



## Urgent FDA Action Turns Power Morcellation Into Rarely Used Gynecological Procedure

*By Matthew Bin Han Ong*

The power morcellator should no longer be used for hysterectomies or fibroid removal in the vast majority of women getting these procedures, FDA declared in a highly anticipated [guidance document Nov. 24](#).

Using a new authority that bypasses public comment, the agency stopped short of imposing an outright ban on the device, but severely restricted its use in the following manner:

- The agency placed a “black box” label on the device, warning that the use of power morcellators during fibroid surgery may spread cancer and decrease the long-term survival of patients. The boxed warning is FDA’s sternest warning for significant risk of serious or life-threatening adverse effects.

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## Top NCI Officials Pledge No Further Consolidation of Clinical Trials System

*By Paul Goldberg*

Top NCI officials made an unusual assurance that the reorganization of clinical trials cooperative groups isn’t a “prelude to reducing the commitment of the NCI to clinical trials-based research.”

The document, published as a letter to the editor of the *Journal of Clinical Oncology* [on Dec. 1](#), follows up on a meeting Sept. 23, where group chairs and directors of statistical centers asked NCI to assure them that no new cuts are in the works.

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## Varmus's 2016 Bypass Budget Seeks "Modest" Increase of \$823 Million

*By Paul Goldberg*

NCI has published the bypass budget for the fiscal year 2016, asking for \$5.754 billion, an \$823 million increase over the estimated budget of \$4.931 billion.

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# FDA Adds Contraindications To Power Morcellation Devices

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- The agency's guidance decreed that power morcellators are contraindicated for removal of uterine tissue in menopausal and post-menopausal women, and in women who are eligible for surgeries that remove uterine tissue intact i.e. through the vagina or mini-laparotomy.

- Similarly, power morcellators are now contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to be cancerous.

Categorized as a Class II moderate-risk surgical device by FDA, the power morcellator is used to cut tissue into small fragments for removal through small incisions. When used in patients with undetected or missed uterine cancers, the device spreads malignant tissue in the patient's abdominal cavity, rapidly upstaging the disease (The Cancer Letter, [July 4](#)).

FDA's move is expected to adversely impact minimally invasive surgical gynecologists, who made power morcellation a routine procedure, which is performed in a subset of an estimated 50,000 to 100,000 women who undergo laparoscopic procedures for hysterectomy each year in the United States.

Class II devices are cleared through the [510\(k\) process](#), which applies to new devices that are based on comparability to predicate devices already in use. Only Class III high-risk devices require an FDA premarket approval application.

Here, semantics mean a lot: the standards for Class II clearance aren't as rigorous as for [Class III approval](#).

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PO Box 9905, Washington DC 20016

General Information: [www.cancerletter.com](http://www.cancerletter.com)

Subscription \$405 per year worldwide. ISSN 0096-3917.

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This week's FDA guidance does not reclassify the power morcellators. It is unclear whether FDA intends to re-categorize power morcellators or require manufacturers to resubmit the devices for approval as Class III devices.

In its decision, the agency cited its earlier estimate that one in 350 women who are undergoing hysterectomy or myomectomy for fibroids is found to have an unsuspected uterine sarcoma. The American Association of Gynecologic Laparoscopists [disagrees with the estimate](#), citing international data reporting lower prevalence rates.

"The FDA decision today is based on what we believe is best for patients," William Maisel, deputy director for science and chief scientist at the FDA's Center for Devices and Radiological Health, said at a press call Nov. 24. "The contraindications cover the vast majority of women who would undergo morcellation during myomectomy or hysterectomy, which should reduce the use of the device in patients at greatest risk."

The contraindications are so broad that they make morcellation appropriate only for young women who may choose, after a consent process, to undergo the minimally invasive procedure to preserve their ability to bear children.

The agency's decision comes nearly a year after former Harvard physicians Amy Reed and Hooman Noorchashm launched a vigorous campaign that drew FDA's attention to the issue (The Cancer Letter, [July 4](#)).

"I think it's a good first step, or second step after the April advisory," said Rick Kaitz, a Boston attorney whose wife, Erica, died after her leiomyosarcoma was upstaged by power morcellation performed at Brigham & Women's Hospital, a Harvard-affiliated institution (The Cancer Letter, [Nov. 21](#)).

"In most circumstances, I can't imagine that this industry is going to continue to survive at the moment. I think FDA's decision is strong enough to significantly impact the nature of the practice," Kaitz said.

"Drs. Reed and Noorchashm should be really saluted for the amount of progress they've made within a relatively short period of time. I know for all of us it seems like forever, but I'm very encouraged."

## Immediately in Effect

This is the first time FDA has used an authority, called the ["Immediately In Effect" guidance](#).

According to Maisel, the IIE was created by CDRH to act swiftly on issues that the agency would normally respond to with a routine guidance.

"We didn't feel that issuing this guidance in draft

form, and waiting for a comment period, and then finalizing it, is in the best interests of the public health,” Maisel said at the press call.

Bill Vodra, a former FDA associate chief counsel for drugs, said the agency’s rapid response is extraordinary.

“The timeframe of this is pretty astoundingly fast, for me at least,” Vodra said to *The Cancer Letter*. “If you get people who understand the system i.e. doctors who become patients, they can push much more aggressively than the ordinary consumer can. What I’m most impressed by here is how quickly they’ve done this.”

Vodra helped draft many agency regulations still in use, including those implementing the Controlled Substances Act and FDA’s rules for Good Manufacturing Practices, Good Laboratory Practices, Good Clinical Practices, bioequivalency and the Orange Book.

“Compare how long it took FDA to address this issue, with, let’s say, the surgical mesh that was being used a couple of years ago—that took years for FDA to finally get around to do something about it,” Vodra said.

The American College of Obstetricians and Gynecologists, a 58,000-member professional society, said it would seek additional clarification of the agency’s guidance.

“We are pleased that the FDA’s action takes steps to enhance patient safety while allowing the appropriate use of power morcellation in gynecologic surgery for select women,” Hal Lawrence, executive vice president and CEO of ACOG, said in a [statement](#). “The FDA’s clarification of contraindications for morcellation will help to ensure that only women at low risk for an occult malignancy will undergo laparoscopic hysterectomy or myomectomy with morcellation.

