REMEMBERING MY FATHER BY *DAVID MEANS*
WITH DONALD TRUMP AND HIS MISFITS BY *PAUL WOOD*

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#SAVEOURCHILDREN

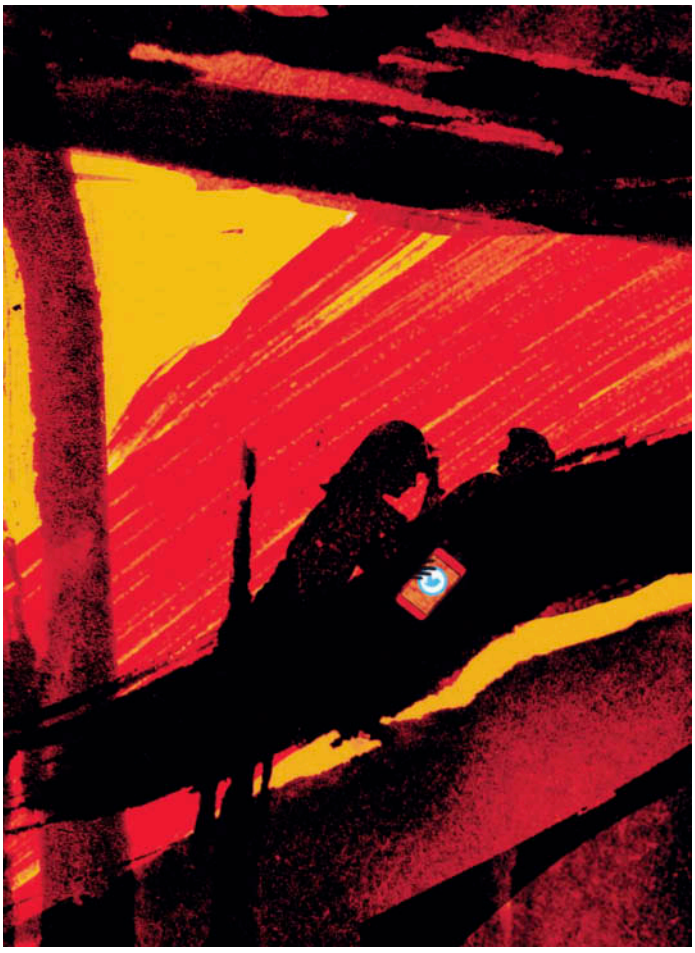
ILLNESS IN THE AGE OF SOCIAL MEDIA

BY HELEN OUYANG

HASHTAG PRESCRIPTION

The hidden cost of crowd-sourcing a cure

By Helen Ouyang



On a cold Thursday evening in March 2014, a New Jersey trial attorney named Bill Burns browsed on his phone while waiting for the bill at a sushi restaurant near his home. He scrolled to a Facebook post by his sister-in-law, Aimee Hardy. "Please help us save our son," the note began. "Share this post if you believe a child's life is more important than money." What followed was brief and heartbreaking:

> The situation is this: Our son, Josh Hardy, who recently had a bone marrow transplant, has developed the adenovirus. This [is] a deadly virus for people who have weak immune systems. There is a drug called Brincidofovir that has been proven to treat the adenovirus effectively. Our doctor at St. Jude told us they ran the study for the drug company and he knows it will work. However, the drug 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.

Helen Ouyang is a physician and assistant professor of medicine at Columbia University.

Josh was a voluble seven-year-old who had been diagnosed with a rare and aggressive kidney cancer as an infant. As Burns knew well, the boy had spent much of his childhood in hospitals, sometimes on life support, but for the most part the surgeries, chemotherapy, and radiation treatments had been effective. Until his bone-marrow transplant, which took place at St. Jude Children's Research Hospital, in Memphis, in January 2014, Josh's hopes of playing for the middle-school baseball team had not seemed wholly implausible.

The transplant had been successful, yet it had also made Josh susceptible to diseases that healthy children shake off without much trouble. Though adenovirus is not usually serious—it is best known as a cause of pinkeye and the common cold—the pathogen quickly overwhelmed his sputtering immune system and left him in critical condition. The doctors at St. Jude told Aimee and her husband that without further treatment their son might have only a few weeks to live.

