THE CANCER LETTER

July 24, 2015 • www.cancerletter.com • Vol. 41 No. 29

MD Anderson No. 1 (Again) In Rankings by U.S. News

By Paul Goldberg

MD Anderson Cancer Center has once again assumed its place at the top of the influential U.S. News & World Report rankings for 2015-2016.

The Houston-based center edged out New York's Memorial Sloan-Kettering Cancer Center.

As MD Anderson returns to the paramount position it has held 11 times over the past 14 years, it does so despite turmoil between its faculty and administration (The Cancer Letter, July 13).

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FDA & NCI Create Unique Jobs Combining Regulatory Science with Clinical Expertise

By Matthew Bin Han Ong

NCI and FDA are recruiting three medical oncologists who would divide their time between clinical and regulatory duties—half at the FDA Office of Oncology and Hematology Products, and half at the NCI Center for Cancer Research.

These clinician-scientists would serve as associate directors for clinical research at the OHOP, and as independent, tenure-track principal investigators at the CCR.

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In Brief

Roberts Named Director of St. Jude Center

CHARLES ROBERTS was named executive vice president and director of the **St. Jude Comprehensive Cancer Center**, effective Sept. 1.

Roberts will also serve as full member in the Department of Oncology and hold the Lillian R. Cannon Comprehensive Cancer Center Director Endowed Chair.

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MD Anderson Takes Back No. 1 Ranking from MSKCC

(Continued from page 1)

Last year, MD Anderson dropped to the No. 2 spot by a razor-thin 0.1 percent margin (The Cancer Letter, July 14, 2014).

This week, MD Anderson beat out its perpetual rival MSKCC by 5.3 percent.

"We're honored by this tremendous national recognition, but the true measure of our success is the number of lives we've impacted with out care, research and support," MD Anderson President Ronald DePinho said in a statement. "We owe our gratitude to the more than 20,000 cancer fighters, including world-class faculty and nurses, and 1,000 volunteers working every day to end cancer for our patients and others around the world."

While scientific validity of the U.S. News index is often disputed, its value to cancer centers is high. A high rank and the license to display the U.S. News shield is one of the great prizes sought by marketing departments. A drop in ranking is believed to have led to removal of top administrators.

To understand how the U.S. News ratings of cancer centers work, it's more useful to eyeball a table within the dense methodology document than a report that appears on the magazine's website.

The tables, which are posted below, come from methodology reports that the magazine publishes alongside the rankings, explaining how the ranking process changes from year to year

This year's full report is posted here and last year's is available here.

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General Information: www.cancerletter.com

Subscription $405 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc.

Undeniably, an institution needs a spectacular "reputation with specialists" component of the score to get to the top spot. That portion of the score accounts for 27.5 percent of the overall grade.

MD Anderson and MSKCC, the highest-volume cancer centers in the country, have the highest reputation scores—64.7 and 62.5 respectively.

After these two front-runners, the reputation score plunges to Mayo Clinic's level of 25.5. (Mayo took the third place overall in the rankings.)

At No. 4, Dana-Farber Cancer Institute and Brigham & Women's Cancer Center has a reputation score of 37.4—and this year's No. 5, Seattle Cancer Alliance, has a score of 10.5.

Some of America's finest cancer centers—which have no problem with routine renewals of their NCI comprehensive cancer center designations—earn spectacularly low reputation scores.

Simple eyeballing of the table reveals that many of these centers have better grades for "outcomes," "structure" and "patient safety" than either of the front-runners.

This year's No. 50 institution on the U.S. News list—UT Southwestern—has the barely detectable reputation score of 0.3—while maintaining the incontrovertibly meaningful designation of NCI comprehensive cancer center, employing six Nobel laureates and, overall, receiving more money from the Cancer Prevention and Research Institute of Texas than its cross-state rival, MD Anderson.

"So much of what drives MD Anderson and MSK [grades] is the reputation score," said Ashish Jha, the K. T. Li Professor of International Health and Health Policy at the Harvard T.H. Chan School of Public Health and director of Harvard Global Health Institute, after glancing at the tables on request from The Cancer Letter.

"On the stuff that matters, i.e. patient outcomes, Mayo and Dana Farber seem to be as good, maybe even better," Jha said. "It seems that, indeed, the reputation score is driving the rankings when patient care should be a higher priority.

"I am not opposed to using reputation—but its weight should be very small compared to a hospital's clinical outcomes and patient safety."

U.S. News & World Report
Best Cancer Hospitals, 2015-2016:

Rank	Hospital	Overall Specialty Score	Reputation with specialists	Survival	Patient safety	Success in preventing pressure ulcers	Success in preventing deaths from treatable complications after surgery	Success in preventing collapsed lung during biopsy, catheter insertion and other procedures	Success in preventing major bleeding and bruising after surgery	Success in preventing respiratory failure after surgery	Success in preventing surgical incisions from reopening afterwards	Success in preventing harm to patients during surgery	Patient volume	Nursing intensity	Nurse Magnet recognition	NCI-designated cancer center	FACT-accredited for BMT and tissue transplant	Advanced technologies	Patient services	Intensivist on staff	
1	University of Texas MD Anderson Cancer Center, Houston	100.0	64.7	10	2	2	4	2	1	2	3	2	6,838	2.1	Yes	Yes	2	8	8	Yes	
2	Memorial Sloan Kettering Cancer Center, New York	94.7	62.5	10	4	3	5	2	1	5	3	4	4,555	1.9	No	Yes	2	8	8	Yes	
3	Mayo Clinic, Rochester, Minn.	91.0	25.5	10	5	4	5	5	3	5	3	5	3,626	2.6	Yes	Yes	2	8	8	Yes	
4	Dana-Farber/Brigham and Women's Cancer Center, Boston	90.3	37.4	8	5	5	4	5	5	5	4	5	3,539	2.4	Yes	Yes	2	8	8	Yes	
5	Seattle Cancer Care Alliance/University of Washington Medical Center	76.8	10.5	10	3	1	4	5	1	3	2	5	1,215	2.3	Yes	Yes	2	8	8	Yes	
6	Johns Hopkins Hospital, Baltimore	73.6	23.8	9	1	1	4	1	1	2	2	1	1,819	2.1	Yes	Yes	2	8	8	Yes	
6	UCLA Medical Center, Los Angeles	73.6	6.3	10	5	5	4	5	4	4	2	5	1,897	3.1	Yes	Yes	2	8	8	Yes	
8	Massachusetts General Hospital, Boston	73.4	11.6	8	5	5	5	5	1	5	2	2	2,690	2.4	Yes	Yes	2	8	8	Yes	
9	UCSF Medical Center, San Francisco	71.5	8.6	9	5	4	3	5	3	4	3	5	1,609	2.7	Yes	Yes	2	8	8	Yes	
10	Stanford Health-Stanford Hospital, Stanford, Calif.	70.5	9.1	9	4	2	4	4	4	4	2	3	1,497	2.4	Yes	Yes	2	8	8	Yes	Top 10
11	Hospitals of the University of Pennsylvania-Penn Presbyterian, Philadelphia	69.7	6.5	10	4	1	3	5	3	4	4	4	2,799	2.4	Yes	Yes	2	8	8	Yes	
12	Cleveland Clinic	69.4	5.5	10	3	1	4	4	2	3	3	2	2,793	2.3	Yes	Yes	2	8	8	Yes	
13	City of Hope, Duarte, Calif.	69.1	4.6	10	5	5	5	3	2	4	4	5	1,131	2.4	No	Yes	2	8	8	Yes	
14	Barnes-Jewish Hospital/Washington University, St. Louis	67.8	5.2	9	2	3	2	3	1	3	2	2	3,766	2.1	Yes	Yes	2	8	8	Yes	
15	University of Colorado Hospital, Aurora	67.3	0.8	10	5	5	4	5	2	5	2	5	1,007	1.9	Yes	Yes	2	8	8	Yes	
16	Northwestern Memorial Hospital, Chicago	66.7	2.1	10	4	2	5	3	2	4	3	4	2,221	1.8	Yes	Yes	2	8	8	Yes	
17	Wake Forest Baptist Medical Center, Winston-Salem, N.C.	66.6	1.6	10	3	2	3	4	4	2	3	2	2,535	1.5	Yes	Yes	2	8	8	Yes	
18	Moffitt Cancer Center, Tampa	66.5	4.1	10	1	2	4	1	2	1	2	2	2,286	1.4	No	Yes	2	8	8	Yes	
19	Mayo Clinic, Phoenix	66.1	0.8	10	5	3	5	4	3	5	3	5	1,086	4.2	No	Yes	2	8	8	Yes	
20	New York-Presbyterian University Hospital of Columbia and Cornell, N.Y.	65.1	2.2	10	3	3	4	3	2	4	2	3	4,551	2.1	No	Yes	2	8	8	Yes	Top 20
21	Fox Chase Cancer Center, Philadelphia	64.7	3.1	10	1	1	4	1	1	4	2	4	1,266	1.8	Yes	Yes	2	8	8	Yes	
22	Emory University Hospital, Atlanta	63.3	1.9	9	5	5	4	5	5	2	1	5	1,917	1.9	Yes	Yes	2	8	8	Yes	
