The Regents of the University of California

HEALTH SERVICES COMMITTEE June 23, 2021

The Health Services Committee met on the above date by teleconference meeting conducted in accordance with Paragraph 3 of Governor Newsom's Executive Order N-29-20.

- Members present: Regents Blum, Guber, Lansing, Makarechian, Park, Sherman, and Sures; Ex officio members Drake and Pérez; Executive Vice President Byington; Chancellors Block, Hawgood, and Khosla; Advisory members Hernandez and Ramamoorthy
- In attendance: Regents Butler, Cohen, Elliott, Estolano, Kounalakis, Leib, Mart, Muwwakkil, Ortiz Oakley, Reilly, and Stegura, Regents-designate Lott and Torres, Secretary and Chief of Staff Shaw, General Counsel Robinson, Executive Vice President and Chief Financial Officer Brostrom, Vice President Nation, Chancellors Christ, Gillman, Muñoz, and Yang, and Recording Secretary Johns

The meeting convened at 10:05 a.m. with Committee Chair Lansing presiding.

1. APPROVAL OF MINUTES OF PREVIOUS MEETING

Upon motion duly made and seconded, the minutes of the meeting of April 6, 2021 were approved, Regents Drake, Guber, Lansing, Makarechian, Park, Sherman, and Sures voting "aye."¹

2. UPDATE FROM THE EXECUTIVE VICE PRESIDENT OF UC HEALTH

[Background material was provided to the Committee in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

Executive Vice President Byington began the discussion by thanking Advisory member David Spahlinger for his service on the Committee. Dr. Spahlinger was the President Emeritus of the University of Michigan Health System. Dr. Byington expressed appreciation for his counsel during the COVID-19 pandemic and for his leadership of the UC Health Working Group on Clinical Quality, Population Health and Risk Management. She thanked Regents Lansing and Sherman, whose terms as Chair and Vice Chair of the Health Services Committee were ending. Committee Chair Lansing added her thanks to Dr. Spahlinger for his service on the Committee.

Dr. Byington reported that, at this time, coronavirus case counts in the U.S. showed that the country was on a desirable downward trajectory, having clearly passed the third surge.

 $^{^{1}}$ Roll call vote required by the Bagley-Keene Open Meeting Act [Government Code 11123(b)(1)(D)] for all meetings held by teleconference.

The trends in California were even better than in the nation as a whole. There were very low case rates, with a seven-day rolling average of two cases per 100,000. The numbers of COVID-19 inpatients at UC medical centers were all in the single digits, a dramatic improvement compared to December 2020 and January 2021. With regard to UC Health's financial performance, she noted that, during the months of March, April, and May, the medical centers and schools of medicine clinical operations had recovered from losses due to COVID-19 and were essentially at their baseline.

These dramatic improvements were due to widespread vaccination campaigns. Dr. Byington presented a chart which illustrated the importance of the COVID-19 vaccines and the remarkable science that had delivered these vaccines so quickly. The chart listed a number of infectious disease agents and indicated the year when they were discovered, and the year when a vaccine was developed to combat them. Malaria was one of the first human pathogens to be identified scientifically in 1880. There was still no vaccine for malaria, and the same was true for tuberculosis. The measles virus was discovered in 1953, and it took ten years to develop the vaccine, which appeared in 1963; at that time, this was considered a wonder of modern medicine. SARS-CoV-2 was discovered in 2020 and three vaccines were delivered in 2020. This was truly a wonder of science, and Dr. Byington believed that the mRNA vaccines would offer new hope for combating many pathogens for which there was still no vaccine, including HIV, malaria, and tuberculosis.

Vaccine effectiveness remained strong against COVID-19 variants. The World Health Organization had changed the names of the variants, using the letters of the Greek alphabet. Alpha, Beta, Gamma, and Delta were the most prominent variants. The Delta variant showed increased contagiousness. It could spread more easily and lead to more potential cases, deaths, and people living with long-term effects of COVID-19. The R-naught for the original virus was between 2.4 and 2.6, so that every infected person might be expected to infect 2.5 more people. The Alpha variant, first discovered in the United Kingdom, and common in the U.S., had an R-naught of four to five, a substantial increase. The Delta variant had an R-naught of five to eight. One was observing the evolution of this virus in real time as it was becoming more able to infect human beings. This was an increase in transmissibility and in the number of people who need to be vaccinated. The higher the Rnaught, the greater proportion of a population that needed to be vaccinated. It was very important that there were effective vaccines and that efforts continued to vaccinate all who were eligible. The Delta variant would not be the last variant the world would have to deal with, and this was why it was essential to vaccinate people now to prevent further transmission and evolution of the virus.

