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Families harmed by power morcellation pose on FDA's White Oak campus July 11, following a two-day hearing on the controversial surgical procedure

FDA Advisors Debate Ban, Black Box And Status Quo of Power Morcellators

By Matthew Bin Han Ong

In a heated two-day hearing, several members of an FDA advisory panel on medical devices expressed low confidence in power morcellation as a treatment for uterine fibroids, and focused on alternatives methods for performing hysterectomies and fibroid removal.

There was no formal consensus on either an outright ban on power morcellators or issuance of a "black box" warning label.

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Capitol Hill

Sen. Harkin Introduces NIH Funding Bill That Boosts Budget to $46.2 Billion by 2021

By Conor Hale

Sen. Tom Harkin introduced a bill that would set NIH on a path to recoup the purchasing power it has lost since 2003, and make funding biomedical research a national priority.

The bill is not an appropriations bill, and does not authorize spending any money. It would, however, raise the limits set in place for NIH by the 2011 Budget Control Act and sequestration, allowing Congress to appropriate $46.2 billion by 2021—a level near where NIH funding would be, had it kept pace with inflation.

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In Brief

Jordan to join MD Anderson Cancer Center

V. CRAIG JORDAN will join **MD Anderson Cancer Center** as a professor in Breast Medical Oncology and Molecular and Cellular Oncology. He will begin work in October.

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Panel Consensus Gives FDA Latitude in Deciding Next Steps

(Continued from page 1)

"Multiple individuals mentioned the desire to avoid any kind of morcellation of tissues, and to remove the specimens intact," said Michael Diamond, chair of the FDA Obstetrics and Gynecology Devices Advisory Committee, summarizing the panel members' responses to one of the questions.

No vote was taken. The panel's wide-ranging discussion and restrained wording of the consensus agreement give the agency considerable leeway to determine the next course of action.

A black box label is the FDA's sternest warning, indicating that the device has serious possible risks.

Power morcellation is performed on an estimated 100,000 women in the U.S. a year with a minimally invasive device that pulverizes a patient's uterus or fibroids into fragments, for easy removal through a small incision.

The problems occur when power morcellators disseminate cells from undetected cancers. The technique became the subject of public discussion over the past year, after a morcellator spread leiomyosarcoma during surgery performed on Amy Reed, a Harvard physician.

Reed's husband, Hooman Noorchashm, a cardiothoracic surgeon at Brigham & Women's Hospital, launched a national campaign against power morcellation, drawing together other patients who were similarly harmed (The Cancer Letter, July 3).

The FDA issued an advisory April 17 discouraging the use of power morcellation, stating that one in 350 women who undergo hysterectomy or myomectomy for fibroids have an unsuspected uterine sarcoma.

The publicity and pressure culminated in the advisory panel's hearing July 10 and 11.

The agency's effort to get advice didn't go smoothly. Days before the hearing, The Wall Street Journal reported that three panel members had received consulting fees from Ethicon, the Johnson & Johnson subsidiary that manufactures laparoscopic power morcellators.

Andrew Brill, a San Francisco gynecologist, stepped down two days before the hearing after an FDA review found that he had received nearly $100,000 in consulting fees in 2013 from Ethicon. The other two panel members—Keith Isaacson, a Newton-Wellesley Hospital gynecologist, and panel chair Michael Diamond, remained on the panel.

The panel's debate on power morcellators was extensive, ranging from dramatically disparate risk estimates, to cancer detection and mitigation strategies, and from alternative procedures to containment systems.

Several panel members discouraged the use of power morcellation, citing the lack of reliable uterine cancer detection methods, and advocated a return to making larger incisions and other treatment options.

Colleen Gallagher, a bioethicist and associate professor at MD Anderson Cancer Center, said that power morcellators can cause real—but avoidable—harm.

"We rarely hear about the principle of non-maleficence being so important," said Gallagher, a panel member and chief and executive director of the MD Anderson Section of Integrated Ethics in Cancer Care. "And non-maleficence is the principle out of which the 'do no harm' comes from. I think for this particular question, that principle of non-maleficence, meaning we want to avoid harm to the very best of our ability—it's really not necessarily avoidable all the time, it's not a zero sum—combined with the principle of justice, specifically that of what the society owes to one, is why the FDA is doing what it is doing.

