THE CANCER LETTER

Vol. 38 No. 40
Oct. 26, 2012

PO Box 9905 Washington DC 20016 Telephone 202-362-1809

Commercialization Texas Style

Politicians Applaud CPRIT's New Direction; UT Gives Waiver to MD Anderson's DePinho

By Paul Goldberg

Scientists across the U.S. may view recent events at the Cancer Prevention and Research Institute of Texas as lamentable: the dissolution of a world-class peer review system that helped dispense $300 million a year.

Top Texas politicians don't want any part of these blues.

The state's governor, lieutenant governor and speaker of the House earlier this week wrote a letter to CPRIT officials, urging them to move beyond funding basic research and broaden the institute's mandate to commercialization.

"It is now time for CPRIT to take further steps to fulfill its statutory mission and expedite innovation that will deliver new cancer treatments to patients within three to five years," wrote Gov. Rick Perry, Lt. Gov. David Dewhurst and Speaker of the House Joe Strauss in a letter dated Oct. 19.

The letter gives CPRIT officials political cover to keep doing what they had been doing all year: moving forward with commercialization projects. These efforts triggered the resignations of top-tier scientists from CPRIT's review boards.

(Continued to page 2)

Conversation with The Cancer Letter

UT System Vice Chancellor Shine Describes Rationale for Granting Waiver to DePinho

The waiver granted to Ronald DePinho allows him to remain active in three biotechnology companies he helped start, but also contains provisions that will be "economically disadvantageous" to the MD Anderson Cancer Center president, said Kenneth Shine, the University of Texas System executive vice chancellor for health affairs.

Shine said he had to weigh the potential pitfalls arising from conflicts of interest against potential benefits of hiring a scientist whose interests include commercialization to lead MD Anderson.

(Continued to page 7)

Komen Under Pressure

Charity Faces Money Woes, Attacks from Right

By Matthew Bin Han Ong

This year's National Breast Cancer Awareness Month didn't improve business at Susan G. Komen for the Cure, as donors continue to appear less than enthusiastic and affiliates are reporting significant dollar dips nationwide.

(Continued to page 11)

DePinho's COI Waiver Requires Blind Trust for Company Stock

(Continued from page 1)

The letter from the troika of top Texas politicos was addressed to Jimmy Mansour, a telecommunications entrepreneur who heads the CPRIT Oversight Committee.

Mansour is on record expressing relief about the exodus of scientists from the institute's boards (The Cancer Letter, Oct. 19). "Better to get them all out of the way now," Mansour wrote in an internal email that inadvertently leaked out of CPRIT's walls. "Gives us the prime opportunity to announce a new regime."

Meanwhile, Perry's enthusiasm for CPRIT appeared to grow. Earlier this week, he made a surprise appearance at the institute's conference.

"Since CPRITs creation, you all have helped lay a sound foundation to establish one of the greatest cancer-fighting tools in human history," Perry said. "The challenge that remains before us is to build on that foundation, and finally begin curing cancer once and for all. It's a lofty goal, but I have full confidence that with your collective intelligence, passion and drive, we can take the next step. We can foresee a day when those waiting for the drug that will shrink their tumor will be waiting no longer."

This statement could mean either that (a) Perry doesn't realize that his claim that Texas has done all the basic science required to proceed to cranking out cancer cures would not gain wide traction among scientists and clinicians, or (b) CPRIT has become precisely what the governor and others in Texas politics want it to be: a pot of public money that can be dispensed for commercial or political purposes.

THE CANCER LETTER

® The Cancer Letter is a registered trademark.

Editor & Publisher: Paul Goldberg
Associate Editor: Conor Hale
Reporter: Matthew Bin Han Ong

Editorial, Subscriptions and Customer Service:
202-362-1809 Fax: 202-379-1787
PO Box 9905, Washington DC 20016
General Information: www.cancerletter.com

Subscription $405 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Founded Dec. 21, 1973, by Jerry D. Boyd.

UT System Grants Waiver to DePinho

The state's enthusiasm for commercialization spilled out in another important way: the UT System granted a waiver for MD Anderson President Ronald DePinho to continue to play a role in three companies he co-founded.

"Among the major issues which I considered was your unique history and experience in developing new agents to help patients and create companies and procedures which would bring research results to the bedside," said Kenneth Shine, the UT System executive vice chancellor of health affairs, in a letter to DePinho. "The Regents of the University of Texas believe that this experience is valuable to the MDACC and the University of Texas System."

In a detailed Q&A with The Cancer Letter, Shine said the decision is consistent with the conditions under which DePinho accepted employment. The UT System declined to grant waivers covering several of DePinho's conflicts.

"Dr. DePinho and his wife have to divest themselves of stock and consultation fees and other benefits, which, in fact, have great financial value," Shine said to The Cancer Letter. "In other cases, no waiver was granted and there were no financial implications. But I'm not going to go into detail as to what companies were there for a whole variety of reasons."

The Q&A with Shine appears on page 1.

MD Anderson officials released the cover letter conveying the decisions, and the UT System released the actual decisions memorandum under the Texas Public Information Act.

The waiver also covers DePinho's wife Lynda Chin, a senior scientist at MD Anderson and his partner in biotech ventures. She is covered by the waivers by virtue of being his spouse, officials say.

Chin is also a key figure in the CPRIT controversy. The explosion at the state institute that spends $300 million a year was caused by the decision to fund an $18 million biotech incubator in which Chin was a co-leader. The proposal was approved as a "commercialization" activity, and received no scientific review.

The decision to fund the incubator without review of its scientific programs delayed approval of peer-reviewed grants, triggered the resignation of Alfred Gilman, CPRIT's chief scientific officer.

Subsequently, scientists—all of them from out of

state—followed Gilman out the door.

In the midst of the controversy, MD Anderson withdrew the incubator proposal. Now it can be resubmitted and reviewed based on new criteria promulgated by the new CPRIT.

"We believe it is important that you evaluate and reconsider CPRIT's organizational structure, and decide on structural changes that would strengthen CPRIT and increase its ability to fulfill its missions," Perry, Dewhurst and Strauss wrote in the letter to CPRIT's Mansour.

