Put It on the Board

Cancer Moonshot has diagnostic thrust

October 2016—Vice president Joe Biden's Cancer Moonshot now has a flight plan, drafted by a blue-ribbon panel and published in September. Coming as it does in the final year of president Obama's term in office, there are doubts about whether the ambitious $1 billion program—aimed at achieving 10 years' progress in cancer research and treatment in a five-year period—will ever get off the launching pad.

Nonetheless, two pathologists involved with the initiative say it has already spurred creative thinking about how to break down silos within the cancer community and reinforced the central role diagnostics will play in detecting, preventing, and better understanding cancer.

Dr. Downing

James R. Downing, MD, a pathologist and president and CEO of St. Jude Children's Research Hospital, was invited in April to serve as one of the 28 members of the blue-ribbon panel. He has long investigated the genetic basis of cancer and was the corresponding author of a *New England Journal of Medicine* study that uncovered new information about the role that genes associated with cancer predisposition play in childhood cancer (Zhang J, et al. 2015;373[24]:2336–2346).

Dr. Downing says the broader cancer community submitted more than 1,600 ideas for the panel to consider. Over the course of many face-to-face and virtual meetings, the panel—with the help of seven working groups composed of more than 120 physicians, scientists, patient advocates, and other experts—narrowed that mammoth catalog of ideas to a relatively targeted list of 10 high-impact recommendations. The report, available in full at bit.ly/moonshotreport, recommends the federal government fund efforts to:

- Establish a network for direct patient involvement.
- Create a clinical trials network devoted exclusively to immuno-therapy.
- Develop ways to overcome resistance to therapy.
- Build a national cancer data ecosystem.
- Intensify research on the major drivers of childhood cancers.
- Minimize cancer treatment's debilitating side effects.
- Expand use of proven prevention and early detection strategies.
- Mine past patient data to predict future patient outcomes.
- Develop a three-dimensional cancer atlas.
- Develop new cancer technologies.

“Pathologists, and other people in the field of laboratory medicine and diagnostics, need to be participants across many of the 10 recommendations,” Dr. Downing says. “In cancer immunotherapy, a tremendous amount needs to be learned about why some patients respond and some don’t. What is the mutational burden? What is the composition of the immune system? And some of that work will be tissue-based analysis. And then there is monitoring response to cancer immunotherapy.”

Pathologists also would be key to the 3-D atlas of cancer, which requires profiling tumors and understanding how they vary over time. And, as long-time experts in informatics, pathologists could prove invaluable to “this idea of developing an ecosystem for sharing and analyzing data,” Dr. Downing says.

“Pathologists have a unique skill set and experience and a viewpoint that can play a role in many of these investigational studies,” he adds. “Within precision medicine—how do we treat more specifically for individual tumors—is buried a lot of genomic analysis, immunophenotypic analysis, tissue environmental analysis, and understanding those dynamics with those tumors. Out of this work will come new diagnostics and treatments.”

Dr. Downing lauds the report’s call to fund more work on the fusion oncoproteins that drive many childhood cancers and turn them from “undruggable” to targets for new drugs. Such research could yield big insights that “would spread into adult cancer,” he says.

“The blue-ribbon panel was instructed not to think about dollars and cents at all,” Dr. Downing says. “We were asked to think about what are the biggest opportunities, irrespective of what they would cost. So we did the exercise without looking at the potential total dollars invested in this, or the reality or likelihood of money being invested in it.”

Of the $1 billion in funding outlined, $195 million was redirected from the National Institutes of Health as part of its 2016 budget. Obama proposed another $755 million of the total as mandatory funding for the NIH and the FDA as part of his 2017 budget, but Capitol Hill watchers say the likeliest scenario—even after the elections in November—is that Congress will pass a continuing resolution that will forgo any new spending.

Dr. Downing says he does not see the moonshot program’s blue-ribbon panel “as an exercise in futility” because it has brought together “a serious group of individuals, representing a broad swath of research, advocacy, and others involved in cancer to think about approaches that, if pursued, could really accelerate progress.”

“My experience over the last 30 years,” he adds, “is that not all funding can come from the federal government. With these kinds of exercises, you can look at what needs to be accomplished and not just what we can accomplish. There is a benefit to having thought leaders focus on these kinds of efforts.”

Aside from the central question of whether Cancer Moonshot will get the funding envisioned, another uncertainty is whether the plan’s reach exceeds its grasp, says Keri Donaldson, MD. He directs the CLIA laboratory at the Penn State Institute for Personalized Medicine and was invited to participate in one of the moonshot task force’s public meetings, held June 29 at Fox Chase Cancer Center in Philadelphia.