UC Health was focusing its efforts on vaccinations and trying to reach every community possible. Nursing faculty and students were taking these efforts to the Tenderloin district of San Francisco. There were efforts to vaccinate thousands of maquiladora workers in Mexico. This was occurring through a partnership of UC San Diego Health, the Consulate of Mexico, and businesses on both sides of the border. UC Irvine was engaged in community vaccination efforts in Orange County. UC Health was working with the State on a privacy-preserving vaccine verification system, the SMART Health card, which was compatible with the Epic electronic health record system used at UC.

Dr. Byington then outlined a few UC Health activities not related to COVID-19. UC Health had been using the Social Vulnerability Index and the Area Deprivation Index to better understand its patients. These data had been important in addressing COVID-19, but they were also useful in addressing many other conditions, such as diabetes, hypertension, and needs for surgical care, and in helping UC Health determine where it could best offer its services.

UC Davis had just launched a telehealth program in the Central Valley for agricultural workers. UCLA was working throughout Greater Los Angeles, partnering with community advocates, sports teams, and the American Heart Association to provide people who are food-insecure with food and medical and vaccine information about COVID-19. UC was also involved in caring for unaccompanied minors who have arrived at the U.S. border. These programs were anchored by UCSD in San Diego, and by UCLA and UC Irvine in Long Beach. Since these sites were opened in March and April, UC had cared for thousands of unaccompanied minors and had helped more than 4,000 of them to be reunited with their families or sponsors. UC would continue to work in these centers through July.

Dr. Byington concluded her remarks by recalling the HIV epidemic; the first cases in the U.S. had been reported 40 years prior. There were epicenters in Los Angeles and San Francisco. The work done to combat HIV had helped to develop the understanding of health disparities, stigma, the need for community involvement, and the need for advocacy to ensure equitable treatment for all patients; these lessons had helped the health profession respond to the COVID-19 pandemic.

President Drake recalled that he had been newly in practice at UCSF in 1981, when the first HIV patients were seen. He referred to the chart shown earlier listing the various time periods of vaccine development. The development of vaccines against COVID-19 was a miracle.

Regent Reilly asked why one variant was more contagious than another. Dr. Byington responded that the variant becomes fitter through genetic mutation. The virus replicated quickly and could try new mutations. Some mutations would increase contagiousness, and this was referred to as "acquired fitness." For this reason, it was important to vaccinate people so that the virus could not replicate and become more fit.

Regent-designate Lott asked when children would be able to receive vaccines. She asked about complications observed in younger children and how this might affect emergency use authorization. Dr. Byington responded that the clinical trials for children aged 12 to 15 years had been completed, and the mRNA vaccines were available for that age group under emergency use authorization. The Centers for Disease Control and Prevention (CDC) were, on that very day, holding a meeting to discuss cases of myocarditis reported in young males following receipt of mRNA vaccines. The data so far indicated that these cases were rare, and likely more rare than the myocarditis that would be associated with natural infection. Dr. Byington was waiting for the CDC to issue its guidance. Trials for children younger than age 12, and as young as six months, were underway at about five centers in the U.S. Those data would be available in the fall.

3. CONSENT AGENDA

A. Approval for Participation in a Cancer Care Joint Venture with a Bay Area Health System, San Francisco Campus

The President of the University recommended:

- (1) Approval of UCSF Health's (UCSFH) establishment, with John Muir Health (JMH), of a joint venture (Walnut Creek Cancer Program, LLC, the Joint Venture) dedicated to operating an outpatient comprehensive cancer center in Walnut Creek, California (the Cancer Center), with UCSFH and JMH as its two corporate members, in furtherance of the charitable and educational purposes of UCSFH and JMH, including promoting health and providing or expanding access to healthcare services for a broad crosssection of the community. The investment of up to \$40 million shall be an exchange for up to a 49 percent stake in the Joint Venture.
- (2) That the following be required, in connection with the above arrangements:
 - a. Purposes/Mission: UCSFH's participation in the Joint Venture shall be in furtherance of its non-profit purposes and consistent with its clinical and academic missions.
 - b. Capital Calls/Additional Investment: Concurrence of the Chair of the Health Services Committee shall be required for any investment (e.g., in response to a capital call) beyond the above amounts, as well as any mergers, acquisitions, joint ventures, or sales of all or substantially all of the assets of the Joint Venture.
 - c. Exclusivity: Nothing in any agreement signed in connection with the Joint Venture will bind the University as a whole, UC Health, or any UC campus or UC medical center (other than UCSF); and all definitive agreements shall preserve UCSF Health's right at all times to participate directly or through the new companies where appropriate in systemwide initiatives notwithstanding any exclusivity agreements or policies otherwise adopted by the Joint Venture.
 - d. Use of University Name: UCSFH shall participate in a joint marketing arrangement for the Cancer Center, consistent with the requirements of California Education Code Section 92000. Any use of the UCSF or University of California name shall be subject to prior approval by the campus and shall be consistent with University policies governing use of the University's names and marks and appropriate licensing agreements.

- e. Access to Records: UCSF Health shall have access to all legal and financial records maintained by the Joint Venture.
- f. Termination: The definitive agreements shall include appropriate provisions for termination or dissolution.
- (3) That the President or his designee be authorized, after consultation with the Office of the General Counsel, to approve and execute any agreements reasonably required to implement UCSF Health's participation in the Joint Venture, including any subsequent agreements, modifications, or amendments thereto, provided that such agreements, modifications, amendments, or related documents are materially consistent with the terms above, and do not otherwise materially increase the obligations of the Regents or materially decrease the rights of the Regents.

B. Participation in a Joint Venture to Develop a Medical Office Building in Fremont, California, San Francisco Campus

The President of the University recommended:

- A. Approval of UCSF Health's establishment, with Washington Township Health Care District, of a joint venture (Warm Springs Health Center Partnership, LLC, the Joint Venture), with UCSF Health (UCSFH) and Washington Hospital Health System (WHHS) as its two corporate members, in furtherance of the charitable and educational purposes of UCSFH and WHHS, including promoting health and providing or expanding access to healthcare services for a broad cross-section of the community, and investment of up to \$31 million over five years and UCSFH's tenancy-in-common interest in the real estate parcel at 45388 Warm Springs Boulevard, Fremont, California, in exchange for a 49 percent stake in the company.
- B. That the following be required, in connection with the above arrangements:
 - (1) Purposes/Mission: UCSFH's participation in the Joint Venture shall be in furtherance of its non-profit purposes and consistent with its clinical and academic missions.
 - (2) Capital Calls/Additional Investment: Concurrence of the Chair of the Health Services Committee shall be required for any investment (e.g., in response to a capital call) beyond the above amounts, as well as any mergers, acquisitions, joint ventures or sales of all or substantially all of the assets of the Joint Venture.
 - (3) Exclusivity: Nothing in any agreement signed in connection with the Joint Venture will bind the University as a whole, UC Health, or any

UC campus or UC medical center (other than UCSFH); and all definitive agreements shall preserve UCSFH's right at all times to participate directly or through the new companies where appropriate in systemwide initiatives notwithstanding any exclusivity agreements or policies otherwise adopted by the Joint Venture.

- (4) Use of University Name: Any use of the UCSFH or University of California name shall be subject to prior approval by the campus and shall be consistent with University policies governing use of the University's names and marks and appropriate licensing agreements.
- (5) Access to Records: UCSFH shall have access to all legal and financial records maintained by the Joint Venture.
- (6) Termination: The definitive agreements shall include appropriate provisions for termination or dissolution.
- C. That the President or his designee be authorized, after consultation with the Office of the General Counsel, to approve and execute any agreements reasonably required to implement UCSFH's participation in the Joint Venture, including any subsequent agreements, modifications, or amendments thereto, provided that such agreements, modifications, amendments or related documents are materially consistent with the terms above, and do not otherwise materially increase the obligations of the Regents or materially decrease the rights of the Regents.

[Background material was provided to the Committee in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

Executive Vice President Byington briefly introduced the consent agenda items.

Upon motion duly made and seconded, the Committee approved the President's recommendations and voted to present them to the Board, Regents Drake, Guber, Lansing, Makarechian, Park, Sherman, and Sures voting "aye."