Waiver Covers Three Companies

The waiver covers DePinho's interactions with three companies: AVEO Pharmaceuticals Inc., Karyopharm Inc., and Metamark Genetics Inc.

According to documents that had been leaked to the Houston Chronicle, DePinho was seeking a broad waiver covering 12 entities (The Cancer Letter, Sept. 21). It's not clear that as many as nine waivers were denied—some may have been deemed unnecessary.

However, the language of Shine's letter suggests that DePinho didn't get everything he wanted.

"I recognize that these decisions will entail a significant financial impact on you and your wife," Shine wrote. "However, this represents a very carefully considered effort to balance all elements in this situation which seek to allow your expertise to be engaged while creating a situation which optimizes the procedures by which patients will be protected, oversight will be feasible and effective, and the principles of the MDACC policies are applied which make waivers an unusual event."

Describing the waivers to the MD Anderson staff, DePinho wrote:

"Limited waivers have been approved for three companies—AVEO, Karyopharm and Metamark—and my holdings in those companies will be put into blind trusts, so that I will have no knowledge of the status of my holdings and no right to intervene in their handling. For other companies, I have divested or will divest my interests in a timely manner so that no waiver is required or granted.

"Dr. Shine's waiver decision has been provided to our conflict-of-interest committee, which will formulate specific management and monitoring plans for overseeing any research at MD Anderson involving products of these companies. The UT System conflicts committee will evaluate and finalize those plans along with Dr. Shine. Of course, our institutional review board also will have every opportunity to review any research involving an IRB protocol, which will provide an additional safeguard to protect patients and ensure research integrity."

The three companies covered by the waiver also figure in the June 15, 2011, letter, in which Shine offers DePinho the top job at MD Anderson. The letter, obtained by The Cancer Letter under Texas open records law, reads:

"You have provided a schedule for resigning from a number of companies with which you are associated. Your knowledge and experience with technology transfer and commercialization is valuable in your role as President.

"You will continue with positions at Karyopharm and Metamark, which will involve no cash compensation, and will be limited to founder shares. You will continue on the Board of Directors of AVEO, from which you are likely to resign once FDA decision is rendered on the approval of its first Phase III drug.

"Any cash you receive for this service will be donated to the MD Anderson Cancer Center graduate programs. Identification of your role with any of these companies will be part of any consent forms signed by a patient enrolled in clinical trials at MD Anderson Cancer Center involving drugs or biological produced by them.

"Your activities in these areas will be monitored by the MD Anderson Cancer Center Conflict of Interest Committee in the course of its usual responsibilities. Any concerns of that committee will be brought to the attention of the Executive Vice Chancellor for Health Affairs."

The waiver appears to at least partially exempt DePinho and Chin from the provisions of a policy that grew out of the business involvement of MD Anderson's former president in ImClone Inc., a company that was developing his drug Erbitux (cetuximab).

Argument Over "Transparency"

Experts in ethics who reviewed the decision to grant DePinho's waiver request said the UT System and MD Anderson haven't yet placed much information on the table.

DePinho's waiver request hasn't been released.

The authenticity of the version that was leaked to the Chronicle is being disputed by MD Anderson officials. The Chronicle story is posted at http://bit.ly/Rim2GM.

Similarly, the UT System didn't release any materials from the advisory group of chairs of conflict of interest committees of all six UT System campuses. The system obtained a ruling of the state Attorney General

to keep these materials shielded from requirements of the state's open records law.

The recommendations of that committee are unknown. "Their recommendations were extremely valuable to me in reaching my decisions," Shine wrote to DePinho. "But the final decisions rest with me."

The decisions were routed to the MD Anderson COI committee, which will formulate the management and monitoring plans for overseeing any research at MD Anderson involving products of these companies.

The UT System conflicts committee will evaluate and finalize those plans, DePinho wrote in a memo to the staff. "Of course, our institutional review board also will have every opportunity to review any research involving an IRB protocol, which will provide an additional safeguard to protect patients and ensure research integrity," DePinho wrote.

The Risk of "Undermining the Trust"

"In trying to allow its new CEO to retain some of the corporate ties he created in his prior position the administration of the University of Texas System is walking a narrow and sharp ethical edge," said Arthur Caplan, director of the Division of Medical Ethics in the Department of Population Health at NYU Langone Medical Center.

"Allowing lucrative ties to exist at the highest levels risks undermining the trust of the faculty and staff in the neutrality of the key institutional decision-maker and potentially the faith subjects bring to the cancer center's clinical trials that what is recommended to them is not driven by commercial interest.

"As pressure builds to link financially stressed, research focused academic institutions to companies large and small, trustees, chancellors, presidents and government agencies need to bring 20th century thinking about how to handle conflicts of interest into the 21st century world, where large monetary returns and the entrepreneurship that creates them collides with the credibility institutions need in order to merit tax payer support and public trust."

Eric Campbell an associate professor of Medicine at Harvard Medical School and a researcher at the Mongan Institute for Health Policy, said publicly available information is insufficiently detailed to make it possible to evaluate Shine's decision.

"Without information, it's hard to know whether this will be effective," Campbell said. "It does come down to the University of Texas is acting the people of Texas and the people of America to trust that they will manage this effectively, which I don't think is unreasonable. We do this all the time with institutional oversight of financial relationships."

Campbell said he couldn't understand why the waiver was necessary.

"The key unanswered question is why these companies need to interact with MD Anderson," he said. "Why can't they find similar resources at other major cancer centers?"

DePinho accepted Shine's decision.

"A scientist's dream is to work on something that ultimately benefits patients," he wrote in a dispatch to the staff. "I have deep respect for all of our scientists and clinicians working to attain this goal. I also recognize how important it is to manage conflicts of interest or perceptions of such. Dr. Shine's decision further confirms MD Anderson's focus on protecting our patients first and making great strides in accomplishing our mission to eliminate cancer."

The text of Shine's letter to DePinho follows:

Dear Ron,

Enclosed are my decisions in responses to your letter of April 20, 2012 requesting waivers from some policies at the MDACC. Though the word "waiver" is embedded in the MDACC policy statement these are really exceptions to policy which are permitted under exceptional circumstances from the overall policies of the institution. Such waivers are permitted under those policies.

