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NIH to Review Intramural Program NCI's Intramural Spending is 17 Percent, Higher than 11.1 Percent NIH-Wide Level

By Paul Goldberg

NIH has launched a systematic examination of its intramural program, which accounts for 11.1 percent of its \$30 billion budget.

The program was last examined in 1993, pursuant to a mandate from the House Appropriations Committee.

[That examination](#) was written by a panel co-chaired by Paul Marks, then president of Memorial Sloan-Kettering Cancer Center and Gail Cassell, then chair of the University of Alabama Department Microbiology.

(Continued to page 2)

Appropriations

President Requests Extra \$200 Mil for NIH

By Matthew Bin Han Ong

President Barack Obama's \$3.9-trillion budget proposal for the 2015 fiscal year would bump NIH funding up to \$30.2 billion—a \$200 million increase over fiscal 2014—and would include an additional \$8 million for NCI, totaling \$4.931 billion for the institute.

(Continued to page 7)

In Brief

Pasche to Lead Wake Forest Cancer Center

BORIS PASCHE has become director of the recently expanded comprehensive cancer center at **Wake Forest Baptist Medical Center**.

(Continued to page 13)

Twenty Years Later
A Transcript of Varmus's
Remarks to NCAB

... Page 3

"The Details of this
Program Remain a
Little Murky to Me"
... Page 6

[Watch Varmus's
Remarks to NCAB](#)

Appropriations

The Requested FY2015
Budget for NIH,
Broken Down

... Page 8

HPV Vaccination Should
Become National Priority,
Says President's Cancer
Panel Report

... Page 10

NCI Publishes Report
On Pancreatic Cancer

... Page 11

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NIH Revisits Intramural Program 20 Years After Marks-Cassell

(Continued from page 1)

The Marks-Cassell report recommended uniform, rigorous reviews of intramural scientists and tying promotions and resources to scientific merit. Just as importantly, the report called for consultation with extramural researchers in setting the parameters for the NIH intramural program.

"In the context of these recommendations, a centralized decision-making process governing the total NIH extramural/intramural allocation should ensure that the total intramural research program budget for institutes, centers, and divisions does not exceed the current rate of 11.3 percent of the total NIH budget," the Marks-Cassell report recommends.

The intramural program accounted for about 11 percent of the NIH budget in 1994, when the Marks-Cassell report was mandated. As director of the NIH between 1993 and 1999, Harold Varmus spearheaded implementation of the report.

The level of intramural spending at NIH depends on how you calculate it, and materials published by NIH

can be confusing. If you include the 15,000 people who manage extramural grants, intramural spending accounts for 19 percent of [the current NIH budget](#).

However, with these employees excluded, intramural spending was at 11.1 percent of the budget in 2013. In 2002, during the doubling of the NIH budget, intramural spending dropped to 9.5 percent of the NIH total. In 2008, the National Library of Medicine was reclassified as intramural, adding 10 percent to the intramural line, NIH officials say. NLM wasn't included in the intramural budget in the Marks-Cassell era.

Insiders say that the Marks-Cassell review set the upper boundary for NIH-wide spending, recognizing that some institutes will spend more while others will spend less. NCI has historically been among the high spenders.

Michael Gottesman, NIH deputy director for intramural research, described the new round of review as "long term planning process," which will involve extramural researchers. Unlike the Marks-Cassell examination, which was mandated by Congress, the latest review is self-generated.

"Because the conduct of science is evolving and resources are becoming more restricted, we are evaluating how we can best mold the future to assure the continued success of research at the NIH," Gottesman said to The Cancer Letter.

"For the past nine months, I have been meeting with NIH leadership to discuss how best to prepare ourselves for the future," Gottesman said. "In January, I discussed a proposal for long-term planning for the IRP at the Leadership Forum of Institute Directors. In February, the NIH scientific directors met for their annual retreat and have worked out a plan to develop a blueprint for the future of NIH intramural research.

"The planning process will begin at the level of NIH institutes and centers with committees of NIH experts and outside experts formulating a 10-year scientific vision for each of the ICs, and determining what will be needed to accomplish these goals.

"These ideas will be discussed by the IC Scientific Directors and by a committee of Institute Directors, and the common themes that emerge will be identified and integrated into a single document. My hope is that this process—beginning within the NIH with outside encouragement and support—will inspire creative, farsighted thinking."

At NCI, the budget authority for intramural research accounted for about \$869 million in fiscal 2014, about 17 percent [of the institute's overall spending](#).

Intramural research is separate from contracts. NCI's largest contract involves running the Frederick

CORRECTION: [The Feb. 28 issue](#) of The Cancer Letter erroneously described the Frederick National Laboratory for Cancer Research as a component of NCI's intramural research. The institute's intramural program contributed 17 percent to the total FNLCR effort in fiscal 2013.



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National Laboratory for Cancer Research, which receives about \$300 million a year. This amount is expected to increase during the current fiscal year (The Cancer Letter, [Feb. 28](#)).

In the past, the contract, which is administered by Leidos Biomedical Research Inc.—formerly named SAIC-Frederick—was often used by NCI directors to fund projects they didn't want to submit to peer review.

Now, NCI Director Varmus is aligning the newly designated national lab with the institute's scientific mission. He has formed an advisory committee to guide the national lab. The lab's projects include [the RAS program](#). Recently, Leidos officials published [informational videos](#) describing the mission of the lab.

Varmus described the upcoming review of the NIH intramural program at the meeting of the National Cancer Advisory Board Feb. 27.

"I want to alert you to a new campus-wide effort to study the intramural research program. The details of this program remain a little murky to me. But it's always healthy to examine things, and [Robert] Wiltout [director of the Center for Cancer Research and scientific director for basic research] and his colleagues [Lee] Helman [scientific director for clinical research] and [Stephen] Chanock [director of the NCI Division of Cancer Epidemiology and Genetics] have been working with the Board of Scientific Counselors to establish some, I'm not sure if they're still called blue-ribbon, but panels that are looking at the intramural program.