“However, we look forward to working with the FDA to provide additional clarification regarding certain language within the contraindications that could be confusing to patients and physicians.”

AAGL, another professional society, characterized FDA’s action as a setback.

“Abandoning power morcellation technology for many patients undergoing minimally invasive myomectomy, supracervical hysterectomy, or hysterectomy for a large uterus will be a setback in the care of patients with gynecologic conditions,” Franklin Loffer, AAGL medical director, said in a statement.

#### **Observers: FDA “Severely Restricts” Device Use**

FDA-watchers said the agency’s decision would likely eliminate power morcellation as a routine surgical procedure in gynecology.

“FDA’s statement is going to discourage a significant amount of use, assuming that most of these

procedures are being done in post-menopausal and menopausal women. That’s a pretty clear statement. They want this to drop substantially,” said Vodra, a retired partner of Washington, D.C., law firm Arnold and Porter. “If 80 percent of the women who undergo power morcellation are peri- or post-menopausal, then 80 percent of these procedures shouldn’t be done anymore.”

“The contraindication means no rational person would use the product this way. So that’s really saying, ‘No doctor out there should use this. If a doctor goes ahead and uses it, it’s not malpractice per se, but, in many or some jurisdictions, it shifts the burden of proof from the patient to the doctor.’”

Normally, in a medical malpractice case, the patient has to show that the doctor did not follow the standards prevailing in his or her community at the time that a procedure was done or a drug was used.

“Now, any physician that continues using power morcellators, and any device company which still wishes to sell and promote these devices will be taking a huge risk in the liability arena, both medical and otherwise,” said David Challoner, emeritus vice president for health affairs at the University of Florida. “It’s de facto, not de jure.”

Challoner chaired the Institute of Medicine committee tasked by FDA and Congress in 2009 to [review the 510\(k\) process](#) that clears Class II devices such as the power morcellator based on predicate devices.

“I see FDA’s action as severely restricting the use of morcellation in the treatment of uterine fibroids,” Challoner said. “That’s a very desirable outcome, and it’s only slightly second-best to just banning the instruments from the market completely.”

More insurance companies may refuse to pay for power morcellation as a result of FDA’s guidance. Several companies have ended payments for the procedure prior to the guidance (*The Cancer Letter*, [Nov. 21](#)).

“It would be up to the insurance company and the laws governing insurance,” Vodra said. “Clearly, they could refuse to pay for any procedure that is contraindicated. But normally, a boxed warning would not be disqualifying from reimbursement.”

FDA said it would continue to consider other steps that may further reduce the risk of spreading unsuspected cancer, including preoperative cancer detection methods, or containment devices, such as bags, that can prevent dissemination of malignant tissue.

The Brigham & Women’s Hospital has [halted a controversial study](#) that combined power morcellators with “containment bags” intended to capture tissue during gynecological surgery.

## Key Advocates Call for Ban

Reed and Noorchashm, the couple who led the campaign against morcellation, called FDA's decision a "failure."

"This is a massive and monumental failure in federal regulation," Noorchashm said to *The Cancer Letter*. "From a scientific, clinical, surgical and common sense perspective, it's very clear that you don't mince up tissues that have any degree of malignant potential inside a patient's body."

"The FDA was confronted with this problem. They chose to not definitively regulate this problem, and that is clear demonstration of regulatory incapacity. They were given a binary decision to make and they failed. This should tell anyone with a remote understanding of the issue that the FDA is a captured agency—beholden to industry interests over patient safety."

Reed said banning the device is the only appropriate action.

"People say we should be thankful that we've gotten as far as we have, that it moved as it did and we raised the level of awareness," Reed said. "But I have to say, overall, I'm overwhelmingly disappointed with the whole decision. There is no question in my mind that they should have outright banned it, and I'm not sure what they thought they were overreaching if they did."

FDA's Maisel said that banning power morcellators would require doctors and patients to choose other options—typically more invasive surgery.

"Banning laparoscopic power morcellators would completely remove them from the market for all patients in all indications," Maisel said. "We recognize that there are risks associated with all fibroid treatment options, and we believe there is a very small population in whom the benefits for this procedure."

"When the patients are appropriately informed of the potential risks, and that the potential benefits may outweigh the risks, the individual women may choose to have their procedure done, knowing the potential benefits and risks."

Maisel said the key to preserving fertility in some women is to minimize the damage to the uterus.

"We recognize that some younger women who are interested in maintaining their ability to have children or wish to keep their uterus intact after being informed of the risk, may be candidates for this procedure," Maisel said at the press call. "Younger women present a lower risk of having underlying cancer than older women."

"Doctors and patients should determine if the patient is in an appropriate patient, together, and the agency believes that women should have this option

available to them should they wish to preserve their fertility and they are informed of the risk.

"Being able to remove the fibroid and reduce the risk of adhesions that might be associated with a traumatic surgery can help preserve fertility," Maisel said. "Some clinicians specialize in this area, and believe that it is an important tool that needs to remain available."

Reed and Noorchashm disagree.

Reed said no data exist to show that fertility is adversely affected in laparotomies vs. laparoscopic removal of fibroids with power morcellation.

"Firstly, I would like to see the data that mini-laparotomy versus full laparoscopy for fibroids has a detrimental impact on fertility," said Reed, formerly an anesthesiologist at Beth Israel Deaconess Medical Center. "That's what they are saying, that adhesions by mini-laparotomy would negatively impact the fertility of women, so they should be allowed to opt for it. I know of no data that supports that claim."

"For such a data heavy driven argument I want to know who said that this was a problem and based on what? Because the adhesions caused by spraying a huge fibroid around likely are as significant as a laparoscopic dissection and mini-laparotomy."

"And I think that is the important point: it's power morcellation vs. laparoscopic dissection and mini-laparotomy, not full laparotomy."

Reed underwent power morcellation at Brigham & Women's Hospital in October 2013. The procedure upstaged her previously undiagnosed leiomyosarcoma, which was then aggressively treated. The disease is now in remission.