23	UC San Diego Health	63.0	0.8	9	5	4	5	2	4	3	3	4	1,118	1.9	Yes	Yes	2	8	8	Yes	
24	Ohio State University James Cancer Hospital, Columbus	62.1	4.1	9	1	3	1	2	1	2	1	2	3,342	2.1	Yes	Yes	2	8	8	Yes	
25	UPMC-University of Pittsburgh Medical Center	61.9	3.4	9	1	2	3	1	1	2	3	1	4,210	1.8	Yes	Yes	2	8	8	Yes	
26	USC Norris Cancer Hospital-Keck Medical Center of USC, Los Angeles	61.8	1.2	10	1	5	3	1	4	1	1	3	965	3.1	No	Yes	2	8	7	Yes	
27	Duke University Hospital, Durham, N.C.	61.6	6.2	7	2	1	2	3	2	4	2	5	2,713	2.2	Yes	Yes	2	8	8	Yes	
28	University of Michigan Hospitals and Health Centers, Ann Arbor	61.5	4.4	8	4	2	2	5	3	3	2	5	2,494	2.7	No	Yes	2	8	8	Yes	
29	Thomas Jefferson University Hospital, Philadelphia	61.3	1.1	10	2	1	4	3	1	3	4	4	2,019	2.3	Yes	Yes	2	8	8	Yes	
30	Seidman Cancer Center at UH Case Medical, Cleveland	60.9	2.4	9	3	2	4	2	1	4	3	4	1,716	2.3	Yes	Yes	2	8	8	Yes	
31	University of Kansas Hospital, Kansas City	60.8	0.3	10	2	3	4	3	3	1	2	2	1,591	2.1	Yes	Yes	2	8	8	Yes	
32	University of North Carolina Hospitals, Chapel Hill	60.6	2.4	10	1	1	2	1	2	1	1	4	1,746	1.8	Yes	Yes	2	8	8	Yes	
33	Vanderbilt University Medical Center, Nashville	60.4	2.2	8	3	2	4	2	3	2	3	5	1,533	2.1	Yes	Yes	2	8	8	Yes	
34	University of Chicago Medical Center	60.2	2.7	9	3	4	3	3	1	3	2	5	1,866	2.4	No	Yes	2	8	8	Yes	
35	University of California, Davis Medical Center, Sacramento	59.6	0.6	9	3	4	4	2	2	4	3	2	997	2.7	Yes	Yes	2	8	8	Yes	
36	Houston Methodist Hospital, Houston	59.3	1.3	10	4	4	4	2	2	4	1	5	1,555	1.8	Yes	No	2	8	8	Yes	
37	Oregon Health and Science University Hospital, Portland	59.0	0.3	10	1	4	4	1	2	2	2	1	1,287	2.0	Yes	Yes	2	8	8	Yes	
38	University of Wisconsin Hospital and Clinics, Madison	58.9	0.7	9	2	2	5	2	2	4	1	2	1,441	1.9	Yes	Yes	2	8	8	Yes	
39	University of Iowa Hospitals and Clinics, Iowa City	58.4	0.4	9	4	2	3	5	2	2	4	4	1,319	1.8	Yes	Yes	2	8	8	Yes	
40	Rush University Medical Center, Chicago	58.1	0.8	10	1	1	3	1	1	3	4	2	1,864	2.2	Yes	No	2	8	8	Yes	
41	NYU Langone Medical Center, New York	57.7	1.0	8	4	2	5	2	2	4	2	5	1,331	2.7	Yes	Yes	1	8	8	Yes	
42	Yale-New Haven Hospital, New Haven, Conn.	57.6	2.2	8	2	3	4	1	1	3	2	2	2,597	1.5	Yes	Yes	2	8	8	Yes	
43	Cedars-Sinai Medical Center, Los Angeles	57.5	2.1	8	4	4	4	2	2	4	3	4	2,143	2.5	Yes	No	2	8	8	Yes	
43	Roswell Park Cancer Institute, Buffalo	57.5	1.5	9	1	1	3	1	1	1	3	1	1,323	2.4	Yes	Yes	2	8	8	Yes	
45	University of Maryland Medical Center, Baltimore	57.2	1.0	10	1	1	2	1	1	1	2	1	1,273	2.3	Yes	Yes	2	8	8	Yes	
46	UF Health Shands Hospital, Gainesville, Fla.	56.9	0.6	10	3	3	2	3	2	2	2	4	1,649	1.9	Yes	No	2	8	8	Yes	
47	IU Health Academic Health Center, Indianapolis	56.2	1.4	8	2	4	2	1	2	2	2	4	1,892	2.0	Yes	Yes	2	8	8	Yes	
48	Mayo Clinic, Jacksonville, Fla.	56.0	0.9	9	5	3	4	4	2	5	4	5	893	2.1	No	Yes	2	8	8	Yes	
49	Mount Sinai Hospital, New York	55.6	1.3	9	3	1	2	2	4	4	3	3	2,303	2.0	Yes	No	2	8	8	Yes	
50	UT Southwestern Medical Center, Dallas	55.4	0.3	10	2	1	5	4	1	4	3	3	1,031	1.9	No	Yes	2	8	8	Yes	