The Food and Drug Administration has not approved any treatments for adenovirus infections, but as Aimee noted, one of Josh's doctors had suggested a new drug called brincidofovir. Because brincidofovir was still undergoing clinical trials—contrary to Aimee's post, the drug had not yet been proved safe or effective—it could be procured only through a special FDA protocol that allows doctors to prescribe experimental drugs. Known as compassionate use, or expanded

Illustrations by Simon Pemberton

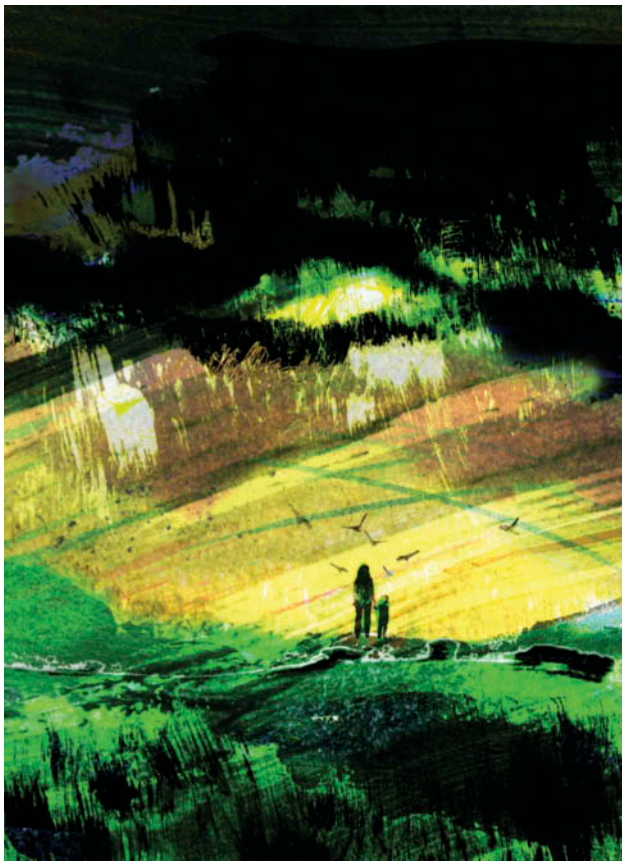
access, the protocol was formalized in the 1980s as a response to AIDS activists who were frustrated with the pace of approval for antiretrovirals. It was designed as a last resort for dying patients who have exhausted their other therapeutic options.

The current compassionate-use protocol requires the assent, on a case-by-case basis, of a drug's manufacturer and the FDA; over the past decade, about 9,000 requests have been granted. Josh's doctors had twice formally asked Chimerix, the North Carolina pharmaceutical company that makes brincidofovir, to release the drug under compassionate use. The company refused both requests.

By the time Burns read Aimee's Facebook post, it was too late in the day to call Chimerix or his congressional representatives. Instead he took to social media, tweeting out, to just ten followers: "Help #Save a 7 year old #life #chimerix #josh needs your #help," with a link to Aimee's post. His second tweet, a few minutes later, included a phone number and email address for Chimerix and reiterated the plea: "#Child #cancer patient needs ur help Release #brincidofovir #savejosh."

The next day, Burns spoke to a friend about Josh's case. The friend tracked down Vickie Buenger, a business professor at Texas A&M and the president of the Coalition Against Childhood Cancer. As soon as Buenger read Aimee's Facebook post, she dispatched a dozen quick emails, including one to Richard Plotkin, a retired trial attorney who had started a childhood-cancer foundation after his young grandson survived lymphoma. Buenger knew Plotkin to be a tenacious activist. She told him, "This sounds right up your alley."

Plotkin had only recently heard of compassionate use, but he was so infuriated by Chimerix's refusal that he went to work instantly. He called every media contact in his address book and instructed the social-media manager of his foundation to attach herself to her computer over the weekend. He emailed Chimerix's board members and investors and had what he described to me as "two very tense, confrontational phone calls" with Kenneth Moch, the company's CEO. Plotkin devised a public-relations strategy to present Chimerix as the murderer of a boy who had just overcome kidney cancer. He told me that Josh had reminded him of his grandson. "If Josh died, I would've destroyed Chimerix," he said. "I would've destroyed Ken Moch also. I was so angry."



While Plotkin and the others spread news of Josh's predicament through an informal network of child-cancer advocates, Aimee's post and Burns's tweets blossomed into a social-media phenomenon. Pictures of the boy circulated on Facebook—one showed him with a puppy, his brown hair streaked blond from the sun; another showed him grinning in a Washington Nationals jersey—and Robert Griffin III, the NFL quarterback, tweeted about Josh to his million-plus followers. CNN interviewed Aimee on Sunday afternoon, and the next day she appeared on *Fox and Friends*. By then, only four days after Aimee's initial public plea, the #savejosh hashtag was one of Twitter's top five trending topics in the United States, a SaveJosh Facebook page had been viewed more than a million times, and strangers had volunteered tens of thousands of dollars to try to buy the drug from Chimerix.

