BENTLEY UNIVERSITY

W. Michael Hoffman Center for Business Ethics

Raytheon Lectureship in Business Ethics

Overcoming Contradictions in the Business of Compassion and Care

Sandra L. Fenwick
CEO of Boston Children's Hospital

September 24, 2018

BENTLEY UNIVERSITY is a leader in business education. Centered on education and research in business and related professions, Bentley blends the breadth and technological strength of a university with the values and student focus of a small college. Our undergraduate curriculum combines business study with a strong foundation in the arts and sciences. A broad array of offerings at the Graduate School of Business emphasize the impact of technology on business practice. They include MBA and Master of Science programs, PhD programs in accountancy and business and selected executive programs. The university is located in Waltham, Mass., minutes west of Boston. It enrolls approximately 4,200 full-time and 140 part-time undergraduate students and 1,400 graduate and 40 doctoral students.

On July 25th, 2016, the CENTER FOR BUSINESS ETHICS at Bentley University was renamed the W. MICHAEL HOFFMAN CENTER FOR BUSINESS ETHICS in honor of the pioneering work and four decades of accomplishments of the center's founder and current executive director, W. Michael Hoffman. The center is a nonprofit educational and consulting organization whose vision is a world in which all businesses contribute positively to society through their ethically sound and responsible operations. The center's mission is to provide leadership in the creation of organizational cultures that align effective business performance with ethical business conduct. It endeavors to do so by applying expertise, research, and education and taking a collaborative approach to disseminating best practices.

With a vast network of practitioners and scholars and an extensive multimedia library, the center offers an international forum for benchmarking and research in business ethics.

Through educational programs such as the Raytheon Lectureship in Business Ethics, the center is helping to educate a new generation of business leaders who understand from the start of their careers the importance of ethics in developing strong business and organizational cultures.

In Memoriam

W. Michael Hoffman, PhD

Founder, Hoffman Center for Business Ethics

February 23,1943 - December 6, 2018

For years, the opening pages of this monograph series began with a reflection from W. Michael Hoffman, the founder and executive director of the Hoffman Center for Business Ethics. While this edition of the series also has such a reflection, we are saddened to say that prior to its publication, on December 6, 2018, Dr. Hoffman passed away.

Dr. Hoffman began working at Bentley University in 1974 as a professor and chair of the Philosophy Department. Recognizing that he was in the right place to teach future leaders about moral leadership, he introduced a course on business ethics to the Bentley curriculum. Soon afterward, in 1976, he opened at Bentley the first center dedicated to all aspects of business ethics.

Mike was a pioneer, an innovator, a philosopher, and an ethicist. He welcomed to his Center scholars and other visitors from across the country and around the world. They, in turn, helped to develop the field and spread the message of business ethics. Today, the impact of business on society is greater than ever. Although Mike is no longer here to lead the Center he founded, the field of business ethics continues to evolve quickly. We at the Hoffman Center for Business Ethics will continue to advance the Center's important work inspired by Mike's example and legacy.

W. Michael Hoffman, PhD

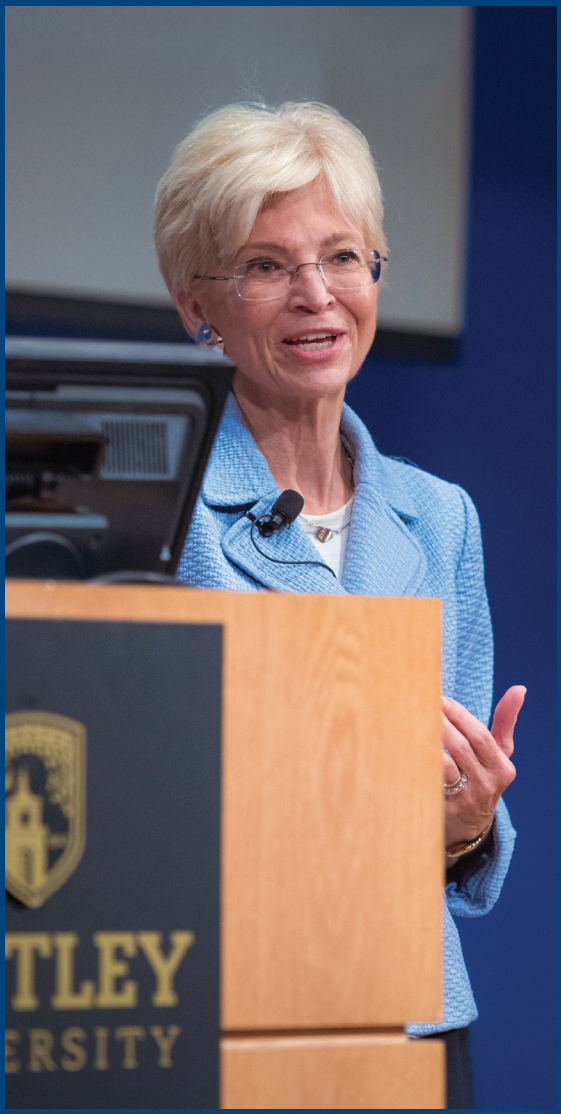
Founder and Executive Director
Hoffman Center for Business Ethics and
Hieken Professor of Business
and Professional Ethics
Bentley University

A vivid example of the diversity of business ethics was illustrated by our most recent Raytheon Lecture in Business Ethics given by Sandra L. Fenwick, CEO of Boston Children's Hospital. Boston Children's is one of the nation's top hospitals for teaching, research, and care. For nearly twenty years, Sandra has been a leader at Boston Children's, and in 2013 she was named CEO. For the last five years, Boston Children's has been ranked as the number one pediatric hospital in the country by *U.S. News & World Report*.