"Because of the wording of the FDA, women will still be on that table having power morcellators used at the discretion of the physician," Reed said to *The Cancer Letter*. "Secondly, I would like the FDA to clarify what its intentions are in regards to studying containment devices. Knowing the potential for harm is great, is this something they intend to support human experimentation on? They clearly state that this is an area that they will watch closely. Will this be done in animals, or will they permit this to be done in humans? Surely one would think not."

"I think the FDA has some serious explaining to do." Noorchashm said that alternative uterus-sparing surgeries are available.

"You don't need to use a morcellator to do a myomectomy, which is what is meant by a 'uterine sparing' operation. Morcellators are only used to extract the tissue from small incisions," said Noorchashm,

a cardiothoracic surgeon who formerly practiced at Brigham and who is now at Thomas Jefferson University. “To perform a uterine sparing operation, these surgeons can dissect out the problematic myomas they’ve ascertained are not malignant using intra-op or pre-op biopsies. Then, they take out the bagged myomas through a small incision. It’s really that simple. There is absolutely no need to use a morcellator.”

“You can, perfectly well, either by using laparoscopic or robotic devices, do a myomectomy and remove the myoma from the body without power morcellation through a small incision at the end of the operation. I think the concept that a uterine sparing myomectomy requires a morcellator is a smokescreen created by device advocates and gynecologists—it’s hogwash.”

Several members at an FDA advisory committee hearing in July expressed a desire to avoid any kind of morcellation of tissues (The Cancer Letter, [July 25](#)).

“Myomectomy, in and of itself, isn’t an oncologically safe procedure. There is a conundrum there,” Reed said. “But you don’t have to make it worse by spreading everything all over the abdominal cavity with power morcellation.”

#### **Vodra: 510(k) Does Not Necessarily Protect Consumers**

Pre-menopausal young women who elect to undergo power morcellation could be waiving the ability to claim medical malpractice against their physicians, if they are harmed by the surgery.

“If a woman is pre-menopausal and elects to undergo power morcellation, then if she has been warned by the doctor that these are the risks and benefits, and she then chooses the procedure, she probably has no claim whatsoever against the doctor,” Vodra said. “When a doctor uses the normal standard of care, in which you’d advise a patient before a surgery on what the risks are, the patient can opt to have it or not have it.”

However, doctors can be vulnerable in these situations if they fail to exercise due diligence.

“I could see situations in which, for example, the doctor did not do any medical history to determine whether the patient was at risk of uterine cancer, and did nothing to check or test whether this patient could have a cancer,” Vodra said.

“If there is a blood test available at some point and he didn’t run the blood test before he did the procedure, that could lead to malpractice.

“The doctor cannot say, ‘What do you want me to do?’ The patient’s not an expert, the doc is, and has an obligation to exercise due diligence according to the

standard of care in the community before surgery is done.”

Young women should not be subject to the risks of power morcellation when there are alternatives, Reed said.

“I had some degree of health literacy, but what do you do with somebody with a third grade education? What do you do with somebody with prejudices against the medical establishment, and there are issues with fertility and management?” Reed said. “There are entire subsets of population who look at all this very differently than Hooman and I do.

“There are a lot of women who’d say, ‘I don’t want you to be taking my fertility away,’ even if they have no intention of having children. That’s a touchy subject, but again, you can do without morcellation.

“FDA is very quick to trash drugs that do not meet safety and efficacy criteria, but on the other hand, here’s a dangerous device, and it’s not banned. What’s the hold up?”

Vodra said the premarket requirements for drugs, and for Class II devices such as the power morcellator are very different.

“In the drug arena, drugs have to be shown to be safe and effective for a specific use in order to get them into the marketplace,” Vodra said. “In the device arena, you don’t have to.

“The [510\(k\) process](#) means you simply have to show that you’re substantially equivalent to another device that’s in the marketplace. You don’t have to show that you’re effective at doing anything, and in a lot of products—like the scalpel—you don’t need to.

“If I read the history of the power morcellator right, it was cleared for one purpose, and doctors started using it for a different purpose, so that’s where the problem arose.

“That’s where drugs and devices differ. Almost all drugs have to be shown to be effective for a specific use before they can get to the market for any use, whereas devices don’t have to do that.

“That’s what the [2011 IOM report on the 510\(k\)](#) is about. The 510(k) is not protecting the consumer in the way people think it is.

“People thought that the devices that were cleared are safe, but they are not approved. FDA approves products that are safe and effective, but it clears devices that can prove to be equivalent to something else.”

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# Brigham & Women's Suspends Controversial Morcellation Study As "Difference of Opinion" With FDA Comes to Light

By Matthew Bin Han Ong

The Brigham & Women's Hospital has halted a controversial study that combined power morcellators with "containment bags" intended to capture tissue during minimally invasive gynecological surgery.

Launched earlier this summer, the study was designed to enroll 400 women to test dye leakage in several commercially available bags that have not been cleared by FDA for use with power morcellators.

The power morcellator cuts uterine tissue into small fragments that are then removed through small incisions. When it hits undetected uterine cancers, the device can spread the disease (The Cancer Letter, [July 4](#)).

"BWH is pausing the study while, together with our collaborators, we consider the FDA guidance," Brigham officials said in a statement to The Cancer Letter.

Officials declined to answer questions about the number of patients that have been accrued to the study, which started earlier this year. A version of the [consent form](#) obtained by The Cancer Letter is dated May 2014.

In a [safety communication issued Nov. 24](#), FDA declared power morcellators as contraindicated for removal of tissue containing fibroids in patients who are menopausal or post-menopausal, or in patients whose uterine tissue could be removed intact through the vagina or mini-laparotomy.

A story on FDA's guidance is on p. 1.

On Nov. 20, prior to FDA's restrictions on power morcellators, Brigham officials said in written response to questions from The Cancer Letter that the institution was conducting the study without an Investigational Device Exemption (The Cancer Letter, [Nov. 21](#)).

Officials at Brigham, a member institution of Partners HealthCare, a Harvard hospital network, said the study did not require the agency's license allowing clinical testing of potentially high-risk devices.

By inference, this would mean that the Partners HealthCare IRB, which is separate from Dana-Farber Cancer Institute's IRB, had concluded the study to be of "minimal risk," and therefore did not see the need for an [IDE submission](#).