On Tuesday, March 11, Kenneth Moch yielded to public pressure. That afternoon, Chimerix sent several doses of brincidofovir by plane to Memphis; two weeks later, the levels of adenovirus in Josh's blood were nearly undetectable. According to Ashok Srinivasan, the physician from St. Jude who recommended the drug to the Hardys, brincidofovir saved Josh's life. "I have no doubt about that," he told me.

To most observers, the #savejosh campaign was an unmitigated success, proof of the speed, power, and democratic potential of the Internet. In the days following Chimerix's delivery of brincidofovir, "How Social Media Saved Josh Hardy" stories were everywhere. The boy's Twitter and Facebook supporters were quick to congratulate themselves for protecting a seven-year-old from the wiles of a profit-driven drug company.

Arthur Caplan, the founder and director of the Division of Medical Ethics at New York University, was not among those applauding. A few hours before Moch announced Chimerix's change of course, at a time when even BIO, one of the pharmaceutical industry's largest trade organizations, was caught flat-footed by the public response, Caplan had published an op-ed on the NBC website arguing that social media and compassionate use were a dangerous combination. The #savejosh campaign had followed Aimee in framing the fight as a dispute

between Big Pharma and an ailing seven-year-old. Caplan, however, insisted that the ethical stakes were more complicated. A full moral reckoning, he said, demanded consideration of the needs of a hidden third party: not just Josh and Chimerix but the other patients who, now or in the future, might also benefit from brincidofovir.

Caplan suggested that giving Josh the drug through the compassionate-use protocol might endanger its approval by the FDA. In the worst case, Josh would die after taking brincidofovir, and that outcome would "be held against the drug and the company until they can show the drug did not kill him." In the meantime, other patients would find their access to the drug severely restricted. What's more, an online campaign powered by photographs of a sick little boy raised hard questions about fairness. "Those who are not very cute get less attention in their pursuit of unproven drugs," Caplan wrote. "If Josh had parents who did not understand how to use social media, he would already be out of luck."

Caplan is a large man with an ebullient demeanor. He is a frequent participant in public debates about bioethical issues, but when I met him recently, at his tidy, sunlit office in Manhattan, he said that "going toe-to-toe with a mother of a very sick child and saying there's other things to think about is very, very hard politically. I think a lot of people just feared being on the wrong side of a pretty articulate and desperate mom."

Caplan may have been alone in voicing his reservations about the #savejosh campaign, but he was not the only person to harbor them. George Annas, the director of the Center for Health Law, Ethics, and Human Rights at Boston University, told me last summer that "this whole community-going-on-a-vengeance thing is not a decent way to get health care for your child." Like Caplan, he believed that allowing public pressure to determine drug access would inevitably result in unfair outcomes. "You have to look good on TV, and you need a group of people who identify with you," he said. "This is not a way to distribute drugs." Even Srinivasan, Josh's doctor at St. Jude, who had been involved with the clinical trials for brincidofovir, told me that he was uncomfortable with the social-media campaign. "Usually we approach these drugs in a logical, scientific manner," he said, "instead of having an emotional outburst about it."

"Don't think for a second that I was unemotional or didn't care about Josh Hardy," Kenneth Moch told me when I met him last July, at a coffee shop near his home in Chapel Hill, North Carolina. Moch was fired from Chimerix a month after sending brincidofovir to Josh—a company spokesperson did not deny that the two events were related—and it was clear that he'd spent much of his time since then considering the case. He has two sons in their twenties, and he says that he sympathized with the Hardys' position. "If it was my Josh, the answer is, 'Of course you would do everything.' But as the CEO of a company, I have to think through the complexities and risks of drug development and risks to the many Joshes."

AN ONLINE CAMPAIGN POWERED BY PHOTOGRAPHS OF A SICK LITTLE BOY RAISED HARD QUESTIONS ABOUT FAIRNESS

Moch, who is sixty-one, has a husky build, gray-blue eyes, and a square face that dimples when he smiles. To become a chief executive is usually the capstone of a career in pharmaceuticals, but he has somehow made a routine of it. Chimerix was the fourth medical company he'd led; he became CEO for the first time when he was thirty-five years old. In conversation he is confident and thoughtful, and he strews his remarks with motivational quotes, the names of his mentors, and provocative anecdotes in a way that reminded me more of a life coach than a corporate executive.

Chimerix was founded in 2000 by a group of scientists at the University of California, San Diego, who were developing brincidofovir as an antiviral. After 9/11 prompted fears of a bioterrorism attack, the company received a $37 million grant from the National Institutes of Health to investigate the drug's effectiveness against smallpox. In 2006, Chimerix ran a phase 1 trial for brincidofovir, which tested the drug in healthy patients.