"As an ethicist, I don't believe at this moment that morcellation—for the purposes that we're talking about today, not for other things, but for this particular thing—is something that I would support."

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"Shame on You…"

At the public hearing session, Noorchashm and other patient advocates called for an outright banning of the device.

"Shame on you," Noorchashm said at the hearing, aiming his comments at those who were defending power morcellation. "Ban this now. People's lives are in your hands."

Representatives of gynecologic professional societies disagreed. "Let us improve, but not abandon power morcellation," Jubilee Brown, a spokesperson and member of the board of trustees of the American Association of Gynecologic Laparoscopists, said to the panel. "Our obligation is not only for patients with leiomyosarcoma. It is to all of our patients."

Brown added that if power morcellation were to be eliminated, 17 more women could be expected to die per year because conventional surgery is more invasive. "We must not sacrifice our patients in an emotional response to a rare event," Brown said.

Most panel members stopped short of recommending a ban. One exception was Craig Shriver, the founding director of the John P. Murtha Cancer Center at Walter Reed National Military Center.

"As a surgical oncologist trained in the core, basic Halstedian principles of cancer surgery, I'm always myself asking, and adhering to and teaching others to adhere to the tenet of treating all masses as cancer until proven otherwise, which is born out of the ancient Hippocratic principle of patient care and first, do no harm," Shriver said at the hearing July 11.

"I've been perplexed over the last two decades, watching the introduction of a laparoscopic power morcellation technique that is totally anathema to these and my core principles as a cancer surgeon.

"After these two days of testimony and data, based on science, I have only more strongly reaffirmed my commitment and belief that there is, at present, no safe way to offer laparoscopic power morcellation as a part of any minimally invasive surgery.

"I conclude and state as a member of this advisory committee to the FDA that my position is that the device under consideration, the power morcellator, should have its Class II device status immediately withdrawn, and its use in any laparoscopic surgery banned.

"Going forward, I answer the FDA questions to the panel only in the context of what a future submission to the FDA for any new technology related to this approach under a submission as a Class III device with relevant preclinical testing, and in the context of properly constituted and informed patient clinical trials, prior to any future approach in this field."

JAMA Paper Consistent with FDA Analysis

New research, published July 22 in the Journal of American Medical Association, reinforces the FDA estimate. Doctors at Columbia University found that 1 in 368 women undergoing hysterectomies have an undetected uterine cancer that could be spread by a power morcellator's spinning blades. http://jama.jamanetwork.com/article.aspx?articleid=1890400

The study looked at 36,470 women who underwent power morcellation from 2006 to 2012 and found that 99 of those women had uterine cancer that was unidentified at the time of the procedure.

"Although morcellators have been in use since 1993, few studies have described the prevalence of unexpected pathology at the time of hysterectomy," the authors wrote. "Prevalence information is the first step in determining the risk of spreading cancer with morcellation. Patients considering morcellation should be adequately counseled about the prevalence of cancerous and precancerous conditions prior to undergoing the procedure."

At the FDA hearing, panel member Shriver said that there is no reliable method of detecting a uterine sarcoma.

"There are no tests that I've been shown on the data or the science that, either in isolation or together, are good enough—good enough at this time—or in the near-term future, that determine the presence of an unsuspected sarcoma in a woman with presumed uterine fibroids," Shriver said. "Even in the best studies, the level of evidence of that uncontrolled—of those data—is uncontrolled longitudinal studies, which are low-level evidence."

Containment Bags?

The safest way to perform a hysterectomy or myomectomy would be to remove the specimen intact, several panel members said.

"The vaginal route is the favorite route for many reasons because it is the least invasive, it is associated with the lowest risk of injury, less amount of pain, and you can remove a specimen—without morcellation—through the vagina," said Cheryl Iglesia, section director of Female Pelvic Medicine and Reconstructive Surgery at MedStar Washington Hospital Center in Washington. "To the degree that it can be done vaginally without morcellation, which is my preferred route, and it is done in 25 percent of hysterectomies in the U.S., we need additional training to make sure that technique stays and that we have the special skills to use it. I have a very strong opinion about the route through the vagina."