When this reporter asked FDA officials to comment on the Brigham study during a press call, William Maisel, deputy director for science and chief scientist at the FDA Center for Devices and Radiological

Health, said that the study should have been conducted only after an IDE has been approved.

"Whether or not we issued this warning, we believe that the investigational use of containment bags is a significant-risk device, and would require submission of an Investigational Device Exemption," Maisel said at the press call Nov. 24.

"Clearly, there's a difference of opinion between the Brigham and its decision-making system, and what the FDA has now declared," said David Challoner, emeritus vice president for health affairs at the University of Florida.

Challoner chaired the Institute of Medicine committee tasked by FDA and Congress in 2009 to [review the 510\(k\) process](#) that clears Class II devices such as the power morcellator based on predicate devices.

"If I were them, I'd stop the study right away, until this gets clarified, or until they have an IDE," Challoner said to The Cancer Letter.

Approving the investigational use of a significant-risk device without submitting an IDE could prompt an FDA review of the institution's IRB.

"Brigham, by having approved their study, could bring FDA in to look at their whole IRB process," said Bill Vodra, a former FDA associate chief counsel for drugs. "I don't know if FDA will do that, but obviously there is a risk of that."

Vodra helped draft many agency regulations still in use, including those implementing the Controlled Substances Act and FDA's rules for Good Manufacturing Practices, Good Laboratory Practices, Good Clinical Practices, bioequivalency and the Orange Book.

"The penalty is the IRB may not do IRB activities anymore," Vodra said to The Cancer Letter. "What the institution would have to do then is to reconstitute the IRB."

"FDA is not in the business of trying to shut down clinical research. Its goal is to make sure research is done ethically and safely," said Vodra, a retired partner of Washington, D.C., law firm Arnold and Porter. "And so if FDA finds an IRB or an institution is sloppy in not instituting the proper ethical or safety standards, the remedy is to go in and get it straightened out."

## FDA: Bags Not "Panacea"

Rick Kaitz, a Boston real estate lawyer whose wife, Erica, died in December 2013 from leiomyosarcoma upstaged by power morcellation at Brigham, said the hospital should permanently stop the study (The Cancer Letter, [Nov. 21](#)).

"Pausing it is a good first step, but I think it should be preliminary to stopping it," Kaitz said to The Cancer

Letter. “That study doesn’t make sense. It’s playing a game of chance with women’s lives, and you’re not supposed to do that.

“Dye is not cancer cells. And a study without a significant number of women with malignancies won’t work. And what woman with a malignancy in her right mind would ever enroll for a study like that? It’s an absurd study, and the fact that it was ever IRB-approved was really troublesome.

“And, it was outrageous that the study was approved without talking to the physicians in the sarcoma center at Dana-Farber, Brigham’s sister institution.”

After Erica’s cancer diagnosis, she and Rick assembled a group of friends and supporters who have raised about \$4 million for leiomyosarcoma research at Dana-Farber (The Cancer Letter, [Nov. 21](#)).

There is no guarantee that containment bags can prevent the spread of cancer via power morcellation, said FDA’s Maisel during the conference call.

“There are some in the clinical community who believe that the use of bags can reduce the spread of tissue within the abdominal cavity, and particularly, reduce the spread of cancerous tissue within the abdominal cavity,” Maisel said.

“This issue was discussed at [an FDA advisory committee hearing] that was [held in July](#). One of the important factors for people to understand is that, with use of a bag, it’s not a guarantee that there will not be the spread of cancer. So the use of a bag is not a panacea.

“It also potentially can create other adverse events related to the reduced visibility in the abdominal cavity, injury to organs et cetera. The agency at this time is not either recommending or discouraging the use of the bag. We view that as an important issue that individual physicians, within their skill and understanding, should decide for themselves.

“That being said, the use of a bag does make inherent sense, and so, for those that do have the ability and skill for using it, it does seem like a reasonable idea.”

The study in question is led by Jon Einarsson, a Brigham surgeon who performed the “open”—unbagged—version of the procedure on Erica. Einarsson and another investigator, James Greenberg, have applied for or own patents on containment bags that are intended for use with power morcellators (The Cancer Letter, [Nov. 21](#)).

“I think if the science can be proven, in a non-risky and effective manner, then I’m for safe medical procedures,” Kaitz said. “To date, anything that I’ve seen about containment systems is premature and exceedingly risky, and really just a crapshoot.

“And you shouldn’t be taking a crapshoot with women’s lives.”

Kaitz said Brigham doctors had mischaracterized the risk his wife was facing when she underwent power morcellation, two years before Einarsson’s study was launched.

“They gave us numbers—one out of 10,000—that they knew to be wrong,” Kaitz said. “The [Seidman, Muto article](#) was published in November 2012. It says right in that article that multiple parties at Brigham said that the number they are quoting for the risk are nine times lower than the real risk.

“These are their own people who are saying that in 2012. Most, if not all of that data was in, I’m sure, by June 2012 when Erica was operated on.”

After Erica’s disease was upstaged, Brigham officials declined Kaitz’s demand for an outright ban on power morcellation at Harvard-affiliated institutions.

“Erica and I went through more medical stuff in the last two years than most people go through in their lifetimes, and I want to emphasize that the vast majority of physicians, nurses, and technicians were caring, sensitive and thoughtful,” Kaitz said. “That’s different from the system.

“The work system is incredibly insular, and arrogant. The reality is, they think that non-doctors don’t have a right to an opinion on anything that has to do with medicine. Well, guess what, they’re wrong.

“The minimally invasive surgeons have proven to be incapable of self-regulation. It has to do with the fact that doctors don’t want to step on other doctors’ toes. And for oncologists and the oncologic gynecological surgeons to say, ‘This procedure needs to be stopped,’ would be stepping on the toes and the livelihood of the minimally invasive gynecological surgeons.”

### **Vodra: The Risk of Patient Lawsuits**

It’s not publicly known how many patients were enrolled in the Brigham study.

Vodra said that patients who have enrolled in the study, regardless of injury, could file lawsuits against Brigham for not conveying that the investigational use of containment bags with power morcellators carry significant risk.