"Now, my view is that this is on a very fast track for reasons that aren't quite clear to me. And the goals are not so clear, except that it's always good to look at things. Well, okay. I think our emphasis is going to be on trying to identify particularly important, exciting, difficult things that the intramural program might uniquely take on.

"While there will be a general examination of procedures and people and all the rest of it, not on a micro level, but the sort that's done by site visits by the BSC, but looking at our procedures and the general constitution of the program."

Marks is president emeritus of Memorial Sloan Kettering Cancer Center and member of the Sloan Kettering Institute. Cassell is a now a senior lecturer on Global Health and Social Medicine at Harvard Medical School.

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The text of Varmus's remarks to NCAB follows:

We had a major body blow to all of us about a week ago, when John Czajkowski, our executive officer, announced that he's going to run Harvard—that means being in charge of the resources, personnel and financials at Harvard Medical School, that is basically Harvard these days.

John has given great service to the NCI and has been an indispensable help to me and to my colleagues. We all congratulate Harvard—we only wish we could pay the kind of salaries Harvard pays.

But for John this is a departure after many years in government. I knew him when he was in Building One in the 90s, and he deserves some respite from all the crap we get in government!

You're aware that communications is a big issue for the NCI. Lenora Johnson, who ably ran our Office of Communications and Education, has headed off for what she may have thought was a greener institute, over at Heart, Lung and Blood.

But we have now quite nicely filled the gap. We recruited Peter Garrett, who's here today, who now runs the communications office. Peter has a rich history both in communications and medical affairs as we were able to recruit him from the Office of the National Coordinator that manages the medical IT. Peter has settled in very well.

To help me with my dealings with the press, especially the important members of the press, I've been able to recruit at least on a provisional basis Anne Thomas, who was head of the NIH communications office when I was NIH director and then spent several years with me at Sloan-Kettering, and now is coming out of retirement to assist me in dealing with some difficult issues with the press.

Always need to have a few words about budget, but I can't give you any details, because everything is shrouded in a cone of silence for the moment.

The important thing is that we did get an appropriations bill before Jan. 15. We avoided another shutdown. You all probably heard the big message in gross terms of post-sequestration, which clobbered our budget in 2013.

We had partial restoration of that loss. We had taken a hit of about \$255 million from sequestration in FY13 compared to FY12 and we got \$144 million back—so that could be called turning the corner, going in the right direction, or it could be called the glass is still half-empty. Depends on how you look at it.

No Surprises in Appropriations

I can't show you an operating plan for NCI this year, but there will be no dramatic changes from expectations, but obviously having more money than we had in 2013 is a good thing. The operating plan approval has not yet come from OMB, so I can't give you details.

One thing about the appropriations bill worth emphasizing is the restrictions on travel and meetings are still in place. OMB has maintained other kinds of restrictions on our freedom of motion. One thing that a subgroup of the NCAB might want to have a look at—and this is not an issue that pertains solely to NCI, but to all of NIH—the burdens placed on our investigators, the difficulty getting to meetings, the difficulty arranging meetings.

Having a chance to assemble with some frequency with important colleagues is fundamental to the conduct of science. We're a science agency; we run science across the country. Yet people can't meet and do so freely.

Now, one does not only have to plan for meetings, they have to plan them 150 days in advance, and the consequences

to that can be both intellectual and even financial. People have to pay late fees and higher airplane rates.

Waiting for approval to go to a scientific meeting is anathema to the way we work here, and it's placed an unfortunate burden on the notion of being a government employee doing science. And that's quite unfortunate.

There will of course be a FY15 budget in the not-too-distant future. In fact [Rep.] Hal Rogers [R-Ky.] and [Sen.] Barbra Mikulski [D-Md.] have been telling us that they hope to have real appropriations bills before Oct. 1, that would be a departure from the current reality. That would be mind-blowing.

But it might happen. There is, as you know, a current budget projection, as opposed to an appropriation, for the whole government as a result of the work of Sen. [Patty] Murray [D-Wa.] and Congressman [Paul] Ryan [R-Wis.] that outlines in large terms what will happen in 2015.

No substantial increase—a very minor increase. There may be additional money for the NIH, that remains to be seen. I think we can expect to be more or less in 2015 where we are in 2014. The president's budget proposal is not going to be unveiled until probably March 4, that is much later than usual, but these have been extraordinary times.

Sen. Mikulski was here this week—and in addition to the highlight of her visit, which was getting a lecture on renal cancer from Marston Linehan—she also addressed the masses and two or three scraggling members of the press on the topic of our budgetary future.

She argued vociferously for supporting NIH, and she got deserved accolades for putting \$1 billion more in our budget this year than last year. On the other hand, if \$2 billion has been taken away in the last few years and you get a billion back, well one hand is still missing. But we do congratulate her for moving things in the right direction.

There are some other changes on the Hill that are worth pointing out. We're losing [Sen.] Tom Harkin [D-Iowa], who has been the head of our authorizing and appropriating committee, and that's a big blow. He's been a stalwart for NIH for a long time. I would like to think that in honor of Harkin's departure, this year's congress is going to give us an extra billion or two, but that hasn't yet been raised as a lively congressional issue.

[Rep.]

Jack Kingston [R-Ga.], who's been serving as chair of our House appropriations

I want to alert you to a new campus-wide effort to study the intramural research program.

The details of this program remain a little murky to me

committee, is running for the Senate and still fighting for the nomination on the Republican side, but it's clear he won't be here as a member of the House in the next Congress. There will be someone to replace him as chair.