4. PROPOSED REQUEST FOR THE UCSF BENIOFF CHILDREN'S HOSPITAL OAKLAND MASTER FACILITIES PLAN PHASE 2 INCLUDING NEW HOSPITAL PAVILION, SAN FRANCISCO CAMPUS

The President of the University recommended that the Health Services Committee authorize UCSF to request approval from the Finance and Capital Strategies Committee at a future date for (1) preliminary plans funding, budget, and external financing for the UCSF Benioff Children's Hospital Oakland Master Facilities Plan Phase 2 including New Hospital Pavilion program and (2) any amendment or modification to the foregoing.

No irrevocable commitment is being made through this authorization.

[Background material was provided to the Committee in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

Chancellor Hawgood recalled that, in January 2014, the Regents became the sole member of Children's Hospital Oakland, a nonprofit public benefit corporation. The hospital has operated in Oakland for more than 100 years as a critical safety net hospital. It served as the hospital for the most underserved children in the San Francisco Bay Area, including a large population of homeless children. It maintained a Level One trauma center and was the only children's hospital in the U.S. operating a Federally Qualified Health Center (FQHC) for children. The hospital facilities were now obsolete. The oldest buildings dated back to 1928. This made state-of-the-art care difficult and made the hospital noncompetitive with new children's hospitals at the UCSF Mission Bay campus and at Stanford Health. When UCSF took responsibility for the hospital in 2014, it developed a two-phase master facilities plan to address the glaring differences in UCSF facilities that served underserved children and their families. Phase One of the plan was nearing completion.

UCSF Benioff Children's Hospital President Matthew Cook underscored the importance of health equity for the community that this hospital serves. Other guiding principles for UCSF in its plans for the hospital were patient-centered care, UCSF's teaching mission, the ability to attract and retain talent, and engagement with the community. The new construction program would provide private rooms for patients. Currently, patients were seen in double occupancy rooms and open wards. If one accepted the parent or guardian to be part of the care model, which was the case in a modern children's hospital, this presented challenges for safety, infection prevention, and privacy in the midst of other patients and families. One expects a parent or guardian to stay overnight with a child, and this was not possible in the current configuration. Patients and their families, who are in a stressful situation, want the privacy and dignity of a private room.

Another challenge for the hospital was related to state-of-the-art technology and operating rooms. In the neonatal intensive care unit, if one wished to place a newborn child on an extracorporeal membrane oxygenation (ECMO) machine, the most invasive form of mechanical support, this currently required moving equipment around the unit. This impeded the hospital's ability to provide state-of-the-art care safely. It was difficult to fit modern equipment in the operating rooms, which were old and undersized.

In addition to COVID-19, there was another ongoing pandemic of mental health among pediatric and adolescent populations. Children's Hospital Oakland has considered different ways of providing inpatient mental health services, but it was not possible in the current facility. In a new facility, UCSF envisioned a dedicated inpatient unit of 20 beds, as well as an outpatient building for mental health. These units would provide a service that was not now available in the community.

Another important consideration was the work environment. The current facility did not lend itself to attracting and retaining talent. The spaces were small and made it hard to collaborate. The plan aimed to provide a modern environment that would support those who work at the hospital and make it a good place to work. The motivation for this plan was essentially to meet the needs of the broader community, but also to meet the needs of clinicians and staff. This hospital was the fourth-largest employer in Oakland, and thus an important element in the economic fabric of the community as well.

Implementation of the plan would require demolition of older buildings from the 1920s and 1940s; these would be replaced by a new pavilion. The plan would also allow for the creation of green space. A clinical support building would be built first and allow people and programs to move out of the buildings that needed to be demolished. A helipad also needed to be maintained during construction. UCSF Benioff Children's Hospital representatives had been meeting with elected officials and community members. The community was supportive of this project.

Advisory member Hernandez underscored that UCSF Benioff Children's Hospital Oakland was the only children's hospital with an FQHC. This was important for UCSF's primary care capacity for this population. She commended UCSF for keeping this clinic viable when it took over the hospital. Inpatient psychiatric services for young people were virtually non-existent in the Bay Area. This capacity for mental health was badly needed. She hoped that the Regents would look upon this recommendation favorably.

Upon motion duly made and seconded, the Committee approved the President's recommendation, Regents Drake, Guber, Lansing, Makarechian, Park, Sherman, and Sures voting "aye."

