University of New Mexico Board of Regents Minutes for July 10, 2019

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Minutes of the Special Meeting of the Board of Regents of the University of New Mexico
July 10, 2019
Domenici Center for Health Sciences Education, North Building, Room 3761, North Campus

Members present
Douglas M. Brown, President; Kim Sanchez Rael, Vice President; Sandra K. Begay, Secretary Treasurer; Melissa Henry; Marron Lee (telephonically); Robert Schwartz

Members not present
Rob Doughty

Administration present
Garnett S. Stokes, President; Paul Roth, EVP and Chancellor for Health Sciences Center; Loretta Martinez, Chief Legal Counsel; Richard Larson, Executive Vice Chancellor for HSC; Michael Richards, Vice Chancellor for Clinical Affairs, HSC; Teresa Costantinidis, Senior Vice President for Finance and Administration; Ava Lovell, Sr. Exec. Officer for Finance and Administration, HSC

Presenters in attendance
Cheryl Willman, Director and CEO, UNM Comprehensive Cancer Center

Others in attendance
Members of HSC and UNM Cancer Center administration, deans, staff, faculty and others.

CALL TO ORDER, CONFIRMATION OF A QUORUM, ADOPTION OF THE AGENDA
Regent President Douglas M. Brown called the meeting to order at 8:32 AM and confirmed a quorum. Five members were present in person; Regent Marron Lee attended the meeting telephonically; however, there were audio issues at the meeting location side that could not be resolved. Regent Lee had to disconnect from the meeting before action on the Cancer Center agenda item took place.

The motion to adopt the agenda passed with a unanimous vote in favor (1\textsuperscript{st} Begay; 2\textsuperscript{nd} Schwartz).

Request for Approval UNM Comprehensive Cancer Center Capital Project: Radiation Oncology and GMP Laboratory Expansion
Dr. Cheryl Willman presented the item. The request is for approval to seek general fund surplus support through the State of New Mexico Higher Education Department (HED) and to present this project during the January 2020 Legislative Finance Committee. Dr. Willman opened with a brief overview of the Cancer Center.

Dr. Willman spoke about the challenges and what led to the request. Over a year ago, a federal executive order reduced reimbursement from CMS (Center for Medicare/Medicaid) for public safety-net hospitals and cancer centers that participated in the 340B drug discount program. This led to a $10 million loss in Cancer Center funding and put difficult financial strains in multiple areas. Additionally, there has been a huge increase in patient volume. The Cancer Center has been running about 525 new patients per month over the last year, and that number has grown in the last 3 months to about 800 per month. Patients are coming from all over the state and the Cancer Center is currently at capacity. These factors have led to an insufficient capacity of radiation oncology. Currently, at capacity about 75 patients per day can be treated, but the need has grown to 95 patients per day. One of the instruments the Cancer Center has, the Tomotherapy Accelerator, which does treat a high-volume number of patients, will no longer be serviced by the company and so will be out of service by 2021. In the area of new modalities, Stereotactic Radiosurgery (SRS), an alternative to invasive
surgery, utilizes radiation beams to treat tumors. This kind of radiation oncology is important to new Neurosurgical Department recruits. Dr. Willman discussed other new opportunities that contribute to the project need, including UNM's bone marrow and stem cell transplantation & cell-based immunotherapies, the only FACT Accredited program in the state, and she talked about the infrastructure needs for laboratories, theranostics, RO/IR interventional radiology, new vault and linear accelerator. Dr. Willman briefly discussed the renovation and new construction plans. The total project cost, including construction and equipment, is $22 million. It has been proposed the request be for either capital outlay or general surplus funds. [See Attachment A - slides presented by Dr. Willman]

This project will provide two new cancer treatment modalities, transplantation immunotherapy and very advanced theranostics and radiosurgery that do not exist in New Mexico and that only UNM can provide. The Cancer Center continues to address huge issues with increased patient volume.

Regent Brown inquired what the replacement plan for the outgoing TomoTherapy machine was. Dr. Willman responded the plan is to replace it with a standard linear accelerator that can do high volume and serve those patients who will not need stereotactic treatment. The challenge with the SRS machines is the treatment is very low volume, treating only 1-2 patients per day.

There was clarification the meeting was noticed as a full Board of Regents meeting. Regent President Brown asked for a motion to approve the agenda item.

The motion to approve the Cancer Center capital project, Radiation Oncology and GMP Laboratory Expansion, passed with a unanimous vote (1st Begay; 2nd Schwartz).