With some $2.6 billion in annual revenues, Boston Children's may be listed as a non-profit, but it faces the same kind of ethics issues as any major business, from employee compensation to managing suppliers. In addition to these, Sandra and her team are responsible for many matters that are unique to the kind of institution she leads. For example, what policies should be adopted knowing that these decisions could have a life or death impact on patients? How should a limited research budget be managed? Who will receive treatment when often the sickest children may lack insurance or the funds to pay?

These are questions with no easy answers. However, as Sandra's talk made clear, guidance can be found in what is most important about Boston Children's — the *children* themselves and the recognition that every child embodies the hopes and dreams of their parents and the communities in which they live. As human beings, the belief that every child deserves to grow healthy and strong seems to be baked into our DNA. Sadly, nature sometimes seems to have other plans.

When health problems strike, Boston Children's is ready to respond. What Sandra's talk makes clear is that what keeps everyone at Boston Children's aligned and on course is a deep and broad commitment to an ethic in which all children are seen as equally deserving of the best care possible. Knowing this, parents are able to entrust to the Hospital that which is most precious to them — their children. Many of us may feel that the stakes are not so high with our work. Nevertheless, let's not forget that many people, including ourselves, are affected by our work. It is, metaphorically, our child, and also deserves to be guided by the kind of care and ethics seen at Boston Children's.



Sandra Fenwick delivers the Raytheon Lectureship in Business Ethics to students, faculty, staff, and friends at Bentley University.

Boston Children's is one of the world's leading research hospitals. It is a 415-bed Harvard teaching hospital with over $2.6 billion of revenues including $375 million in research funding. The Hospital has 1,600 physicians, trains over 1,000 residents and fellows annually, and has over 12,000 employees. It has been ranked by *U.S. News and World Report* as the country's number one children's hospital in all of the previous five years. As the top pediatric hospital in the nation, Boston Children's Hospital has built a 150-year reputation for providing the safest, world-class care to children and families from around the world, while also leading healthcare forward as the world's largest pediatric research and innovation enterprise.

The **Raytheon Lectureship in Business Ethics** at Bentley University is made possible through the generous support of the Raytheon Company.

Raytheon is a technology and innovation leader specializing in defense, homeland security and other government markets throughout the world. With a history of innovation since its founding in 1922, Raytheon provides state-of-the-art electronics, mission systems integration, capabilities in C5I (command, control, communications, computing, cyber, and intelligence), sensing, effects and mission support services. The company reported sales of $27 billion in 2018 sales and employs 67,000 people worldwide. It has built a reputation for adhering to the highest ethical standards in the industry. The Raytheon Lectureship in Business Ethics series aims to illuminate and promote ethical values and conduct in business, highlighting best practices in corporations throughout the United States. Learn more about Raytheon online at raytheon.com.

(From left) Tim Schultz, Vice President, Ethics and Business Conduct, the Raytheon Company; Sandra Fenwick, President and CEO, Boston Children's Hospital; Alison Davis-Blake, President, Bentley University; and W. Michael Hoffman, Founder and Executive Director, Hoffman Center for Business Ethics and Hieken Professor of Business and Professional Ethics, Bentley University.

Thomas A. Kennedy, PhD

Chairman of the Board and
Chief Executive Officer
Raytheon Company

Raytheon believes in a values-based ethics program, and we believe in the value of ethics education. We invest in ethics and provide employees with robust, award-winning ethics education to reinforce how important doing the right thing in business is to our success. We talk about ethics so our employees know it is okay to ask questions and raise concerns, to take an "ethics check," if you will. By supporting this process, we build upon a strong ethical foundation and reinforce a culture of integrity at the company. A strong ethical culture requires work. We believe that working at ethics pays dividends and that it gives us a competitive advantage.

Raytheon's support for the Hoffman Center for Business Ethics at Bentley University has a long history. The center has provided leadership in this important field for the academic and business communities extending now for two generations. Bentley is increasingly recognized for promoting ethical business practices and cultures not just in the United States, but internationally as well. This is especially significant as our world is increasingly interdependent, and having ethical business partners is a global imperative.

The Raytheon Lectureship in Business Ethics at Bentley has added relevance in this environment. Having respected corporate leaders share their insights and commitment to business ethics helps show the way for all of us. Promoting further dialogue and discussion about ethical business practices enlightens and inspires us to redouble our own commitment. Raytheon is proud to partner with Bentley and the Hoffman Center for Business Ethics to give voice to ethical excellence in business.