5. SPEAKER SERIES – SEARCHING FOR THE CURE: A CLINICAL TRIAL OF CRISPR TECHNOLOGY IN SICKLE CELL DISEASE, BERKELEY, LOS ANGELES, AND SAN FRANCISCO CAMPUSES

[Background material was provided to the Committee in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

Executive Vice President Byington began the discussion by explaining that sickle cell disease causes anemia, pain, and many life-threatening effects, such as stroke. It was the first human disease to be explained at the level of genetics; it was the result of a single nucleotide mutation, one letter change in the human DNA code. Sickle cell disease was an inherited disease and could be found among people of any race, though it was most common in African Americans. One in every 365 African American infants born in the U.S. was affected by sickle cell disease. Individuals with sickle cell disease have experienced inequity in treatment and in the research undertaken to combat the disease.

Jennifer Doudna, UC Berkeley Professor of Biochemistry, Biophysics and Structural Biology, Nobel Laureate, and founder of the Innovative Genomics Institute, addressed the Committee in a recorded video. She explained that the Institute had begun as a UC Berkeley-UCSF partnership to address challenges in human health and the environment using CRISPR-based genome editing. Working with partners and collaborators across UC, the Institute took advantage of innovative science and exciting technology to address real world problems in health care.

Sickle cell disease and thalassemia were blood disorders with well-known and welldocumented genetic causes. Now, with CRISPR technology, they could be cured. This was not a fantasy; it was happening now. The Institute wished to ensure that everyone who could benefit from this technology would have access to it.

Ms. Doudna reflected on the reasons for studying sickle cell disease. It was a well-studied genetic disorder. The patient population was underserved. There was an unmet need for affordable sickle cell disease care and cure. The Institute had end-to-end in-house expertise in advancing the CRISPR technology to the clinic, beginning with innovation and ending with cured patients. Current treatments for sickle cell disease were harrowing and expensive. Treatment began with bone marrow stimulation, followed by cell harvesting. Patients were then treated with aggressive chemotherapy to destroy their natural bone marrow. The harvested cells were edited using CRISPR to correct the disease-causing mutation in the patient's DNA. The edited cells were infused into the patient, followed by a long process in which the cells were able to recreate the blood supply. This was a grueling process for the patient and it was expensive, at a cost of about \$2 million per patient.

The Institute's vision was to identify a one-step cure for sickle cell disease. This would be an in vivo treatment, treating the patient directly, without having to go through the steps of removing cells from bone marrow and using chemotherapy. The Institute believed that it could make this process much easier and much more affordable, while keeping it safe and effective. The Institute carried out this work with an eye toward ethics, and was mindful of ensuring that new technologies like CRISPR are made available to those who need them.

Mark Walters, M.D., UCSF Professor of Pediatrics and Director of Bone Marrow Transplantation at UCSF Benioff Children's Hospital Oakland, presented a diagram of a hemoglobin molecule, which consists of two alpha and two beta hemoglobin chains. Each chain binds an oxygen molecule at its center, and this delivers oxygen to human tissues. This molecule is responsible for the fact that oxygen can be dissolved in the bloodstream and delivered to vital organs and tissues. In sickle cell disease, a single DNA change created an amino acid substitution, which, after the oxygen has been delivered to the tissues and the hemoglobin is carried back to the lungs to pick up more oxygen, can form an initiation point at which long strands of sickle hemoglobin can form, stiffen the red blood cell, and cause it to become blocked in blood vessels. This causes pain and anemia and can lead to reliance on red blood cell transfusions and chronic illness due to damage to vital organs.

This disorder had historically led to a high rate of death in childhood. With the institution of newborn screening programs and comprehensive supportive care, almost all children with the disorder survived to age 20. The median age of survival for persons with sickle cell disease was 48 in the most common genotype which was being targeted in the CRISPR

project. Even with improved supportive care, this disorder resulted in an at least 30-year decrement in life span.

There have been U.S. Food and Drug Administration (FDA)–approved treatments for sickle cell disease. For many years, there was only one approved drug available, which reduces inflammation and raises the level of hemoglobin. In 2018–19, three more FDA-approved drugs were produced. These drugs reduce pain and anemia. The small number of approved drugs were a demonstration of the fact that this disease was under-resourced and that curative therapies were urgently needed.

