Saved Josh: The gears of a successful patient advocacy campaign

CASE STUDY

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“Where there’s a will, there’s a way.”
-- Aimee Hardy

By March 2014, it was hard to recognize Joshua Hardy. The pale, thin, and weak second-grader from Fredericksburg, Virginia, did not resemble the healthy, smiley boy portrayed in photos wearing army fatigues or a football jersey, and lovingly described by his family as the loudest kid you’ve ever met. In January, seven-year-old Josh had received a bone marrow transplant. A post-transplant adenovirus was attacking his vital organs, and every day, despite excellent medical care and his family’s prayers, Josh was getting worse.

While the adenovirus is endemic in children, it frequently causes severe disease in patients whose immune system is compromised, such as bone marrow transplant recipients. When infection spreads, mortality rates are as high as 60%. Until recently, serious adenovirus infections could only be managed by treating symptoms and complications. The only antiviral treatment options approved to treat adenovirus infection have serious side effects, most often negatively affecting kidneys. Despite being treated with the best available drugs, Josh’s kidneys, lungs, and heart were failing, and he was put on dialysis. His doctors and parents watched helplessly as his viral load numbers kept climbing up, a sign that infection was worsening. He developed gastrointestinal bleeding. The standard treatment protocol was failing. Josh was dying.

Josh’s battles

Aimee Hardy, an insurance agent, and Todd Hardy, a real estate construction business owner, were delighted when Josh was born on March 31, 2006, joining brothers Jack and Joe.

When Josh was nine months old, he was diagnosed with malignant rhabdoid kidney tumors, an aggressive and lethal cancer. The average survival rate for this kind of tumor is only 20-25%, but by September 2007, after 10 rounds of chemotherapy, six days of radiation and surgery, Josh was cancer-free.

The next year, in July 2008, a biopsy revealed the presence of cancer cells in his thymus gland, and Josh received 12 days of radiation therapy and several more rounds of chemotherapy.
The third round of Josh’s battle with cancer began on January 19, 2009, two weeks after his little brother Jude was born. Aimee Hardy, who has kept a journal on the CaringBridge.org website throughout Josh’s ordeal, wrote on that day: “It is with excessive disappointment that I update to you Josh’s scans indicated that there are 3 spots on his lungs. They have scheduled the biopsy for tomorrow at 1 pm. My prayer is that the biopsy shows the spots are benign. Dr. Godder feels they are tumorous. Miracles happen, though.” A week later, on January 26, Aimee posted an update: “Well, we did not get our Miracle this time. The biopsy came back rhabdoid.”

Josh’s doctors put together a complex plan: enroll Josh in a clinical trial at St. Jude Children’s Research Hospital in Memphis, Tennessee, to shrink the tumors. Then go to New York for surgery to remove any remaining cancer, travel to Richmond to harvest his bone marrow, go back to New York for radiation therapy, and finally return to Richmond for high-dose chemo combined with a stem cell transplant using Josh’s harvested bone marrow. “And then we will be done with Cancer treatment forever!!! Or at least that is what we need to pray to happen,” Aimee wrote.

Josh completed his 20th round of radiation on October 14, 2009. “That makes 38 radiation treatments, 24 courses of chemo (and still counting), 3 surgeries and too many hospital stays and clinic visits to count in 34 months. And he is still going strong. He has done beautifully and continues to thrive,” Aimee shared on the CaringBridge.org.

Despite his illness, Josh was a real boy and a fun-loving kid. When Josh is not sick, “you hear him a mile away,” says William Burns, Josh’s uncle. Josh played baseball and football all the time. In the breaks between his treatments, Josh and his family enjoyed visiting the Firemen’s Museum, going to the Zoo and watching the ducks, going to baseball games, playing basketball, and eating hamburgers.

Josh attended Hugh Mercer Elementary School in Fredericksburg and bonded well with his teachers. His classmates were very supportive throughout Josh’s illnesses.

In May 2013, he celebrated being cancer-free for two years.

The next setback came in the Fall of 2013. On November 12, Josh was diagnosed with myelodysplastic syndrome (MDS), a form of blood cancer similar to leukemia that is caused by poorly formed or dysfunctional blood cells produced in the bone marrow. It often occurs as a result of chemotherapy and radiation treatments.

To cure his MDS, a bone marrow transplant was needed. The highest rate of success from bone marrow transplantation is achieved through finding a matching human leukocyte antigen (HLA) donor. Siblings are the best match, with each brother or sister having a 25%
chance of matching a patient. However, 70% of patients do not have a match in their family. Josh’s brothers were a match for each other, but not for Josh, and neither were his parents. Burns said that when he saw Josh “on Thanksgiving, he didn’t look good. He was very sick, had no energy, and was very weak.” Josh spent Christmas at home, and on New Year’s Eve was hospitalized at St. Jude Hospital.

On January 10, 2014, Josh received a bone marrow transplant from an unrelated donor. In the last week of January adenovirus was detected in his blood.