Best Cancer Hospitals, 2014-2015:

Rank	Hospital	U.S. News Score	Reputation with specialists	Survival	Patient safety	Patient volume	Nursing intensity	Nurse Magnet recognition	NCI-designated cancer center	FACT-accredited for BMT and tissue transplant	Advanced technologies	Patient services	Intensivist on staff	
1	Memorial Sloan Kettering Cancer Center, New York	100.0	64.7	10	5	4,749	1.9	No	Yes	2	8	8	Yes	
2	University of Texas MD Anderson Cancer Center, Houston	99.9	67.5	10	2	6,288	2.0	Yes	Yes	2	8	8	Yes	
3	Mayo Clinic, Rochester, Minn.	93.4	29.9	10	5	3,614	3.2	Yes	Yes	2	8	8	Yes	
4	Dana-Farber/Brigham and Women's Cancer Center, Boston	84.6	36.1	8	4	3,350	2.4	Yes	Yes	2	8	8	Yes	
5	Johns Hopkins Hospital, Baltimore	81.2	28.2	10	1	1,759	2.2	Yes	Yes	2	8	8	Yes	
6	University of Washington Medical Center, Seattle	77.2	13.2	10	3	1,218	2.4	Yes	Yes	2	8	8	Yes	
7	Massachusetts General Hospital, Boston	75.4	14.3	9	4	2,499	2.3	Yes	Yes	2	8	8	Yes	
8	UCSF Medical Center, San Francisco	75.0	10.1	9	5	1,653	2.6	Yes	Yes	2	8	8	Yes	
9	UCLA Medical Center, Los Angeles	74.7	9.8	9	4	1,822	3.0	Yes	Yes	2	8	8	Yes	
10	Stanford Hospital and Clinics, Stanford, Calif.	71.5	11.4	9	4	1,441	2.6	Yes	Yes	2	8	8	Yes	Top 10
11	Hospitals of the University of Pennsylvania-Penn Presbyterian, Philadelphia	71.4	6.7	9	5	2,745	2.6	Yes	Yes	2	8	8	Yes	
12	City of Hope, Duarte, Calif.	70.8	4.3	10	5	1,093	2.3	No	Yes	2	8	8	Yes	
13	Cleveland Clinic	70.1	6.4	9	3	2,684	2.3	Yes	Yes	2	8	8	Yes	
14	New York-Presbyterian University Hospital of Columbia and Cornell, N.Y.	69.9	3.2	10	5	4,312	2.4	No	Yes	2	8	8	Yes	
15	University of Colorado Hospital, Aurora	69.6	1.7	10	4	1,015	1.8	Yes	Yes	2	8	8	Yes	
16	Moffitt Cancer Center, Tampa	69.4	2.8	10	5	2,029	1.4	No	Yes	2	8	8	Yes	
17	Northwestern Memorial Hospital, Chicago	67.6	3.3	9	4	2,248	1.8	Yes	Yes	2	8	8	Yes	
18	Seidman Cancer Center at UH Case Medical, Cleveland	67.0	2.9	9	5	1,668	2.2	Yes	Yes	2	8	8	Yes	
19	Fox Chase Cancer Center, Philadelphia	66.2	3.8	10	3	1,251	1.4	Yes	Yes	2	8	8	Yes	
20	Wake Forest Baptist Medical Center, Winston-Salem, N.C.	66.0	1.6	10	1	2,421	1.6	Yes	Yes	2	8	8	Yes	Top 20
21	Barnes-Jewish Hospital/Washington University, St. Louis	65.7	4.7	9	1	3,617	2.1	Yes	Yes	2	8	8	Yes	
22	Duke University Hospital, Durham, N.C.	64.1	5.6	8	3	2,726	2.1	Yes	Yes	2	8	8	Yes	
23	USC Norris Cancer Hospital-Keck Medical Center of USC, Los Angeles	64.0	0.9	10	2	851	3.4	No	Yes	2	8	8	Yes	
24	Emory University Hospital, Atlanta	63.7	1.2	9	5	1,815	1.8	Yes	Yes	2	8	8	Yes	
25	UC San Diego Medical Center	63.3	0.4	9	5	1,095	2.0	Yes	Yes	2	8	8	Yes	
26	Mayo Clinic, Phoenix	63.2	0.1	9	5	1,079	4.0	No	Yes	2	8	8	Yes	
27	Thomas Jefferson University Hospital, Philadelphia	63.0	0.8	9	3	1,871	2.3	Yes	Yes	2	8	8	Yes	
27	University of Iowa Hospitals and Clinics, Iowa City	63.0	0.4	10	4	1,282	1.7	Yes	Yes	2	8	8	Yes	
29	University of Kansas Hospital, Kansas City	62.4	0.2	9	4	1,441	2.1	Yes	Yes	2	8	8	Yes	
30	Ohio State University James Cancer Hospital, Columbus	61.8	4.0	9	1	3,445	2.1	Yes	Yes	2	8	8	Yes	
31	UPMC-University of Pittsburgh Medical Center	60.8	2.7	8	1	4,241	1.9	Yes	Yes	2	8	8	Yes	
31	University of Chicago Medical Center	60.8	4.9	10	1	1,661	2.5	No	Yes	2	8	8	Yes	
33	Oregon Health and Science University Hospital, Portland	60.2	0.0	10	1	1,185	2.1	Yes	Yes	2	8	7	Yes	
34	University of California, Davis Medical Center, Sacramento	59.4	0.0	9	2	981	3.0	Yes	Yes	2	8	8	Yes	
34	University of Michigan Hospitals and Health Centers, Ann Arbor	59.4	4.1	9	2	2,400	2.8	No	Yes	2	8	8	Yes	
36	Nebraska Medical Center, Omaha	59.0	0.5	9	3	1,029	2.7	Yes	Yes	2	8	8	Yes	
37	Hackensack University Medical Center, Hackensack, N.J.	58.6	0.5	8	5	2,136	2.3	Yes	No	2	8	8	Yes	
38	University of North Carolina Hospitals, Chapel Hill	58.5	2.2	10	1	1,635	1.9	Yes	Yes	2	8	8	Yes	
39	Vanderbilt University Medical Center, Nashville	58.3	2.7	8	1	1,343	2.5	Yes	Yes	2	8	8	Yes	
39	Yale-New Haven Hospital, New Haven, Conn.	58.3	1.8	8	1	2,565	3.2	Yes	Yes	2	8	8	Yes	
41	Cedars-Sinai Medical Center, Los Angeles	58.0	1.1	8	5	2,111	2.5	Yes	No	2	8	8	Yes	
42	Houston Methodist Hospital, Houston	57.5	1.0	9	3	1,449	1.8	Yes	No	2	8	8	Yes	
43	University of Wisconsin Hospital and Clinics, Madison	57.1	0.4	9	2	1,389	1.9	Yes	Yes	2	8	8	Yes	
44	Beth Israel Deaconess Medical Center, Boston	56.7	2.3	9	2	1,665	1.4	No	Yes	2	8	8	Yes	
45	Florida Hospital Orlando	56.3	0.0	8	5	3,990	2.0	Yes	No	2	8	8	Yes	
46	University of Maryland Medical Center, Baltimore	56.2	0.6	10	1	1,200	2.2	Yes	Yes	2	8	8	Yes	
47	Loyola University Medical Center, Maywood, Ill.	55.8	1.3	9	3	1,338	1.6	Yes	No	2	8	8	Yes	
48	Mount Sinai Hospital, New York	55.4	1.3	9	2	2,317	2.1	Yes	No	2	8	8	Yes	
48	Rush University Medical Center, Chicago	55.4	0.6	10	1	1,759	2.0	Yes	No	2	7	8	Yes	
50	NYU Langone Medical Center, New York	55.2	0.7	8	4	1,431	2.3	Yes	Yes	1	8	8	Yes	
50	Robert Wood Johnson University Hospital, New Brunswick, N.J.	55.2	0.7	8	1	1,471	2.3	Yes	Yes	2	8	8	Yes	
50	Roswell Park Cancer Institute, Buffalo	55.2	1.1	8	1	1,302	2.2	Yes	Yes	2	8	8	Yes	

The Question of Reputation

The physicians who get to decide the reputation score are asked to answer the following question:

"Please name up to five U.S. hospitals that you believe provide the best care in oncology for patients who have the most challenging conditions or who need particularly difficult procedures. Do not consider location or cost. Individual hospitals should be listed, not hospital systems or medical schools."