Regent Rob Schwartz commented the Cancer Center is a treasure in New Mexico. There are probably few people in the state who have not had contact with the UNM Cancer Center in one form or another. It is a truly remarkable place and an extraordinary institution, from front to back.

ADJOURN
There being no further business, Regent Brown asked for a motion to adjourn; Regent Begay motioned; Student Regent Melissa Henry seconded; motion passed unanimously; the meeting adjourned at 8:53 AM.

Approved: Attest:

Douglas M. Brown, President Sandra K. Begay, Secretary/Treasurer

Minutes originated and finalized by Mallory Reviere
Request for Approval:

UNM Cancer Treatment & Clinical Research Facility
Phase III: Radiation Oncology and GMP Laboratory Expansion

Collaboration Between UNM Comprehensive Cancer Center,
UNM College of Pharmacy, UNM Hospital, and School of Medicine
Departments of Radiology, Internal Medicine, and Pathology
UNM Cancer Treatment & Clinical Research Facility
Phase III Expansion: Radiation Oncology and GMP Laboratories

UNM Cancer Treatment & Clinical Research Facility
History & Function

- **Phase I:** Completed 2009; 206,432 sq. ft.
- **Cost:** $140 million; Fully funded by State GO Bonds (Cigarette Tax), Capital Outlay, Institutional, Donor Funds
- **Phase II:** Completed 2016 (Finish Out of Shelled Space); 2nd Floor: Expanded Clinics; 4th Floor: Infusion Suite Expansion and Suite for Transplantation/Immunotherapy
- **Cost:** $12 Million (UNMCCC Reserves)
- **Function:** Fully integrated cancer clinical practice with multidisciplinary clinics for medical, gynecologic, radiation, surgical, and dermatologic oncology specialties; 2 infusion suites (72 chairs/bays); UNM Women’s Cancer Center; 3 ORs /minor procedure rooms; Cyclotron; Cancer Clinical Trials Program; Adjacency to OSIS Imaging
- **Service:** 7 Days Per Week
- **Exemplary Accreditations:** NCI, TJC, ACR, ASCO QOPI, Commission on Cancer, USN&WR

Attachment A cont.
UNM Cancer Treatment & Clinical Research Facility

Phase III Expansion: Radiation Oncology and GMP Laboratories

The Need: Challenges

- **CMS Reimbursement Reductions for Cancer Drugs (340B):** $10 Million Annual Revenue Loss
- **Significant Increase in Patient Volumes:** 525 vs. 800 New Patients Per Month (External Referrals, VA, Dermatology)
- **Insufficient Radiation Oncology (RO) Capacity (4 Vaults: 3 Accelerators; 1 HDR):** Capacity: 75 Pts/Day; Demand: 95 Pts/Day; RO Clinics: 7:00 AM to 9:30 PM
- **Tomotherapy Accelerator (IMRT; 25 Pts/Day):** Recently Informed at End of Life in 2021 / No Further Service Contracts
- **Lack of State of the Art Stereotactic Radiosurgery Capabilities (Integrated RO/Neurosurgery Practice):** Required Sending Patients to Lovelace (Gamma Knife) or Out of State
- **UNMCCC:** Fully Occupied Office/Administrative Space

Attachment A cont.
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UNM Cancer Treatment & Clinical Research Facility
Phase III Expansion: Radiation Oncology and GMP Laboratories

UNM Cancer Treatment & Clinical Research Facility
The Need: New Opportunities
Building Cancer Service Lines Not Currently Available for New Mexico’s Cancer Patients

- **Bone Marrow and Stem Cell Transplantation & Cell-Based Immunotherapies** (Only FACT Accredited Program in NM)
- **Infrastructure Need**: GMP Cell Processing Laboratory for Clinical Program and Access to New Therapies from Industry

- **Targeted Radioisotopes / Theranostics**
- **Infrastructure Need**: GMP Radiochemistry and Radiopharmacy Laboratory for Isotope Synthesis/Handling
- **Infrastructure Need**: Theranostics Shielded Infusion Suite
- **Infrastructure Need**: RO/IR Interventional Radiology Room

- **Stereotactic Radiosurgery** (Brain & Spinal Cord Tumors; Organ Metastases; Vascular Malformations)
- **Infrastructure Need**: New Vault and Linear Accelerator

Matthew Fero, MD, PhD
Leslie Andritsos, MD
Heloisa Soares, MD, PhD
Reed Selwyn, PhD
Joanna Fair, MD