Sandra Fenwick

Chief Executive Officer
Boston Children's Hospital

Sandra L. Fenwick joined Boston Children's in 1999 as senior vice president and was appointed chief operating officer that year. She was named president in 2008 and was named chief executive officer in 2013. As CEO of Boston Children's Hospital, Ms. Fenwick leads the nation's foremost independent pediatric hospital and the world's leading center of pediatric medical and health research. Ms. Fenwick has been a driving force to improve the effectiveness and efficacy of the care provided at Boston Children's while at the same time reducing the costs of care. Through a combination of hospital affiliations, outpatient specialty care centers, community health centers, and regional partnerships, she has helped create a children's health network providing high quality pediatric care in local settings. She has also expanded its commitment to and investment in both basic, translational and clinical research, care, technology, and delivery innovations and as well as prevention efforts focused on asthma, obesity and mental health. She is a tireless advocate for children's health and has been instrumental in developing strategies that position Boston Children's as the scientific and thought leader in pediatric health.

She currently serves on the board of directors of CRICO, Ltd., Harvard's Wyss Institute for Biologically Inspired Engineering, Children's Hospital Association, Children's Hospitals Solutions for Patient Safety, Greater Boston Chamber of Commerce, MASCO, Inc., Massachusetts Digital Health Council and Boston Children's Hospital. She is also a member of the Massachusetts Women's Forum and Women Corporate Directors/Boston.

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Overcoming Contradictions in the Business of Compassion and Care

Sandra Fenwick
CEO, Boston Children's Hospital

September 24, 2018

I am honored to be here today and thrilled to be able to talk about our work at Boston Children's Hospital from a slightly different perspective than I usually do. More often than not, when I'm asked to speak about Boston Children's, it's about what we do, not the ethical questions that drive how we do it.

If you're not familiar with what we do, this gives me an opportunity to share a bit.

A little about me. I have always loved science and medicine. With a background in biology, chemistry, and pre-med, my journey took me from bench research at Harvard to clinical research in Saudi Arabia to hospital administration at Beth Israel in Boston and now to Boston Children's. My role today brings together all the elements that fuel my passion — partnering with the brightest minds in science and medicine, watching the compassion and care of all our caregivers, addressing some of the most difficult and transformative changes occurring in health care and working to improve the lives of children and their families. I have the best job in the world in the finest institution in the world.

Now, a little about us. This year, *U.S. News & World Report* named Boston Children's the top pediatric hospital in the nation for the fifth year in a row. It's an honor that we're tremendously proud of, but it only tells part of the story. Let me give you some context about Boston Children's — and about children, broadly.

We *are* best known for our care, whether we're providing primary and preventative care for families in our local community, or treating children with complex conditions treatable by only a few, or rare diseases that no one fully understands. We see more than 3,000 patients annually from more than 100 countries and an equal number from every state in the nation. We have approximately 25,000 inpatient admissions and more than 650,000 outpatient visits every year. We offer health care services that can begin at 15 weeks into gestation, and in some situations,

we can treat patients through adulthood — particularly adults who have survived childhood diseases because of innovations in care, but for which the providers of care for adults lack the treatment experience. These adult patients are often covered by governmental payers and may have lifelong disabilities.

We're what's known as a safety net hospital. We're the top provider of Medicaid services to children in the Commonwealth, with 37 percent of our patients from Massachusetts covered by Medicaid. Additionally, 13 percent of our inpatients are transferred from hospitals and medical centers across Massachusetts for care that no one else can provide.

We're also the world's largest pediatric research enterprise, committed to partnering with academic, medical and industry colleagues to accelerate the translation of new scientific discoveries to new therapies and technologies at the bedside. We are also the primary pediatric teaching hospital for Harvard Medical School — teaching the next generation of caregivers, scientists, and innovators.

For 150 years (in fact, we're celebrating that anniversary next year), our entire focus has been on improving the lives of children. In the '30s, we were the first to repair a heart defect in a child born with congenital heart disease. In the '40s, we were the first to develop chemotherapy for acute lymphocytic leukemia in children. In the '50s, we cultured the first poliovirus which led to the vaccine that has saved the lives of millions of children worldwide.

Today, we're leading the way in the fields of genetics, genomics and precision medicine. Our capability to heal is accelerating as we develop new approaches including gene therapies, stem cell transplant procedures, and fetal surgical interventions. Through our Simulation Program, we are piloting new ways to

Boston Children's seek to mitigate the risks that accompany innovations in medicine with strict safety guidelines.

directly involve children in the planning for extraordinary treatments, and we strive to change not only the care we provide but also how it is provided. Our mission is to better understand disease and to transform our learnings into treatments, devices, technology, and we hope, even cures and prevention.

As caregivers, care innovators, and advocates for improving the lives of all children, we recognize the critical importance of our work. Children are 100 percent of our future and that future has never been in more jeopardy.

Right now, we're living in the greatest age of health care innovation in history, and yet 1 in 5 children has an identified emotional, mental or behavioral health issue. Seventy-five percent of our nation's children have

experienced an Adverse Childhood Experience — the kind of event that can impact brain development, as well as social and emotional well-being. Twenty-two percent of our nation's children under the age of 12 live in poverty, while 54 percent of all children have a chronic health condition, are overweight, obese or at risk for emotional developmental delays. Half of the children in our country have healthcare coverage through a state Medicaid program and that funding is both unpredictable and at risk.