The words "process" and "reputation" are used interchangeably by U.S. News and its contractor RTI International.

"For these rankings, the concept of reputation speaks to an institutional ability to develop and sustain a system that delivers high-quality care to especially challenging patients."

The reputational score is composite of two surveys:

• Surveys were sent to 200 oncologists, of whom 34.5 percent (69 individuals) responded.

• The Doximity Masterfile member survey was conducted with a sample of 85,423 physicians across the 16 specialties. There were 6,843 cancer specialists in this group. Altogether, 17.3 percent of them responded to the survey.

The sample was stratified by census region and by specialty. The results are weighted, put through log transformation and averaged over three years.

In 2013, this publication reported that systematic misclassification of emergency patients at MD Anderson Cancer Center enhanced that institution's rating by U.S. News over the past seven years (The Cancer Letter, July 19, 2013).

The miscounting led to exclusion of nearly 40 percent of admissions, was discovered and corrected in mid-2009, but no reliable way could be found to adjust the results to reflect the missing data, officials at U.S. News and MD Anderson stated.

Insiders say that MD Anderson had been submitting incorrect data to the Centers for Medicare and Medicaid Services. U.S. News doesn't ask hospitals to provide data directly, relying instead on government databases, which are less prone to tampering.

The problem was caused by an error, MD Anderson officials said, discovered by MSKCC officials and acknowledged by their counterparts at MD Anderson, but U.S. News editors said a recount would be impossible, because of the volume of missing data. Just as importantly, a methodological pillar of the index—not accepting data from institutions directly—was at stake.

The U.S. News index was never intended to provide bragging rights—or a marketing advantage—based on minute differences in scores, magazine officials say.

FDA, NCI Create Job Track For Clinician-Regulators

(Continued from page 1)

This unique opportunity could not exist outside of government, OHOP Director Richard Pazdur said at a joint meeting of the NCI Board of Scientific Advisors and the National Cancer Advisory Board June 24.

"We want to create a unique position in the government that you can't get on the outside. Hence, we've had these discussions on a joint position," Pazdur said. "For instance, they can create and run a clinical trial at NCI's CCR and then do the review work at the FDA."

The unique job provides a way for FDA and NCI to recruit skilled oncologists who would otherwise command higher salaries in the private sector.

"One of the difficulties I've had in recruiting oncologists in government is attracting them to mid-career level positions," Pazdur said. "When it comes to attracting very good physicians at the mid-level, we come across salary issues and conflicts with consulting agreements that government employees would potentially have.

"We designated three positions. These are FDA positions that I have dedicated toward this program. This may not be limited to three positions in the future, and we may want to expand this pilot program if it is successful."

Why would two government agencies need clinician-regulators to connect the White Oak and Bethesda campuses?

"The oncology drug development landscape is changing, due to the increasing scientific understanding of cancer and its treatment, and to the increasing specialization of the oncology community," NCI and FDA officials said in a statement to The Cancer Letter. "Together, these forces are creating the need for more sophisticated approaches to oncology drug development, which requires detailed knowledge of regulatory process as well as fluency in the intricacies of treating specific malignancies."

This is why medical oncologists with disease-specific expertise and an active track record in clinical trial design are invaluable, according to NCI and FDA officials.

"Academic oncologists with real-world clinical trial experience could be an important resource for meeting the growing needs in federal oncology drug regulation," officials said. "Similarly, an academic investigator trained in drug regulation could bring an important perspective to the clinical research being done at the NCI."

FDA's Disease-Specific Divisions

The announcement comes four years after OHOP was reorganized into disease-specific divisions—similar to most large academic centers—to better meet the demands of an increasingly complex and rapidly changing knowledge base in the diagnosis and treatment of malignant diseases.

The positions are tailored to augment the agency's new research infrastructure—a part of an OHOP initiative called "Towards a Federal Workforce in Hematology and Oncology," as dubbed by Pazdur.

FDA expects the recruited physicians to become experts in regulatory processes focusing on a specific disease type, from investigational new drug to new drug application and post-marketing, and to develop pivotal roles in guiding industry and academic in their approach to drug development.

At NCI, the investigators will develop and execute clinical trials, identify translational correlates, enroll and treat patients, and analyze and publish data.

Instead of only disease-specific oncologists, FDA and NCI might benefit from physicians with expertise in phase I development, NCAB member Max Wicha said at the joint meeting June 24.

"What you're doing now is really getting away from the disease focus and more towards pathways and immune therapies," said Wicha, founding director emeritus of University of Michigan Comprehensive Cancer Center. "So why not have this open for people who are also experts in phase I development?"

It has more to do with finding the "right person," Pazdur responded.

"I think we would entertain that. If you noticed, we didn't say we need a breast cancer person or a myeloma person," Pazdur said. "We're set up at the present time in disease-specific teams, but obviously, with the types of applications that we're getting, there's a lot of cross-fertilization and discussion between these disease-specific teams.

"So we would certainly be open to a phase I person."

Professors, Associate Professors May Apply

FDA is looking for medical oncologists who are experienced in disease-specific clinical research, and who have successfully competed in an academic environment.

"It's not that restrictive," Pazdur said at the NCI meeting. "We generally are not looking for people right out of their fellowship. We want somebody that has an established program already for a university.

"It's somebody that has a 'presence' in the field for a lack of a better word. It isn't somebody who's going to need mentoring, but someone doing the mentoring."

Candidates will be chosen from academic levels equal to associate professors and professors with a background in oncology or hematology, with five to 10 years of clinical experience following completion of an oncology or hematology fellowship.