The company received its first compassionate-use request in 2009, a year before Moch became CEO. When a young Marine with undiagnosed leukemia became ill from a smallpox vaccine, the federal government asked for a treatment dose of brincidofovir. The company provided the drug, the Marine got better, and that, Moch says, "began a slow, word-of-mouth, not planned program for compassionate use of brincidofovir." It took nine months for Chimerix to field its first fifty requests for the drug; the second fifty needed just three months. In 2011, the company signed an $81 million federal contract to continue its bioterrorism research. By the end of the following year, more than 400 people had received brincidofovir through compassionate use.

The funding that Chimerix had received for the clinical component of its federal contract ran out in 2012. Two years later, when the Hardys submitted their first request for brincidofovir, the company had only fifty-four employees on the payroll. Moch said that the financial and human resources required by compassionate-use programs created significant constraints for small companies like his. "We treated the equivalent of eleven percent of our study centers' stem-cell-transplant population with an unapproved drug under compassionate use," Moch told me. "If you blew that up and made it more widely available, how could you run randomized controlled trials at the same time?"

The randomized controlled trial, in which one group of patients receives an experimental treatment while a control group receives a placebo or the current established therapy, is the most direct way to compare the effectiveness of a new therapy with that of existing treatments. R.C.T.'s are the

gold standard for testing drugs, but it can be difficult to recruit participants even in the best of circumstances: patients often have to travel to the large academic centers where the trials are held, and they are required to limit the number of concurrent treatments they receive in order to ensure that the effects of the experimental drug are discernible.

Compassionate use creates recruitment difficulties that not even large companies with abundant resources can avoid. Why, after all, would you risk getting a placebo or the existing therapy when you know that you can obtain an experimental drug through other means? And since every patient who is treated through compassionate use is one less research subject who can volunteer for a trial, the diversion of patients away from R.C.T.'s can have real effects on the scientific process. Without research subjects, a company can't conduct a trial; without a trial, a drug won't be approved by the FDA; without approval, future patients can't get the drug.

In 2013, as part of an effort to bring brincidofovir to market, Moch made what he called a "heart-wrenching" but "not a business-wise complex decision" to end its compassionate-use program. During the next year, Chimerix received more than 300 requests for brincidofovir, including from politically connected foreign leaders and from Moch's close personal friends. Until Josh Hardy, Chimerix refused each of them. "How could I give the drug to one and not to others?" Moch asked me. "How could I choose?"

The photographs that circulated during the #savejosh campaign made it easy enough to understand how a pink-cheeked boy had, for a couple of days, gained the sympathy of a wide swath of the Internet. As Arthur Caplan suggested, however, not everyone has been so lucky. Last summer, I visited Gainesville, Florida, to speak to Kathy Liu, an ESL teacher who emigrated from China with her family a decade ago. In 2014, her ten-year-old son, Joey, died of kidney cancer after his mother tried, and failed, to secure experimental drugs for him through compassionate use.

Kathy answered the door of her modest one-story house wearing a flower-print skirt and a necklace with a sky-blue pendant that said JOEY'S WINGS, the name of a research organization she established after her son died. We sat down in her dining room, where I saw an expansive shrine to Joey's memory. Hanging from a wall were origami birds, soccer and math-team ribbons, Boy Scout badges, drawings, and a letter from *Highlights*, the children's magazine, which had published a poem he'd written. When I commented on the wall, Kathy brought over an incomplete rendition of a dragon that was still taped to a small easel. "This is his last painting," she said. "I want to frame it but I just feel …" She fought back tears. "I just feel like he'll come back and finish it."

Kathy said that Joey had seemed healthy when she took him for a routine checkup in March 2013. His pediatrician, however, had felt a mass in the boy's abdomen and sent him to the hospital for an ultrasound. The scan showed a tumor on Joey's left kidney. Further testing that day revealed that the cancer had already proliferated throughout his body.

Joey's diagnosis jolted Kathy into action. She contacted patients, families, doctors, and researchers, and spent hundreds of hours on cancer-support websites, where information about new drugs often becomes available before official announcements are made. She read obscure international medical journals, emailed with lab scientists around the world, and attended scientific conferences all over the country. She brought Joey to see at least five oncologists and spoke on the phone with many others. As six successive chemotherapy treatments proved ineffective, she sought out experimental therapies with a sense of frantic determination.

To hear Kathy tell it, hers was a passionate but amateur effort. "I still get lost on phone calls because of all those terms," she said. "I don't know how to pronounce them. I contact everyone first by email. Then, if we talk face-to-face, I read all the studies first and write everything down." But when I spoke to Joanne Lagmay, an oncologist who treated Joey at the University of Florida, I heard another account. "I

have literally witnessed somebody go from a mom who taught ESL to becoming an expert on a very rare renal tumor," Lagmay said. "There was a time, I was like, 'What are you talking about, Kathy? TFE-3? Translocations?' I feel like she became the expert."