We are aware of the problems facing our children, and the possibilities to improve their health and well-being are enormous — if we can just focus on what's most important. That's the responsibility that we take such pride in upholding every day.

But with that responsibility, with that mission, come significant ethical decisions. Today, I'd like to focus on two ethical dilemmas that impact Boston Children's mission and how we take on the greatest challenges facing children. I'm going to focus on *Clinical Risk* and *Cost of Care* — two ethical minefields that we navigate virtually daily in our work. The ethical questions are embedded within both of these issues and they frequently become intertwined.

Boston Children's is a charitable institution — we have a societal responsibility to invest in our children, and provide them with the care and support they need to grow into healthy adults. However, we're also required to operate as a business given an ambiguous national commitment to research funding, medical education, and health care finance. In order to continue to invest in the research and innovation on which our mission is built, we must generate a clinical margin.

This clinical margin is supported by employers and individuals who subsidize the government's failure to cover its share of the actual costs of care. It enables our commitment to making the impossible possible and developing the cures and therapies that will revolutionize healthcare for children and adults.

But we are also 100 percent dedicated to safety and superior outcomes for our patients, and the safest care is care that is performed exactly the same, every time, without defect. No change, though, means no evolution and likely no improvement in outcomes. So, let me begin with the issue of risk.

Over decades of applying continuous quality improvement and high-reliability practices to health care, we strive to achieve consistently safe outcomes through standardization, team-based work, and individual accountability to stop a procedure or practice if something appears not to be in order. We improve our safety record through

"The core of every ethical decision that we make at Boston Children's is our patients and their families."
–Sandra Fenwick

standardization and minimizing individual discretion. The care team has checklists, they engage in cross-checking — having each other's backs. And we put these same safeguards in place everywhere throughout our work.

We draw from success in the aviation industry. Airline pilots don't deviate from their checklists — we don't really want them getting creative — they do everything the same way, every day. The reality is that in most instances, it's safer to deliver medical care if the approach and process are exactly the same, every time. But that also means that what doesn't work today, won't work tomorrow.

And that's not what we do at Boston Children's.

Good is not good enough at Boston Children's. We've never been satisfied with the tools, knowledge, and solutions available when we know that we can do more. We are guided by the principle of "do no harm," but with a twist: "do no harm, but try to make it better." We're searching for cures, but that journey isn't always a straight line, and it sometimes involves asking questions no one has yet asked.

So, how do we encourage innovation in a culture of safety where we are constantly striving to ensure that no harm reaches our patients? Our dilemma is to innovate to make miracles happen but a miracle cannot cancel out taking uncontrolled risks. The riskiest of our innovations — the game-changers delivered at the bedside or in the operating room — are guided by two beacons: collaboration and need.

Despite what you've seen on TV, the iconic lone-wolf doctor, going against his colleagues because "he's got a hunch" doesn't work in the real world. It may have in the past, but it cannot be that way today. When it comes to innovation at Boston Children's, *no one goes it alone*. Doing something no one has ever tried before takes time. It takes data. It takes collaboration. And it is never done without oversight, transparency, the patient's participation, consent, and placing the patient's well-being at the center.

More often than not, and especially at Boston Children's, innovation is the result of a clinician who has a need, making a connection with another clinician or scientist who has an idea. That is the greatest value of having physicians, physician-scientists, and researchers working side by side. The ability to go from bench to bedside with clinical problems, with teams from many disciplines eager to design studies to answer questions and pose solutions, is what advances new options for our patients. These new care approaches can be brought to them with a greater likelihood of success and speed.

Boston Children's employs a number of oversight and approval processes that review clinical research and innovative therapies and procedures. These procedures are intended to ensure peer oversight, patient protection, patient understanding of the innovative nature of the new procedure, and consent. Our Institutional Review Board (IRB) reviews all clinical research studies and trials, and our Innovative Therapy Guidelines and Tool Kit address innovative and novel approaches to care. Explicitly determining whether a new intervention is research or an innovative therapy (a non-standard treatment used solely to enhance the well-being of a patient) can be the first dilemma but must be carefully considered and determined.

And when time is of the essence, there *are* also options to address the acute nature of the situation. All cases, however, center around need where the risks and benefits must be carefully weighed. Could this procedure help a child whose time is running out? Have other conventional therapies or treatments failed? Are there

Agustin was born with Severe Immunodeficiency (aka "Bubble Boy Syndrome"). He was the first child enrolled in a new gene therapy trial, and today, at 13, he is thriving.

simply no other options?

That was the case with Agustin, who was born with x-linked Severe Immunodeficiency (SCID-X1) — a complicated name for a condition most of you know as "bubble boy syndrome." Agustin's bone marrow was unable to create the T-cells (white blood cells) that fight germs and infection. At home in Buenos Aires, he spent his life in isolation. His mother, Marcela, was the only member of his family to come in contact with him, and she only left his controlled environment for meals.