The only current cure for sickle cell disease was stem cell transplantation or bone marrow transplantation. This worked best for patients with a healthy sibling with the same transplant type who served as a donor. In these cases, overall survival exceeded 90 percent. Outcomes were not as favorable for patients with unrelated donors. Dr. Walters presented a chart with outcomes for patients by age and type of donor. For adult patients with matched unrelated donors, the success rate was about 50 percent, while a surprising 29 percent died of the therapy itself. The Institute's project aimed to eliminate the complication that led to patients dying after the bone marrow transplantation by using the patient's own stem cells and editing them in a way to correct the sickle cell mutation.

There were barriers to the transplant approach. Only 18 percent of families had a matching sibling donor, and only 19 percent had a well-matched, unrelated donor. Many clinicians and families themselves did not pursue a transplant due to complications that could increase the risk of dying from the procedure itself. The transplant approach was largely restricted to children and it was applied sparingly.

For the Institute, one challenge was whether it can modify a patient's own cells for clinical benefit, and another was to ensure equitable access to novel curative therapies. The current state of CRISPR technology was such that one was not likely to correct 100 percent of the sickle mutations in 100 percent of the stem cells; however, this was not necessary, due to a condition known as mixed donor-host hematopoietic chimerism, which developed after a conventional bone marrow transplant for sickle cell disease. After the transplant, as little as 20 percent of the patient's marrow, made up of the healthy donor cells, can cure sickle cell disease. This phenomenon occurred because the life span of the sickle red blood cell, ten to 20 days, was eclipsed by the life span of a healthy red blood cell, which was 120 days. To the researchers, this suggested that the target for the project, using the CRISPR gene editing reagent, was to achieve correction of one simple mutation in at least 20 percent of the engrafted cells in order for this approach to be curative. Dr. Walters described this as the first step in a pipeline of improvements that he and his colleagues hoped would optimize the use of these reagents. Ideally, this cell therapy would provide protection from sickle cell disease-related complications, both clinical and subclinical, have an acceptable toxicity profile in the short and long term, be accessible and available to most patients, and be safe for children and adults; in addition, comparative trial design would show evidence of the benefit of this curative therapy.

Donald Kohn, M.D., UCLA Professor of Microbiology, Immunology, and Molecular Genetics and Pediatrics, then discussed how this approach was taken from the research level to clinical application. The pre-clinical research studies to develop the method for correcting the sickle cell mutation in patient stem cells were carried out at a small scale, with one-half to one million cells per sample, and used research-grade reagents. Producing sufficient edited stem cells for a clinical stem cell transplant required editing 100 million to 300 million cells. Cell processing needed to be increased. Clinical-grade CRISPR reagents were needed to produce cells for human administration. The Institute had to work with vendors to develop suitable reagents and documentation for the FDA. Scale-up studies were performed testing the clinical-grade reagents and close to patient doses of cells, purchased from healthy donors.

Dr. Kohn described the process of getting stem cells from the patient and editing the cells. In the future, one hoped that stem cells would stay in the patient and that one could deliver the gene to the patient. Currently, sickle cell patients received a drug called Plerixafor, which causes stem cells to leave the bone marrow and go into circulation. The stem cells are collected and enriched, then put into a cell culture for two days with a combination of growth factors that activate the cells. The cells are electroporated and bathed in a solution of CRISPR editing reagent; the cells receive a jolt of electricity to drive the reagents into the cells. The cells are cultured for an additional day to allow CRISPR to fix the sickle mutation, and then frozen. The cells are tested to ensure that they are sterile and that enough cells have been edited.

As part of its process with the FDA, the researchers carried out multiple cell manufacturing runs. The outcomes of these runs showed that the cells had 80 to 90 percent viability after electroporation. About 20 to 30 percent of the sickle mutations in the cells were corrected, a sufficient amount to give rise to healthy red blood cells. The researchers also examined within individual stem cells to determine how much of the cell was corrected. Close to 50 percent of the stem cells had one or both copies of the sickle mutation corrected.

Dr. Kohn presented a clinical development timeline. The Institute planned a Phase One study with nine patients with severe sickle cell disease, had received Investigational New Drug authorization from the FDA in October 2020, and was in the process of applying for funding for the trial. The goal was to treat the first sickle cell disease patient with gene editing in this year, 2021. If the treatment of an initial group of patients proceeded well, the Institute planned to treat three adolescent patients, 12 to 18 years old, by 2022.

Dr. Byington noted that, as a pediatrician who had cared for sickle cell disease patients, she found this prospect for a cure to be remarkable.