My decisions were based on a number of considerations. Under no circumstances, would any waivers or exceptions to policy be granted which in any way compromised the safety of patients, the integrity of the clinical trials or research process, the transparency of the relationships you have, or the roles which you play. I know that you share my views in this regard.

As you know I appointed a UT System level Committee to consider your requests. The committee consisted of the Chairs of the Conflict of Interest committee at all six campuses with the understanding that the Chair at the relevant campus i.e. MDACC would provide information to the Committee but did not participate in its deliberations or influence the committee's final recommendations to me. Their recommendations were extremely valuable to me in reaching my decisions. But the final decisions rest with me.

While the results of this process will be public and you and Dr. Chin must operate transparently pursuant to my decisions, it is important to ensure the integrity of the committee and committees like it in the future and

therefore protect the confidentiality of the committee's deliberations and the information considered by the committee.

Accordingly, as you are aware we have successfully argued before the Texas Attorney General that all such information is exempted from public disclosure. Barry Burgdorf and I have reminded the committee of these obligations of confidentiality and ask that you continue to be cognizant of them also.

Among the major issues which I considered was your unique history and experience in developing new agents to help patients and to create companies and procedures which would bring research results to the bedside. This is reflected in the large number of startup companies with which you have been associated as well as the other companies with whom you have worked.

The Regents of the University of Texas believe that this experience is valuable to MDACC and to the University of Texas System. It was reflected in the employment offer letter which I sent to you, in which three of these companies were specifically identified.

Maintaining some relationship with this expertise and these companies, is in my opinion warranted, provided it is combined with scrupulous attention to the issues of transparency, safety and integrity to which I have referred.

At the same time not allowing patients at MDACC to have the benefit of clinical trials involving drugs or other agents from these companies, which trials might benefit patients, would not be in the patient's best interests so long as adequate safeguards are in place.

At the same time I have concluded that allowing a waiver for a particular relationship must be a very limited event, particularly in view of the need for scrupulous oversight of each trial for which a waiver has been granted and in view of the principle that a waiver is granted only in exceptional circumstances.

I detailed a summary of my decisions which are contained in the enclosed documents including the specific conditions for each set of activities.

These do include decisions in regard to your wife, Dr. Lynda Chin, in so much as MDACC conflict of interest policies must apply to your immediate family. I recognize that these decisions will entail a significant financial impact on you and your wife. However this represents a very carefully considered effort to balance all of the elements in this situation which seek to allow your expertise to be engaged while creating a situation which optimizes the procedures by which patients will be protected, oversight will be feasible and effective, and the principles of the MDACC policies are applied which make waivers an unusual event.

Yours truly,

Kenneth I. Shine, M.D.

The text of the Texas government officials' letter to CPRIT follows:

Chairman Mansour and Members of the Board:

In 2007, Texas voters approved a state constitutional amendment to establish the Cancer Prevention and Research Institute of Texas and authorize issuing $3 billion in bonds to fund cancer research and prevention programs and services in Texas.

CPRIT laid a solid foundation for this endeavor, by focusing its efforts and funding predominantly on basic scientific research.

It is now time for CPRIT to take further steps to fulfill its statutory mission and expedite innovation that will deliver new cancer treatments to patients within three to five years. The legislature established CPRIT to create and expedite innovation in the area of cancer research, to promote breakthroughs in the prevention and cure of cancer, to promote high quality new jobs in this most important field, and to implement the Texas Cancer Plan. CPRIT offers a once in a generation opportunity to improve the lives of Texans, while building our biotechnology industry that grows our economy and provides new careers for Texans.

Like you, we are interested in receiving and reviewing the results of CPRIT's six-month "Future Directions" efforts around the state seeking public input for the next phase of CPRIT' s research, prevention and commercialization programs. This is a good time to evaluate what CPRIT has accomplished, how it operates and how CPRIT can have the greatest impact on cancer in Texas over the next seven years.

We believe it is important that you evaluate and reconsider CPRIT's organizational structure, and decide on structural changes that would strengthen CPRIT and increase its ability to fulfill its missions. We encourage that those recommendations be considered as you continue your selection of a new chief scientific officer, so that the nature and responsibilities of that important position will be determined and clear both to CPRIT and to the potential candidates.

We look forward to working with you to continue this important work.

Sincerely,

Rick Perry, Governor
David Dewhurst, Lieutenant Governor
Joe Straus, Speaker of the House

Conversation with The Cancer Letter

Some Terms of UT COI Waiver "Disadvantageous" To DePinho

(Continued from page 1)

"So, it's a holistic process, which had to take into consideration a variety of factors, not the least of which is that the System and the Regents believe that the opportunity to take drugs or other biologics to the bedside to help patients is an important goal of the System, including MD Anderson," Shine said to The Cancer Letter.

"Though we are not particularly interested in the financial returns that are associated with that kind of technology transfer, we are interested in the impact on health of getting products to patients," he said.

DePinho sought a broader waiver, which would cover up to 12 entities. He was allowed to remain in his roles at AVEO Pharmaceuticals Inc., Karyopharm Inc., and Metamark Genetics Inc.

During the conversation with The Cancer Letter, Shine, who is the ultimate author of the waiver, was accompanied by Barry Burgdorf, the UT System vice chancellor and general counsel.

The Q&A was conducted by Paul Goldberg, editor of The Cancer Letter.

Paul Goldberg: *How does this limited waiver differ from the offer letters that Dr. Shine wrote to Drs. DePinho and Chin?*

Kenneth Shine: There is fundamentally no difference. That is, the approach is consistent. When we were negotiating with Dr. DePinho to accept the presidency, he indicated that he was very committed to these three projects.

They were specifically mentioned in the offer letter, but it was also indicated in the offer letter that the conflict of interest policies at the institution would have to apply in terms of those relationships—and that's exactly what's happened.

PG: *So why was the waiver request necessary if this was in the offer letter? Maybe I am not understanding something.*

KS: The UT MD Anderson Cancer Center has a process for dealing with conflicts of interest. Our intent from the very beginning, including the intention in that letter, was that we would go through the processes of that conflict of interest policy, just as we would for any other faculty, or in this case, for a president.