Worse, hopes that gene therapy could hold a cure for SCID-X1 were dashed in the early 1990s when a promising gene therapy trial in Paris and London yielded tragic results. Six patients developed T-cell leukemia or lymphoma as a result of therapy — and all efforts ended for close to a decade.

Timing was everything for Agustin, and by the time he was 5 months old, Boston Children's Drs. David Williams and Sung-Yun Pai had collaborated with a multinational team of investigators to reignite hope for a gene therapy solution for SCID-X1. They recognized the ethical issues of returning to an approach that had previous disastrous results but was fueled by the desire to help children whose time was running out. While current treatments were failing, they doubled back to those trials of the 1990s, figured out what went wrong, and fixed it.

In 2010, Agustin became the first child to enroll in a new gene therapy trial, funded by the NIH and based at Boston Children's. Since that was 8 years ago, I think you've probably guessed that this story has a happy ending. Agustin's bone marrow was extracted and purified, and blood cells were manipulated to carry replacement genes. His T-cells rose from nothing to the normal range for his age. Today, Agustin is *thriving*. He's going to school with other children, and he's shown no sign of infections.
Drs. Williams and Pai went on to enroll 13 more patients.

Nearly a decade later, the gene therapy trial that started by saving one child's life is bearing even greater fruit. While an even safer next-generation trial for SCID-X1 has been launched, the underlying approach that allowed its success is now being trialed in the treatment of other immune deficiencies, like Wiskott-Aldrich Syndrome; metabolic diseases; and even neurologic diseases like spinal muscular atrophy. From one gene therapy trial that brought hope to a very specific group of children, we've created ripples that hold the key to a brighter future for thousands of children with a multitude of conditions.

While the need can be so obvious, other

factors can weigh just as heavily and can create thorny dilemmas. Safety is the obvious concern, whether attempting a brand new, never-before-tried procedure, or even a new version of long-accepted, but not optimal treatment. Cost of care is another factor.

As I said in the beginning, Boston Children's is a charity with a mission, but government and society expect us to be economically self-sufficient and to limit cross-subsidization of care between government and private employers, and between the poor and the wealthy. As noted, without a margin, we cannot invest in research and teaching missions. To do so, we are expected to operate as a business that supports itself by making a margin.

On a daily basis, we balance our responsibility to provide care for patients who can't get care elsewhere with our role as the primary provider of Medicaid services in Massachusetts; as a destination hospital for out-of-state Medicaid services that are consistently under-reimbursed, if they're reimbursed at all; as a teaching hospital for the next generation of caregivers with only partial government funding; as a major research hospital that requires significant subsidies; and for the care and services provided to our community to keep kids healthy and thriving, particularly in underserved neighborhoods.

The cost of care for advanced medical treatments can be very high. The hospital must balance concern for patients with a need to be highly cost effective.

We balance all of that with the need to make a financial return in order to reinvest in the work we're doing to keep pushing boundaries, seek new cures, and provide care for more children. Making the impossible possible is a resource-intensive business.

If we know that our care may not be reimbursed and that research, early novel clinical approaches, teaching and community service will require subsidization, how do we decide what to do? What clinical problems do we try to solve? Which new treatments do we underwrite? Which patients do we accept or not accept? For standard treatments or early stage treatments? Reimbursed or not?

From an ethical basis, there are so many factors we need to consider: Do we have an obligation to save a life where we can? Do we have a *unique* ability to make a difference? Have other therapies failed? Is this an extraordinary teaching opportunity to apply to the next child? Can we improve a child's quality of life?

Is this care one-and-done, or will it require lifelong follow-up care? If a child is local, we can support the follow-up care to get them to adulthood. If the child is *not* local, are we sending the family back to a situation where they can't receive adequate follow-up care? Will our care be undone? Sometimes deciding who we say “yes” to is a thorny

question.

I'd like to tell you about Charles, another Boston Children's patient. Charles was born with gastroschisis, a birth defect where the intestines develop outside the body. He lived with us at Boston Children's for the first 8 months of his life, receiving IV nutrients through a tube. But at that point, prolonged use of traditional formulas of IV nutrition had a disastrous side effect. Over time, Charles' liver was damaged to the point where most children either required a liver transplant or died. By September 2004, Charles' liver had deteriorated to the point where he was going to die without a transplant. He was out of traditional options and running out of time.

This is where non-traditional options come into the story. A Boston Children's surgeon, Dr. Mark Puder, had grown anguished watching babies dying slowly from liver failure that should have been preventable — and he had been working on a solution since 2001. He was convinced that the secret lay in the lack of a fat component of the IV nutrition — known as the intralipid found in a fish-oil based formula, Omegaven. He had lab data from mice that showed liver disease disappeared with the formula.

One of his Boston Children's colleagues — Dr. Rusty Jennings — "had a child and an idea." The FDA and Boston Children's Institutional Review Board approved the use of Omegaven on a compassionate-use basis, and in September 2004, Charles became the *first baby in the world* to receive Omegaven as the sole lipid in his IV nutrition solution. With Omegaven, Charles quickly began to recover. Labs showed his liver was working perfectly. Just over a month later, he was taken off the transplant waiting list…and went home.