Human adenovirus reactivation is a frequent and potentially fatal complication in pediatric allogeneic stem cell transplantation recipients like Josh. Adenovirus infection in post-transplant patients is treated with cidofovir. Although it is highly effective, with one study reporting 98% of patients achieving complete resolution of clinical symptoms, kidney problems – nephrotoxicity – is common. Josh developed renal failure, and the therapy had to be discontinued. Starting that moment, Josh’s life was counted one day at a time.

One of the doctors who worked at St. Jude in the department of Bone Marrow Transplantation & Cellular Therapy, Dr. Ashok Srinivasan, was familiar with Josh’s case. And Dr. Srinivasan was also familiar with a drug that might save his life. From late 2010 through June 2013, Dr. Srinivasan was St. Jude’s principal investigator in the ADV HALT clinical trial sponsored by Chimerix Inc., a small biotech company based in Durham, North Carolina. The Phase 2 trial, involving 52 patients, investigated the safety and efficacy of preemptive treatment with Chimerix’s experimental drug, brincidofovir (CMX001), for the prevention of adenoviral disease in recipients of bone marrow transplants. The study was trying to prevent adenoviral infection, not to treat it. But St. Jude’s doctors wanted to try to treat Josh with this experimental drug because of its promising efficacy in the clinical trial. On February 12, 2014, they contacted Chimerix and asked it to provide brincidofovir to Josh. The request was denied.

Josh’s family learned about the drug from his doctors, and hoped that despite the initial denial they would be able to obtain it in the future if Josh’s condition did not improve.

Wednesday, March 5, 2014

By the first week of March, Josh was in the ICU fighting for his life. He was too weak to sit up, in a lot of pain, and sleeping most of the time. There were days when he was unable to talk to his parents. In an attempt to save him, Dr. Victor Santana, Vice President of Clinical Trials Administration at St. Jude, decided to approach Chimerix again. In a letter to
Chimerix, he stated that after the initial denial of St. Jude’s compassionate use request of brincidofovir for Josh,

“we proceeded to treat him with intravenouscidofovir, but he has developed oliguric dialysis-dependent renal failure. Adenoviral copies are rising with gastrointestinal involvement, and it is likely that after having fought a childhood cancer for so long, he may succumb to this infection without a non-nephrotoxic medication with superior efficacy proven in clinical trials. We respectfully request that given our failed attempts to treat his life-threatening adenoviral infection with the current standard, that you reconsider our request for compassionate use of brincidofovir.”

Compassionate use, which is one form of what the Food and Drug Administration calls “expanded access,” is a program that can make unapproved but promising drugs available to patients with documented serious or immediately life-threatening diseases – if the manufacturer agrees. These investigational drugs have not been proven to be safe and effective. According to the FDA, “the company that makes the drug is not required to offer it outside their clinical trials, and they may not be willing or able to do so. [...] The company may not have enough of the drug available for all patients requesting expanded access. Some companies establish a lottery system to determine which patients will have treatment access. Others make the decision on a case-by-case basis.”

FDA cannot compel a company to provide expanded access to a drug. When a company agrees to compassionate use, it does so voluntarily.

The reply to St. Jude from Chimerix, signed by Vice President for Clinical Research Herve Mommeja-Marin, was brief:

“We appreciate the dire situation of your subject and are sorry to see the lack of response to IV cidofovir. Unfortunately, Chimerix is not in a position to provide drug for this and other subjects in similar circumstances due to a limited inventory and our limited resources.

We wish our response could be different and that, through clinical trials, CMX001 will become available to patients in need.”

Thursday, March 6, 2014

On March 6, Josh was very, very sick, remembers Bill Burns. He and his wife Erin, Todd Hardy’s sister, were on a dinner date in New Jersey, where they live. "We finished eating and had a conversation,” Burns recalls. “I was planning to give notice to leave my job in four
weeks. In the middle of the conversation, Todd called and said how bad it was and that the drug was needed immediately. Todd sounded desperate.”

Burns contacted Lori Boyko, whom he had met on social media a few years earlier while they were both helping with Superstorm Sandy relief. Boyko, a real estate agent who lives in Connecticut, has been involved in disaster relief since the Haiti earthquake in 2010. They had not met in person. When Burns texted her saying he needed help, Boyko thought the request was related to the storm. When she heard about Josh, her first thought was, “I am not a miracle worker. I can’t get the company to release the drug.” Drawing from her disaster relief experience, Boyko advised Burns to create a Facebook page with photos of Josh in health and in sickness: “If it is going to get shared, people need to see the little boy,” she told him. Burns had to convince Aimee and Todd to post the photos. The SaveJoshHardy page on Facebook was born that night.

“We took it on ourselves to reach out,” Aimee said. “By March 6, his [viral] log copies were dangerously high.”