After Joey had exhausted all available therapies, Kathy put her hopes in so-called PD-1 inhibitors, drugs that targeted some of the proteins expressed by his tumor. At the time, PD-1 inhibitors were still experimental, and they were being tested for adults with skin cancer, not children with kidney cancer. Kathy submitted compassionate-use requests to three large pharmaceutical companies and was refused each time. In April 2014, barely a month after the successful completion of the #savejosh campaign, she turned to social media to rally interest in her son's cause. Instead of Twitter she used QQ and WeChat, two messaging apps popular in China. She had set up a page on Facebook, but its name was so complicated—"Xp11.2 translocation RCC," the name of Joey's tumor—that she had a hard time reciting it for me. And while she had some success with a Change.org petition, most of her efforts had little effect. Kathy believes that the media's interest in compassionate use was already spent. "They didn't want the same story," she told me. "Josh's was already the big one."

Finally, in September of that year, Merck received FDA approval for a PD-1 inhibitor. Clinical trials for metastatic melanoma, the only available evidence at the time, suggested that the drug worked in fewer than a quarter of cases, and produced an effect that lasted, in some patients, less than six weeks. Nevertheless, Kathy rushed Joey to Cincinnati, where a pediatric kidney-tumor specialist prescribed him the inhibitor. The treatment seemed to stabilize Joey's cancer at first, but in November, after two doses, he died.

Michael Rosenblatt, the chief medical officer of Merck, told me that he could not comment specifically on Joey's case. In general, however, he said that Merck considered compassionate-use requests only when the company had "reason to believe, based on clinical data, that the benefits are likely to outweigh the risks," which in practice often means waiting until the end of phase 3 trials. He defended the stance in terms that resembled Arthur Caplan's case against the #savejosh campaign. "There's a common belief that you have the individual or the family pitted against a pharmaceutical company," Rosenblatt said. "I think that if you stand back, it's the individual whose very important and real and desperate interests are pitted against everyone else with that illness."

Kathy, of course, doesn't see things that way. She believes that even a fleeting extension of Joey's life could have made a crucial difference. "Maybe it's two or three months, but for us it's precious time," she said. "I still have that hatred toward the drug companies. Why didn't you release the drug? Why do you have to wait for the FDA to approve it?"

For many doctors and public-health experts, the answer to Kathy's second question can be summed up in a single word: thalidomide. It is thanks to the FDA, after all, that Americans, unlike Europeans, did not suffer thousands of infant deaths and many more severe birth deformities when Richardson-Merrell, a pharmaceutical company, introduced the anti-nausea drug thalidomide, in the 1960s. Richardson-Merrell had pushed hard for the drug's approval and maligned those who initially questioned its safety, but the FDA stood its ground.

On the occasions when the agency has failed at its basic mission—as it arguably did with rofecoxib, an anti-inflammatory for everyday aches sold as Vioxx by Merck—the results have been devastating. By 2004, when Vioxx was withdrawn from the market, five years after it was approved, more than 20 million people had taken the drug. A safety director for the FDA testified before the Senate Finance Committee that Vioxx had caused as many as 160,000 heart attacks and strokes—the equivalent of "two to four jumbo jetliners . . . dropping from the sky every week" for five years.

Despite these precedents, and despite a 2011 study showing that the FDA approves cancer drugs nearly

twice as fast as its European counterpart, it's still not uncommon to hear complaints about the agency's sluggishness, especially when it comes to pediatric therapies. In part, of course, this is to be expected; as one parent-advocate told me, "no cure is fast enough" when your child has cancer. But the delay is not merely subjective: children do generally have to wait longer than adults for new drugs.

Pharmaceutical companies and the FDA maintain that the discrepancy has to do with their duty to protect the most vulnerable patients, as well as the difficulty in finding and clearing young research subjects for clinical trials. Many activists believe that money offers a more direct explanation. The relative lack of pediatric cancers, they argue, discourages companies from producing therapies and skews research agendas. The National Institutes of Health spends twice as much money on breast-cancer research as it does on all pediatric cancers; in 2012, less than 5 percent of the National Cancer Institute's research budget was directed at childhood cancers.