“If any one of the subjects already treated in the study is injured in any respect, they can go back and sue on the grounds that they would not have participated in the study had they known it was a high-risk study, not a minimal-risk study,” Vodra said.

“In theory, even the patients who weren’t injured might sue for what we would call invasion of privacy. You have to consent to be touched.

“I can see a clever lawyer trying to make an

argument on the fact that a doctor used a misleading consent form to perform an operation on a woman without telling her what the real risks were. Now, what the damages would be, I don't know.

"There might be some sort of punitive damage or compensatory damage—I don't know what the injury was other than a loss of control and autonomy, and invasion of privacy."

Brigham's first priority would be to resolve the dispute with FDA, Vodra said.

"It's not a matter of looking at liabilities. As a major research hospital, you do not want to have FDA unhappy with you," Vodra said. "It's not what you want.

"If you're hoping to send studies to FDA, in order to support applications for you or your contract with industry, and FDA says, 'We can't accept research from an institution that doesn't have ethical standards,' that's going to dry up your research contract within minutes.

"What you would do is say, 'OK, we'll submit this as an IDE.' And if FDA says, 'We won't allow that study to be done,' then you say, 'OK, we stop the study.'

"There is no sponsor in this study. Why would the hospital fight for anybody to continue doing the study if they are doing it? It's not in their interest to fight FDA on the matter."

Kaitz, who continues to raise funds for research at Dana-Farber, said he understands why patients and their families would seek recourse.

"It's unfortunate that the medical system requires you to consider various alternatives that you would never ever want to consider in order to try and influence institutional change," he said.

## NCI Officials Pledge No Further Consolidation of NCTN Groups

(Continued from page 1)

JCO is published by the American Society of Clinical Oncology, a professional society that has issued strong expressions of concern about several aspects of consolidation of clinical trials cooperative groups into the National Clinical Trials Network, stating at one point that the changes have placed publicly funded clinical research in jeopardy (The Cancer Letter, [June 6](#)).

"Understandably, concerns have been expressed that budgets for the NCTN are insufficient to support all the trials that could be done," the letter to JCO states. "It is true that resource constraints have had an impact on the breadth of trials that the NCTN can conduct.

"In response, we have developed processes to evaluate trial concepts and prioritize trials that have the greatest promise to answer important scientific questions and change clinical practice in the most beneficial ways," the letter states. "Some fear that the processes required for prioritization will stifle investigator enthusiasm and reduce participation in federally supported clinical trials, but we believe that the opposite is true: new approaches will increase the value of NCI-supported clinical trials, energize the clinical research community, and enhance patient participation. Moreover, NCI's need to prioritize its research activities extends well beyond clinical research and has affected all of our programs."

The letter was signed by Jeffrey Abrams, acting

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director for clinical research and associate director of the Cancer Therapy Evaluation Program at NCI; Barry Kramer, director of NCI Division of Cancer Prevention; James Doroshow, director of the Division of Cancer Treatment and Diagnosis; and Harold Varmus, NCI director.

“An integrated network is essential to the research goals of the NCI,” the authors wrote. “We have not invested in major changes to this critical infrastructure—including a national central institutional review board; a uniform clinical trials data management system for all research sites; and national systems for accrual, regulatory support, and protocol prioritization—only to gradually eliminate our support for clinical trials research.

“We have also not re-envisioned our community-based clinical research program (NCI Community Oncology Research Program)—with its new mandate to conduct health services research, as well as cancer control and prevention trials—with the intention of discontinuing clinical investigations best pursued at the level of hospital networks and community clinical practices.

“These changes are not a prelude to further consolidation of the NCI clinical trials infrastructure.”

At the joint meeting of the National Cancer Advisory Board and the Board of Scientific Advisors Dec. 2, Doroshow re-emphasized the point that no further consolidation is in the works:

“One of the issues that was brought to the fore [at the meeting with group chairs and heads of statistical centers] was the notion that there was a perception that the reorganization of the NCTN was a really prelude to, in essence, phasing out our clinical trials commitment from the NCI.”

“And so the purpose of this letter [to JCO], was to make it clear that the purpose of the reorganization was in fact to allow us to screen patients, to do precision medicine trials, to have an organization that was more facile, and in no way should be construed to be a lack of strong support and appreciation for the activities of our National Clinical Trials Network.”

Charles Blanke, chair of SWOG and professor of medicine at the Oregon Health Sciences University Knight Cancer Institute, said the assurance from top NCI officials would build confidence in the system of publicly funded clinical trials.

“This is a huge boost to the publicly funded national cancer research effort, which already has resulted in huge advancements in our treatments for patients with cancer,” Blanke said to The Cancer Letter. “Network members can in particular show the letter

to their young investigators, as proof cooperative, genetically driven clinical oncology research is alive and well and represents a viable and even vibrant career path.”

When NCI started to consolidate the nine cooperative groups focused on adult cancer to create four adult groups and one pediatric group, the plan was to add \$25 million to the system to make it possible to increase payment for each patient placed in a clinical trial. However, the money didn’t come through and the number of patients was reduced.

Also, group chairs said that over \$20 million was cut out of the groups’ operations and statistical centers (The Cancer Letter, [May 16](#)).

At the Sept. 9 meeting of the NCAB, group chairs asked for a voice in the running of the institute’s new network.

“I think the governance has to be a partnership between the group leadership and the NCI,” Walter Curran, an NRG Oncology group chair, executive director of the Winship Cancer Institute, and the Lawrence W. Davis Professor and Chairman of Radiation Oncology at Emory University.

Curran said that a NCTN Leadership Management Committee has been formed and has met once.

“This committee has network group and biostatistics chairs and NCI leaders as members,” Curran said. “The network group leaders look forward to working as partners with NCI within this important management committee.”

## NCI 2016 Bypass Budget Seeks \$823 Million Increase

(Continued from page 1)

“As a measure of how modest this funding recommendation is, consider the following: If the NCI’s annual budget had kept pace with inflation in the cost of biomedical research since fiscal year 2003, NCI cancer research funding would total \$6.76 billion for fiscal year 2016,” the document states.