Attachment A cont.
UNM Cancer Treatment & Clinical Research Facility

Phase III Expansion: Radiation Oncology and GMP Laboratories

UNM Cancer Treatment & Clinical Research Facility

Process

- UNMCCC Approved to Contract with Huitt-Zollars, Inc. (Approved UNM Vendor) for Assessment and Program Planning
- UNMCCC Formed Planning and Advisory Committee:

**UNM Comprehensive Cancer Center:**
- Richard Lauer, MD, CMO
- Thomas Schroeder, MD, RO
- Heloisa Soares, MD, Theranostics
- Rodney Martinez, CFO
- Stewart Livsie, UNMCCC Facilities

**SOM: Radiology**
- Gary Mlady, MD, Chair
- William Schaeffer, MD, IR
- Reed Selwyn, Ph.D.
- Saeed Elojeimy, MD

**SOM: Department of Pathology**
- Douglas Clark, MD, Chair
- Jay Raval, MD, Transfusion Med

**SOM Chair of Neurosurgery**

**SOM: Department of Internal Medicine**
- Leslie Andritsos, MD
- Matthew Fero, MD
- Jigar Trivedi, PharmD

**College of Pharmacy:**
- Don Godwin, PharmD, Dean
- Jay Simon, PhD, PharmD
- Kristina Wittstrom

**UNMH:**
- Michael Chicarelli, DNP, COO
- Enrico Volpato

**UNM Health Sciences Center:**
- Ava Lovell, MA
- Ryan Reynolds

- Scope and Plan Presented to and Approved by Unanimously by HSC Operations (4/3/19) and HSC Executive Committee (4/12/19)

Attachment A cont.
UNM Cancer Treatment & Clinical Research Facility

Facility Plan and Program

1. Radiation Oncology Expansion / Theranostics (New 11,060 GSF; Ground Floor)
   • New Radiation Oncology Vault: State of the Art Linear Accelerator for Sub-millimeter Tolerance Stereotactic RadioSurgery (SRS).
   • Replacement Linear Accelerator for end-of-life Tomotherapy (Renovating Existing Vault).
   • New Theranostics Therapy Suite: Shielded Suite for Intravenous Delivery of Therapeutic Radioisotopes Targeted to Specific Receptors on Cancer Cells (NET, Pancreas, Prostate)
   • Interventional Radiology Room for Intra-Body/Organ Delivery of Targeted Radioisotopes

2. GMP Radiopharmacy / Radiochemistry Laboratory for Theranostics
   • Renovation of Existing Shelled 1410 GSF for GMP Laboratory to Locally Produce, Synthesize, Package, and Distribute Innovative New Particle Therapies (FDA approved; Clinical Trials)

3. GMP Cell Based Processing Laboratory for Transplantation & Immunotherapy
   • New 2700 GSF, FDA 351/361 certified cGMP Laboratory: Support FACT Accredited Marrow and Stem Cell Transplant Program; Processing of New Cell Based Immunotherapies (CAR-T Cells; Cancer Vaccines)

4. Administrative / Office Space (11,060 GSF): Clinical Research Office; Administration, IT

Attachment A cont.
Phase III – Radiation Oncology and GMP Laboratory Expansion

Proposed Floor Plan – Ground Floor

GROUND FLOOR

Renovation
- 3,870 Level G entry and expanded Lobby Services
- Replace Tomotherapy Equipment in Renovated Vault
- 1,410 SF GMP Radiochemistry & Radiopharmacy Laboratory

New Construction
- 9,450 SF Radiation Oncology Expansion; 1 New Vault
- 1,610 SF Interventional Radiology/Radiation Oncology
- Relocated Ambulance Entry
- 1,950 SF GMP FDA 351/361 Cellular Therapy Lab

LEVEL 1

New Construction
- 1,950 SF Warehouse, Materials Management, and EVS
- New Chilled Water Plant
- New Cooling Towers
LEVEL 2

New Construction
- 2,700 SF Cellular Therapy Lab – 361/cGMP 351
Phase III – Radiation Oncology and GMP Laboratory Expansion
Project Cost, Potential Funding Sources, Benefits

Total Project Cost: $22 Million

Potential Project Funding
- Capital Outlay
- General Fund Surplus

Project Benefits
- Delivers New Cancer Treatment Modalities Not Available in New Mexico that Only UNM Can Provide
- Addresses Increasing Cancer Patient Volumes and Demands
- Provides New Advanced and Enhanced Medical (Physician) and Technical (Health Professions) Education and Training Programs in Pharmacy and Medicine
- Provides Infrastructure for Significant Clinical/Translational Research Opportunities and UNM Main Campus Collaborations (Engineering)