Aimee made a plea on her personal Facebook page: “Please help us save our son. Share this post if you believe a child’s life is more important than money. [...] the company has refused to release the drug for compassionate care because they are trying to take it to market. Basically they are not going to save a child’s life for money. [...] If anyone with influence can help us convince the Chimerix Inc to release the drug for compassionate care for our son, we would be forever grateful. The phone # of Chimerix Inc is [...].”

Burns turned to Twitter: “Josh 7 needs a drug to save his life and the comp will not release Call Chimerix 919-806-1074 & ask 4 release of Brincidofovir #savejosh.” He sent his last tweet of the night at 3:22 am: “Josh is as brave, strong and tough as a Navy Seal he needs an air strike. Fire for effect guys.”

**Friday, March 7, 2014**

Although the Hardy family was desperate, the initial SaveJosh Facebook page post was short: “Josh is 7-year-old son has been battling cancer since he was 9 months old. He recently received a bone marrow transplant at St. Jude’s in Memphis but now is in the ICU with the adenovirus. We are asking the pharmaceutical company Chimerix to provide a compassionate dose of Brincidofovir for Josh.” Next to it, the family posted photos – Josh with his brothers when he was healthy, and Josh without hair, with tubes in his nose, surrounded by his brothers in his hospital bed.
The Hardys contacted friends and relatives asking them for help in getting the drug. Burns tweeted to ABC, NBC, CBS Evening News, the Washington Post, Associated Press, McClatchy Newspapers, other media and friends, and everyone else he could think of.

Chimerix had provided brincidofovir to over 80 medical centers worldwide for the treatment of 430 people under compassionate use starting in 2009, but halted its compassionate use program in 2012, focusing 100% of its resources on clinical trials and getting the drug to the market.

After calling the FDA and learning that the company had to consent to release of the drug, Boyko posted Josh’s story on her own Facebook page, and through a chain of reposts, got some key advice: Get the information to a childhood cancer group, they will know what to do. Boyko sent an email via a Facebook page to People Against Childhood Cancer (PAC2), a grassroots, volunteer-operated organization. Boyko “had no idea who PAC2 was, who was involved, how they could or couldn’t do it. But I asked, could you help us lean on Chimerix?” she remembered.

The email reached Vickie Buenger, who administers the PAC2 page. Buenger, a professor at Texas A&M University, lost an 11-year-old daughter to cancer. She is President of CAC2, the Coalition Against Childhood Cancer, an umbrella organization that aims to unify the childhood cancer community through coordinated action.

“The email was general, discussing Josh’s situation and looking for someone to share this information with,” remembers Buenger. “There is a child at St. Jude, can you help us by sharing this information? Here is a letter from mom, some pictures, could you put it on your website?”

The email reached Buenger in a hotel room in San Antonio, where she was visiting with her husband while he was attending a conference. Luckily, it was the first day of her spring break, and Buenger had free time. “When I got an email from Lori I did a bit of investigating. Has the doctor recommended this treatment? Was it urgent?” she wondered. “As I gathered the information, I made a decision to reach out to people at both CAC2 and PAC2 who might have media contacts, know somebody, or could share this information in any other way. PAC2 has a Facebook page, it is a membership website with five or six thousand members and two to three times as many follow PAC2 on Facebook,” Buenger recalled.

One of the people Buenger reached out to that day was Richard Plotkin, a retired attorney and grandfather of a child cancer survivor. Plotkin serves as Vice Chairman of the Max Cure Foundation which he co-founded with his son David. Max Cure, located in New York, funds and advocates for increase in government funding for childhood cancer research.
“I was supplied with certain documents, correspondence between St. Jude Children’s Hospital, the family and Chimerix, that I thought was very stoic and cold and unsympathetic. I was told that Josh will die within the next week or so if he does not get the drug,” Plotkin said. He does not recall how he got the phone number for CEO of Chimerix Kenneth Moch, but he called him the same day, “just to get a sense for why they are not giving the drug. I got him on the phone, which was a surprise. They were far along in a Phase III trial, and did not have the time or resources to deal with one child. There was no turning back. Josh would not be given the drug,” Plotkin recalls.

Plotkin had never heard of the Hardy family before that day, but he contacted Burns to ask to be put in contact with Josh’s parents. After having recently followed the case of a girl who needed a lung transplant and was put on an adult lung transplant list “through the power of television,” Plotkin wanted to ask Josh’s parents if they would be willing to speak to news media if he could arrange it. Plotkin was thinking of a Max Cure Board member who worked at NBC, Haleigh Raff, and of a long-time supporter of the foundation, Stefanie Weiss, who he knew had media contacts.

“By the evening of March 7 the network was getting pretty wide,” says Buenger. She wrote an email to CNN senior medical correspondent Elizabeth Cohen, whose name she kept on the list of media contacts for her work at CAC2. Cohen responded, asking for the phone number and email for Josh’s parents. Buenger got the information through Boyko and sent it to Cohen by 5 pm. “I was pretty shocked that CNN reacted immediately, contacting the family in one hour,” she said. “At that point, Josh was in the ICU vomiting blood and deteriorating rapidly. Within four to five hours we were corresponding with the family, trying to find out if there were other drugs that could help. It was a multichannel effort, not just pressure on the company.”