“Thus, the \$5.75 billion recommended in the table that follows is \$1 billion below the amount the NCI would have received if the budget had merely kept pace with inflation. In other words, a budget of \$5.75 billion restores only 41 percent of the funding required for the NCI to recover its losses due to inflation.”

The 63-page document is posted [here](#).

NCI directors have the unique authority to submit a summary of scientific opportunities and funding recommendations directly to the White House,

bypassing review by the NIH director and the HHS Secretary. Created by the National Cancer Act of 1971, the bypass budget has been a part of the political landscape since 1974.

However, no bypass budget was produced for the fiscal years 2014 and 2015. It now appears unlikely that these documents will be produced.

Peter Garrett, a spokesman from NCI, reiterated that the institute was focused on sequestration (The Cancer Letter, [Oct. 10](#)).

“The FY 2012 and 2013 bypass budgets required extensive involvement from the NCI director, the two chief deputies and the heads of the divisions, offices and centers,” Garrett said to The Cancer Letter.

“Rather than direct our efforts on proposing unrealistic increases for NCI, we have focused on holding the line with the rest of NIH, and defending against cuts.”

Describing the document at the joint meeting of the National Cancer Advisory Board and the Board of Scientific Advisors Dec. 2, Varmus noted that the new document is different in format from its earlier iterations.

*Varmus’s comments follow:*

Let me say a couple of things about what you have in front of you, the bypass budget and narrative. A document that we’re pleased with, it is somewhat different in character from the previous ones that were issued in the current realm.

It has an account of very broad themes, not so many specific projects, and very few people mentioned. It compiles our important programs, but doesn’t address progress made against specific cancers as we did in some of our previous bypass budget narratives.

It emphasizes a large number of changes that have been made at the NCI over the past couple of years, despite budgetary shortages, and obviously we are proud of that. Doug [Lowy, NCI deputy director], who wrote the rough draft that we all worked on, has said that it’s a pretty good account of how our team has changed the NCI.

The focus is on elements of the infrastructure, such as new grant mechanisms like the outstanding investigator award and the provocative questions, and on other parts of the infrastructure, like the cancer centers, clinical trial systems, training mechanisms, intramural research program, our informatics infrastructure and the Frederick National Lab.

And it also says a number of things about some specific, broad advances in new scientific programs in basic science, genomics, clinical trial design, immunotherapies, pediatric cancer, the RAS oncogene,

cancer prevention and cancer health disparities.

There is a strong budget rationale, in my view, which is founded on the precept that the proposed 15 percent increase that we’re asking for—one that I do not expect to see achieved in the current Congress.

That increase would only partially compensate for the money we’ve lost over the past decade because of attrition. In fact it’s about a billion dollars less than where we would be if we had the biomedical research price index increase—40 percent of that loss would be recovered by the budget that we’re proposing, which seems like an outrageous proposal to ask for a 15 percent increase.

It’s not going to happen, but it’s a useful way to put things in perspective.

## **NYC Doctor Pays \$2.35 Million To Settle False Claims Act Suit Over Radiosurgery Reimbursements**

*By Paul Goldberg*

A New York City radiation oncologist who specializes in fractionated stereotactic radiosurgery and stereotactic body radiation therapy agreed to pay \$2.35 million to resolve a 10-year-old Medicare fraud lawsuit.

In a settlement announced Nov. 24, Gilbert Lederman, who now heads [Radiosurgery New York](#), settled a whistleblower suit related to Medicare claims for 300 patients treated between the mid-1990s and 2003.

Lederman is known in the New York area for the radio ads in which he promotes his treatment as an alternative to chemotherapy and radiation for newly diagnosed and recurrent cancers.

He may be even better known as the doctor who treated George Harrison’s brain metastases in 2001, convincing the former Beatle to sign an electric guitar. The episode [is described in detail](#) in New York Magazine.

In 2008, Lederman’s previous employer, Staten Island University Hospital, agreed to pay \$25 million to settle the government’s charges of systematically miscoding Medicare claims to indicate that he had treated patients above the neck in order to obtain Medicare coverage.

The autographed guitar didn’t turn out well, either. Lederman had to destroy the instrument in 2004, after Harrison’s estate claimed in a lawsuit that the doctor took advantage of a dying patient.

During the period in question, Medicare paid

for fractionated stereotactic radiation only when it was delivered above the neck. However, in 2003, a code was added to cover stereotactic radiation below the neck.

“Providers who misrepresent their services—whether for the purpose of obtaining greater reimbursement or in an effort to conceal the fact that a treatment was deemed investigational—continue to pose a threat to Medicare, our nation’s largest insurer,” Brooklyn U.S. Attorney Loretta Lynch said in a statement, as she announced the Nov. 24 settlement with Lederman. “In response, we will continue to vigorously pursue those providers who place their own self-interest above their obligation to accurately report the nature of the services they provide to their Medicare patients.”

Lynch is currently President Obama’s designee for the post of the U.S. Attorney General.

Lederman, who didn’t admit wrongdoing, agreed to pay \$2.175 million to the government in the whistleblower suit brought under the False Claims Act. Of that money, \$326,250 will go to the whistleblower, Elizabeth Ryan, whose husband was treated for pancreatic cancer at the hospital. Another \$175,000 will cover Ryan’s legal expenses.

Ryan had received \$3.75 million as part of settlement of an earlier *qui tam* suit against SIUH. That action [was settled in 2008](#).

Before the settlement with Lederman, Judge John Gleeson of the U.S. District Court for the Eastern District of New York, ruled that the doctor’s claims for reimbursement for body radiosurgery from Medicare were false, because the services were not covered by Medicare at the time and because the doctor had misrepresented the nature of the services for which he was billing.

“Although the case was near trial, appeals and further proceedings would likely last several more years,” Lederman’s attorney Jack Tracy said in a statement.

“Dr. Lederman was willing to continue his fight for vindication and justice, however, the threat of losing his Medicare privileges and thus his ability to continue to help his patients, which was and is his primary goal, convinced him to settle the case and move on with his practice.”

According to [the complaint](#), the materials Lederman distributed to prospective patients greatly exaggerated the ability of his treatment to control diseases that included metastatic lung pancreatic cancers.