Originally, I had anticipated that the process would be carried our internally, that is by the conflict of interest committee at MD Anderson. That was the intent of the original communication.

However, it became increasingly clear that it would be desirable for that conflict of interest committee to be evaluated by a group outside of MD Anderson, and we do have a System conflict of interest committee that is made up of the chairs of the conflict of interest committees on the various campuses.

So I requested that Dr. DePinho go forward with his request, just as they would as part of the usual conflict of interest approach, but that these would be reviewed by the system conflict of interest committee, which would receive some additional information from the conflict of interest committee at MD Anderson, but then the representatives from MD Anderson would not participate in the deliberations nor in the recommendations.

This was to assure that the requests were evaluated by as objective and arms-length a process as we could carry out.

PG: *What prompted you to decide that this process was necessary? As opposed to the standard process?*

KS: It was basically prompted by the notion that it would be desirable.

This process is in place not only to deal with DePinho, but to deal with any situation in which a principal decision-maker was in an institution, and where we wanted to be certain that conflict of interest people at that institution did not feel any undue pressure or concern based on the fact that request was coming from, in this case, the president.

We would do the same thing for a president elsewhere, but we might also do it for a vice president for research. There are a variety of individuals where it would be advantageous to have the process separated from the institution, and in this case, since this is a president and since I have a responsibility to oversee any of the relationships which involve him and research resources that might be applied to his own activities, the logical process was to have that committee established in the system and to have that committee make its recommendations to me.

PG: *Does Dr. Chin have to step down from any of the boards of directors?*

KS: The process of evaluating the conflict of interest of either a president or a faculty member is that one has to look at all of the potential conflicts involving not only them, but their spouses or their children, particularly if those children are still at home, or by other close relatives.

So in the process of evaluating Dr. DePinho's requests, we also had to review Dr. Chin's status. And

the short answer to your question is yes.

Not only does she have to step down in a timely manner from boards, but also it's understood that both she and Dr. DePinho cannot receive cash or stock or other material as a consequence of any consultation that they may give to an outside company.

So in this particular case, Dr. Chin has been close to a couple of companies. She can continue to provide scientific input, but she cannot receive any compensation for doing that.

In the case of Dr. DePinho, he can continue under this arrangement to serve on the board of AVEO, but any money he receives from that goes to the graduate programs at MD Anderson. Which was again a stipulation that I made in the offer letter.

PG: *Correct me if I'm wrong: you were guided completely by the terms of the offer letters when you were deciding on these, and as I read Dr. Chin's offer letters some time ago I don't remember seeing anything allowing her to be on any of the boards of directors. Were you were guided by the letters?*

KS: No. I was guided by the process, which we undertook to look at Dr. DePinho's request for waivers.

It was clear that the three companies—one public, two private—that we had discussed in the offer letter had to be part of the consideration here.

But there were other elements that we were not, including the recommendation and the conclusion that for example stocks should be put into a blind trust, and a number of other details. So, it's a holistic process, which had to take into consideration a variety of factors, not the least of which is that the System and the Regents believe that the opportunity to take drugs or other biologics to the bedside to help patients is an important goal of the system, including MD Anderson.

Though we are not particularly interested in the financial returns that are associated with that kind of technology transfer, we are interested in the impact on health of getting products to patients. And for that reason we indicated in our offer letter that we were going to look very closely at these relationships to these companies.

Keep in mind, of course, that, in the interests of full disclosure and in the interests of not leaving any stone unturned, [DePinho] made requests for a large number of companies, some of which he had relationships with, some of which he had potential relationships, some of which were past relationships and in the process, we concluded that he would in fact have to divest from certain companies.

That in many other cases we were not going to grant waivers, and that this was all part of a process to be as transparent as possible, to be as fair as possible, both to DePinho, and, most importantly, to make sure that patients at MD Anderson on the one hand have the opportunity to have access to the new and important medicines and biologics, but on the other hand be adequately protected.

The protections that are associated with a wavier are very explicit, and there are a whole variety of issues that were a part of this process, but obviously were not included in my letter.

They include, among other things, applying policies, such that for example his involvement with the company has to be part of the consent form associated with any patient that goes into a clinical trial of a drug that is made by one of these companies.

It includes the requirement that—although there has to be someone at MD Anderson implementing the trial—the principal investigator for the overall trial cannot be at MD Anderson and must be at another institution.

These must be multi-institutional trials.

There are a number of other conditions that are associated with these relationships, and you have to take all of that into consideration when someone tries to come up with an appropriate policy.

PG: *I don't see anything that's really outside the framework of the offer letter, and I did not see anything mentioned in Dr. Chin's offer letter that suggests she can stay on the boards of various companies.*

Barry Burgdorf: Underneath the MD Anderson conflict of interest policy, Dr. Chin is considered to be a part of Dr. DePinho. Her conflicts or potential conflicts are his potential conflicts or conflicts.

PG: *So that's why she had to step down from the boards?*

BB: The definition of it includes the president and his spouse and his dependent children.

PG: *I notice in the cover letter that you released, you state that Dr. DePinho that there would be a "significant financial impact" of these decisions on Drs. DePinho and Chin. In the context of the letter, this suggests that they didn't really get everything they asked for, and that some losses would have to be incurred. Is this correct?*

KS: The inference that you're drawing is correct.

PG: *Can you tell me more?*

BB: The deliberative process of the committee is protected under the Texas Public Information Act.

The rationale and the theory there is that you want a committee like this to make candid, honest, all-encompassing decisions and allow them to have those

deliberations confidentially.

So we have, in accordance with state law, protected the deliberations and recommendations of the committee. We have, in an effort to be transparent, released Dr. Shine's findings and determinations, and of course Dr. DePinho's responses to those are public, and his actions that are required by those will be public, and all of the actions that are required to be taken with regard to informed consent of patients will be public and transparent. But the actual recommendations that the committee made are protected for the reasons that I stated, as recognized under state law.

KS: I would like to make a couple of points. First, I didn't release any letter. This material that was released was released by MD Anderson, and it was their decision to release that material. That was their choice.