The vaginal route would also preclude the need for a containment system, said Carol Brown, director of the Office of Diversity Programs in Clinical Care,

Research, and Training at Memorial Sloan Kettering Cancer Center.

"We have evidence from the specialty of gynecologic cancer and gynecologic oncology that you do not need to put a known cancer specimen in a bag," Brown said. "The vast majority of known endometrial cancers including uterine carcinosarcomas, including known leiomyosarcoma, at my institution and my practice, if the patient meets the other criteria, we do choose minimally invasive because it is better for that patients in terms of significant outcomes, and we remove the specimen through the vagina. I do think that, again, the best thing to do is to not chop cancer up, no matter how you chop it up.

"We know that you can take uteruses out through the vagina without a bag even if they have cancer in them, as long as they are intact. But I would focus on a technique of, again, avoiding any type of morcellation when you're doing a hysterectomy, or removing a fibroid, and the best potential orifice to get that out is going to be the vagina."

Panel chair Diamond, professor and chair of the Department of Obstetrics and Gynecology and associate dean for research at Georgia Regents University, said in a summary of the consensus:

"First of all, there are some techniques such as vaginal surgery, when it's possible, for the removal of an intact uterus—that would be a mitigation strategy that could be utilized. There is also concern with supracervical hysterectomy, and potentially cutting across a tumor. Multiple individuals mentioned the desire to avoid any kind of morcellation of tissues, and to remove the specimens intact.

"There was a lot of discussion about the use of bags, and while it was thought that, intuitively, that that may have advantages in reducing dissemination of an unrecognized malignancy, the data to support that appears to be totally lacking at this point in time.

"Therefore, the conclusion is that we don't know through the use of the bags to what extent, if any, we're able to reduce the risk at this point."

Panel Members: A Black Box Warning Is Insufficient

Power morcellators should be labeled with a black box warning, should it continue to stay on the market, some panel members said, adding that additional cautionary measures need to be adopted to ensure patients are aware of the risk.

"I don't think a black box alone would be sufficient; I have no confidence that that would actually get to the patient," said Paula Hillard, professor of obstetrics and gynecology at the Stanford University Medical Center. "So I would completely agree that a black box warning [should be accompanied by] a document that the patient and the physician would sign as a special control."

Some panel members expressed concern that the warning would not be heeded, even by hospitals and physicians. Robert Mattrey, vice chairman of research and professor of radiology at the UC San Diego School of Medicine assured that the warning would have impact:

"When there's a black box warning, everybody knows about it, whether on the drug side or the device side," he said. "It's difficult to avoid. Whether it trickles down to the consumer, I don't know, but I think the medical community is aware of every black box that relates to their work."

The warning does not protect the patient, Shriver said.

"What the weakness of a box warning is, we think the physician is accepting the risk, but they're not, it's the patient who is accepting the risk," he said. "Not using the device on the market is the solution."

Even with a containment system, the risk that accompanies power morcellators—with these warnings in place—may well encourage patients to seek other treatment options, Iglesia said.

"I think that even if you do mention a bag, there is never a 100 percent guarantee to prevent tissue fragment dissemination with this generation of power morcellators," she said. "To some degree, I really do respect industry who are going to be looking at and hopefully inventing safer devices that don't disseminate.

"But I don't think that we can really say anything on a label, and quite frankly, if you have that label and the patient and the physician are both signing it, I think it's going to bring the discussion of, 'What are the alternatives again, doctor?'"

Even if the FDA allows power morcellators to stay in use, the black box label could ultimately drive the devices off the market, said Mark Talamini, professor and M.J. Orloff Family chair of the department of surgery at UC San Diego Medical Center.

"An equally plausible scenario is that, if this remains on the market with these sorts of warnings, they may disappear entirely, because I doubt they're a large margin item for most of these device companies," Talamini said. "If this remains on the market with this set of warnings, it may be very hard to find a power morcellator."

FDA: A High-Priority Issue

The severity of spreading an unsuspected cancer is great, said Ben Fisher, director of FDA's Division of Reproductive, Gastro-Renal, and Urological Devices in the Office of Device Evaluation.