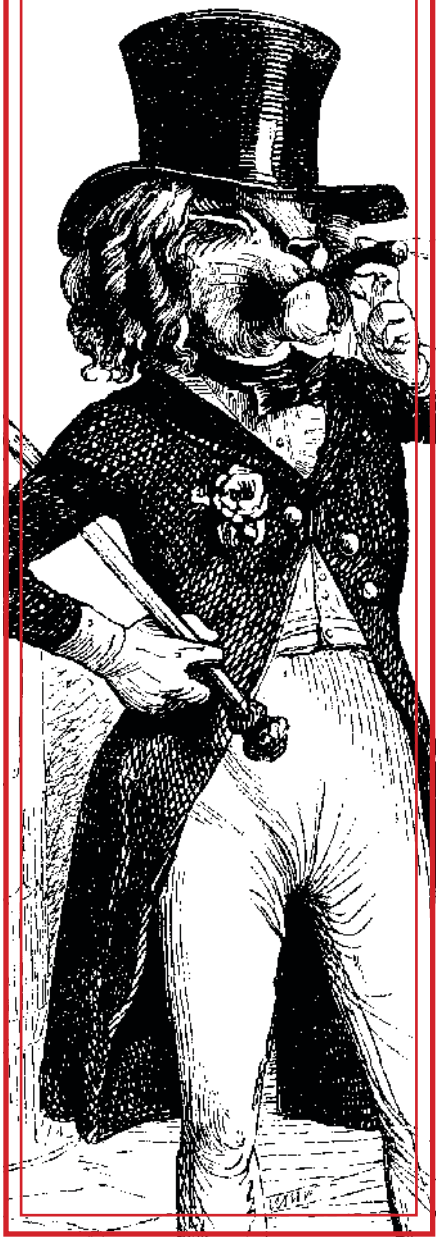
In recent years, the libertarian Goldwater Institute has promoted the passage, at the state level, of so-called Right to Try laws, which allow compassionate-use requests to circumvent the FDA completely. To critics such as Caplan, these laws seem like a political stunt, an ostentatious way to undermine the authority of the federal government, rather than the solution to a real problem. Though the Supreme Court has ruled that the terminally ill do not have a constitutional right to unapproved drugs, the FDA has granted 99.4 percent of the compassionate-use requests it has considered since 2009. Nearly all the refusals have come from the pharmaceutical companies. "Right to Try doesn't force people to give anything," Caplan told me. "Right to Beg laws is what it should be called."

At the coffee shop in Chapel Hill, Kenneth Moch pulled out his laptop and showed me some of the emails he'd received during the #savejosh campaign. The first had arrived sixteen minutes after Aimee Hardy posted her initial note to Facebook. Many of those that followed were cruel, even vile, and a few included what the FBI called "threats of substance," which led Moch and his wife to stay at a hotel. The responses shared a consistent story line: a seven-year-old boy was very sick, and an evil CEO was too concerned with profits to save that boy's life.

Like Caplan and Rosenblatt, Moch tends to think of compassionate use in utilitarian terms, as a conflict between the visible needs of the present and the invisible needs of the future. "It's the person right there versus the statistical future people who are only real when you get to that point in time. But they're there! What if your loved one is going to be sick in the future, and they're not going to get the drug?"

Moch told me many times that his initial unwillingness to release brincidofovir to Josh had "nothing to do with money." And yet given the economic realities of pharmaceutical development in the United States, which depends almost entirely on for-profit companies to bring drugs to market, it is rarely possible to separate financial and therapeutic motivations. Current estimates suggest that it takes a decade and anywhere from $500 million to $2.6 billion to develop a new FDA-approved drug. Just one in ten treatments that begin clinical trials will eventually receive approval, and even those drugs that reach phase 3 trials, the final stage before approval, face a 50 percent rate of rejection. Moch's critics weren't wrong to suggest that financial considerations, in the broadest sense, had something to do with the decision not to give Josh the drug. But few of them acknowledged that Chimerix was a small company with a single product, which by law it was not yet allowed to sell to the public. In the short term, at least, if the company went under, there would be no brincidofovir for anyone.

Some pharmaceutical companies became even more wary about compassionate use after the FDA temporarily halted a clinical trial in 2014, following the death of a patient who received an experimental cancer drug through the protocol. What's more, as Moch and others were quick to mention, most compassionate-use requests are Hail Mary efforts, with little to no



chance of making a significant long-term therapeutic difference. Moch said that it had been his responsibility, as the CEO of Chimerix, to ask himself what he called "the very, very difficult emotional question": "What would've happened if Josh Hardy died on the public stage?"

That counterfactual became less speculative six months after Josh's successful treatment. In October 2014, brincidofovir was given to Thomas Duncan, a Liberian man who was the first person to be diagnosed with Ebola in the United States. Though Duncan was already very ill when he received the treatment, and though brincidofovir had not been developed as an Ebola drug, Chimerix's stock closed nearly 10 percent lower on the day his death was announced. The stock's dip mattered less than what it signified: declining confidence in the company and its drug, which could make it more difficult for Chimerix to raise money from investors and to recruit patients for its trials.