“If you look at the primary goals of the moonshot, some of them are pretty lofty,” says Dr. Donaldson, who also directs the clinical processing specimen laboratory at Milton Hershey Medical Center and is an assistant professor of biochemistry and molecular biology at Penn State. “Whether they are attainable or not is a reasonable question.”

He sees some of the recommendations as more achievable than others.

“Earlier detection of cancer, whether it be through liquid biopsies or earlier risk-stratification of patients using combinatorial factors based on EHRs and family history, is the most likely attainable goal of the Cancer Moonshot,” Dr. Donaldson says.

Dr. Donaldson

The CAP can play an important role in that element of the moonshot plan through its work to standardize how cancers are reported, he says. Already, a California pilot project to create a cancer registry based on the CAP's electronic forms and reporting module is underway. The data, transmitted by 10 hospitals to the state health department, are being used to improve care and cancer control efforts for other patients throughout the Golden State. CAP president Richard Friedberg, MD, gave a talk about the CAP's cancer-reporting and registry work at a Washington, DC, moonshot summit in June.

Dr. Donaldson says another achievable plank in the moonshot plan is the call for "standardization of the detection technology out there." He sees a "huge need to go through and classify and quantitate the performance characteristics of these methods," such as next-generation sequencing and liquid biopsy.

Pathologists and laboratory medicine professionals "need to sit at the table and let people know there are experts in this area, on the traceability of these methodologies," Dr. Donaldson says. "We need to make sure these tests are measuring the same thing and that they're comparable." *—Kevin B. O'Reilly*

Survey: MACRA will push doctors to leave small practices

Medicare's new physician incentive and alternative payment models will lead to more doctors seeking employment with large practices or hospital systems, says a *Modern Healthcare* survey of 93 health care leaders.

Under the Medicare Access and CHIP Reauthorization Act of 2015, known as MACRA, doctors who fail to meet certain metrics under the Merit-Based Incentive Payment Program were initially in line for a penalty. Centers for Medicare and Medicaid Services acting administrator Andy Slavitt responded last month to complaints from organized medicine by withdrawing any physician pay cut for 2019 so long as doctors, in 2017, report some data to the agency's Quality Payment Program or take part in what the CMS calls an Alternative Payment Model. After that one-year reprieve, the MACRA physician pay penalties will take full effect.

Prior to Slavitt's announcement, 70 percent of the health care leaders surveyed said MACRA's reporting requirements were more burdensome than the agency's previous physician quality incentive payment efforts. Ninety-one percent of the leaders from hospitals, health insurers, physician groups, and trade associations told *Modern Healthcare* they expect the MACRA requirements will lead to even more doctors seeking salaried positions with health systems or large practices over the next few years.

Three-quarters of respondents predicted the CMS program would lead to greater stress among physicians. About half said more physician practices would take on risk-based contracts as a result of MACRA and that more doctors would opt out of Medicare. Just three percent of respondents said MACRA will result in "little change in physicians' relationships with the CMS" or have "little impact on where or how physicians choose to practice." Eight in 10 respondents said that, overall, physician burnout is on the rise. The survey results were published in the Sept. 5 issue of *Modern Healthcare*. *—Kevin B. O'Reilly*

War College, DxMA meetings coordinated

The Dark Intelligence Group and Diagnostic Marketing Association will hold their 2017 annual conferences in sequence, in the Sheraton New Orleans Hotel, to make it easier for laboratory leaders to attend both meetings.

The DxMA Global Marketing Summit will begin the evening of April 30, 2017 with the Dx Creative Communications Awards ceremony, and it will continue May 1 with the Global Marketing Summit featuring technology and

marketing sessions.

The Dark Intelligence Group, publisher of the *Dark Report*, will kick off its Executive War College conference the evening of May 1 with its welcome receptions and will continue May 2–3, featuring sessions on regulation, payment, and management.

The DxMA Global Marketing Summit gathers leaders from more than 50 diagnostics companies.

Registration opens Dec. 1.

Danaher to buy Cepheid for $4 billion

Danaher has entered into a definitive merger agreement with Cepheid pursuant to which Danaher will acquire all of the outstanding shares of Cepheid for $53 per share in cash, or a total enterprise value of about $4 billion including indebtedness and net of acquired cash.

The acquisition has been unanimously approved by each company's board of directors. The offer is subject to customary conditions, including approval by Cepheid's shareholders and receipt of applicable regulatory approvals. The transaction is expected to be completed before the new year.