"If the issue that was on the table was just morcellation of a truly benign tissue, none of us would be here today," Fisher said in his closing remarks. "I think one of the major challenges we are facing is identifying the uterine sarcoma prior to any procedure.

"Now, when you look at risk, we talk about rate and severity, and we've talked about a lot of different numbers over the past two days: one in 350, one in 7,000. Although we may not agree on the actual number, I think it's very encouraging that there are a number of parties already working in this area.

"It's been said we should really look at this further because this is an important part to helping to inform not only the patients, but also the physician. Regardless of the rate, when we talk about risk, we also have to talk about severity.

"We've talked about mitigation strategies. We've talked a little about trying to identify low-risk populations. One of the things we talked about was imaging—is this a possible modality that, in the future, will improve to a point where we're actually able to discriminate or to tell a difference between a fibroid and an LMS?"

FDA is cautious about making statements that would jeopardize innovation, Fisher said.

"The one thing we don't want to do: FDA does not want to put forward a front that's going to discourage technical innovation," he said. "So, hopefully I got my point across when we were talking about bags—I'd like to expand that to a containment device because I think we are open to innovation and we want to encourage that."

Fisher thanked the patient advocates for bringing the issue to the agency:

"In this situation—we're talking about the morcellation of uterine fibroids—I think we all agree that there is an increased awareness and acknowledgement that there is a real public health issue here.

"I hope that, based on the actions that FDA has taken thus far, that everybody realizes that FDA considers this to be a high-priority issue."

The FDA will be taking public statements on the issue through Aug. 11.

The Numbers

GYN Group: Open Surgery Would Cost More Lives than Morcellation

By Matthew Bin Han Ong

More women would die from open surgery each year if the FDA decides to ban power morcellation, said Jubilee Brown, an associate professor at MD Anderson Cancer Center and a spokesperson of the American Association of Gynecologic Laparoscopists.

Addressing the FDA medical device advisory committee July 11, Brown said that a modeling study suggests that net loss of lives from returning to the more invasive open surgery would be greater than the combined mortality from leiomyosarcoma and the potential dissemination through power morcellation.

"Converting all hysterectomies currently undergoing power morcellation to open surgery would result in an annual increase of 17 more women dying from surgery each year, and a substantial increase in morbidity from open surgery," said Brown, director of gynecologic oncology at The Women's Hospital of Texas, and associate professor in the Department of Gynecology Oncology and Reproductive Medicine at MD Anderson.

Her slides and remarks are posted on The Cancer Letter website.

Brown is a co-author of the modeling study she cited in her presentation to the panel, which has been submitted for publication (Naumann RW, Brown J, Herzog TJ, Coleman RC).

Critics say that the base assumptions and estimates built into Brown's model are very conservative, potentially leading to dubious results.

The study assumes that 1 out of 1,000 women have a uterine cancer, a number nearly three times higher than the FDA's 1 in 350 estimate. An independent study (n=36,470) by Columbia University doctors recently published in JAMA found that 1 in 368 women undergoing hysterectomies have an undetected uterine cancer that could be spread by power morcellation.

"The level of precision in the results that [Brown] shared of 17 deaths that would come from this potential policy change is so high, that it really makes me want to understand the assumptions that are built into the model and the level of precision in those assumptions," said Michael Paasche-Orlow, an associate professor of

medicine and a bioethicist at Boston University School of Medicine. "The sensitivity analyses must have been done to evaluate a range of possible alternatives.

"You can see that they are interested in testing the sensitivity of their model by varying the risk of local spread from 15 to 35 percent, but that is such a conservative estimate, it makes me worried that they may not have actually tested adequately across the range of possible risks."

Paasche-Orlow is the author of the initial analyses of the risk estimates that led to the FDA's independent April 17 advisory against power morcellation.

Brown did not respond to requests from The Cancer Letter for further clarification of the data used in the model.

"We have to use risk adjusted numbers for the relative risk of death between one group and another," Paasche-Orlow said. "Ostensibly, if you said no power morcellation, even if you assumed that everyone must now have an open hysterectomy, you would be taking the healthiest women with the lowest co-morbidities and putting them into that other bucket. You can't just apply the rate of death in that subset from some historic data."

Paasche-Orlow said more explanation of the assumptions and details built into the model would be needed.