On the morning of March 10, 2014, as Aimee was pleading her case on *Fox and Friends*, Chimerix started private discussions with the FDA about the #savejosh campaign. The company and the agency came up with a plan that sidestepped the question of compassionate use entirely. "The FDA did an extraordinary thing," Moch told me. "They said, 'You can start a new phase-three clinical trial,' which I think was tremendous flexibility." The agency allowed Chimerix to immediately open a twenty-person study without a control group—a so-called single-arm trial—to further test the drug against adenovirus. Josh Hardy was the first patient enrolled.

"One of the things that's most interesting in the Josh Hardy situation is that everything went well, except the collateral damage of the CEO," Moch said last July. "Josh did well, other patients have done well, we're collecting new patient data with this phase-three trial, the stock price is now double where it was when I left. People look at that and say, 'See, it's easy.' But there are dozens of things that could have gone wrong, any one of which could have led to a very different outcome for the company, Josh, or future Joshes."

And while the FDA's innovative response to Chimerix's dilemma might seem like a model for similar cases in the future, single-arm trials are far from a panacea. Because R.C.T.'s make it possible to directly attribute outcomes to the experimental therapy in question, they remain the most rigorous way of determining a treatment's effectiveness. A single-arm trial, by contrast, does not always offer clear evidence about whether a patient improved because of a therapy, the natural course of the disease, other medications, or even diet.

Peter Bach, the director of Memorial Sloan Kettering's Center for Health Policy and Outcomes, told me recently about a new leukemia drug that was approved by the FDA on the basis of single-arm trials alone. The drug costs $187,000 per course, but because of the way it was tested, there is no way to know how it compares with other treatments. "I look at that unbelievable price, and I say, 'Show me, how much better is this drug?' But there's no control arm, so the answer is, we don't know. We just know that it costs a hundred and eighty-seven thousand dollars, which is an unheard-of price for cancer." When I asked Richard Pazdur, the head of oncology products at the FDA, whether he thought single-arm trials would soon become the norm, he was emphatic. "No way. R.C.T.'s should still be the default position."

Pharmaceutical companies are not required to keep track of individual compassionate-use requests, but between 2013 and 2014 the number of applications processed by the FDA doubled. And while aggressive social-media campaigning for experimental drugs is "almost exclusively an American strategy," according to Annas, the BU health-law professor, the trend is likely to spread beyond the United States. Immediately after the #savejosh campaign, a woman in Italy asked Aimee Hardy for advice about mounting a similar social-media protest on behalf of her dying son.

To address the issue, and to offer guidance to companies considering compassionate use, Arthur Caplan

recently organized a pilot program that he hopes will resolve many of the controversies and inconsistencies that accompany these difficult decisions. In May of last year, he selected a ten-person committee to evaluate compassionate-use requests for an experimental drug made by Janssen, the pharmaceutical subsidiary of Johnson & Johnson. By this spring, the committee had reviewed more than a hundred cases.

Caplan's committee is not without precedent, but that's not exactly a point in its favor. In Seattle in the 1960s, testing began on the first outpatient hemodialysis machines, for chronic kidney failure. A volunteer committee of seven people—nicknamed the Seattle God Squad—selected ten patients to receive the lifesaving treatment. A harrowing account published in *Life* magazine later revealed that members of the God Squad had made their decisions after considering the patients' marital status, income, occupation, education, and religion. Critics of the trial noted that the patients who were selected for hemodialysis tended to be those who most resembled the God Squad.

When Caplan told me about his committee—which includes members from several countries, ethnicities, and religions—I told him that I was skeptical, and not only because of the Seattle example. My father died of liver cancer in the early 1980s, just three weeks after being diagnosed. At the time, treatment was inconceivable for cancers as advanced as his, but it's possible that a liver transplant would have saved his life. My family accepted, however, that transplantable organs are a limited resource, and we conformed our expectations accordingly.

Experimental drugs are not perceived similarly, even though it's often the case that preapproval drugs exist only in limited quantities. Most of us, when pressed, share Aimee Hardy and Kathy Liu's conviction that drugs ought to be available for the terminally ill. It didn't seem to me that a committee—no matter how fair, representative, and transparent—could surmount that deep impulse.

"The pilot committee is meant to try to show you're wrong," Caplan said. He reminded me that he had worked with Al Gore to create the national organ-transplant list in 1984. "When people said to me then, 'You're never going to get rules that people agree to,' my response was, 'Yes, we did.'" Caplan is confident that his committee, by establishing its criteria transparently and by withholding patients' personal details from the committee members, will be "the antidote to the God Squad."