The more people got involved, the more Buenger needed “to stop the prospecting role and assume the shepherding role,” so that everyone would be on the same page: Receive clear information from Memphis, share Chimerix’s responses, discuss strategy and ideas. “In a matter of an hour I got connected with Bill [Burns]. I thought that maybe there was a more efficacious drug. I spoke with Richard, who was doing a lot of brainstorming, and with many CAC2 members,” Buenger recalls. She created a list of news organizations who she thought might carry the story about Josh. “Social media was a part of our effort, but on Friday we were concentrating on being articulate and trying to find regular media, like CNN,” she said.

The first news media outlet to report Josh’s story was The Free Lance-Star, a newspaper in Fredericksburg, VA. It published a story about Josh on its Fredericksburg.com website at 9 am on March 7. The story was promoted on Fredericksburg.com’s Facebook page, which has more than 29,000 fans.
Later Moch remembered the events of that day: “Overnight, and intensifying the next morning, the company received hundreds of phone calls and emails pleading for access for Josh. By Friday morning, March 7, several state and national politicians contacted Chimerix’s CEO.”

“It really was a blur,” remembers Aimee. “It was a machine that we started.” Although the hospital provided housing, Aimee slept in Josh’s room, sending emails and posting updates on Facebook and CaringBridge.org from her cellphone.

Saturday, March 8, 2014

The day started with an update on the SaveJosh Facebook page: “Today is Josh’s Day. Though he gets weaker with each passing hour we get stronger and our voices louder. Today we act with singular purpose. Today...Josh lives #savejosh.”

Another letter from Chimerix’s CEO extinguished the ray of hope the Hardy family was nurturing – but not for long.

“My colleagues and I are acutely aware of this situation, and there are no words to express our compassion for what he and his family are going through.

It is situations like these that drive all of us at Chimerix to move as quickly as we can to complete the development of brincidofovir. Chimerix is a small biopharmaceutical company founded 14 years ago specifically to develop brincidofovir. This is our only potential product. We now have just over 50 employees, and we are committed to the discovery and development of new, oral antiviral therapies in areas of high unmet medical need.

Brincidofovir is a new investigational medicine currently being studied in the US in a Phase 3 clinical trial - the last stage of clinical development before a potential approval. Brincidofovir is not FDA approved, and the Phase 3 trial is the required next step. The specific clinical trial, which we call SUPPRESS, is being performed under regulations set forth by FDA to evaluate the safety and efficacy of brincidofovir for the prevention of cytomegalovirus (CMV) in adult patients undergoing allogeneic stem cell transplant. This trial is currently enrolling patients throughout the US.

Five years ago, early in brincidofovir’s clinical development pathway, Chimerix began receiving requests from physicians for the emergency use of brincidofovir, in patients with many different viral infections, and we were able to supply brincidofovir for
relatively small numbers of these requests. The volume of requests accelerated significantly, prompting Chimerix to establish a formal Compassionate Use program.

As our small company progressed to larger and more complex efficacy and safety trials designed to gain FDA approval of brincidofovir, we made the difficult decision two years ago to cease our Compassionate Use program and focus on earning FDA approval. This is the only path to making brincidofovir widely available to those who need it in the fastest manner allowed.

Our limited resources are dedicated to successfully completing the SUPPRESS trial and submitting the safety and efficacy data that would allow for brincidofovir to become available to physicians and patients in the US and, ultimately, around the globe. Each one of us at Chimerix is committed to achieving this goal and thereby enabling access to this potentially life-saving drug.

We continue to receive many requests every week from around the world for this experimental drug. The great need for access to brincidofovir drives our commitment to seeing the Phase 3 trial to its completion and to ultimately providing what we believe is an important new medicine to people in need.

Sincerely,

Kenneth Moch.”

In the morning, Plotkin spoke with Todd Hardy to check if he and Aimee would agree to talk to the media. Todd replied he would do whatever was necessary, and Plotkin reached out to Raff and Weiss, asking for their help in getting the story out. Then he contacted Erica Bailey.

Bailey lives in Chandler, Arizona. She had been working remotely for Max Cure as a social media manager and marketing director for the past 18 months and had built the foundation’s fan base from about 3,000 to 38,000. Plotkin asked Bailey to do what she could “to get the story out about Josh’s need for the drug to save his life.”

It was a pleasant day in Arizona, and Bailey was enjoying an early birthday party in the backyard of her mom’s house in Mesa. “I got a phone call from Richard, asking me to start posting on social media that we need support. I didn’t even have the whole story, but I immediately pulled out my iPhone and put information on Facebook. I thought that at least we would be loud enough to be heard. I didn’t expect it to actually work,” Bailey remembers.