"These candidates will be board-certified and recognized as 'experts' in a specific area of oncology," Pazdur said. "FDA is looking to strengthen its ranks by integrating these individuals who have proven real-world experience."

Candidates need to have that experience in order to be successful in the Center for Cancer Research at NCI, said Sanjeeve Bala, a medical officer at OHOP.

"Ideal candidates will have developed and conducted their own investigator-initiated clinical trials and have a strong history of collaboration with translational scientists," Bala said.

The recruitment process is ongoing, and applications may be submitted directly by email to Richard.Pazdur@fda.hhs.gov.

Since these are new positions directed towards recruiting experience academicians, the jobs will evolve and take shape as the incumbents take on their new role.

"We anticipate that the incumbent will spend half their time FDA, initially learning the regulatory landscape with a focus on their disease of interest, and quickly get involved in interacting with key drug development stakeholders in that disease focus," officials said. "The other half of the time will be at NCI, where the candidate will be expected to develop and run a clinical research portfolio in their disease focus; we anticipate that they would be able to have at least two clinical trials ongoing, with support provided by a specific NCI intramural branch.

"There, they would also collaborate with translational scientists and continue to perform other academic duties, such as serve on editorial boards.

"In both cases, a high level of scholarship will be an important part of the candidate's focus. OHOP is committed not only to regulatory processes but also to regulatory science and scholarship, leveraging the tremendous data resources and capabilities at the agency."

The recruited physicians will report to Pazdur and William Dahut, clinical director at NCI, as well as the appropriate CCR branch chief.

"A Unique Job Opportunity"

The recruited physicians will be full-time FDA employees, drawing the salaries at the associate director level. They would also receive support for academic and regulatory scholarship.

NCI will provide resources related to opening and running clinical research trials, including research staff support, as well as resources pertaining to translational studies and scholarship.

"Moreover, given the focus of the new workforce initiative, both the FDA and CCR—separate government agencies—acknowledge the mission for the advancement of medical research and, in particular, the development of new therapies for cancer treatment," Pazdur said. "To that end, the two agencies, through this program, have agreed to increase opportunities for sharing information, material, and intellectual resources."

By bridging the regulatory and clinical roles, the associate director-investigators will foster greater connection and dialog in the drug development community, said Susan Bates, a senior investigator in the Developmental Therapeutics Branch of the CCR.

"The FDA/NCI investigator will be in a unique position to contribute to protocol development locally and in cooperative groups—identifying key issues relevant to the regulatory process," Bates said to The Cancer Letter. "Experience running clinical trials will allow the FDA/NCI investigator to create feedback for the FDA that could lead to new initiatives on clinical trial efficiency and efficacy.

This unique opportunity will bring a fresh perspective to the CCR, Bates said.

"Our mutual goal is to create better therapies for patients and we envision that by better understanding the FDA viewpoint on drug development both investigators and trainees at the NCI will be able to achieve greater alignment with that goal.

"This can include avoiding the use of resources on clinical trials that do not advance an agent toward FDA approval. It is hoped that by interweaving FDA and CCR investigators new ideas and energy will accrue to the development of clinical trials."

The initiative is an experiment, and if it is successful, it will be ongoing.

"I need the right person for these jobs," Pazdur said at the meeting. "I tend to take a look at a much bigger perspective and it's like, 'Okay, this is a go, let's get this drug out,' whereas the review staff may stay focused in the weeds or the process. Sometimes you need to take a look outside of the weeds and see the big issue with the drug.

"I think one of the things that OHOP is moving away from is looking at an application only after it is completed and having much more of an iterative process throughout the entire development of the drug.

"The whole breakthrough therapy designation in which oncology has been a major player was aimed at having a more iterative, continuous assessment of a development program rather than waiting for the clinical trial to be done and asking what's wrong with it."

Training and Fellowships

At the meeting, NCAB members suggested using the job for training.

"Maybe we should look at one of these positions being more of a training position, and the idea would be for someone to come in for five years and get this kind of training with the intention of getting out of the office," Wicha said.

FDA already serves as a sort of training ground, according to Pazdur.

"I really look at our FDA employees as two groups of people, Pazdur said. "People who are here for a short experience and venture out into pharma, and a group of people who are long-term survivors and remain at FDA throughout their career."

What about extramural training programs?

"There are in fact a lot of oncology training programs that really train people to do clinical trials that are investigator initiated," said NCAB member Olufunmilayo Olopade, associate dean for global health and Walter L. Palmer Distinguished Service Professor in Medicine and Human Genetics at the University of Chicago. "The challenge we have is not having enough training slot and not being able to access this training early on in their careers."

FDA has had fellows from MD Anderson and other institutions for several months, according to Pazdur.

"I would be happy to have fellows come to the FDA and we would establish a curriculum for them," Pazdur said. "In fact, we've established a position at the FDA within the office titled as the educational director, which Bala will assume shortly after the position is established."

According to Pazdur, the oncology workforce program could be a model for other sectors in the government.

"The reason I called this initiative the oncology workforce program is, if it is successful, I can see it branching outside of the FDA into other agencies of the Health and Human Services department," Pazdur said to The Cancer Letter. "But those discussions have not taken place at this time."

Nick Crispino contributed to this story.

In Brief

Roberts Named Director Of St. Jude Cancer Center

(Continued from page 1)

He joins St. Jude from Dana Farber Cancer Institute, where he served as deputy chief scientific officer.

Roberts co-led an initiative on DNA sequencing of pediatric solid tumors at the Broad Institute. He also has chaired the pediatric Institutional Review Board for Dana Farber Cancer Institute and Boston Children's Hospital and co-led the pediatric solid tumor disease program.

