncology Group network, Alex was essentially being cared for by all the doctors in the network. We had the head of Pediatric Oncology in Atlanta, the leading expert in AML in the country, consulting on Alex’s case. Despite those overwhelming resources, Alex’s care was incredibly inferior to the care and treatment for the average adult with cancer.

The doctors and nurses struggled to save Alex throughout his 14-month ordeal, but the total lack of child specific treatment options forced doctors to treat Alex as a small adult. Within 48 hours after he was finally declared cancer free, Alex died at age 10 from the toxic effects of the drugs. In the final months, Alex experienced life threatening side effects, including cardiac arrest, pulmonary failure, and kidney failure. His quality of life was greatly diminished and he was in constant pain. Blood transfusions were part of Alex’s daily routine, as was some type of organ failure or a life threatening infection. Each day brought new health challenges for Alex. Every moment and every breath was a struggle.

The state of childhood cancer is not what most people perceive it to be. Anyone who has seen a child fight cancer is forever changed. Alex’s struggle is commonplace in the world of childhood cancer. Children with cancer are cared for by experienced pediatric oncologists and pediatric oncology nurses, but the available treatment options are not designed for children. They are *adapted* for children out of necessity. Child-specific drugs are not being developed. The adult drugs being used to treat childhood cancer cause major complications. Adult drugs are adapted for use in children years after the drug has gone through initial development for adults, clinical trials for adults and used on adults for many years. If after that 15+ year process it shows enough promise, then some additional research is conducted to determine dosage for children. Clinical trials then begin on children, attempting to find the ‘sweet spot’, striking a balance

of killing the cancer without killing the child. If a 'sweet spot' can be found, the drug is approved for use in pediatric oncology. Alex was the sixth child to receive his toxic mix of old drugs. The other five children had the same outcome. This outdated system is the best we have to offer our children when they are diagnosed with a life threatening cancer. Kids are not small adults.

The efforts being made to improve outcomes for children with cancer are failing to yield sufficient long term meaningful results. Adult cancer care continues to outpace treatment options for childhood cancer. Hospitals and research facilities are doing the best they can with the limited resources available. Several attempts to legislatively produce results have fallen short, but not for lack of effort or partisanship. The key to successfully treat childhood cancer is still missing. All efforts continue to be focused and/or based on adult cancers hoping to benefit childhood cancer. **Childhood cancer needs to be classified as a separate disease from adult cancer. Only then can the correct questions be asked, creating a path for the right solutions – child specific treatment options and appropriate funding.**

The Truth About Childhood Cancer in the USA

Over 60,000 children are in cancer treatment right now, and over 15,000 more children will be diagnosed each year (*American Cancer Society Facts & Figures 2014*). Childhood cancer represents over 16 cancers with endless subtypes (*American Cancer Society Facts & Figures 2014*) and 'the types of cancers that occur most often in children are different from those seen in adults' (*American Cancer Society, Cancer in Children 2017*). There has been a 35% increase in childhood cancer incidence since 1975 (*SEER program 1975-2012*). Cancer kills more children (57%) than all other diseases combined (*CDC National Vital Statistics Report, 2/16/16*). The average age of children diagnosed with cancer is 6, and 34% of survivors will die by age 36 (*St. Jude Lifetime Cohort Study*). This study also determined two out of three long term survivors will develop chronic health conditions, including reduction in I.Q., reduction in height development, neurologic damage, secondary cancers, cardiac damage, kidney disease, liver disease and infertility. 43% of those conditions will be life threatening or disabling.

Children who are fortunate enough to survive the cancer and treatment have a short and limited future rife with complications. The children who do not survive suffer greatly, not only from the life threatening disease, but also as a result of the toxic treatment. Childhood cancer is not preventable.

Despite these overwhelming odds for saving our children, and improving the quality of life of those we cannot save, lack of funding (public and private sector) and child specific drugs remain serious obstacles. All childhood cancers combined receive only 4% of all federal cancer funding (*NCI 2015 Budget*). The problem is also misunderstood in the private sector. All childhood cancers combined receive only 1% of American Cancer Society funding (*American Cancer Society Facts & Figures 2014*).

Of the 202 cancer drugs approved by the FDA since 1995, only two have been for childhood cancer; yet in the same period, 15 drugs were approved for prostate cancer. Of those precious two childhood cancer drugs, one was approved this year and is only used to treat neuroblastoma, which accounts for 5% of childhood cancers, and it is only useful for some of those patients. (*Centerwatch.com/drug-information/fda-approved-drugs/therapeutic-area/12/oncology*)

A great deal of legislation has been developed to tackle the issue of child specific drugs by encouraging adoption of more adult drugs for children, expediting approvals for drugs used in adults for life threatening pediatric diseases and subsidies to stimulate this process. There have been legislative efforts at increasing funding for childhood cancer. Efforts are there but not the results and solutions.