Three other figures who have played an important role in the government's relationship to science are leaving—they're all worth mentioning.

One is [Rep.] Rush Holt [D-N.J.]—who's been a very good friend of mine, and is a trained physicist, taught at Swarthmore, and has always carried the torch for science of all kinds in the government—has decided to step down. I'm not entirely clear what his new plans will be, but hopefully still a figure to watch in Washington.

[Rep.] Henry Waxman [D-Calif.], who's been a major figure on the oversight side primarily, but also a tremendous supporter of NIH is leaving. And [Rep.] John Dingell [D-Mich.] has announced his departure, and the relationship there has been, how to put this, hot and cold. He's been fundamentally a very strong supporter of healthcare reform and research, and his departure will be noted with interest as well.

FY2014 Bypass Budget to be Folded into FY2015's

NCI is obliged to provide a bypass budget. Some of you watching this closely may have noted that the FY14 bypass budget proposal has not seen the light of day. Since FY14 has happened, it will be folded into a FY15 budget request and we hope that will be done within the next few weeks, shortly after the president unveils his request for FY15.

NCI had a staff retreat, as we do semi-annually in January. A couple of things that were discussed there—it was actually one of the best retreats we had and we had a lot of good discussion—but two things I wanted to draw to your attention as being of special interest:

First, we had a very good discussion about diversity, especially in the intramural research program. Not too surprisingly we found that the number of underrepresented minorities, especially black and Hispanic, remains woefully low in that intramural research program.

But one bright light here was a rather robust representation, especially of African-Americans in our post-docs. Seven to 10 percent of our post-docs have been African-American for the past several years and a substantial number of Hispanic folks as well. We had two really inspiring and wonderful talks by minority members of our staff. One junior faculty member who is Hispanic and an African-American senior post-doc both gave us a lot of insight into the difficulty of finding your way to NIH and working at the NIH, but also an overall endorsement of what we try to do here.

And the result was we put together a group, headed by Jonathan Weiss and many of our senior staff, who presented to try and take advantage of some of the things we learned. I'm quite encouraged by the results of their first meeting, where they laid out a series of steps including some special training programs and greater efforts at recruitment and retention.

I'm hopeful that we can make better inroads than we've made in the training programs, and take advantage of some of our extramural training programs, as well as to try to adjust to current realities and have a better representation of America's ethnic groups in our intramural program.

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Wrangling Over Seven Year Investigator Award

We also talked about new ways to think about career pathways in science, especially supported by the NCI.

You've heard before about our efforts to create a new outstanding investigator award. That has still not been released, because we still are hoping for that to be a seven-year award with an opportunity for various kinds of extension. But we're getting a lot of pushback from the department on this, which is currently not allowing us to advertise the seven-year award. We're still working to make that happen. If it doesn't we'll make it a five-year award. We're still in there pitching.

Some of the new ideas include transition awards between graduate and post-doc years. Training programs that emphasize the possibility of becoming staff scientists, as opposed to independent faculty, and awards that might ease the departure of senior scientists from the scientific workforce. Some desperately try to hang on and don't see a graceful exit.

But all of these things are not yet in the form of formal proposals, I just wanted you to know that we are thinking about these, and will have some fairly specific proposals for ways to change the way training and support the most vital times of someone's career, and plans to think about how we change the demographic somewhat by finding new ways for people to finish up their work and exit the scientific community.

The Scientific Workforce

There was also a retreat of all the institute directors, which occurs at least annually. During that retreat there was a fair amount of discussion about the scientific workforce, let's put it that way, and how we evaluate them and how we support them.

There were a lot of new ideas about supporting careers in the ways that I just mentioned, but also including efforts to support scientists in the early phases of their careers, and in the phase between the first grant and renewals. There was some discussion about the evaluation process, including peer review. And a discussion about the NCI biosketch proposal and I know you're going to be hearing more about that from NIH in the near future.

Some of you have been following our response to the Recalcitrant Cancers Act. Our report on pancreatic ductal adenocarcinoma has been sent to the Hill. We have discussed it briefly in the past. If requested there will be a more detailed presentation of that report at the next meeting.

We have another report on small-cell lung cancer,

another that fits the criteria for the first round of reports for so-called “recalcitrant” cancers—a term I’m not all that fond of. But it is working well. I think we’ve had good workshops to examine certain types of cancer.

I emphasize that a type of cancer is not a cancer that arises in a certain organ, it’s a cancer that arises in a certain lineage in that organ. That’s the best definition at the moment. Steve Jobs did not die of pancreatic ductal adenocarcinoma, a very common confusion. It’s important to make the separation between the cancers that arise in different cell lineages, and I echo that here.

There is no such thing as lung cancer. There’s lung adenocarcinoma, which my friend over here studies, and small cell lung cancer, which he also studies, but they’re two different diseases, as he and I would agree.

The Intramural Program

I want to alert you to a new campus-wide effort to study the intramural research program. The details of this program remain a little murky to me. But it’s always healthy to examine things, and [Robert] Wiltout [director of the Center for Cancer Research and scientific director for basic research] and his colleagues [Lee] Helman [scientific director for clinical research] and [Stephen] Chanock [director of the NCI Division of Cancer Epidemiology and Genetics] have been working with the Board of Scientific Counselors to establish some, I’m not sure if they’re still called blue-ribbon, but panels that are looking at the intramural program.

Now, my view is that this is on a very fast track for reasons that aren’t quite clear to me. And the goals are not so clear, except that it’s always good to look at things. Well, okay. I think our emphasis is going to be on trying to identify particularly important, exciting, difficult things that the intramural program might uniquely take on.

While there will be a general examination of procedures and people and all the rest of it, not on a micro level, but the sort that’s done by site visits by the BSC, but looking at our procedures and the general constitution of the program.