His research in cancer epigenetics has provided insight into the role of chromatin remodeling in germline and sporadic cancers.

Roberts received his medical and doctoral degrees from Washington University School of Medicine in St. Louis. He completed his pediatric residency and pediatric hematology/oncology fellowship at Boston Children's Hospital.

ERIC ROHREN was named chair of radiology at **Baylor College of Medicine**. His appointment is effective Oct. 1.

Rohren currently serves as a professor in the Departments of Nuclear Medicine and Diagnostic Radiology at MD Anderson Cancer Center, and is chief of the Section of Positron Emission Tomography.

Rohren has been on the MD Anderson faculty since 2007, and prior to that held appointments as a faculty physician at the Mayo Clinic and as medical director of several molecular imaging centers in Florida.

Rohren has held leadership positions in several national groups, including the American College of Radiology, the Radiologic Society of North America, the American Board of Nuclear Medicine and the Society of Nuclear Medicine and Molecular Imaging.

His research interests include cancer imaging, novel radiotracers in oncology and neurology and targeted radioisotope therapies. He has worked extensively on PET/CT reporting and has developed guidelines for report structure and content through his work with the PET Utilization Task Force.

CARRIE KITKO joined **Monroe Carell Jr. Children's Hospital at Vanderbilt** as associate professor of pediatrics and director of the Pediatric Stem Cell Transplant Program in the Division of Hematology/Oncology.

Kitko was previously assistant professor of the Blood and Marrow Transplantation Program in the Department of Pediatrics and Communicable Diseases at the University of Michigan School of Medicine.

While at University of Michigan, her research focused on understanding graft-versus-host disease. Kitko will continue her research at Vanderbilt and plans to start a clinic focused on GVHD treatment.

In her research, she studies biomarkers that can help determine which post-transplant patients are most likely to develop GVHD. She also looks at extracorporeal photopheresis for treatment and prevention of both acute and chronic GVHD.

Kitko will be the primary investigator on a national multi-center clinical trial investigating extracorporeal photopheresis for the treatment of pediatric acute GVHD and plans to have the study open for patients at Vanderbilt.

BRUCE QUINN joined **FaegreBD Consulting** as a senior director with the firm's health and biosciences team in Washington, D.C., where he leads the firm's health markets and reimbursement strategy consulting practice.

Quinn is a national leader on Medicare policy, the impact of health reform on innovation and the crafting of successful business strategies within the U.S. health care reimbursement system.

Prior to joining FaegreBD, Quinn was a senior health policy advisor with Foley Hoag after serving as the medical director for the Medicare Administrative Contractor in California. Earlier in his career, Quinn was a physician executive in the health and life sciences division of Accenture, working with the pharma, biotech and genomics industries.

Quinn is a board-certified pathologist. As a physician-scientist on the faculty of Northwestern University School of Medicine, he led pathology research for Northwestern's Alzheimer Research Center. Quinn has also held academic positions at New York University School of Medicine and the UCLA Center for Health Sciences.

THE CHILDREN'S HOSPITAL OF PHILADELPHIA will open its **Buerger Center for Advanced Pediatric Care** July 27, just across from the main hospital. The center is part of the newly named Raymond G. Perelman Campus.

The first clinical departments to occupy the new center will be orthopedics, oncology, radiology, and otolaryngology, with other subspecialties to follow.

"Many families, doctors and nurses participated

in the planning of this building, and the generosity of thousands of donors, most-notably the transformational $50 million gift from the Buerger family, has made this center a reality," said Madeline Bell, CHOP's president and chief executive officer. "We are confident that we have achieved our goal of providing an ideal patient experience by utilizing design features that anticipate and meet the needs of our patients and their families."

The Buerger Center stands 12 stories high, with a curving façade of primary colors, and a glass-lined exterior. It features a rooftop garden, a fountain and water channel, a play area, and a running path.

Other features include: a gym with a two-story climbing wall; sub-areas for different age and developmental levels; an outdoor dining terrace adjacent to a 2.6-acre landscaped plaza with a Children's Discovery Garden; and several interactive play installations in the waiting areas of each clinical department.

There are family lactation rooms and a rehab kitchen for patients to practice activities of daily living, as well as a mock scanner room, where children can practice lying motionless during an MRI session.

Drugs and Targets

Odomzo Capsules, Kyprolis Combination Approved by FDA

FDA approved Odomzo (sonidegib) capsules for the treatment of patients with locally advanced basal cell carcinoma that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy. Odomzo is marketed by Novartis Pharmaceuticals Corp.

The approval was based on demonstration of a durable objective response rate in an international, multi-center, double-blind, randomized, two-arm, non-comparative trial in patients with locally advanced basal cell carcinoma not amenable to local therapy or metastatic basal cell carcinoma.

The trial enrolled 230 patients who were randomized to receive Odomzo 800 mg (n=151) or 200 mg (n=79) daily until disease progression or unacceptable toxicity.

Randomization was stratified by disease stage (locally advanced or metastatic), histologic subtype (aggressive or nonaggressive) and geographic region. Eighty-four percent of those enrolled had locally advanced disease.

Approval was based on demonstration of durable objective responses in patients with laBCC as determined by central independent review according to a modification of RECIST. The ORR for the 66 patients with laBCC randomized to the Odomzo 200 mg arm was 58 percent (95% CI: 45, 70), consisting of three complete responses and 35 partial responses.

A pre-specified sensitivity analysis using an alternative definition for complete response, defined as at least a PR according to MRI and/or photography and no evidence of tumor on biopsy of the residual lesion, yielded a CR rate of 20 percent. A similar response rate was noted in the 128 patients with laBCC randomized to the Odomzo 800 mg arm [44 percent (95% CI: 35, 53)]. Among the 38 responding patients with laBCC in the 200 mg arm, seven patients experienced subsequent disease progression, and four of these seven patients had maintained a response of six months or longer.