Charles is now 14. He still receives IV feedings, but he's doing well. He loves fishing and the outdoors, and he starts high school this fall.

Despite this success, formal clinical trials needed to be conducted before the FDA would grant approval for use of Omegaven in children for this condition. But as Dr. Puder and his team continued using Omegaven to successfully treat patients on a compassionate-care basis, more children began arriving from across the nation, seeking care they could only get at Boston Children's.

As a baby, Charles (pictured above at 4 and 14) was waiting for a liver transplant. Thanks to an experimental treatment at Boston children's, his liver recovered and no transplant was needed.

And this led to an ethical dilemma for Boston Children's. We had a treatment that could mean the difference between life and death for hundreds of children, but as an "experimental" treatment, it wasn't covered by insurance. We made the decision to accept and care for these children. As a result, for the last 14 years, Boston Children's has provided Omegaven to any child who qualified for it, at our own expense. The investment has been considerable — approximately $1 million per year for the Omegaven alone. That's not even attempting to put a price on the support that our Vascular Biology Program has provided over the 17 years since Drs. Marsha Moses and Judah Folkman first took a chance on
Dr. Puder's research. Or the financial support provided for both care and further research by Boston Children's Surgery Foundation, the NIH and the March of Dimes.

But would you ever try to compare that to the value of 280 children's lives? Despite those 280 patients who have received Omegaven under compassionate-use guidelines, it has taken 14 years for the FDA to approve Omegaven for general use for children with liver disease associated with parenteral nutrition, which they did just last month.

And that brings us back to the core of every ethical decision that we make at Boston Children's — our patients and their families. And as long as we're on the subject of our families, I'd like to point out that Charles and Agustin's families not only agreed to let me share their stories with you today, they have been active in sharing their stories with the world, so families with children facing the same challenges know that there is hope.

And given the resources and knowledge that we have available to us today, how can we not be frustrated and dissatisfied with our inability to provide that hope to every child. How can we not embrace the responsibility of seeking out better solutions, even when it can take years, the cost is daunting, and the result is far from certain? There are limits and no easy answers, and that is why each time there is a new and innovative therapy, we convene a team of caregivers, members from our ethics committee, and experts in finance, law, and government advocacy, among others. The answer cannot always be yes and the reality is that we cannot always solve the cost/cure dilemma.

How do we weigh the risk and benefits of applying new treatments, procedures, drugs, and therapies while continuously striving for safe, reliable care? Can we afford to supply Omegaven at no charge to 280 children? Can we afford not to? We have invested in Agustin and Charles, and thousands of children like them. Can you imagine the dividends that investment will pay over the next many years of their lives?

To put that investment in perspective, I'd like to share the story of one more Boston Children's patient — Lorraine Sweeney. At age 7, Lorraine's mother brought her to Dr. Robert Gross, who diagnosed her with a congenital heart defect. In 1938, that was a death sentence. Accepted practice dictated that surgery was not a survivable option. Dr. Gross, Boston Children's chief surgical resident at the time, disagreed. After two years of animal testing, he was sure he could correct the defect in Lorraine's heart, but his chief explicitly forbade him from attempting the surgery.

Now, this was 1938, and the approval process for an experimental treatment was very different than it is today. In fact, Dr. Gross simply waited until his chief boarded a ship bound for Europe. Then, with the blessing of Lorraine's mother, and his career very much on the line, he performed that revolutionary surgery. Today, he could not have done this without oversight and

In 1938, Lorraine (picture above on left) was the first person to have heart surgery. Now, at 88, (second from right in photo above) we can say the operation was a great success!

explicit approval. Even in 1938, if Lorraine had died, he never would have worked again. Instead, he went on to become Boston Children's Surgeon-in-Chief, effectively creating the field of pediatric cardiovascular surgery.

And Lorraine? Here's a picture of Lorraine just last month, at a lunch with our Archives Committee. She's 88 — an impressive age for anyone, but an astounding age for a woman born with a congenital heart defect. I feel quite confident that her children and her grandchildren believe that her life was worth the risk.

Every risk we take. Every boundary we push. Every cost we incur, knowing we won't get it back. I couldn't sleep at night if I didn't see the choices we make as an investment in our children and our future.

The families who need world-changing breakthroughs and cures need them now. And their well-being is the compass that guides every choice we make. When children thrive, a society thrives. If we want to thrive, we must build a society that puts children first and makes sure their lives are complete from the beginning.

And I couldn't be prouder of the 11,000+ members of our Boston Children's team who come to work every day, continuously delivering the highest quality, most innovative care, yet always seething with discontent towards the status quo. We face these challenges and ethical dilemmas constantly, knowing that we can do more and tirelessly committed to redefining our future.

Thank you all for coming today. And thank you for all that you do in your own work, across your own fields, to ensure that our future is one built on the simple but essential value of doing the right thing for the right reason.

Q&A

Below are edited highlights of Sandra L. Fenwick's question-and-answer session with Bentley University students, faculty, staff, and guests.