Secondly, I indicated to you before that there were requests for a substantial number of waivers.

I indicated to you that in three cases—and this is in the public domain—that, consistent with proper oversight monitoring, that we were prepared to provide three exceptions to policy based on the MD Anderson waiver policy.

I also indicated to you that in some cases, Dr. DePinho and his wife have to divest themselves of stock and consultation fees and other benefits, which, in fact, have great financial value. In other cases, no waiver was granted and there were no financial implications.

But I'm not going to go into detail as to what companies were there for a whole variety of reasons.

PG: *Some redundancy is helpful. This is complicated enough. I just want to make sure that I get it absolutely right. Would you have any objection to having MD Anderson releasing the actual decisions? Because all that was released was the cover letter.*

BB: Just so we are all on the same page here, tell me what you've got and what you're considering the cover letter.

PG: *I got the letter of Oct. 10. I do not have the actual decisions. Is there more, or is this the whole letter?*

BB: And so, as the actual decisions, those are in another two-page letter, which obviously goes into a little more detail than the cover letter.

And we have no objection to releasing that. To be consistent with past practices and our dealings with the press on other similar matters, we've always just said make an open records request and we'll make that available to you so we're not being seen as favoring one press person over another. [The Cancer Letter filed a request for the document.]

PG: *Now, the trust. Will it be a double-blind trust, and would the trustees be able to buy or sell stock?*

BB: The trust would be, I guess the term would be a single-blind trust, there's no requirement in Dr. Shine's decision that it be a double-blind trust.

As the particulars of this blind trust, the onus is on Dr. DePinho and his attorney to draft that, and we have to review it and approve it. We will do so.

It is not contemplated that it would require any need to include buy decisions. What you would do is contribute the assets in question into this blind trust, and then the trustee would have the power and the discretion to sell those assets completely divorced from any communication with Dr. DePinho or Dr. Chin.

KS: But it is clear that we have stipulated that the trustees of these blind trusts may not add to the trust.

PG: *So they cannot buy?*

KS: They cannot buy.

PG: *And the fact that the trust exists is open. Everybody knows about this now. I guess what this means is that researchers at MD Anderson who may be working with the companies in question, will know that their findings could affect the value of the holdings of the president of MD Anderson. Is this a concern?*

KS: We anticipate that it will be widely known among the faculty that Dr. DePinho has an interest from that point of view.

At the same time, the process by which the faculty carries out its work, including doing any clinical trials, has to be done in such a way that it is completely insulated from Dr. DePinho, that he have no influence on that, and I have confidence in the faculty and their integrity that I believe that they will do what they think is the best thing for patients, and I don't think that they are going to be unduly influenced by the fact that there is this one activity.

I would emphasize that MD Anderson does more in clinical trials than any other cancer center in the country. It enrolls more patients.

This is a relatively small activity, compared the overall activity that faculty are engaged in at any given time. And our fundamental interest is in finding ways to bring scientific products to patients, and we want to create an environment in which that indeed can happen.

We know that many of our faculty and scientists are involved in startups. In fact I'm often required to sign off on the conflict of interest provisions which are developed at a campus in order to allow individuals to do startups, so there are many, many faculty members who are, in fact, engaged in these activities, and their

colleagues don't necessarily behave differently because of those kinds of startups.

We believe that DePinho's insights, plus the potential for the Institute of Applied Cancer Biology offers some unique contributions to cancer care.

And that's our goal—to improve care.

I want to reemphasize the point that I made to you earlier, that MD Anderson cannot be the sole site for a trial, it has to be a multi-center trial, it also has to be a trial in which the principal investigator for the overall trial is not located at MD Anderson, so that the overall conduct of these trials is handled by somebody at a distance site.

BB: Those are important checks and balances on anybody's proclivity to try and do anything that favors DePinho.

PG: *The word "transparency" has been used quite a bit in this context, and this is sort of whining on my part perhaps, but the waiver request itself is not public. The recommendation of the group that advised you isn't available, with legal justification, of course, the terms of the management plan may or may not be available publically. So how would you propose to ensure that this is transparent and that the patients and the staff and others in the press would be able to keep track of how this is going on?*

KS: Let me answer this in two ways.

First of all, the transparency began in the summer of 2011, when I introduced DePinho to the community as the sole finalist for the presidency at MD Anderson.

And when I introduced him, I indicated that he has, in fact, extensive experience in commercialization, in companies, and that he was going to continue to be involved with AVEO, a public company.

And we anticipated that he was likely to be involved in one or two others. So from the very beginning, we made these relationships public.

Interestingly enough, this was during the 21-day period when we named the sole finalist and we finally appointed, we received not a single inquiry, or statement of concern, or whatever.

Secondly, the way the process works is that I have communicated to the conflict of interest committee at MD Anderson my decisions, and that includes recommendations as to how and what way one would protect patients.

The conflict of interest committee will then develop a monitoring plan for how and in what way that would be monitored. And they have to do that within 60 days. That plan has to come back to me, and I will be reviewing that plan with the System-wide conflict of interest committee, and if they approve it, that plan will be public.

They'll have access to that plan. We are not going to publish it in the newspaper.

PG: *But if I ask you for it, you would give it to me?*

KS: This is the plan with regard to how one is going to assure that the processes involving the patients are monitored in a manner that's entirely consistent with what our obligations are.

We do not intend to make public proprietary information about companies, ownership details and so forth at that time.

But the monitoring plan by which this is implemented, and again, and I have to defer to my—I keep wanting to call him Dr. Burgdorf here because of his J.D.—my lawyer sitting here, he can take exception to this, but my intent was that once we had a plan in place which included all of the provisions that I'm telling you about some of which I've been explicit about, that that would be public.

BB: The only things we are protecting, again, are the deliberations and the work of the committee for the policy reasons that I stated earlier.

But absent that, and honoring that important policy that we think is important to the operation of these committees going forward from now until the end of time, everything else will be transparent.

PG: *But the waiver request is not going to be out either, right?*

BB: Right, because that's part of that deliberative process. Knowing what they are considering now and how they considered it and how they had an honest and candid banter back and forth about the issues coming up with the recommendations, all that falls under that umbrella.