The remaining 31 patients continue to respond with ongoing responses ranging from 1.9+ to 18.6+ months; 16 patients have ongoing responses of six months or longer, and the median duration of response has not been reached.

Richard Pazdur, director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research, said: "Thanks to a better understanding of the Hedgehog pathway, the FDA has now approved two drugs for the treatment of basal cell carcinoma just in the last three years." In 2012, Genentech's Erivedge (vismodegib) was the first drug approved to treat locally advanced and metastatic basal cell carcinoma.

Odomzo carries a Boxed Warning alerting healthcare professionals that Odomzo may cause death or severe birth defects in a developing fetus when administered to a pregnant woman. Pregnancy status should be verified prior to the start of Odomzo treatment, and both male and female patients should be warned about these risks and advised to use effective contraception.

FDA approved Kyprolis (carfilzomib) in combination with lenalidomide and dexamethasone for the treatment of patients with relapsed multiple myeloma who have received one to three prior lines of therapy. Kyprolis is sponsored by Onyx Pharmaceuticals Inc., an Amgen subsidiary.

The approval was based on a demonstration of improved progression-free survival in a multicenter, open-label trial (PX-171-009 ASPIRE). The trial enrolled 792 patients with relapsed or refractory multiple myeloma after one to three lines of prior therapies. The patients were randomized to receive lenalidomide and dexamethasone with or without Kyprolis for 18 cycles. Lenalidomide and dexamethasone were continued

thereafter until disease progression. There was no planned cross-over from the control arm to treatment with Kyprolis.

A statistically significant prolongation of PFS, as determined by an independent review committee, was demonstrated [HR 0.69 (95% CI: 0.57, 0.83); p = 0.0001, stratified log-rank test].

Median PFS was 26.3 months in the Kyprolis arm and 17.6 months in the two-drug arm. A treatment effect was observed across all subgroups tested, but the magnitude of the treatment effect was reduced in patients with higher tumor burden at study baseline (improvement in median PFS: 11 months for ISS Stage I, 8 months for ISS Stage II and 2 months for ISS Stage III).

An interim analysis of overall survival was conducted at the same time. The difference in OS did not reach the prespecified boundary for statistical significance. A partial response or better was achieved by 87 percent of patients on the Kyprolis arm and 67 percent on the two-drug arm.

The safety profile of Kyprolis in the 3-drug combination was similar to that described in the current label. Cardiovascular events, venous thromboembolic events, and thrombocytopenia occurred more frequently in the Kyprolis arm than in the Kyprolis arm.

In Cycles 1-12 of therapy, the VTE rate was 13 vs 6 percent, respectively, despite protocol-mandated use of thromboprophylaxis.

The revised labeling includes new Warnings and Precautions for VTE, cardiac toxicities, acute renal failure, pulmonary toxicities, and hypertension.

FDA granted an Orphan Drug Designation to Anisina (ATM-3507) for neuroblastoma. Anisina is developed by Novogen Ltd.

The designation was based on data from preclinical studies which were done as part of the Children's Oncology Drug Alliance involving Australian charity, The Kids' Cancer Project, The University of New South Wales, The Nationwide Children's Hospital of Columbus, Ohio, and Novogen.

The key findings from these studies showed that Anisina significantly improved the effectiveness of the standard of care microtubule targeting compound, vincristine, in an animal model of neuroblastoma. The data from these studies were recently announced and presented at Eighth Annual Cancer Molecular Therapeutics Research Association meeting in Boston.

Novogen is now conducting pre-clinical studies to further validate the combinatorial effect of Anisina with a range of microtubule-targeting compounds in animal models of adult cancer. Once the company has completed its pre-clinical toxicology program for Anisina, the drug is expected to enter the clinic for adults in mid-2016 with clinical trials in childhood cancer in Australia and the U.S. to follow in early 2017.

Amgen submitted a supplemental New Drug Application to the FDA for Kyprolis (carfilzomib) for Injection to seek an expanded indication for the treatment of patients with relapsed multiple myeloma who have received at least one prior therapy.

The sNDA is based on data from the global ENDEAVOR trial. ENDEAVOR is the first of two head-to-head phase III trials of Kyprolis versus Velcade (bortezomib).

Relapsed multiple myeloma patients treated with Kyprolis and dexamethasone in the ENDEAVOR study lived twice as long without their disease worsening, demonstrating statistically and clinically significant superiority over Velcade (median progression-free survival of 18.7 months versus 9.4 months, HR=0.53, 95% CI, 0.44 - 0.65; p<0.0001).

The Kyprolis combination demonstrated superiority over the Velcade combination for secondary objectives of higher overall response rate and lower neuropathy events. Overall survival data are not yet mature and continue to be monitored.

Kyprolis is also being evaluated in the CLARION study, a head-to-head Phase 3 multicenter, open-label, randomized study in transplant-ineligible patients with newly diagnosed multiple myeloma. The study is evaluating the safety and efficacy of Kyprolis, melphalan and prednisone versus Velcade, melphalan and prednisone.

IriSys LLC was awarded a five-year contract worth up to $3 million by the NCI Developmental Therapeutic Program of the Division of Cancer Treatment and Diagnosis for the pharmaceutical development and production of new therapeutic agents for use in clinical trials supported by NCI.

Under this agreement, IriSys will be supplying NCI with oral, topical and injectable dosage forms to be used in NCI-sponsored and/or investigator-initiated clinical trials in humans. IriSys will be responsible for formulation studies, process optimization, manufacture of the clinical dosage forms, release testing, quality control and quality assurance.