On a balmy afternoon last July, in Reedville, Virginia, I drove past countless porches that were adorned with American flags for Independence Day. When I reached the summer home owned by Aimee Hardy and her husband, a charming gray house with a lush yard, I let the front tires of my rental car bump up against a colossal pile of oyster shells. Aimee greeted me in running shorts and flip-flops. A tall, athletic insurance agent with long brown hair that was swept back in a half-bun, she introduced me to Josh, who wore a Memphis Redbirds baseball cap and a Memphis Grizzlies T-shirt. Though he was nine years old, he stood about two inches shorter than his six-year-old brother. He had a steroid-swollen face, a protruding belly, and translucent skin that was covered in bruises. Aimee told me that "when he hits a Wiffle ball, he just has that natural look of a ballplayer," but at the time of my visit, Josh couldn't walk more than a quarter of a mile without taking a break to sit in his stroller.

After a trip down to the bay to pick up live crabs for dinner, Aimee and I settled into Adirondack chairs while two of her boys did cannonballs off the dock. Josh, who is still susceptible to freshwater infections, stayed on dry land. Aimee explained that she uses Facebook the way some people send group emails, and said that she had quickly tapped out her initial post after learning about Chimerix's second refusal. She had no idea that her words would launch a social-media protest. "I was honestly thinking of our friends who might know our congressman. I thought political things might help. The old boys' network, right?"

Josh interrupted our conversation to remind us that it was dinnertime. The steroids had given him a spectacular appetite, and as we ate the steamed crabs, he gleefully amassed the biggest pile of shells at the table while cracking jokes with his brothers. For the Hardys, the moral dilemma identified by Moch was no dilemma at all. "It made no sense for us not to get the drug," Aimee said. "You have it, we need it." She understands the criticisms leveled by Caplan and others against the #savejosh campaign, but to her they all missed the point, which is that she, like Kathy Liu, would have done anything to help her son. "Whether it's fair or not," she said, "social media is a tool that's available."

The ethical complexities of compassionate use were perhaps nowhere more evident than in my conversation last July with Richard Plotkin, the activist who had vilified Chimerix and Moch. He told me that he had become much more informed about compassionate use since the #savejosh crusade. "If I were in Ken Moch's position with what I know now," he said, "I would not give Josh the drug." As an explanation, he cited "the numerous patients down the line who might be adversely impacted if something occurred that delayed approval of the drug or caused Chimerix to dissolve and not bring the drug to market." He told me, "I could've just imagined what would've happened if Josh Hardy died."

Initial results from the single-arm adenovirus trial that launched with Josh have so far been favorable. Last December, however, Chimerix announced the results for its first phase 3 clinical trial, which tested brincidofovir against cytomegalovirus, a pathogen that shares structural properties with smallpox and adenovirus. The drug failed the trial: overall, research subjects who received brincidofovir did no better than those who received a placebo. Chimerix also noted that the brincidofovir group showed a higher—albeit statistically insignificant—death rate, which raised questions about the drug's safety. The company halted enrollment in two other trials, and saw its stock fall 80 percent.

When I called Moch, he told me that he was "absolutely surprised" about the news. "We all wanted it to work. We believed it would work, but you just can't jump to these conclusions," he said. "That's the complexity of human physiology and the risks of drug development." He was disappointed, but he saw the results as another reminder that anecdotal evidence is not a substitute for scientific data. "Josh Hardy had one of the strongest positive reactions of anybody that we've ever seen," he said. "It would've been a beautiful ending if brincidofovir had sailed through."

Though the possibility that Caplan and others had warned about—that a poor outcome in a single patient might taint an otherwise successful drug—did not come to pass, something like the opposite may well have occurred. Josh Hardy's high-profile success with brincidofovir created expectations, and demand, for a drug that might in the end turn out to be ineffective, or even harmful. What unites both instances is the understandable human tendency to give disproportionate weight to concrete individual cases at the expense of the abstract many.

In this respect, the debate over compassionate use offers a microcosm of a central dilemma of American health care. In a system that encourages us to expect instant and endless access to every test, every procedure, and every drug, even those that might do us real harm, it's all but impossible to imagine withholding brincidofovir from Josh. And the speed and ease of social media, which make it almost effortless to lend a click to a cause, create the opposite of an incentive to reckon seriously with the trade-offs of our decisions. But as Arthur Caplan noted, those trade-offs don't cease to exist merely because we neglect to consider them. "When you're desperately ill, you're kind of coerced by your disease. The fact that you're desperate and you're willing to take anything doesn't mean the best way we can respond is to honor that request," he said. "Because we can make you die faster, and we can absolutely make you die sicker." ■