And we have a complicated program, with essentially three divisions working at various places.

But beyond that, we’re looking for opportunities to do something not unlike what we’re trying to do at the Frederick National Lab. Jennifer Pietenpol [director of the Vanderbilt-Ingram Cancer Center and a member of NCAB] participated recently at a discussion we had at a meeting of the Frederick advisory committee where we

were specifically vetting new proposals for new projects to be carried out at the national lab, and new ways to think about how to run the national lab.

I’d like to see that be an element of this review of the NCI intramural program. And that will be something we will report on either the next or the one after the next NCAB meeting.

Perhaps worth mentioning, of course our intramural program is as a major component of the work at the National Clinical Research Center. And as I discussed with the budget committee last night, the financial support for the clinical center is still a source of concern for many institute directors, and again I think the NCAB might be able to play a role.

The NCI accounts for about 40 percent of the research activity in the clinical center, far beyond what we predicted to do, because we are roughly one-sixth of the NIH by budget comparisons, and yet we’re 40 percent of the clinical research activity. Maintaining the vitality of the clinical center is vital to our research efforts. And I am concerned with dealing with the fixed costs of the center at a time when our budgets have been shrinking.

You recall that I’ve been helping to organize an annual meeting of cancer research funders, and we had this year’s meeting in Paris led by Chris Wild of IARC, and Fabien Calvo of the French Cancer Institute.

Representatives of about 20 different countries were there. There were important new working groups, about the control of cervical cancer, to tobacco control, to harmonizing clinical trials to be set up with representatives from various countries.

The tobacco issue was particularly important because we were in Paris when Francois Hollande was releasing his new cancer plan for France, and we had petitioned him as a group for him to raise taxes on tobacco, because tobacco rates have not fallen in France recently even though they have instituted some very good efforts to control tobacco in public places, including restaurants. But he did not include our recommendation. Nevertheless, it was interesting to see this group take some political action.

I was also in India for a little over a week and there are some major issues with respect to conduct of clinical trials in India, which we might come back to at a subsequent meeting. It’s one of the thornier issues in global health at the moment, because essentially all NIH-supported, including NCI-supported trials have been shut down, pending a re-evaluation and re-examination of the terms in which we do trials in India.

And last I’ll just mention briefly, something that

I've mentioned here before, the number of institutions and people trying to establish a global alliance, now called the Global Alliance for Genomics and Health. Representatives of about 120 institutions will be meeting in London next week, including representatives from the NCI, to try to work out the means to establish ways to have interoperable databases containing some of the rich horde of genomic information that's been developed, especially by cancer, rare genetic diseases, and hopefully microbial diseases, in terms that are politically and ethically acceptable.

That's a huge chore that have been led by people in the U.S., Canada, and England especially, and I'll give you a fuller report on that at our next meeting.

Appropriations

Varmus: "We Are Halfway Back to 2012 Levels"

(Continued from page 1)

"There is not much in that budget that is surprising, or subject for applause, because [Obama] is operating under severe constraints," NCI Director Harold Varmus said March 6 at a meeting of the Board of Scientific Advisors. "That increase is more for the NIH overall, in percentage terms, than the NCI, as there are certain programmatic assignments—called the earmarks, if you will—for the BRAIN initiative, for diabetes, for Alzheimer's research.

"It means that NIH overall has a slightly higher number than NCI," Varmus said. "Money is appreciated, I'm glad we didn't take any further cuts, and it is the president's proposal, which, if you follow the news, you know is a request from the president, which Congress may not honor in many respects, because there are tax changes built into it. Some folks think that none of those tax measures will ever get passed.

"I think we simply need to work as hard as we can with Congress to be sure that the president's aspirations for NIH are not only met, but possibly exceeded," Varmus said. "I'm probably not supposed to say that, but I think that's what all of us would like to see happen."

The [added funding](#) in Obama's budget proposal, published March 4, reflects his recent call to reverse cuts made to basic research in the federal budget.

"Congress should undo the damage done by last year's cuts to basic research so we can unleash the next great American discovery—whether it's vaccines that stay ahead of drug-resistant bacteria, or paper-thin material that's stronger than steel," Obama said during his State of the Union ([The Cancer Letter, Jan. 31](#)).

The budget request exceeds sequestration limits by \$56 billion, when including a separate proposal, the Opportunity, Growth, and Security Initiative, which would allocate \$5 billion for research.

NIH would receive an additional \$970 million if Congress approves the OGSi—effectively eliminating previous sequestration cuts.

However, Congressional approval is unlikely according to critics, given that the initiative would be funded through tax increases on retirement funds owned by the wealthy and spending changes in airport security programs, unemployment, telecommunications, and crop insurance.

In his budget request, Obama's new number for NIH is about \$450 million below the pre-sequester level, as well as the 2012 levels of \$30.6 billion. The small increase would support 9,326 new and competing grants—329 more than fiscal 2014.

The budget's \$4.931 billion request for NCI comes in about \$105 million below the pre-sequester and 2012 amounts of \$5.07 billion.

The request includes an additional \$50 million for the [NIH Common Fund](#), an increase of 9.2 percent over FY14 to \$583 million, a program enacted by Congress through the 2006 NIH Reform Act to support trans-NIH programs that require participation by at least two NIH institutes or centers or would otherwise benefit from strategic planning and coordination.

The recent 2014 appropriation restored a little more than half the money taken away by sequestration ([The Cancer Letter, Jan 17](#)).