PG: *Is there anything we've overlooked? Anything you'd like to add?*

KS: I guess I would make two points: one is that I think in my conversations with Dr. DePinho, and his behavior ever since, he has made it very clear that he was going to be completely forthcoming with regard to all of his relationships, that he was going to follow the policies at MD Anderson with regard of how to deal with them, and in fact that's what we've done.

And I think that, to his credit, having made a whole series of decisions, some of which will in fact be economically disadvantageous, that he has accepted those, as has Dr. Chin, for the reasons I've mentioned before.

Secondly, I would want to emphasize that the

process for requesting what is really an exception to policy or a waiver is implicit in the conflict of interest policies at MD Anderson.

What he did was not an unusual event in the sense that any faculty member who wants to do something that might be otherwise proscribed can apply for a waiver.

The word waiver is a term that many people dislike.

Even my own committee has said to me that really it's an exception to policy. But, in any case, my feeling is that Dr. DePinho has been willing to participate in this process, which has been lengthy.

And, I have to tell you, it took an enormous amount of time and effort. The due diligence here is extraordinary in terms of getting all the information you need, and I'm very comfortable that we've come out with something which satisfies our desire to protect patients and the integrity of the research process, but also will allow us to have somebody on board who really understands new drugs and biologics are developed.

And that's my parting comment.

Komen Under Pressure

Dioceses Urge Parishoners To Forgo Komen Events

(Continued from page 1)

The world's leading breast cancer advocacy group's recent 3-Day Walk saw diminished turnouts and a 46 percent donation plunge in the nation's capital this past weekend. The event is Komen's second largest fundraiser, trailing the Global Race for the Cure in Washington, D.C.

Altogether, 1,600 walked in D.C. compared to 2,500 last year. Event donations did not fare any better, falling from $7 million in 2011 to $3.8 million this year, Komen officials said.

The organization's PR agency for the event, Crossroads, declined to discuss the numbers and refused to provide further information on Komen's fundraising efforts. Local affiliates across the country are also keeping a tight lip, redirecting all media requests to Crossroads on the issue.

Earlier this year, Komen triggered a public relations disaster when, in an apparent bow to anti-abortion groups, the charity announced a plan to stop allocating grants to Planned Parenthood, which provoked a public relations disaster (The Cancer Letter, Feb. 3).

Critics, as well as current and former Komen officials, said that Catholic groups and abortion opponents had a strong hand in influencing the organization's decision to halt funding (see story on p. 13).

Komen quickly reversed itself, but the about-face brought down the wrath of the very anti-abortion groups it had initially attempted to appease. Now, Komen's detractors include prominent Catholic leaders, who have opposed the charity's links with Planned Parenthood from as early as 2005.

The archdiocese of Atlanta marked Breast Cancer Awareness Month by issuing a memo instructing Roman Catholic organizations and churches in the region to end support for Komen because of what it described as the charity's "direct cooperation with evil."

News reports in major U.S. cities reflect a continuing downturn in Komen's fundraising.

Participation fell from 1,700 in 2011 to 1,000 this year for the same event in Boston, with donations plummeting from $4.8 million to $3.2 million—a 33 percent falloff, said a Chicago Tribune report. Cleveland had 300 fewer participants and raised $600,000 less than in 2011.

The Tribune reported that Komen would not reveal signup totals for the Chicago walk, but acknowledged that two controversial decisions about Komen's support for Planned Parenthood have "driven away some long-time donors and walkers."

Nancy Brinker, the former Republican political appointee who had founded Komen after her sister died of breast cancer, ultimately reversed the foundation's decision, making Planned Parenthood again eligible for grants used to provide education and breast cancer screenings for up to 170,000 women over the years.

The move galvanized both sides of the debate, resulting in an almost immediate downturn in participation and donations at Komen's Global Race for the Cure.

Only 27,000 runners showed up, instead of the usual 40,000, for the race on the National Mall in June. Elsewhere, affiliates saw a $700,000 drop in Seattle, while the race in Hartford, Conn., took a $200,000 hit (The Cancer Letter, June 8).

During the race in D.C., Brinker declared that the foundation is "pro-cure," as opposed to pro-life or pro-choice. "We've extricated ourselves," Brinker said to The Cancer Letter, then corrected herself: "We've never been involved in that issue, and never will."

Detractors disagree, citing Komen's continued financial support for Planned Parenthood as proof that the organization is pro-choice.

The Atlanta archdiocese made the announcement in anticipation of Komen's "Worship in Pink Weekend" fundraiser in Atlanta, which took place Oct. 19-21.

"It would be a scandal for the parishes and schools of the archdiocese of Atlanta to support Komen because they grant funds to Planned Parenthood," archdiocese spokesperson Pat Chivers told The Cancer Letter. "We cannot in any way support an organization that supports destroying human life."

The Komen-Catholic conflict began in 2005 when the diocese of South Carolina refused to participate in a local fundraiser.

Over the next four years, Baltimore, St. Louis and individual dioceses in at least eight states publicly stated their opposition to Komen or discouraged constituents from contributing to the advocacy group, according to Chivers.

The controversy, however, reached new heights when Ohio bishops created a joint resolution in 2011 to direct "Catholic parishes and schools away from fundraising for Komen for the Cure and toward activities and organizations that are fully consistent with Catholic moral teaching."

The North Dakota Catholic Conference soon joined Ohio's crusade, nearly doubling the number of dioceses unfriendly to Komen.

"Had they ceased to fund Planned Parenthood, we would've been happy to continue our support for Komen," Chivers said. "Komen could do their work without cooperating with Planned Parenthood because other organizations offer breast screening programs."

Atlanta parishes will be participating in their own breast cancer awareness activities instead of joining Komen's weekend, Chivers said. Proceeds will go to pro-life organizations such as the Coalition on Abortion/Breast Cancer and the Breast Cancer Prevention Institute, groups claiming that abortion causes an increased risk for breast cancer.

"We feel a responsibility to share with women that there is a risk," Chivers said. "Komen and Planned Parenthood won't share that information because they have a vested interest."

There is no medical evidence supporting the link, experts say (The Cancer Letter, March 7, 2003).