We know cancer develops differently in children. We know most cancers occurring in children are not seen in the adult population. We know children's bodies react differently to toxic adult drugs. Despite this knowledge, childhood cancer is still classified as a disease in the same category as adult cancer. The federal government classifies childhood cancer no different than any other singular cancer but it is not a singular cancer and is not comparable to adult cancers. Past legislative efforts all recognize the distinction of childhood cancer and considerable effort is placed on attempts to provide better solutions for children with cancer. However, the efforts are all directed toward the world of adult cancers, with no increased funding for childhood cancer, resulting in continued adoption and adaptation of adult drugs being used on children. Increased efforts encourage more of the same, but a little faster. **Childhood cancer must be recognized as a separate disease so all efforts are targeted to being child specific. Without this first fundamental step, efforts will continue to be ineffective or at best, marginally effective.**

Increased funding alone is not the solution. If childhood cancer funding were doubled, treatment options would not be significantly impacted. If childhood cancer is classified as its own disease group, the current funds could be better spent by focusing on child specific options. Lack of funding is a real problem, but childhood cancer needs 100% of its own budget and not 4%, or any percentage, of adult cancer's budget. Scientific breakthroughs occur every day. We are constantly learning more about diseases we thought we understood. Initially, very little was known about cancer and all cancers were classified under a singular cancer classification. A budget was provided and policies were developed. The policies continued to develop as we learned more about each cancer but, under this system a child with cancer would be treated as an adult with cancer. No distinction was made to separate childhood cancers from adult cancers, and all variations of childhood cancer were grouped into one line item, unlike the multiple varieties of adult cancer, further restricting progress for each type of childhood cancer. Despite now knowing how distinct childhood cancer really is and despite acknowledging that child specific drugs are necessary, the classification change has not occurred in the same way it has for all other diseases as we learn more about them.

Disease classification is important and common. For years, the lines were blurred between Alzheimer's and Parkinson's disease. Through research and experience, the medical community learned more and each of those neurological diseases, primarily affecting the elderly, were proven to be distinct with some shared traits and commonalities but requiring their own specific research and treatment. That is when real advances are made. This has yet to occur for childhood cancer.

Until recently autism was entirely dismissed as being a unique disease and children were misdiagnosed, ostracized and untreated. Autism is now classified as its own disease group, and even encompasses an entire spectrum of severity. Asperger's syndrome was originally understood to be a type of autism but was later classified separately. Further research found it to be a type of autism and it is once again classified within the spectrum of autism. The classification and subsequent acknowledgment of autism has progressed disproportionately to childhood cancer's efforts.

Childhood cancer has historically lacked a voice in government and in the general public. Childhood cancer is the silent cancer. The effect of childhood cancer on a family is unlike any adult cancer. Families are destroyed and silenced in the wake of childhood cancer diagnosis, treatment, and especially in the loss of a child to cancer. It leaves a path of destruction unlike any other disease.

The request for childhood cancer classification change is not a request for more funding. Until we change the classification, the true budget needed to combat childhood cancer will remain a mystery and funds will not be spent efficiently. **A classification change will encourage more efficient spending.** The

world of childhood cancer is reactive and based on trial and error, primarily attempting adaptation of adult drugs to treat children.

Childhood cancer classification change will provide the opportunity to focus all efforts, guidelines, budgets and policies from a child-specific perspective. This is the first step in true childhood cancer reform and the key to moving to the next stage in the fight against childhood cancer.

When Alex found out his cancer was back in January 2016, he created *Lambs for Life* to bring comfort to children in cancer treatment by giving every one of them a special care package. Alex said that the lamb, like his lamb (Lamby), could help these children since, as Alex said, 'because it's the lamb of God, it's holy!' We developed this organization last year while Alex was in the hospital for two reasons: to bring 'Lamby Packs' to all children in cancer treatment in the US, and to promote fundamental change to childhood cancer federal policy. After Alex died on April 27, 2016, we sold our business and devoted our lives to developing the organization as Alex envisioned it. We are delivering Lamby Packs to hospitals for kids in treatment, and through strategic partnerships we are launching education programs this fall to reach millions of children throughout the country over the next year. Children in treatment need support and all children need a voice to help the government and public understand the truths about childhood cancer. *Lambs for Life* will support children and work with elected officials and the public to bring the necessary change. We have received the endorsement and support of pediatric oncologists, who in their words are "forced to treat sweet little children as small adults" and from the families who have suffered through this journey of hell on earth.

Neither legislation nor the medical community can stop childhood cancer from occurring. Childhood cancer is neither preventable nor detectable in early stages unless by symptomatic accident. Legislation and the medical community can however provide the tools to better care for our children in cancer treatment so survivors can hope to live longer than their mid-thirties and lead more productive lives without the lifelong health complications and other cancers resulting from the toxic side effects of adult drugs. We will also be able to better care for the sweet children like Alex with very aggressive cancers, enabling them to have a more dignified experience while in treatment, free of the extreme constant pain and discomfort associated with tougher childhood cancers.

Our children deserve the best effort we can possibly give them. As parents, our primary purpose for living is to help our children live a healthy and happy life. For government, a primary goal is to give our children a better future. Without their health, our children cannot enjoy the freedoms this amazing country provides us. The United States of America is the greatest country in the world and the leader in most medical breakthroughs. **Changing the classification of childhood cancer is a policy decision that will provide the single most impactful change to childhood cancer in the history of cancer. You have an opportunity to change the entire world of childhood cancer.**

Simply put, we owe it to our children to give them a shot at the future they deserve. This is something we can do, must do and most importantly, should do.

Thank you for your consideration and support.