Regent Park asked how soon this treatment might become readily available. Dr. Walters responded that this would at first be an expensive procedure and only available to those participating in clinical trials. Trials take several years to complete. If, at the end of the trial period, the treatment was licensed, it would become more widely available. This might take five to ten years. He noted that the Institute project team already had new techniques to be developed in parallel and hoped that, once the researchers had demonstrated proof of

concept, they would be able to quickly test iterations of the editing machinery that would be used widely.

Regent Muwwakkil asked how the application of this type of discovery could be expanded; he asked about obstacles and how were they overcome. Dr. Kohn responded that a major factor was funding made available through the California Institute for Regenerative Medicine (CIRM). CIRM facilitated and accelerated what can be a difficult funding process.

Regent Reilly asked which other diseases could be addressed by this technology. Dr. Walters responded that the technology could be applied to a related hemoglobin disorder, thalassemia, in which there is a series of many genetic mutations that cause decrease or absence of production of the globin gene. Thalassemia patients must begin red blood cell transfusions early in life and they need to continue this for their entire lives. The Institute was already taking on some common thalassemia mutations which might result in therapies. Dr. Kohn added that the technology could be used to treat dozens of blood cell diseases.

Committee Chair Lansing asked if it would be possible to treat cancer using this technology. Dr. Walters anticipated that the first way this technology would be applied to cancer would be in the identification of precise targets for cancer cells. Dr. Kohn explained that there was a need for 100 percent targeting efficiency in order to effect a cure. Efficiency in vivo was not yet at that level. This was a theoretical possibility, but there would need to be improvements in the delivery of corrective reagents to the tumor cells in the body. This was a technical challenge.

6. **COMMUNITY BENEFIT AND IMPACT, UC HEALTH**

[Background material was provided to the Committee in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

UC Health Director of Finance Todd Hjorth explained that, in 2007, the Internal Revenue Service (IRS) created Form 990 Schedule H, which was intended to capture the financial impact of not-for-profit or tax-exempt hospitals on the communities they serve. Government-owned hospitals were exempted from having to complete this form. Until the prior year, UC medical centers had not officially reported their community benefit. Last year, UC Davis Health Chief Financial Officer Timothy Maurice led the effort to compile the first UC Health systemwide report of community benefit. UC Health engaged the assistance of Verity Healthcare Consulting, which is recognized nationwide as an expert in this type of reporting. Verity provided guidance again this year for the second annual report of community benefit.

Mr. Hjorth presented reasons for reporting UC Health's community benefit, even though this was not required. UC Health wished to highlight its significant resources devoted to serving low-income and underserved populations; to demonstrate its commitment to its mission of patient care, education, and research; to document its effort to improve population health and to improve the quality and affordability of care; and to demonstrate its commitment to health education and research that benefit the public.

Although not required by law to submit this report, UC Health complied with all IRS instructions and nationally accepted guidelines in compiling the report. This provided transparency and allowed UC to benchmark itself against other tax-exempt hospitals and health systems that submit Form 990 Schedule H. The report this year included charity and unreimbursed care provided by the Faculty Practice Group. UC Health has 20 health professional schools that also provide benefits to communities throughout the state. UC Health intended to expand its reporting in the coming year to include the health professional schools.

In fiscal year 2020, UC medical centers provided \$1.7 billion in net community benefit. This number included charity care, uncompensated costs in caring for Medicaid or Medi-Cal patients, and other community-based programs and initiatives. This \$1.7 billion was benchmarked against other tax-exempt health systems. UC Health incurred other uncompensated costs when it cared for Medicare patients; this added another \$2 billion in community benefit. The Faculty Practice Group reported \$136 million in community benefit. The total of all these amounts equaled nearly \$4 billion. The community benefit provided by UC Health was equal to 10.7 percent of its operating expenses.

Mr. Hjorth drew attention to the fact that the \$1.7 billion in community benefit was an increase of about \$200 million over the prior year. The cost of caring for Medicare patients had also increased, by about \$762 million. UC Health's statistic of community benefit as 10.7 percent of expenses had been benchmarked against other not-for-profit or tax-exempt hospitals and health systems, and this percentage was close to that for medical centers at Stanford, the University of Chicago, Dartmouth, and Johns Hopkins.