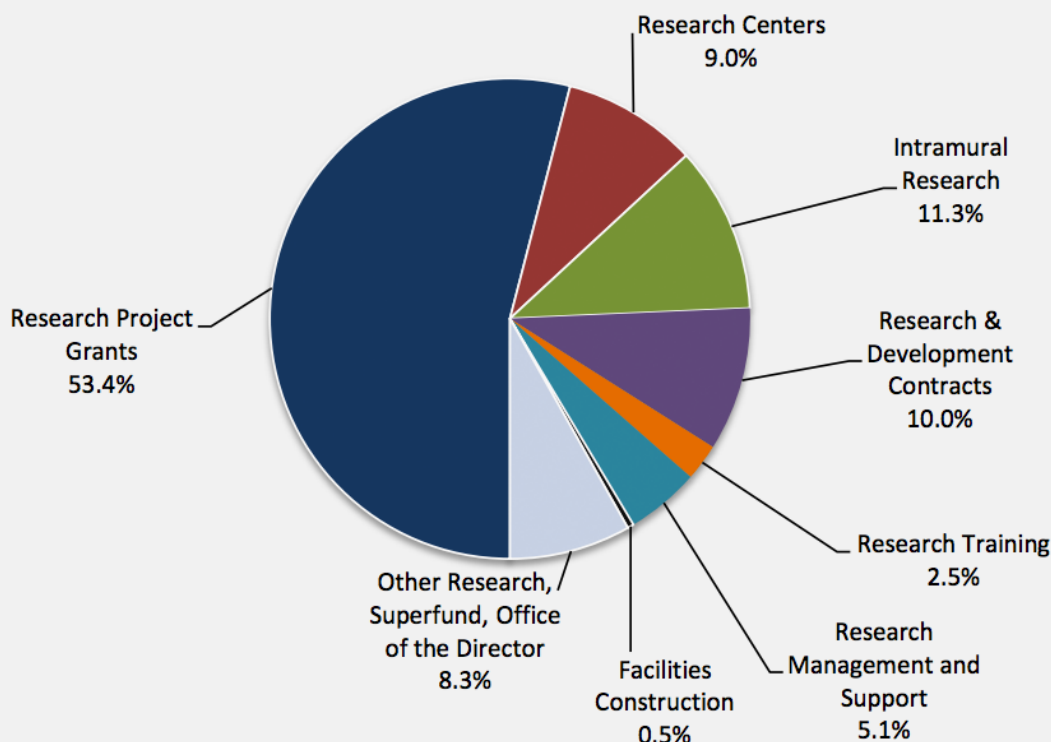
"This is a classic glass half-empty, glass half-filled—the good news is that NIH got \$1 billion back," Varmus said. "The bad news is almost \$2 billion had been taken away, and we don't have that back, so we are about halfway back to 2012 levels, and as all of you probably remember, 2012 was a flat year after a year when we had lost 1 percent of our budget, so overall, we're still down about 3 percent in real dollars compared to 2010, the year that I was first here. That is, on the whole, a lamentable decline. On the other hand, one can argue that we have turned a corner—we hit bottom in 2013 and we are halfway back in 2014.

"The operating plan approval will be released very soon, but I think all of you probably have some idea of, more or less, how these increases will be distributed."

Medicare Reimbursement and Self-Referral

Obama's budget includes a proposal to reduce reimbursement for cancer drugs, among several cost-cutting measures for the Medicare program.

FY 2015 NIH Budget \$30.4 Billion – Estimated Percent Total by Mechanism



According to the American Society of Clinical Oncology, current reimbursement to physicians for Part B drugs is based on the average sales price plus a 6 percent payment for services needed to administer chemotherapy in physicians' offices, where most cancer patients receive their care.

"The president has proposed to reduce the 6 percent service payment to 3 percent," ASCO President Clifford Hudis said in a statement. "The budget proposal appears to apply cuts primarily to physicians, but also mentions rebates that will be required by manufacturers. This further threatens access to convenient care nationwide."

The budget proposal would curtail imaging and radiation oncology self-referral, reflecting recommendations in a recent series of reports from the Government Accountability Office (The Cancer Letter, [Aug. 9, 2013](#)). Obama's budget would also restrict self-referral of anatomic pathology and physical therapy services.

The GAO reports found significant and inappropriate increases in referrals when physicians are allowed to self-refer—this drains Medicare of hundreds of millions of dollars each year, according

to the American College of Radiology.

"The ACR applauds steps to reign in medical imaging and radiation oncology self-referral included in the President's Fiscal Year 2015 budget," said Paul Ellenbogen, chair of the ACR Board of Chancellors. "However, prior authorization for imaging services, also included in the FY 2015 budget, is unnecessary and will ultimately raise costs, interfere in the doctor-patient relationship and restrict ready access to imaging care."

"Imaging use and associated costs [are down significantly since 2006](#)," Ellenbogen said in a statement. "Only self-referred imaging grew significantly since the middle of last decade. It is past time for government to address self-referral."

"Radiology benefits managers and prior authorization programs take medical decisions out of doctors' hands, may delay or deny lifesaving imaging, and often result in longer waiting times for patients to receive care. A 2011 [Moran Company report](#) found that prior imaging authorization would produce no meaningful cost savings, could cost insurers and the government more than it saves, and impose tremendous administrative burdens on already strapped physician practices."

“The Sustainable Growth Rate Repeal and Medicare Provider Payment Modernization Act of 2014 would require ordering providers to consult physician-developed appropriateness criteria when prescribing advanced medical imaging studies for Medicare patients.

“This is a far more effective and efficient policy than blanket prior authorization,” Ellenbogen said. “Electronic ordering systems, based on these criteria, are compatible with hospital electronic health records systems and are shown to reduce duplicate and unnecessary scanning and associated costs without taking decisions out of doctors’ hands or affecting access to care.

“This approach enjoys bicameral, bipartisan support,” Ellenbogen said. “We will continue to work with Congress to advance this policy.”