The first post generated 4,000 likes, 8,800 shares and 711 comments, reaching 540,000 people, according to Bailey. In 48 hours, the message reached one million people on
Facebook and 400,000 on Twitter. “During the time I’ve been working for Max Cure I built up the fan base, I knew how to communicate with fans and friends, how they respond, what they respond to. And I knew immediately that I would get great support,” says Bailey.

Bailey did not go to bed for 48 hours straight. “I didn’t shower, didn’t sleep. I have three kids and they were ignored, my husband took care of them. I kept talking to people. We were communicating every half an hour; the maximum break between communications was two hours. We were on Twitter responding to people, reached every bigwig name in America, every news anchor, we were going to other people’s pages. If I wasn’t on the computer, I was on the phone, on Facebook. We were sending messages to Obama, Kardashians, and sending pictures and photos,” she recalls. Bailey also asked people to change their Facebook profile pictures to #SaveJosh, and thousands of people did.

Burns posted on Facebook the text of a letter from Moch. “Rather than mitigating the growing social media pressure, the uncle’s commentary on the letter further inflamed supporters, who then posted the personal contact information of Chimerix’s CEO and board of directors,” Moch remembered.

Meanwhile, Plotkin learned that one of Weiss’s contacts had arranged an interview for Aimee on the Fox & Friends TV program for Monday, March 10th.

Stefanie Weiss, a mental health consultant in New York who appears on Fox News to discuss parenting issues, was at a basketball game with her son when she got an email from David Plotkin, who is Richard’s son and the Chairman of Max Cure. David “emailed me and said I know you speak to the news, this family is in dire need, there is a medicine that can save the boy’s life and there is red tape. We are friends with Dave, he knows I support Max Cure, and I said let me contact some producers.” She emailed two Fox producers, and Kelly McNally got back to her in five minutes saying Fox & Friends wanted to cover the story. “I put them in touch with David and Richard Plotkin by email. It was a domino effect,” Weiss said.

Then Plotkin learned that CNN’s Elizabeth Cohen would interview Aimee on Sunday, March 9th.

That day Regina Breedlove, a relative of Josh, started a Change.org petition. After describing the situation, she wrote: “Josh’s family continues to keep their faith in God and pray for Chimerix to find a way to help or for the virus to go away on its own! Please join us in asking Chimerix to provide compassionate use access to this drug for Josh!” The petition was signed by 17,500 supporters in four days.

A first grade teacher from Josh’s school, Kathryn Obert, started another petition on the WhiteHouse.gov website asking for release of the drug.
In the evening, Aimee wrote: “We didn’t win today but the battle will continue on tomorrow and the next day and the next day. They could have released the drug quietly but they didn’t. So we press on.”

Sunday, March 9

Bailey kept working on the social media campaign. She created a new name for her Twitter followers. “I needed something to say, I thought -- how do I get people engaged? So I thought I would call them Twitter Warriors. A huge part of why people reacted the way they did was that we showed gratitude for their efforts,” she says.

The Fairview Baptist Church in Fredericksburg, which the Hardy family attends, held a special prayer service for Josh on Sunday. Darcy Spencer, an NBC4 Washington television news reporter, interviewed a few of Josh’s classmates and his grandmother, Mae Staton, who fought tears on camera.

During its prime time programming, at 7:40 pm, CNN aired an 8-minute segment about the Hardy family’s efforts to obtain brincidofovir. It was the first national media coverage of Josh’s fight. After anchor Deborah Feyerick’s overview of Josh’s story, Aimee was interviewed live by Cohen. Asked for her thoughts after the drug was denied to Josh, Aimee replied: “It’s just unimaginable that they have what we need and they won’t get it to us. [...] There is no good excuse for us. There is nothing they can say that’ll really keep us from asking them to give it to us. [...] None of that matters to me, what their excuses are. I feel like where there is a will, there is a way.”

Cohen also claimed that Chimerix told her one of the reasons for denying Josh access to brincidofovir was the $50,000 cost to provide the drug.

That evening, the Max Cure Foundation and several individuals offered to pay for the drug. Stock Market Media twitted: “@StockMktMedia · Mar 9. @chimerix Just watched the CNN piece. If the $50k price tag is the problem Mr Moch, Stock Market Media Group will foot the bill to #savejosh.”

CNN’s story brought the campaign to the nation’s attention. “I think the turning points in the campaign were when the pediatric cancer community became aware of it through Lori Boyko and when CNN’s Elizabeth Cohen interviewed Aimee on Sunday,” Burns recalled.