"Considering the body of literature that has been published since 2003, when NCI held [an] extensive workshop on early reproductive events and cancer, the evidence overall still does not support early termination of pregnancy as a cause of breast cancer," according to an NCI factsheet.

Chivers said that studies showing an increased risk do exist and that the archdiocese doesn't "accept one organization's (NCI's) response on that."

Other Catholic leaders question NCI's impartiality on the issue.

"We think the NCI has allowed itself to become involved in political controversies and this has diminished its credibility," said Edward Furton, director of publications at the National Catholic Bioethics Center, an agency that provides ethical consultation on life science and medical issues based on Catholic moral teachings.

"The research that was made available, we believe, was not treated in a balanced manner," Furton said.

NCI has reviewed research from the 1950s and concluded that studies suggesting an increased risk had flawed research methodologies. Since then, better-designed studies have been conducted, and the newer studies "consistently showed no association between induced and spontaneous abortions and breast cancer risk."

On the issue of Catholic organizations receiving funding from Komen, Furton said it is not morally inconsistent for the Church to accept donations from an organization it refuses to support.

Catholic institutions have received substantial funds from Komen. For example, Georgetown University Lombardi Cancer Center was awarded $1 million a year for the past five years in Komen grants. Planned Parenthood received $684,000 in Komen funds last year.

"[Komen] gives money from one column to morally upright organizations and the other to those who support abortion," Furton said. "How does that implicate Catholic organizations in any way? If Komen wants to cease giving money to Catholic institutions, they're free to do so. We will continue to discourage Catholic dioceses from supporting Komen as long as they support Planned Parenthood."

Former Official Gives Inside Account of Komen PR Fiasco

By Conor Hale

For an author, a political autobiography is a means to reopen and settle old scores. For a reader, it's an opportunity to get a fresh look at events that were once hidden from public view.

Karen Handel, a former conservative politician who, for a brief time, was a senior vice president at Susan G. Komen for the Cure, had a good view of the public relations disaster between Komen and Planned Parenthood. Her work precipitated the debacle.

Handel's insider memoir, Planned Bullyhood, isn't particularly insidery, but it does contain a few revealing tidbits strewn throughout a quintessentially biased narrative of endless finger-pointing.

Handel's story depicts a one-sided war; a sneak attack intended to make breast cancer more political than it already is, while she and her colleagues resisted. She paints Komen as the victim of schoolyard bullies, mean-girls-once-thought-friends, and leftist radicals—and herself as a reluctant soldier. Handel blames Planned Parenthood and the Democratic Party for Komen's woes.

However, Handel also provides glimmers of an account of Nancy Brinker's inability to separate from the organization she founded. Brinker, Komen's CEO at the time, is a "dynamic, inspirational leader" who could also be very vulnerable to criticism, "especially in the press," Handel writes. Whether Handel realizes it or not, this story is a tragedy.

Set in the months surrounding Komen's decision to halt grants to Planned Parenthood for breast cancer screening, the book is littered with Handel claiming that she didn't know where all the anger was coming from; that she didn't understand why Komen was being attacked at all for its decision—and that she "should've anticipated the fury of the liberals."

"It was a battle of wills," Handel writes. "And Komen lost."

Handel says she turned into an accidental soldier after Planned Parenthood—aka "[President] Obama's consigliere and the DNC's enforcer," as she describes it—decided to bully Komen into submission. She was forced into "the eye of the storm."

After the storm passed, Brinker would step down as CEO, and Komen's president, Elizabeth Thompson, would resign, along with two other board members. In fiscal 2011, before troubles began, Komen was raising about $471.8 million. Today, the group's post-fiasco financial data aren't publicly known, but participation in some Komen events has been down by as much as 40 percent.

Would Komen survive if Brinker truly separates from its operations? Currently, a similar situation is occurring at another Texas-based non-profit: the Lance Armstrong Foundation. Will Livestrong live without Lance?

In Handel's view, Komen made a reasonable, professional decision to phase out future grants to Planned Parenthood—with that decision being made through her, Brinker, Thompson and others—in an effort to take Komen to some sort of neutral ground in the abortion issue, and instead focus on curing breast cancer.

Planned Bullyhood
by Karen Handel
Howard Books
304 pages; $24.99

But Komen had given millions to Planned Parenthood over nearly two decades—counting them as sisters among non-profits dedicated to women's health—and decided only to stop during a countrywide debate over where money should go and why.

When Handel was brought on board, Komen was taking heat from its donors about its modest grants to Planned Parenthood, an organization that had been the subject of undercover sting videos, political acrimony, and state and congressional investigations for months.

Several of Komen's partners, race captains and participants did not want to donate to a charity that donated to an abortion provider, and they had made it known publically. Originally, the financial stakes in this fight were relatively low: Komen had given Planned Parenthood $600,000 in 2010 and $700,000 in 2011, according to Handel.

In the second half of 2011, Komen was faced with losing donor support. The fighting surrounding Planned Parenthood, abortion and its funding began to threaten the Komen brand.

A Catholic bishop in Toledo, Ohio, made a statement saying he and other bishops would "find alternatives to Komen for Catholic fundraising efforts…to avoid even the possibility of cooperation in morally unacceptable activities." Two Catholic schools unregistered from participating in Komen races in as many days. The races lost sponsorships from local banks and grocery store chains.

Senator Marco Rubio (R-Fla.) withdrew from serving as honorary chairman of Komen's Perfect Pink Party in Palm Beach, Florida—Brinker's hometown.

"[She] did not seem to take it well at all," writes Handel. Meanwhile, affiliates were losing tens of thousands of dollars in donations. Indeed, some U.S. Catholic dioceses are following through on their warnings, with several diocese urging parishioners to stay away from Komen's pink events.

In September 2011, a documentary debuting in Canada—Pink Ribbons, Inc.—criticized Komen's pinkwashing and marketing practices. In December, the publishing division of the Southern Baptist Convention halted the production of bright-pink, Komen-branded Bibles, and recalled them.

"Nancy now wanted to move, and fast," writes Handel. "Komen was trying to keep a lot of balls in the air—financial concerns, organizational changes, global expansion—while also managing the fallout from various other public relations issues. Something had to give—and that something was Planned Parenthood."