"I would say, it's unfortunate that we didn't have an opportunity to hear more [at the hearing]," he said. "Invariably, they had to make some choices, so [Brown] was able to share that they made a choice to make a guess, which has to be done in these kinds of projects about the risk of local spread.

"However they chose a very conservative estimate. The highest they tested was a 35 percent rate of risk of local spread. That seems to be quite low.

"On the same side, by the way, it says they utilized a conservative estimate of leiomyosarcoma risk of 1 out of 585. That number is not what is in the model she showed us. When we made it big you can see it's one in one thousand that is what they tested. At least in the slides she shared."

There are no significant differences in morbidity between abdominal and laparoscopic hysterectomy, Alison Perate, an assistant professor of anesthesiology and critical care at the Hospital of the University of Philadelphia and the Children's Hospital of Philadelphia, told the advisory panel, citing four published studies.

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One in 7,450 Women

Critics also questioned Brown's citation of the estimate that one in 7,450 women are at risk of leiomyosarcoma, an aggressive uterine cancer.

Elizabeth Pritts, an obstetrician and gynecologist in Middleton, Wis., presented that estimate at the FDA committee hearing. The study Pritts cited has not been published.

Brown should not have endorsed Pritts' estimate in her presentation, said Hooman Noorchashm, the Harvard physician whose wife, Amy Reed, had her undetected leiomyosarcoma upstaged by power morcellation.

"The fact that Dr. Jubilee Brown, as a spokesperson for the AAGL, was so willing to jump on this new one-in-7,450 number proposed by Dr. Pritts was extremely irresponsible," he said. "This group of surgeons seems primarily motivated to protect and defend the practice of morcellation, not patient safety.

"This stems from a real and systemic blindness to the deadly hazard involved in what they have been doing. I think it was tragic that someone like Jubilee Brown, as a gynecologic oncologist at MD Anderson, has taken this position."

Paasche-Orlow said Pritts' study included other studies going back as far as the 1960s.

"It appears she did some things to expand the denominator, the number of subjects in the studies in question," he said. "One of the things she did there was to include articles from other languages. I think that's good.

"Another thing she did was to include studies even though they are really small. The FDA had required for prevalence estimate studies to include at least 100 women. She included much smaller studies. However, the smaller you get, the more liable you are to have a selection bias influencing any kind of estimate.

"When I initially looked at [past risk estimate] studies, and the FDA looked at them as well, we both independently came up with the idea of excluding projects that were small and chose the number 100—which is an arbitrary number—but is typically used for these kinds of projects.

"But for whatever reason, [Pritts' team] were motivated to include lots of small articles. Maybe that is a source of where some of the differences crept in."

With power morcellation, physicians must also consider other uterine cancers, not leiomyosarcoma alone, Paasche-Orlow said.

"For whatever reason, [Pritts] decided to exclude and focus only on leiomyosarcoma, which means she

excluded cases of endometrial stromal sarcoma or endometrial cancer, or any other kind of cancer. In the FDA numbers, they included both kinds of sarcoma. They weren't exclusively on leiomyosarcoma.

"Clearly, that is a methodological difference or a difference in focus."

Capitol Hill

Funding Bill Would Raise Cap To Keep Pace with Inflation

(Continued from page 1)

"This is the minimum," Harkin (D-Iowa) said as he introduced the bill in the Senate July 24, commonly referred to as the Accelerating Biomedical Research Act.

"Where do we stand today?" he asked. "We're short about $8 billion from where we would be if we had just kept up with inflation."

"NIH has lost about 20 percent of its purchasing power. Success rates for applicants fell from the traditional 30- to 35-percent range to just 16 percent last year. Promising research was not funded."

Harkin chairs the Senate subcommittee in charge of funding NIH, which received $29.9 billion for the current fiscal year.

In seeking co-sponsors, he described how investment in NIH pays off abundantly in economic activity.

"[Economists] have estimated that for each dollar of investment in [the NIH] generates anywhere from $1.80 to $3.20 in economic output," he said.

"I'm always hearing that we should have a robust debate on the budget and the spending priorities of the country. This bill starts that debate."

Internationally, of the ten leading countries in the field of scientific research, the U.S. is the only one that has reduced its funding, in terms of percentage of GDP since 2011.