The campaign supporters were exploring every avenue, brainstorming even what seem like wild ideas. “By mining a wide variety of alternatives we were trying to figure out a solution,” Buenger said. Is it possible to transfer Josh to another hospital that might be involved in a clinical trial of the brincidofovir? Can a doctor from another hospital with an access to the drug be brought to St. Jude and take Josh over as his patient? Will a personal visit to Karl Hostetler, the Chimerix’s founder and co-inventor of brincidofovir, currently professor emeritus at the University of California San Diego School of Medicine, help
release the drug? Can money offered by the individuals and organizations be used to reinstate the compassionate use program at Chimerix? Is it possible to obtain the FDA’s assurance that any adverse results from compassionate use will not affect the review of Chimerix’s Phase III trial? Is there a similar drug that might help?

In the evening Plotkin emailed for help to Nancy Goodman, Founder and Executive Director of Kids v Cancer, a pediatric cancer research policy organization in Washington, D.C. Goodman, a lawyer, started the non-profit organization after her son died from cancer in 2009. Through her policy work, Goodman had contacts at FDA.

**Monday, March 10, 2014**

Burns started the day with a tweet: “Good morning @chimerix time to wake up and #savejosh Find the funding, deliver the cure. Do what you started the company to do cure people.” He then re-tweeted Max Cure Foundation’s tweet with the link to the CNN story to Michele Obama.

Aimee appeared on Fox’s morning show, Fox & Friends. She was interviewed from Memphis for five minutes by Peter Johnson Jr. at 8:23 am. Speaking about the drug, she said: “He needs it, he absolutely needs it. If he does not get it, he is going to die.” By the end of the interview, appearing calm but her voice breaking occasionally, Aimee said: “I am grateful for you to have us here, but I want to be by his bedside, holding his hand and telling him it’s going to be ok. But because of this unwillingness to release this drug I have to leave him and come talk to you. It infuriates me.” Johnson ended the interview by displaying the phone number, email and Twitter handle for Chimerix. Aimee mentioned the Facebook page and CaringBridge.org site.

The media jumped on the story, and social media played an enormous role in spreading the word. Fox & Friends invited Plotkin to come for an interview on Tuesday. Aimee was scheduled to appear on CBS News Tuesday evening and on ABC News Thursday evening. ABC7 News in Washington, D.C. aired an evening story about Josh. USA Today and many other media outlets reported Josh’s story. The #SaveJosh Twitter feed trended in the top five national stories, and the Facebook page reached over one million views.

Josh’s older brothers, Jack and Joe, tweeted at every sports figure they could think of to ask for support. Around 10 am, Washington Redskins quarterback Robert Griffin III, who has 1.12 million Twitter followers, joined the #savejosh movement by re-tweeting the Fredericksburg.com story.
Chimerix's CEO, management and Board members were deluged with thousands of phone calls and emails, some of which included death threats. The company hired security for corporate leadership.\textsuperscript{42}

Plotkin invited Burns to join him at his home in Westfield, New Jersey, one hour drive from Bill's house, to create a "command center" to coordinate the Save Josh campaign. Burns, who is a lawyer, came after a morning court session.

At around 5 pm Plotkin called Moch again and told him that he had a TV appearance scheduled on Fox & Friends the next day. "The call was confrontational," Plotkin recalls. "He told me he was getting death threats and the company had hired security for him and his family. He also told me that security was hired to protect corporate offices. He was very critical of social media, which by that time reached Brazil, Germany, England, France, and the Middle East. Ken told me that he was receiving emails from friends in the Middle East who heard about the issue, asking him if he were all right given that he was being made into the villain. [...] I knew Ken Moch was not going to give in to the pressure being applied through the media. I concluded we needed to go through the Board of Directors to have them overrule the decision by Ken Moch."

Plotkin also attempted to indirectly communicate with substantial Chimerix shareholders. "I believe my efforts were successful and if so, hoped that one or more of the larger shareholders communicated with Chimerix in an effort to convince them to give the drug to Josh – to avoid adverse publicity that would befall the company through the efforts to get the story out in the media," he said.

Josh's warriors also contacted members of Congress. Rep. Rob Wittman (R–Va), who represents the Fredericksburg area, spoke to the Hardy family and contacted the Food and Drug Administration.\textsuperscript{43} "I've been in touch with the family and am doing everything in my power to help #savejosh," he tweeted.

Sen. Mark Warner (D–Va) sent letters to Chimerix and the FDA on Josh's behalf. In the letter to Moch, Warner wrote, "As a former businessman, I understand many of the pressures you face running a company. However, I strongly believe that denying a child what very well may be the only potentially lifesaving treatment simply because it might potentially slow the approval process does not seem to be an adequate reason."\textsuperscript{44}

Warner also appealed to the FDA: "FDA regulations allow individual patient access to investigational drugs for treatment purposes on a case-by-case basis. I strongly urge you to consider what assistance may be available to help Josh and his family through this situation."\textsuperscript{45}
In an interview with The Free-Lance Star, Moch said his company tried to respond through the media with a “consistent message.” “This started on Thursday, growing on Friday night, it was in crescendo by Saturday, it was national on Sunday and global on Monday,” he added. “We didn’t have a crisis management team because we weren’t prepared for this type of crisis.”