Groups: Budget “Falls Short”

FDA would receive an increase of \$358 million, or 8 percent, above fiscal 2014 levels in the budget, according to ASCO. This increase consists of \$23 million in budget authority and \$335 million in user fees.

“ASCO is deeply concerned about continued stagnation of federal research funding and sustained attacks on the nation’s cancer care delivery system,” ASCO’s Hudis said. “Continuing on this path jeopardizes quality and access to care for patients with cancer across the U.S.—and slows the tremendous progress made possible by our nation’s historic leadership in science and medicine.”

The president’s budget request does not reflect the potential the U.S. has to advance scientific

discovery, said Research!America president and CEO Mary Woolley.

“While welcome, the minor increases for the NIH and FDA diminish our ability to accelerate the pace of medical innovation, which saves countless lives, helps our nation meet its solemn commitment to wounded warriors, and is a major driver of new businesses and jobs,” Woolley said in a statement.

“These funding levels jeopardize our global leadership in science—in effect ceding leadership to other nations as they continue to invest in strong R&D infrastructures that have already begun to attract our best and brightest innovators.

“We simply cannot sustain our nation’s research ecosystem, combat costly and deadly diseases like Alzheimer’s and cancer, and create quality jobs with anemic funding levels that threaten the health and prosperity of Americans. The administration and Congress must work together to boost funding for federal research and health agencies in FY15 and end the sequester in order to truly meet the level of scientific opportunity.”

The president’s budget proposal for biomedical research falls short of reversing the damage done by a decade of flat funding to the NIH and recent cuts from sequestration, said Carrie Wolinetz, president of United for Medical Research.

“President Obama’s FY 2015 budget proposal for biomedical research falls short of reversing the damage done by a decade of flat funding to the NIH and recent cuts from sequestration,” Wolinetz said. “Our nation urgently needs a significant and sustained investment in lifesaving research to meet the unmatched need afforded by scientific opportunity and human health

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and to close the gaping innovation deficit.

“The U.S. once stood firmly at the forefront of the research revolution, but after a decade of budgets that have not kept pace with inflation and last year’s across-the-board sequestration cuts, NIH has seen a more than 20 percent decline in its purchasing power and can only fund one in every seven research grants it receives. As such, the U.S. is slipping in its position as the global leader in the life sciences.

“President Obama’s proposed NIH budget won’t meaningfully turn us in the right direction toward restoring hope to millions of patients, advancing scientific innovation and spurring further job growth,” Wolinetz said. “We call on the administration and Congress to make a significant increase in NIH funding a reality.”

HPV Vaccines Should be Priority, Says President's Cancer Panel

By Conor Hale

Human papillomavirus vaccines are underused in the U.S. and need to be made a national public health priority, according to a report from the President’s Cancer Panel.

In a presentation to the National Cancer Advisory Board Feb. 27, panel chair Barbara Rimer outlined three goals to accelerate uptake of HPV vaccines, including having providers strongly encourage HPV vaccination to adolescents when other vaccines are being administered.

In 2012, only one-third of girls ages 13 to 17 completed the three-dose series. In some states, utilization was as low as 20 percent. About 71 percent and 60 percent of girls are vaccinated in Australia and the United Kingdom, respectively. The Department of Health and Human Services hopes to have 80 percent of girls complete the vaccination series as part of their Healthy People 2020 program.

The panel’s three goals included reducing missed clinical opportunities to recommend and administer HPV vaccines; increasing the public acceptance of the vaccines among parents, adolescents, and caregivers; and to maximize access to vaccination services, specifically by allowing pharmacists to administer vaccines to adolescents themselves. The report also focused on efforts to promote global uptake of the vaccine, especially in low- and middle-income countries.

The report, released Feb. 10, laid out objectives

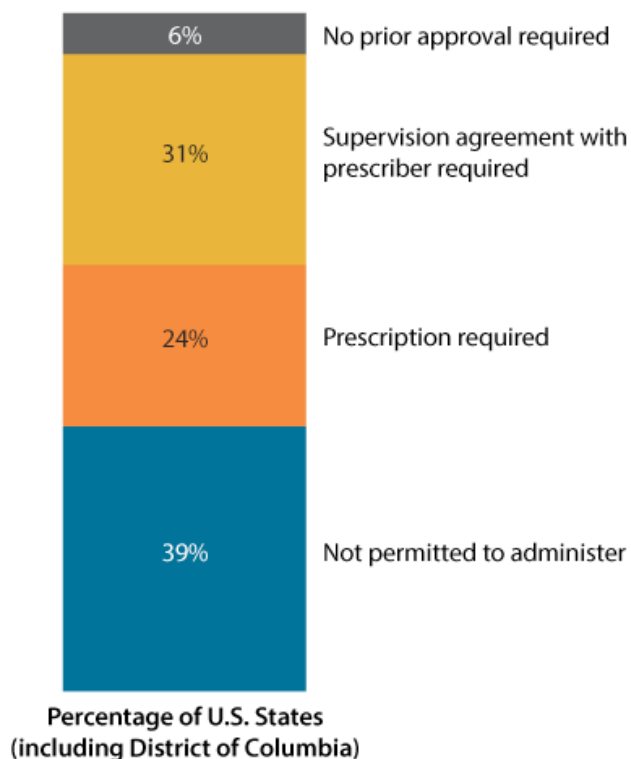
for payers to adequately reimburse providers for vaccination services, and to create a Healthy People 2020 goal for male vaccination rates. In 2012, 6.8 percent of boys ages 13 to 17 completed the three-dose series in the U.S., however the male vaccine was approved years later, according to the report.

“One of the conclusions that we came to is that it has to be a priority—it has to have strategies that are used nationally,” Rimer, dean of the Gillings School of Global Public Health at the University of North Carolina, said during her presentation to the NCAB. “Some CDC analyses estimated that if we could get vaccination levels to about 80 percent...that we would prevent an additional 53,000 cancers among girls who are now 12 or younger.”