Regent Park referred to figures shown earlier of community benefit as a percentage of operating expenses by campus. She asked about local factors that affected community benefit as a percentage of operating expenses at UCLA, UC Irvine, and UCSF. UCLA Health President Johnese Spisso responded that UCLA Health was primarily located on the West Side of Los Angeles. There were fewer underserved patients in these local neighborhoods than elsewhere. UCLA had been working with and had a contract with L.A. Care Health Plan, the largest Medicaid provider in Los Angeles, to treat Medi-Cal patients needing tertiary and quaternary care. UCLA would be launching a homeless health care initiative with mobile vans. UCLA Health Sciences Vice Chancellor John Mazziotta added that the facility recently acquired by UCLA, the Olympia Medical Center, would provide a site six miles east of the main UCLA campus; patients at this location would increase the percentage of underserved and underinsured UCLA patients. UC Irvine Health Chief Executive Officer Chad Lefteris commented that the lack of a true county hospital in Orange County accounted for the high percentage shown for UC Irvine.

Regent Park observed that the community benefit statistic was affected by payer mix and the number of Medicaid patients. UCSF Health Chief Executive Officer Mark Laret commented that each medical center was in different circumstances. The community benefit statistic for UCSF would have been lower before UCSF had brought the UCSF Benioff Children's Hospital into its organization. This hospital had increased UCSF's percentage of Medi-Cal patients. For UC medical centers there would be a balancing act in the coming years of ensuring that the hospitals were generating enough money to support the quality of their services, and, at the same time, making a meaningful contribution to improvement of the health and welfare of those who receive the least care in California. Ms. Spisso added that UCLA provided services at Harbor-UCLA Medical Center, Olive View-UCLA Medical Center, Martin Luther King, Jr. Community Hospital, and the Venice Family Clinic. That service was not reflected in these figures because UCLA did not own and operate those facilities. UCLA could not include this service in its own community benefit report.

Regent Pérez asked if UCLA was in fact removing patient beds from service in the acquisition of the Olympia Medical Center. Dr. Mazziotta responded in the affirmative. UCLA was converting medical surge beds to psychiatry beds at that location, and converting psychiatry beds at the Westwood hospital to medical surge beds. In sum, UCLA had additional beds, and psychiatric beds at a location east of the campus. Regent Pérez expressed concern about the effect of the closure of the Olympia Medical Center on the surrounding community. Dr. Mazziotta responded that this hospital had been largely empty, even during the COVID-19 pandemic. Ms. Spisso added that the Olympia Medical Center had closed before UCLA acquired the physical campus.

Regent Sherman asked if any of the community benefit statistics included affiliations. Dr. Byington responded in the negative. The numbers reflected services that UC Health provided in its own facilities. UC San Diego Health Chief Executive Officer Patricia Maysent noted that there were exceptions. UCSD had an affiliation with the El Centro Regional Medical Center and took patients needing tertiary and quaternary care from this hospital into UCSD facilities. This hospital had an underserved market with a poorer payer mix. UCSD Health's service to these patients was included in its community benefit calculation.

Regent Sherman asked if there were data on what the UC medical centers' community benefit statistics would be if one included affiliations. Mr. Hjorth responded that UC Health had not yet captured these data but could do this in the future. Dr. Byington observed that calculating UC's community benefit in healthcare affiliations was a complex task and would take time. When calculated, these data would demonstrate even higher percentages of community benefit than stated in this report. Mr. Laret added that UCSF's community benefit numbers would be considerably reduced without UCSF's affiliations with Catholic hospital facilities.

Regent Park asked how this report was used and how it would be used in the future. Dr. Byington responded that capturing these data helped UC Health to see its ongoing work and identify additional opportunities. She hoped that the next iteration of the report would include the community benefit provided by the health professional schools. She would like to combine this report with data that UC Health was capturing on the vulnerability of communities, so that UC Health can target its efforts. UC Health should show how the communities where it provided services were healthier. The provision of nearly \$4 billion in community benefit was extraordinary.

Mr. Laret thanked Committee Chair Lansing for her leadership of the Committee and for her work on and commitment to health sciences issues.

Committee Chair Lansing commented that she had seen growth and profound change in the UC Health system. She commended the capable leadership of UC Health. She thanked Dr. Byington, Dr. Byington's predecessor Dr. John Stobo, the medical center chief executive officers and deans, and all who worked for UC Health. They were the people who had made the growth of UC Health happen. Serving as Chair of the Health Services Committee had been a great honor for her.

The meeting adjourned at 11:40 a.m.

Attest:

Secretary and Chief of Staff