And the crisis was about to get worse for Chimerix. Friends and supporters of the Hardys were planning a trip to the company’s offices in Durham to hold a protest rally on Thursday, March 13. The trip was being organized by Duane Adams, a close friend and co-worker of Aimee Hardy. Organizers also had an idea to have Duke University’s basketball team and students join the protest.

In Washington, D.C., Kunal Joshi, research manager of Kids v Cancer, learned about Josh when he came to work on Monday morning from Goodman. “I was trying to coordinate, so all the people would come [to Durham] at the same time,” he remembers. “I was checking the SaveJosh Facebook page constantly, every 30 minutes, and posting: if you are interested to go please contact me. I created a Facebook Event page for people to coordinate carpools. There was already an extremely passionate group of people. We kept thinking, we have so many people, how do we use them in an effective way? So I called many places around Durham, asking ‘Do you mind if we use your facilities to meet up?’” Joshi called recreation centers, churches, Walmart, other places that could act as a meeting point. He checked parking availability near Chimerix’s offices.

Kids v Cancer social media coordinator Jennifer Flynn started her work day as usual in her Manhattan apartment. The email from Goodman about Josh was clear: Today, this is what we are going to push for. Flynn began posting on Facebook. She sent personal messages to other organizations, asking them to join the campaign and to change their profile pictures to #SaveJosh. “This hashtag was brilliant,” she says. “We started putting #SaveJosh everywhere. Our idea was to every few hours put out articles, Max Cure Foundation postings, or refer people to the SaveJosh page. It was grassroots. I sent personal messages to my friends,” she recalls.

Goodman turned to her contacts at FDA. She wrote brief emails to two senior officials asking for ideas about ways to get the drug to Josh. “The issue isn’t the FDA -- but perhaps the FDA could help,” Goodman wrote.

Dr. Debra Birnkrant, director of FDA’s Division of Antiviral Products, heard the story about Josh on television, and she was “very uncomfortable” about it. “I was, like, wait a minute, when did this happen?” If Chimerix agreed to the Hardy family’s request, Birnkrant’s division would make the final decision about granting Josh access to brincidofovir. She had worked with Chimerix for years and couldn’t understand why Chimerix was refusing to provide the drug to Josh. On the way to work, Birnkrant called her project manager from
her car to arrange a conversation with Chimerix. “We had a telephone conversation and they explained that they had received hundreds of requests to which we were not aware at all. Had we been aware of all of these requests we would have worked even more quickly to get a trial up and running to try to collect the data from these patients,”51 she remembered.

CBS6-WTvr in Richmond broadcast a story about Josh on its 6 pm news program featuring Josh’s grandmother, Mae Staton. She gave an overview of Josh’s battle, mentioning the 16 days he had spent in a coma after the bone marrow transplant, and pleaded: “Mr. Moch, have a heart, this child needs to live, release this drug, so that he can have a healthy, happy life.”52

Tuesday, March 11, 2014

Plotkin woke up early and went to Manhattan for his 7:20 am appearance on Fox & Friends. He was waiting in the green room when the anchor, Peter Johnson Jr., introduced himself. “We discussed the issues he would cover in the interview. I said to him, ‘Do me a favor, leave me 30 seconds at the end to appeal to the Board of Directors to overturn the decision of Ken Moch.’ Peter said, ‘Fine,’” Plotkin remembers.

At the conclusion of the interview, Plotkin made the plea to the Board of Directors: “I’d steal a page out of a playbook of Matthew McConaughey in the movie A Time to Kill. I ask the Board to close your eyes, and as you close your eyes, there is a little boy lying in a hospital bed who says to his father, ‘Daddy, am I gonna die, and if I’m gonna die, who will take care of me in heaven?’ And then I want you to assume that this little boy is your child or your grandchild, and, members of the Board of Directors, I have no doubt how you would respond to that.”53

After the show, Plotkin went to his New York office and wrote an email to the Board of Directors urging them to watch the Fox & Friends interview. He ended his email with a request: “Please get back to me, individually or collectively, by the end of today to indicate if the Board will overrule Mr. Moch and give the drug to St. Jude. It is needed today – Josh does not have too many tomorrows if the drug is not forthcoming.”54

Local Fredericksburg businesses teamed up to try to influence Chimerix, running a letter-writing campaign to Moch. The Foode restaurant offered free burgers -- “joshburgers” -- in its courtyard to anyone who signed a letter to Moch. They gathered 500 signatures in the morning and by the afternoon ran out of burgers.55

At about 5 pm Plotkin got a call from a “person [who] wanted to remain anonymous” that he should call Ken Moch. “I called him, and he said I should be on the lookout for a possible
announcement that the drug would be on the plane to Memphis, to St. Jude," Plotkin remembered. "I was told by Ken Moch that Chimerix was working behind the scenes with the FDA, that the drug would be given to Josh as the first patient in a new clinical trial for 20 children with the adenovirus infection."