“Adolescents are seeing physicians and they’re not getting the vaccine,” she said. “If physicians gave strong recommendations to get the vaccine, adolescents would be four to five times more likely to have received it. It’s the same kind of lesson that we learned in the tobacco domain.”

In order to lower barriers to receiving the vaccine, one of the main proposals is to pursue state laws and policies that allow pharmacists to administer the vaccine to adolescents and to boys and girls 11 to 12 years old.

Authority of Pharmacists to Administer HPV Vaccines to 12-Year-Old Girls in 2012



Source: President's Cancer Panel

A 2012 survey highlighted in the report found that one-third of the states had policies prohibiting pharmacists from doing so, though many states allow it for women ages 19 and older.

“In the most permissive states, pharmacists could administer HPV vaccines to 12-year-old girls without prior approval from a prescriber, while in other states pharmacists were required to sign supervision agreements with a specific prescriber or could vaccinate only individuals with a prescription,” the report stated.

Regarding the idea that vaccine should only be administered in physician’s offices, Rimer said: “I think it’s an argument that has kind of run out, and we will see changes.”

“People deserve convenience on this one,” she continued. “It’s really hard. Getting the first one done is one thing. What we’ve seen is a big gap between getting the first dose, and getting the second and third.”

“CVS recently announced they’re going to discontinue tobacco sales—I wonder if the major pharmacy chains are interested in being a force of change for this?” asked NCAB member William Sellers, global head of oncology for the Novartis Institutes for BioMedical Research.

“We [spoke with] somebody from the industry organization, but we didn’t take that on,” said Rimer. “I think the tobacco precedent now may be a good opportunity to open the door on this.”

Following the release of the report, four national medical associations urged physicians to educate patients and strongly recommend the HPV vaccine.

The American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Physicians, and the American College of Obstetricians and Gynecologists issued a “Dear Colleague” letter, highlighting how HPV vaccination rates have not improved at the rate of other adolescent vaccines over the past seven years.

“As OB/GYNs, we have a responsibility to encourage our patients to help protect themselves against cervical cancer by getting the HPV vaccine,” said ACOG President Jeanne Conry. “We should be routinely recommending the vaccine for all of our adolescent patients as well as women up through age 26, even if they are already sexually active. In addition, we want to encourage our patients who are mothers to vaccinate their sons and daughters at 11-12 years.”

Recently, the European Committee for Medicinal Products for Human Use delivered a positive opinion for a two-dose schedule of the Gardasil HPV vaccine in boys and girls ages 9 through 13.

A CHMP positive opinion is one of the final steps before a final marketing decision is made by the European Commission. Gardasil is sponsored by Sanofi Pasteur MSD.

A study demonstrated that antibody levels after two doses of Gardasil given six months apart in girls aged 9-13 years are non-inferior to levels observed after three doses—with the second and third doses at two and six months—in women 16-26 years old, where efficacy has been previously demonstrated.

The [full report](#) from the President’s Cancer Panel is available online.

NCI Publishes Report On Pancreatic Cancer

By Matthew Bin Han Ong

NCI has issued a report detailing a “scientific framework” for advancing research on pancreatic ductal adenocarcinoma, indicating potential new funding opportunities for genomic studies for early detection of pancreatic cancer.

The [institute’s report](#) is the result of the Recalcitrant Cancer Research Act, a bill proposed by the Pancreatic Cancer Action Network, and passed Jan. 2, 2013.

The bill mandates NCI to identify, within six months, two or more cancers with a five-year survival rate of less than 20 percent. The director of the institute will then convene a working group of experts to identify research questions and recommend, within 18 months, actions that should be taken to advance research on these cancers.

The version signed into law watered down the original controversial measure, which, according to critics, threatened to touch off a “disease Olympics” and dilute NCI’s authority to set research strategy (The Cancer Letter, [Aug. 3, 2012](#)).

According to the report, initiatives that have been proposed to expand PDAC research include:

- Understanding the biological relationship between PDAC and diabetes mellitus
- Evaluating longitudinal screening protocols for biomarkers for early detection of PDAC and its precursors
- Studying new therapeutic strategies in immunotherapy
- Developing new treatment approaches that interfere with RAS oncogene-dependent signaling pathways

“Each year, tens of thousands of Americans are

diagnosed with pancreatic cancer and those numbers have steadily increased for more than a decade,” said Sen. Tom Harkin (D-Iowa), chairman of the Senate Health, Education, Labor, and Pensions Committee. “One of the best ways we can fight this terrible disease is through strong investments in medical research.

“The announcement by the National Cancer Institute highlights both the progress that has been made in understanding this deadly cancer and the promise of ongoing research,” Harkin said. “I look forward to learning more about this critical progress as NIH continues to support this vital research.”

NCI spent \$105 million in fiscal 2012 on pancreatic cancer research, a five-fold increase since 2000.

“If one considers NCI’s total investment per year in research relevant to PDAC, the amount is much greater than \$105 million, because many areas of study that are central to PDAC research—the KRAS signaling pathway [and other developments]—are shared with studies of other types of cancers and are supported by numerous NCI grants and contracts as well,” the report states.

NCI spends \$12.3 million on RAS research—including salaries for 55 full time equivalent employees—at the Frederick National Laboratory for Cancer Research in Frederick, Md. The operation received nearly \$300 million from NCI in the 2013 fiscal year, and is slated for an increase this year (The Cancer Letter, [Feb. 28](#)).

The PDAC report offers a commitment that “the Cancer Immunotherapy Trials Network, which employs the collective expertise of expert academic immunologists together with the NCI, and foundation and industrial partners, will design and conduct cancer therapy trials with the most promising immunotherapy agents” in pancreatic cancer.