QUESTION: *Could you tell us about your leadership style and how it has changed based on your years at Boston Children's?*

SANDRA FENWICK: First and foremost, it is to surround myself with people who are far, far smarter than I am. I have done so all the years I have been in these roles because leadership really is a team effort; it is not about any one individual. And so I surround myself with the best executive team — the clinical, scientific, and nursing leadership, and leadership across every aspect of what we do. We are like a small city. We have people in many functions from environmental services to valet services. Everyone has to be a part of what we do for our patients and families. Therefore, I surround myself with the very best, and then it's about finding a way to give them both the voice and support to do their own, important things.

One of the challenges at places like Boston Children's Hospital is to allow individuals to go off and do really wonderful things. Then, how do you knit these silos together into one common enterprise with one common set of goals? We have people at Boston Children's who work across those silos. They may be doing this from a business standpoint for one goal, whether it is a financial challenge or an ethical, public relations, or reputation challenge. One of the things we have to do is be one and to put ourselves together, inside and outside the organization as *one* institution. That's always a challenge when you have incredible individual players and need them to be one enterprise. So for me, it has been about

trying to figure out how to balance individual discretion and leadership and still be one organization that really brings people together toward one goal.

Have I changed? No, I guess that is something I have always felt is important wherever I worked, but it is probably the most challenging piece of what I do. The second most challenging piece is having sufficient resources to invest in everyone who has a noble and wonderful program, project, clinic, idea, research program, and the like. If there's anything I go to bed frustrated with, it's not having the resources to be able to support the next person in line and having to say "no." I think that is the hardest thing we ever do is saying "no." It is a skill and is required of anyone in a leadership position.

QUESTION: *As we enter this new age of medicine where treatments are no longer costing a million dollars per year, but possibly a million dollars per patient, how is Boston Children's preparing for that and how do you think it will impact your ability to provide care and pay for it?*

SANDRA FENWICK: Some of these new therapies are indeed million dollar therapies, Whether it is the new CAR-T cell therapy or the new drug for spinal muscular atrophy, these therapies can be close to a million dollars just for the drug. It is not an easy question, especially before they are approved for reimbursement. However, even with the reimbursement, often the full cost of care is not covered. We are constantly working closely with payers and the government to ensure that there is an acknowledgment of not just the care we provide, but the endpoint. We need to ask, "Is this just life continuing or is it also life altering? Is this something that could potentially enable us to avoid future care and costs?"

We are trying to get out the message on these kinds of things, but it absolutely is a challenge, especially for a place like Boston Children's. We have been trying to move all the low complexity care outside the hospital because we are expensive and we are becoming more expensive as we take on kids with more complex conditions. It is becoming difficult to deliver care in the clinic, the emergency room, and in the inpatient setting. As a result, we have been saying, "Let's move as much care to the local community. Let's move it to the offices of the primary care physicians and not have kids come to the hospital at all." This is becoming very challenging because we stand out as the most expensive hospital in Massachusetts — not in the country because we are very cost-effective as a children's hospital when compared to our peers. However, in Massachusetts, we are targeted as the most expensive hospital. So trying to describe and have people understand who we care for, where those costs are going, and how we can justify the full value of what we're delivering, is something we are working on every day.

QUESTION: *Is it a concern that Boston Children's Hospital and other large teaching hospitals around the country could lead to the closure of smaller hospitals that could be serving minority and poorer communities? Could this consolidation of hospitals lead to a reduction in services offered and a decline in the number of children cared for?*

SANDRA FENWICK: I think what you are asking is if consolidation, including horizontal consolidation of systems, is going to affect access for children. For example, might a hospital decide that it cannot keep all its services open, and will that have an impact on the ability of children or adults to get care?

That is always a worry. I am proud to be in Massachusetts because that has never been the approach our institutions have taken. In fact, we take on more and scramble to take on even more, and hope to make it all work out economically. This state was one of the

first in the country to say that we have to figure out how to provide — especially for kids — over 99 percent access to cover them somehow, whether it be the Medicaid program, the Children's Health Insurance Program, commercial coverage or some other form of insurance. We have done a great job in this state in saying that we really need to figure out how to open up access and make sure that kids have coverage first, and that no children are turned away from care. That's not the case for the rest of the country. I hate to say it, but especially among some of the for-profit hospitals — they've closed services because they're not profitable. The non-profits and public hospitals are then picking up the children and even adults, who are traveling farther distances for care. That is an issue I think we are all concerned about.

QUESTION: *What would you say is Boston Children's Hospital competitive advantage that has kept it rated the number one hospital over the past five years?*

SANDRA FENWICK: Interestingly, that is something we have talked about a lot in the last couple of years. Like most businesses, we have done strategic and scenario planning, as we see consolidation both vertically and horizontally as financial pressures have only increased. The question is, what's distinctive about what we offer? As people say, you have to deliver something that's not just excellent, but also unique or different. What we see that is different is caring for children that cannot be cared for locally, nationally, or even internationally. We care for kids whose conditions don't even have a name, who have failed therapy at other places, and who have parents who are frustrated because they are not seeing any progress or they are dissatisfied with the way that the whole team has surrounded them and cared for them holistically. We see ourselves with the research program, translating research as fast as we can to create clinical solutions. We think about how we can bring those solutions from a scientific perspective, closer to the bedside, and offer them as a distinct advantage to kids and their families.