FDA worked out a solution – it reached agreement with Chimerix for the immediate initiation of a pilot trial of open-label brincidofovir for the treatment of adenovirus infections in immunocompromised patients.

Instead of getting the drug through compassionate use, Josh would get it through a new clinical trial. Chimerix would start a study, and Josh would be enrolled immediately as the first participant. Birnkrant proposed a study because “it was clear the company was uncomfortable” providing the drug and not collecting the data on possible benefits or adverse events, which is standard in clinical trials. “We said let’s do a pilot study just to give us some time to develop a Phase III trial,” she recalled.56

In its press release, Chimerix announced: “Josh Hardy's story brought to public attention the often-devastating impact of adenovirus infection, and helped accelerate a discussion between the FDA and Chimerix regarding the need for additional clinical development to assess brincidofovir’s potential in adenovirus infection. This study is expected to begin with Josh Hardy as the first patient enrolled on Wednesday, March 12, 2014.”57

Josh’s father Todd received the news in a call from Moch about 30 minutes before the public announcement.58 Arden Farhi, a CBS News White House producer, tweeted the news to Burns.

Aimee hadn’t heard the news yet. In the evening she was being interviewed by CBS News. That night CBS broadcast an edited segment that included an interview with Moch, who announced: “I know that Josh is very ill, and we’ve worked as hard as we could as a company to get the processes in place to make this medicine available. And it will be available to him. Today.” Aimee learned about the development while on camera, and doubled over, crying.59

Bailey remembered that day: “My birthday was March 11, and I was in my house, watching the Twitter feed, and I got a message that Josh would get his medication. I dropped on my knees and cried. [...] It was me starting the message but it was everyone on social media who made the message heard. It was inspirational. I called Richard [Plotkin] and he was so calm, he said yes, Josh got his medication. I cried, ‘I can’t believe we did it!’”

The rally in Durham was cancelled. The hashtag SaveJosh was changed to #SavedJosh that night.
Wednesday, March 12, 2014

Brincidofovir was delivered to St. Jude and Josh got his first dose.

Monday, March 31, 2014

Josh, still hospitalized, turned 8 years old. By then, brincidofovir had eradicated adenovirus infection.

Thursday, April 10, 2014

Josh left St. Jude hospital and moved to a nearby apartment to continue care on an outpatient basis. Media reports announced that Ken Moch had resigned as CEO of Chimerix the previous day.60

Josh left Memphis for home on Wednesday, July 16, 2014.

As Bill Burns put it, there are too many people to thank individually. Everyone’s actions, thoughts and prayers have made a difference: “Words cannot express how grateful the family is for your encouragement, conviction, and involvement.” The Hardy family would like to specifically acknowledge and thank the following groups, organizations, and individuals: Beth Anne Baber and The Nicholas Conor Institute, Max Cure Foundation and Richard Plotkin and Erica Bailey, Vickie Buenger & People Against Childhood Cancer, Lori Boyko, Nancy Goodman and Kids v Cancer, Coalition Against Childhood Cancer (CAC2) and Karen Jaffe, Alex’s Lemonade Stand, CaringBridge, Children’s Cause for Cancer Advocacy, Jeff Gordon Children’s Foundation, Solving Kids Cancer, The Truth 365 and everyone else working tirelessly behind the scenes. They also thank “the dedicated, gifted and talented employees and Board Members of Chimerix, especially Kenneth Moch, whose skill, dedication and expertise developed and made available this life saving drug.”61 Special thanks also go to all media professionals who helped to get the story out.

Please support these organizations in their fight against childhood cancer.
Endnotes:
5 Family posting, Caring Bridge, http://www.caringbridge.org/visit/joshuahardy
6 William Burns, personal interview, October 3, 2014.
7 William Burns, personal interview, October 3, 2014.
17 Facebook posting, https://www.facebook.com/SavedJoshHardy/photos/pb.6664815233930217/6664814833930217/?type=1&theater.
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22 Lori Boyko, personal interview, January 30, 2015.
23 Aimee Hardy, personal interview, October 27, 2014.
25 Twitter, #savejosh, https://twitter.com/search?q=%40%23savejosh%20since%3A2014-03-06%20until%3A2014-03-08&src=typd
27 Vickie Buenger, personal interview, October 16, 2014.
Saved Josh: The gears of a successful patient advocacy campaign

28 Richard Plotkin, personal interview, October 6, 2014.
32 Facebook, https://www.facebook.com/SaveJoshHardy/posts/10203200745921081
33 Erica Bailey, personal interview, October 13, 2014.
35 Stefanie Weiss, personal interview, October 14, 2014.
37 Aimee Hardy’s Facebook page. https://www.facebook.com/aimee.hardy.5
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Saved Josh: The gears of a successful patient advocacy campaign


54 Email text provided by Richard Plotkin.