In television interviews following the publication of her book, Handel has said that Komen's decision to phase out funding to Planned Parenthood had nothing to do with politics. She echoes the points made by Brinker months earlier in a television interview with NBC's Andrea Mitchell during the peak of the controversy.

A "murder board" role-play meeting was arranged to prepare Brinker hours before her interview. The board consisted of public relations experts and former journalists, former political appointees, consultants, and Komen board members, each grilling her with questions.

Why was Planned Parenthood no longer eligible to receive Komen grants? Komen's scripted answer detailed the new funding criteria—and that Planned Parenthood was an agency under investigation.

That answer "was technically correct, but also somewhat incomplete," Handel writes. "The response did not address our broader concerns about the impact of Planned Parenthood's controversies on our organization and how these issues were indeed a part of our decision."

Handel describes the session as "complete pandemonium," that led to Brinker heading into her interview "dazed and unsure."

When asked about Brinker's choice to hire Handel in a key policy role, she explained that Handel did not have any part in the decision to defund Planned Parenthood.

"This was not true," writes Handel—qualifying her concern not around her contributions to policy decisions, but the possibility that liberal "blogs would immediately jump on Nancy's statement as a 'lie.'"

The decision to defund Planned Parenthood was received as intensely political. Seventy-two hours later, Komen reversed course.

Handel describes how Brinker came to her, saying that even conservative guru Karl Rove urged Komen to walk back its position and reinstate the grants. Rove has described the account as "not accurate."

"We didn't even put up a fight," Handel writes. "I should have factored in Nancy's susceptibility to public opinion and pushed harder for a more aggressive posture."

There are other problems with Planned Parenthood's breast cancer screening programs, outside of the spheres of media relations and public perception; there are possible implications for public health.

Nearly all the women served by Planned Parenthood are in their twenties and thirties, and the breast health claims they see on the Planned Parenthood website go far beyond the evidence-based recommendations for cancer screening from the U.S. Preventive Services Task Force (The Cancer Letter, Feb. 10). Planned Parenthood's clinical guidelines for these younger populations appear to have been compiled cafeteria-style, and combine elements of guidelines used by other organizations and professional societies.

Brinker recently stepped down as a Komen's CEO, but remains on the board, and so far the search for a new CEO has produced no takers. Meanwhile, Planned Parenthood has benefited from a boost in public support. In August, the organization announced an expansion of its breast health programs.

Handel announced her resignation from Komen three days after the decision to reverse course.

Obituary

Thomas, Nobel Laureate Who "Wrote The Book" On Bone Marrow Transplantation, 92

E. Donnall Thomas, who won the 1990 Nobel Prize in physiology or medicine for his pioneering work in bone-marrow transplantation to cure leukemias and other blood cancers, died Oct. 20. He was 92.

Thomas joined the faculty of Fred Hutchinson Cancer Research Center in 1974 as its first director of medical oncology. He later became associate director and eventually director of the center's Clinical Research Division. He stepped down from that position in 1990 and officially retired from the center in 2002.

Thomas, along with his wife and research partner, Dottie, a trained medical technologist, and a small team of fellow researchers pursued transplantation throughout the 1960s and 1970s.

"To the world, Don Thomas will forever be known as the father of bone marrow transplantation, but to his colleagues at Fred Hutch he will be remembered as a friend, colleague, mentor and pioneer," said Larry Corey, president and director of Fred Hutchinson Cancer Research Center.

"The work Don Thomas did to establish marrow transplantation as a successful treatment for leukemia and other otherwise fatal diseases of the blood is responsible for saving the lives of hundreds of thousands of people around the globe."

His work is among the greatest success stories in cancer treatment. Bone marrow transplantation and its sister therapy, blood stem cell transplantation, have had worldwide impact, boosting survival rates from nearly zero to up to 90 percent for some blood cancers. This year, approximately 60,000 transplants will be performed worldwide.

Thomas edited the first two editions of the seminal bone marrow transplantation reference book, "Hematopoietic Cell Transplantation," in 1994 and 1999. He also contributed a chapter to the third edition, published in 2004, at which time the book's title was changed to "Thomas' Hematopoietic Cell Transplantation."

"Don quite literally wrote the book on marrow transplantation," said Fred Appelbaum, director of the Hutchinson Center's Clinical Research Division, a friend of Thomas' and an editor of the book. "Don was a hero. He was, by far, the most influential person in my career, and I know that many others would say the same thing."

Thomas was a member of 15 medical societies, including the National Academy of Sciences. He also received more than 35 major honors and awards, including the Gairdner Foundation International Award and the Presidential Medal of Science.

He was past president of the American Society of Hematology and served on the editorial boards of eight medical journals.

Thomas came to Seattle in 1963 to be the first head of the Division of Oncology at the University of Washington School of Medicine. Continuing work begun in Cooperstown, N.Y., Thomas led a small team that labored in the basement of temporary facilities at the former U.S. Public Health Hospital.

"We moved to Seattle…at a time when it seemed that marrow transplantation would never be successful," Thomas recalled during an interview in 2000. "So we focused our attention on laboratory experiments."

As chief of medicine at the Mary Imogene Bassett Hospital in Cooperstown, N.Y., Thomas began studies of marrow grafts, treating relatively few human patients.

After moving to Seattle, Thomas and his colleagues worked almost exclusively in the laboratory well into 1967, postponing work on patients until treatment complications could be resolved.

It took almost 20 years after Thomas's seminal paper on bone-marrow transplantation was published in The New England Journal of Medicine in September 1957 for the procedure to become an accepted therapy. During that time most medical professionals dismissed the idea.

"In the 1960s in particular and even into the 1970s, there were very responsible physicians who said this would never work," Thomas said. "Some suggested it shouldn't go on as an experimental thing."

"I've said in the past that I have two attributes: one is I'm stubborn to keep doing it and other is I attracted some good people to work with me," Thomas told an interviewer in 2006.

Today, bone marrow transplants are a proven success for treating leukemia and other cancers as well as blood disorders such as aplastic anemia.

Thomas is survived by his wife, two sons and daughter.