A multitude of advocacy organizations and professional societies have come out in support of the bill.

"The Accelerating Biomedical Research Act comes at a critical time, and we share your belief that the current budget caps must be reevaluated," said Joseph Haywood, president of the Federation of American Societies for Experimental Biology. FASEB is also grateful that the bill will create a more predictable, multi-year program of sustainable growth for NIH."

"[NIH's] budget has remained virtually stagnant over the last decade, jeopardizing promising research to combat disease and deflating the aspirations of early career scientists," said Mary Woolley, president of Research!America.

Harkin—who has announced that he will retire from the Senate at the end of his current term, in 2015—presided over the doubling of NIH's budget, which ended in 2003. "We have slowed down and stopped, resting on our laurels, so to speak," he said.

"It's time for us, on a bipartisan basis, for Congress to reverse this erosion of support for biomedical research" he said. "It would allow for NIH to make up for lost ground.

"Quite frankly, I could argue that we have to do even more."

Appropriations

Senate Committee Approves 4.5 Percent Cut to Defense Dept. Cancer Research Funding

By Tessa Vellek

The Department of Defense appropriations measure for the fiscal year 2015, approved by the Senate Appropriations Committee July 17, decreased overall funding for peer-reviewed cancer research programs by 4.5 percent.

The committee recommended adjusting DoD's health research budget to $120 million for breast cancer research, $64 million for prostate cancer research, $10 million for ovarian cancer research, and $50 million for the peer-reviewed cancer research program that would research cancers not addressed in the aforementioned programs, according to the Senate report.

The breast cancer program will see no changes from the current fiscal year, but both prostate cancer research and ovarian cancer research were slated for decreases in funding of 20 percent and 50 percent, respectively. There was no mention of a lung cancer research program in the Senate's report for the next fiscal year, although in fiscal year 2014 the program received $10.5 million.

Nine cancers are eligible to compete for the funding provided through the $50 million adjustment: colorectal cancer, kidney cancer, liver cancer, melanoma, mesothelioma, myelproliferative disorders, neuroblastoma, pancreatic cancer, and stomach cancer.

The House has not acted on its version of the spending bill.

The House report, dated June 13, recommends $120 million for breast cancer research, $80 million for prostate cancer research, $20 million for ovarian cancer research, $10.5 million for lung cancer research, and $15 million for the peer-reviewed cancer research program that would research cancers not addressed in

Proposed DoD Cancer Research Appropriations in Congress

For FY 2015 - $ in millions

Senate	House
Breast Cancer	
$120	$120
Prostate Cancer	
$64	$80
Ovarian Cancer	
$10	$20
Lung Cancer	
N/A	$10.5
Other Cancers	
$50	$15

the aforementioned programs.

"Funding for the DOD peer reviewed breast cancer research program is vital to making real progress in breast cancer," Frances Visco, president of the National Breast Cancer Coalition, said to The Cancer Letter. "This program focuses on research that has the greatest impact for women and men with and at risk for breast cancer in addition to innovative approaches to the issue.

"The program is a model for advocate involvement as collaborators with scientists and affects not just what is funded through DOD, but breast cancer research everywhere."

The Senate report encourages investment in melanoma research because of the rise of melanoma and the extreme conditions and high exposure to solar radiation that service members face in theater.

"The Melanoma Research Foundation has worked with many melanoma patients who were or currently are in the military and we see the impact this disease has on their lives," said Tim Turnham, executive director of the Melanoma Research Foundation. "The increasing incidence of melanoma among service personnel is not surprising, given the undeniable link between melanoma and exposure to UV radiation. The MRF and MRA jointly applaud the Senate Appropriations Committee for expanding its protection for those who are sacrificing to protect us."

In total, $1.4 billion of the DoD's appropriations are dedicated to health research and development. The 2015 fiscal year appropriations increased DoD's core medical research budget as well as congressionally-directed medical research funding by $789 million, or 5 percent more than the amounts in the current fiscal year.

"This bill also protects America's leadership at the cutting edge of innovation," Sen. Dick Durbin (D-Ill.), chairman of the Defense Subcommittee, said in a statement.