QUESTION: *I think what you are doing is remarkable, but how much risk are you and Boston Children's taking financially and in terms of reputation with the experimental treatments you are pursuing, given the potential of malpractice suits if an operation on a patient goes wrong?*

SANDRA FENWICK: There is always risk, and the risk is not just with novel or innovative therapies, but there is risk every day because we are humans. As I mentioned, putting safeguards around the delivery of care doesn't mean someone can't make a mistake. The first thing we do is to put systems in place that are like safety nets, including checklists intended to provide an environment that is as safe as can be for a person to really do their work. The challenge is, if something does go awry, the most important thing we do is to ensure that we analyze everything that went wrong. For example, how much was a systems issue? How much was a personal error? We have a whole system called the “Serious Event Reporting System.” We ask everyone to not only tell us when things go wrong but also when there are “near miss events,” which occur when nothing went wrong but there was an opportunity to learn to correct something. There is that constant need to evaluate when something goes wrong and we need to put a fix in place so it won't happen again. It may be that someone needs training, and needs to be taken offline to do that training, all the way to systems changes that put other protections in place to ensure that the problem won't happen again to another child.

QUESTION: *Because Boston Children's is a charitable organization, what percentage of the hospital's resources come from philanthropy?*

SANDRA FENWICK: On an operating basis, a relatively small amount of funds that are raised annually — about $15 million of a $1.6 billion hospital operation — comes from philanthropy. Most of the philanthropy goes directly to projects and people. They underwrite professors, teaching fellowships, scientists, and projects before they are eligible for NIH funding. They underwrite funds that are dedicated to the care that supports families. Fifteen million dollars is raised on an annual basis for what we call "unrestricted." There's another $30 to $40 million that comes from funds that we draw on to support specific programs such as child-life specialists who surround a child and family in every unit we have in the hospital that is not covered by insurance. We have various social workers, educational experts, and others who help children when they are in the hospital for long periods of time. There are many things we do to surround a child and family during these tough times that would not be reimbursed through insurance that draw from these funds. On the research side, philanthropic donations represent close to 25 percent of our research budget. It is a very important part of our research budget, and, in fact, many projects would have never gotten started if it weren't for philanthropy. We are in the last throes of a major capital campaign and we are very close to reaching and even exceeding our goal of $1.2 billion. We are raising significant funds to continue to support all of these things, but they are parsed through a lot of endowments and special funds that directly support specific projects.

QUESTION: *Because medical ethics and business ethics handle different things, does Children's have separate medical and business ethics committees?*

SANDRA FENWICK: We definitely have a medical ethics committee. It is so huge that we had to split it into two different sub-committees. We also have two full-time ethicists and a number of physicians who have embraced this as their area of expertise. In fact, one of them is a professor of medical ethics at Harvard Medical School and was involved in founding that program. It is very near and dear to our hearts. You are raising a very good question. Per se, we do not have a named business ethics committee. We have a program in risk and compliance and we have a compliance officer. When questions come up about business ethics that cross over into the clinical world, we call up special groups. We put the right people together depending on the issue. It is more ad hoc, although the issues are always addressed with experts in both clinical and business matters. As needed, we draw on experts in business, lawyers, communications, and even government relations who will come together around a complex set of questions. It tends to be ad hoc and depends on the situation.

QUESTION: *Over the history of the hospital, how have its ethical principles changed over time?*

SANDRA FENWICK: In the distant past, we did have times when people faced really challenging clinical decisions and even moved forward with a patient treatment when it went against an explicit lack of approval. That would now be grounds not only for termination but also for a whole set of hearings. There are ethical dilemmas in research where we have wonderful physicians and scientists coming up with new products, devices, and compounds, and they want to start companies. They have an opportunity to bring their work to the market. However, this raises the question, are you investing in the company for your own interests or for the good of the patients and future patients? Consequently, we have conflict of interest

committees both at Boston Children's and at Harvard Medical School. They aren't the same and don't always ask the same questions. However, every time we have this kind of problem, it is incumbent that the people involved come forward and declare their conflict, say what they would like to do, and ask for permission to do it. Then we create a series of checks and balances, management plans, and the like. These kinds of issues clearly cross over into the area of patient care. We are very careful that when we get into one of these issues that it be explicit when there is an ethical dilemma regarding how we manage business interests and patient care issues.

What we are finding is that it is not just about how we protect patients when introducing a new treatment or therapy, because those are coming up all the time. We have new checklists, guidelines, and toolkits. We explicitly require everyone on the committee to make a determination if something proposed is research or a variation on an existing approved treatment or therapy.

Now, new issues are bleeding in as we try to separate what fulfills our role as a hospital and what is really focused on advancing business or commercial interests. This is a whole new area that all of us, particularly hospitals, are venturing into. I can see that these things will continue to come up. We need to make sure we are always asking those questions about conflict of interest, appropriateness, and putting the patients' well-being at the center. From a corporate perspective, we need to ensure that we are asking the important ethical questions about business ethics and patient care concerns simultaneously.

Thank you.

Moments before the program begins, the auditorium begins to fill with students, faculty, staff, and guests.

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