The suit quotes the following claims:

- “Of the overwhelming number of patients we have treated, well over 90% have had successful outcomes of their Fractionated Body Radiosurgery.”

- We are “highly successful in treating selected primary or metastatic cancers.”

- “Indeed, the vast majority of cancer treatment at Staten Island University Hospital with Body Radiosurgery—95 percent—is successful.”

- “We’re seeing tremendous results; results in many hopeless cases. People who thought there were no chances for them are coming and many, many are having chances of, of another break in life... The final line is: There’s a very high success rate, over 90%. While no guarantees, it’s a very high success rate and avoids the invasion of surgery and the toxic systemic chemotherapy for many patients.”

According to court documents, Lederman and SIUH had convinced a large number of Italian citizens—as well as Harrison—to get the treatment.

The [2012 practice guidelines](#) of the American Society for Therapeutic Radiology takes a measured approach to describing appropriate uses of stereotactic body radiation therapy:

“The efficacy of SBRT is established for a variety of clinical indications as a primary treatment for selected early-stage cancers or as treatment for discrete tumors in patients with oligometastatic disease, selected benign neoplasms in or near the central nervous system, or recurrent cancer in previously irradiated regions.

“The utility of SBRT is perhaps best exemplified in the case of inoperable early-stage lung cancer, where the 3-year primary tumor control rate of 98% is roughly twice what would be expected from conventional RT given over a 6- to 7-week period. To date, reports of prospective clinical trials of SBRT have typically documented similar high rates of tumor control, coupled with a low incidence of serious toxicity, despite the high-dose fractions of radiation given to tumors.”

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## Drugs and Targets

# Accelerated Approval Granted for Blincyto in R/R ALL

**FDA granted accelerated approval for Blincyto (blinatumomab)** for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia.

The approval was based on the achievement of durable complete remission and response with a reduction in minimal residual disease to less than 10-4 in a multicenter single-arm trial (Protocol MT103-211) that enrolled 185 patients with R/R ALL. Blinatumomab was administered by continuous infusion for 4 weeks of a 6-week cycle. Up to two cycles were used for induction and three cycles for consolidation.

In Protocol MT103-211, 32 percent (95% CI, 26% - 40%) of patients with R/R ALL attained CR with two cycles of treatment with single-agent blinatumomab, and the response was durable (median 6.7 months; range, 0.46 to 16.5 months). Furthermore, 31 percent (95% CI, 25%-39%) of the patients in the study had a CR with or without complete hematological recovery but with reduction in MRD to <10-4.

Blinatumomab is a bispecific CD19-directed CD3 T-cell engager that activates endogenous T cells when bound to the CD19-expressing target cell. Activation of the immune system results in release of inflammatory cytokines. Cytokine release syndrome, including life-threatening or fatal events, was reported in 11 percent of the patients.

A Boxed Warning regarding cytokine release syndrome and neurological toxicities is provided in the product labeling. In addition, FDA approved blinatumomab with a Risk Evaluation and Mitigation Strategy. Blinatumomab is sponsored by Amgen Inc.

**The Broad Institute, Harvard University, the Massachusetts Institute of Technology and Editas Medicine** entered into a worldwide license agreement to grant Editas access to intellectual property related to the the CRISPR-Cas9 system genome editing technology.

Researchers at Harvard Medical School, the Wyss Institute for Biologically Inspired Engineering at Harvard University, the Broad Institute, MIT, the McGovern Institute for Brain Research at MIT, and Harvard University Faculty of Arts and Sciences, have optimized the CRISPR-Cas9 system to allow for insertion, replacement, and regulation of targeted

genes in higher organisms, with the potential to one day be used in humans.

The agreement includes a mechanism to ensure that no promising target genes will be neglected. Genes that are not being pursued by Editas will be made available for licensing to other parties so that new medicines based on this technology can be developed for any disease that could be treated by this approach.

Also included in the agreement are additional technologies relating to engineering and optimization of transcription activator-like effector proteins that can also be programmed to target and modify specific genes, as well as a novel protein-based drug delivery system.

**FDA granted clearance for IQQA-BodyImaging**, developed by EDDA Technology, as the latest addition to the IQQA platform and product suite for imaging-guided cancer treatment.

IQQA-BodyImaging extends the platform's 3D features to include thoracic, abdominal and pelvic multimodality scans. Features such as virtual knife for surgery and virtual needle for interventional procedural planning, monitoring and follow-up, provide tools for tumor board assessment.

**The Centers for Medicare & Medicaid Services** issued its final payment decision regarding the **Cologuard** stool DNA colorectal cancer screening test, and will reimburse it at \$502 per test.

The final payment decision follows a joint FDA and CMS parallel review pilot program. Cologuard, developed by Exact Sciences Corp., is the first technology to gain approval through this program.

Available through a health care provider by prescription in all 50 states, Cologuard is for people 50 years and older. The test found 92 percent of colorectal cancers in average risk patients with 87 percent specificity in the pivotal clinical trial that enrolled more than 10, 000 patients. Cologuard does not require medication, dietary restrictions or bowel preparation, and is included in the American Cancer Society's Colorectal Cancer Prevention and Early Detection national guidelines.

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**Janssen Research & Development LLC submitted a new drug application for Yondelis (trabectedin)** to the FDA for patients with advanced soft tissue sarcoma, including liposarcoma and leiomyosarcoma subtypes, who have received prior chemotherapy including an anthracycline.

Janssen also announced plans to amend the protocol for the phase III, randomized, open-label study ET743-SAR-3007, on which the NDA submission is based. The protocol will be revised to offer patients who were randomized to the dacarbazine comparator arm the option of receiving Yondelis treatment at their physician's discretion. This trial is evaluating the safety and efficacy of Yondelis versus dacarbazine for the treatment of advanced liposarcoma and leiomyosarcoma in more than 500 patients previously treated with an anthracycline and ifosfamide, or an anthracycline followed by one additional line of chemotherapy.

Yondelis is a novel, multimodal, synthetically produced antitumor agent approved in 76 countries for the treatment of advanced soft-tissue sarcomas as a single-agent, and in 69 countries for relapsed ovarian cancer in combination with Doxil (doxorubicin HCl liposome injection).