"For decades, Defense Department technologies have revolutionized the world. Many of these breakthroughs began as a novel solution to a military problem. We must continue to invest in medical breakthroughs and technological advancements that keep us at the forefront of innovation, improve the health and safety of our troops and contribute to our overall national security."

In Brief

Breast Cancer Researcher V. Craig Jordan to Move to MD Anderson Cancer Center

(Continued from page 1)

Jordan will focus on the biology of estrogen-induced cell death, with the goal of developing translational approaches for treatment.

Currently, he serves as scientific director of the Lombardi Comprehensive Cancer Center at Georgetown University and as the Vincent T. Lombardi Chair of Translational Cancer Research.

He also serves as vice chairman of the Department of Oncology and professor of oncology and pharmacology at Georgetown University's Medical School. In addition, he's a visiting professor of molecular medicine at the University of Leeds in England, and an adjunct professor of molecular pharmacology and biological chemistry at Northwestern University in Chicago.

Jordan was elected to the National Academy of Sciences in 2009, and has been awarded the St. Gallen Prize for Breast Cancer, the American Cancer Society Medal of Honor, and the David A. Karnofsky Award from the American Society of Clinical Oncology.

Jordan is credited with reinventing a failed contraceptive, known then as ICI 46474, as the breast cancer drug tamoxifen. The drug, in existence since the 1960s, was originally created to block estrogen in the hopes of preventing pregnancy.

Jordan developed the strategy of long-term adjuvant tamoxifen therapy, as well as describing and deciphering the properties of a new group of medicines called selective estrogen receptor modulators.

Prior to joining Georgetown University, Jordan served on the faculties at Northwestern University Medical School; the University of Wisconsin School of Medicine; the Ludwig Institute for Cancer Research at the University of Berne, Switzerland; and the University of Leeds, England.

KEVIN FITZGERALD, a Jesuit priest, Georgetown bioethicist and cancer researcher, has been appointed by Pope Francis to serve as a consultor to the **Pontifical Council for Culture**.

FitzGerald, a research associate professor in the department of oncology and the David P. Lauler Chair for Catholic Health Care Ethics at Georgetown University Medical Center, began his five-year term July 1 as one of 34 newly appointed consultors from around the world.

FitzGerald will advise the council on areas including bioethics, genetics, neuroscience and transhumanism, which refers to a movement that seeks to transcend the human condition through technology, artificial intelligence and other related concepts.

JOHN BIRKMEYER was named executive vice president for enterprise support services for the **Dartmouth-Hitchcock health system**.

Birkmeyer is the George D. Zuidema Professor of Surgery at the University of Michigan, and is head of the Center for Healthcare Outcomes and Policy. He also directs the Michigan Value Collaborative, a partnership between Blue Cross and Blue Shield of Michigan and leaders of 54 Michigan hospitals.

Between 1989, when he began his surgical residency, and 2004, when he was recruited to the University of Michigan, he served as chief of surgery at the White River Junction VA Medical Center, as chief of the section of general surgery at Dartmouth-Hitchcock, and as a core contributor to the Dartmouth Atlas of Healthcare. He was elected to the Institute of Medicine in 2006.

Birkmeyer's research career has focused on understanding variation in surgical outcomes and cost-efficiency. He is also founder and chief scientific officer of ArborMetrix, a venture capital-funded analytics and services company.

ELLEN MILLER SONET was named chief strategy and alliance officer of CancerCare.

Sonet will serve on the nonprofit's executive leadership team. She previously served for nearly 17 years as vice president of marketing at Memorial Sloan-Kettering Cancer Center.

Prior to her tenure at Memorial Sloan-Kettering, Sonet worked in pharmaceutical marketing on brands such as Afrin Nasal Spray and Bayer Aspirin.

REP. HENRY WAXMAN received the Lifetime Achievement Award from The 340B Coalition.

The coalition honored the California congressman for his role in the creation of the 340B drug discount program and for his stewardship of it over the years.

Waxman, who is retiring from Congress at the end of the year, received the award during the opening of the coalition's 18th annual meeting. The coalition is an umbrella organization of groups that represent safety-net providers and programs participating in the 340B program.

Past recipients of the award include Sen. Tom Harkin, and former Sen. Jeff Bingaman.