“We applaud the National Cancer Institute and Dr. Varmus for their work on this crucial report, which addresses questions that are critical to advancing research and improving pancreatic cancer patient outcomes,” said Julie Fleshman, president and CEO of PanCAN. “We look forward to working with the NCI and our colleagues in the pancreatic cancer community on implementing the recommendations and developing benchmarks to measure progress on achieving the recommendations and on critical issues like ensuring adequate availability of qualified researchers.”

In early 2013, a series of NCI meetings were held with experts in the RAS field to discuss appropriate projects to pursue. Five projects were defined as having high priority:

- Pursuing allele specific compounds for those RAS alleles most prevalent in human cancer (e.g., KRAS G12D and G12V in pancreatic cancer)

- Developing KRAS selective binding compounds for KRAS ablation without allele specificity

- Developing imaging methods and screens to identify and disrupt KRAS complexes in cells and to monitor their disruption

- Mapping the surface of KRAS cancer cells and identifying epitopes that could be targeted by immunotherapy and proteins that could be targeted for drug delivery by nanoparticles

- Developing and conducting next-generation synthetic lethality screens and engineering mice to facilitate these screens

“Progress, as the project relates to advances in pancreatic cancer, will be measured by periodic reports, publications, and presentations,” the report states. “Some of these will report on the creation of the tools necessary to support the activities of the five projects.

“These include methods for solving the structures of mutant proteins complexed with relevant effectors and regulators; determining the significance of other types of modifications to RAS proteins, including acetylation and ubiquitination; identifying compounds that disrupt RAS dimers or other aspects of RAS superstructures; developing a comprehensive map of surface proteins on specific RAS cancers; and developing synthetic lethal screens in vitro and in vivo.

“Other reports will cover the generation and validation of data, using these tools, to target mutant RAS cancer cells, and the application of the new methods to the treatment of PDAC in pre-clinical and clinical trials.”

The Pancreatic Cancer Action Planning Group, formed in 2010, will assess NCI’s ongoing investment of the NCI in PDAC research.

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In Brief

Pasche Named Director of Wake Forest Cancer Center

(Continued from page 1)

Pasche will be the principal investigator of the center's NCI core grant, and will serve as chair of the department of Cancer Biology at Wake Forest Baptist. Previously, he was director of the division of hematology/oncology at the University of Alabama at Birmingham.

Pasche identified the first mutation of a gene that controls cell growth and found that some individuals carry an altered form of the gene, which increases their risk of developing several forms of cancer. He also identified one of the first genetic links between obesity and breast and colon cancer.

He has also served as director of the Cancer Genetics program and leader of the Cancer Genes and Molecular Targeting program at the Northwestern University Robert H. Lurie Comprehensive Cancer Center. In 2008, Pasche joined UAB where was a professor of medicine and holder of the Martha Ann and David L. May Endowed Chair in Cancer Research. He also served as associate director for Translational Research and deputy director at the UAB Comprehensive Cancer Center.

Pasche is currently an associate editor for the Journal of the American Medical Association and editor of both The Journal of Experimental and Clinical Cancer Research and Cancer Hallmarks. He has served on numerous study sections and is a permanent member of the NCI Cancer Genetics study section.

The cancer center recently opened after a \$125 million capital construction project that began in June 2011, which added an oncology intensive care unit, four inpatient floors, a day hospital floor, and one administrative floor.

JIALI HAN was named the Rachel Cecile Efrogmson Professor in Cancer Research at the **Indiana University Simon Cancer Center**, pending approval by the IU board of trustees. He is also professor and inaugural chair of the Department of Epidemiology at the Fairbanks School of Public Health.

He will also serve as co-leader of the IU Simon Cancer Center's cancer prevention and control research program. The professorship was established with a \$2 million gift from the Efrogmson Family Fund.

As chairman of the department of epidemiology, Han intends to recruit three more faculty members

specializing in cancer epidemiology.

Han most recently was an associate professor of dermatology and medicine at Harvard Medical School and an associate professor of epidemiology at the Harvard School of Public Health.

Han's research involves comparing the genes of those who are exposed to environmental risks and get cancer with those who have the same environmental exposure but remain cancer free. He demonstrated a link between tanning bed exposure and increased risk of basal cell carcinoma. He has also published studies that indicate caffeinated coffee consumption lowers the risk of developing this specific skin cancer. Most recently, Han has shown that those with a personal history of prostate cancer also have a greater chance of developing melanoma.

CAROL BIER-LANING will lead a new comprehensive head and neck cancer program launched by **Cancer Treatment Centers of America at Midwestern Regional Medical Center**.

Bier-Laning, a surgical oncologist, is also an associate professor at Loyola University Medical Center, and also sees patients at the Edward Hines, Jr. VA Hospital in Chicago.

She completed her fellowship in head and neck oncology at The Ohio State University and performed her residency in otolaryngology at the University of Minnesota. She is a graduate of the University of Colorado Medical School.

CURIE-CANCER, the body responsible for developing Institut Curie's industry partnership activities, and is renewing its partnership with **DNA Therapeutics**.

The ongoing collaboration will aim to provide a new class of therapeutic cancer products to patients, including those who are resistant to conventional therapies.

The first molecule based on Dbait molecular technology, DT01, is currently being assessed in combination with radiation therapy, in a phase I clinical trial for approximately 20 patients with cutaneous metastatic chemotherapy-resistant melanoma. DT01 is the result of the partnership between Curie-Cancer and DNA Therapeutics.

Initial results indicate that cancers that are resistant to conventional therapies, including advanced-stage melanoma, can be treated with Dbait technology, and that DT01 is effective and very well-tolerated in combination with radiation therapy. The full results are expected within the next year.