**Pharmacylics Inc. and Janssen-Cilag International NV submitted a type II variation application for Imbruvica (ibrutinib)** to the European Medicines Agency for the treatment of adult patients with Waldenstrom's macroglobulinemia. If approved, Imbruvica would be the first label specifically authorized to treat WM in the EU.

The acceptance of the WM Type II variation submission for Imbruvica triggers a \$20 million milestone payment to Pharmacylics under its collaboration agreement with Janssen Biotech Inc.

The filing follows the supplemental new drug application submission for Imbruvica to FDA in the same indication, which was submitted by Pharmacylics in October. Both the FDA and EMA filings were based on data from a phase II study evaluating the use of Imbruvica in WM patients.

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*In Brief*

## **David Chambers Appointed Deputy Director at NCI DCCPS**

**DAVID CHAMBERS** was named deputy director for implementation science in the **NCI Division of Cancer Control and Population Sciences**.

Chambers will provide national scientific leadership on numerous research projects between research discovery and program delivery in public health, clinical practice, and health policy. He will also be responsible for guiding some of NCI's research dissemination tools such as Cancer Control P.L.A.N.E.T, Research to Reality, Cancer Trends Progress Report, and State Cancer Profiles.

Prior to joining DCCPS, Chambers spent 13 years at the National Institute of Mental Health, working to disseminate and implement research across the NIH.

Chambers received the NIMH Director's Merit Award for Significant Achievement in 2009 and again in 2013; the Hubert H. Humphrey Award for Service to America in 2009; the Association for Behavioral and Cognitive Therapies DIS SIG Achievement Award for dedication to the science of dissemination and implementation in 2011; the NIH Director's Award in 2013; and, most recently, the Team Science Award from the Association for Clinical and Translational Science in 2014.

**LINDA WEISS** said she intends to retire from her job as director of the **NCI Office of Cancer Centers**.

Weiss's retirement was announced in an email from NCI Director Harold Varmus Nov. 25.

*The text of the email follows:*

Dear Colleagues,

I'm writing to let you know that Linda Weiss, Ph.D., Director, Office of Cancer Centers, NCI, recently announced her plans to retire in March 2015, after 13 years leading the NCI Cancer Centers program. I'm sure you'll agree that the cancer centers have benefitted greatly from her outstanding management during those years.

In planning for the future of the NCI Office of Cancer Centers, we will be conducting a national search for Linda's successor. You will likely see a position announcement in leading journals in the coming weeks and months.

On behalf of her many admirers in the cancer research community, I'd like to thank Linda for her many years of exceptional stewardship of NCI's cancer

centers program, a remarkable and enduring enterprise that has enhanced its stature under her guidance.

Best regards,  
Harold Varmus

**THE JOHN SCOTT AWARD** was awarded to **Susan Band Horwitz, Leonard Hayflick and Paul Moorhead.**

Horwitz is honored for her work in developing Taxol, a drug isolated from the bark of the Pacific yew tree, into a prototype for a class of cancer drugs that have helped more than two million people. She is the Falkenstein Professor of Cancer Research and co-chair of the Department of Molecular Pharmacology at Albert Einstein College of Medicine School.

Hayflick and Moorhead will share the award for their work in proving that normal human cells are mortal and have a limited capacity to replicate, a phenomenon known today as the Hayflick Limit.

Hayflick is as a professor of anatomy at the University of California, San Francisco. He helped develop the first strain of cultured normal human cells, known as the WI-38 cells, which are used to manufacture almost all human virus vaccines in the world.

Moorhead, now retired, is a cytogeneticist who co-authored the research work with Hayflick in 1961 at the Wistar Institute in Philadelphia; and later served at the Children's Hospital of Philadelphia and the University of Pennsylvania Medical School.

The winners will receive a cash prize and the copper Scott Medal, and will be honored at the American Philosophical Society in Philadelphia. The award was endowed by chemist and pharmacist John Scott as a legacy to the scientific achievements of Benjamin Franklin and awarded each year since 1822 to "ingenious men and women who make useful inventions."

Past recipients include 15 winners of the Nobel Prize, among them Marie Curie, Guglielmo Marconi, R. Buckminster Fuller, Baruch Blumberg, Kary Mullis, K. Barry Sharpless and most recently physicist Saul Perlmutter, who won the Scott Award in 2005 and went on to win the Nobel Prize for Physics in 2011.

**NICHOLAS PETRELLI** received the 2014 Clinical Research Award from the **Association of Community Cancer Centers** in recognition of his initiatives promoting and advocating for oncology clinical research.

Petrelli is the Bank of America endowed medical director of Christiana Care's Helen F. Graham Cancer Center & Research Institute. Previously, he was chair

of the Department of Surgical Oncology and director of the Surgical Oncology fellowship training program at Roswell Park Cancer Institute.

The ACCC presented him with the award at the 31st National Oncology Conference in San Diego, Calif.

The center has served as a NCI Community Cancer Center Program site and has achieved an accrual rate of 24 percent in NCI-sponsored clinical trials. In August 2014 the center earned a five-year, \$8.2 million grant from NCI's Community Oncology Research Program to support cancer screenings, prevention, control, treatment and imaging research trials.

In addition, Petrelli helped develop a Tissue Procurement Center with more than 5,000 specimens, which led to \$4.6 million funding for participation in the Cancer Genome Atlas Project. He also developed the first Delaware statewide High Risk Family Cancer Registry, consisting of 5,640 families with more than 200,000 individuals.

**ANJEN CHENN** was named **Metamark's** senior vice president of clinical operations. He will oversee operational execution and pathology services across Metamark's laboratories in Cambridge, Mass.; Collegeville, Penn.; and Augusta, Ga.

Chenn most recently served as the associate professor of pathology at the University of Illinois, Chicago, where his research lab focused on understanding developmental brain disorders and brain cancer. He also served as the director of clinical pathology at the University of Illinois Hospital in Chicago, where he established a new program for Personalized Diagnostics, also known as the Laboratory for Innovative Care and Research.

Previously, Chenn was a faculty member at Northwestern University Feinberg School of Medicine and served as the director of molecular diagnostics at Northwestern Memorial Hospital in Chicago.

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