THE CANCER LETTER

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Conversation with The Cancer Letter

Seffrin To Retire After Restructuring ACS

The American Cancer Society has started a search to replace its chief executive officer, John Seffrin.

Seffrin, who became the CEO in 1992, recently completed streamlining of the society's organizational structure, eliminating the autonomy of divisions, decreasing the number of board members, and making the century-old organization into a single corporate entity.

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Capitol Hill

ASCO, COA Present Plans For Cancer Care Beyond the Fee-for-Service Pay Structure

By Paul Goldberg

The Community Oncology Alliance and the American Society of Clinical Oncology issued a joint statement on payment reform in cancer care and proposed alternative approaches to paying for cancer care.

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Cancer Advocacy

Komen Officials Say Charity is Stabilizing Despite 22 Percent Drop in Contributions

By Matthew Bin Han Ong

The Susan G. Komen Breast Cancer Foundation reported a 22 percent decline in contributions in fiscal 2013—totalling over $77 million—in recent financial statements.

Overall, the charity's revenues fell by 18 percent from the 2012 fiscal year.

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Seffrin to Retire After Creating One Corporate Entity for ACS

(Continued from page 1)

In a conversation with The Cancer Letter, Seffrin, 69, was unable to say how much money has been saved at this point, but efficiency will continue to be enhanced in the future.

In one change, ACS, which has usually been funded through small contributions from the public, will now focus more on corporate giving and major gifts.

Seffrin's more controversial stances included advocating for the Affordable Care Act, a decision he describes as a policy position—as opposed to a partisan one.

"It's tough to get into the policy arena and not appear to be partisan," Seffrin said he said in a conversation with Paul Goldberg, editor and publisher of The Cancer Letter. "I would simply say that we have in writing that we are not to be partisan, but we are to take stands on policy issues that affect people facing cancer.

"So we had no problem in coming out and saying healthcare needs to be reformed, because people facing cancer are discriminated against by health insurance companies. Treatment of cancer sometimes gets extraordinarily expensive, and people go over their caps. It's a major cause of bankruptcy.

"These things are not easy.

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"But to me, for the society to be faithful to its mission, it had to speak out."

The search for Seffrin's replacement will take about a year, ACS officials say.

"Having gone through our transformation, we are in a great position to move forward and help to finish the fight against cancer," said Pamela Meyerhoffer, chair of the ACS board. "We have some consistency in terms of our programs and a strategic plan across the nation, and so we are able to be more nimble to try and assure that we are all moving forward."

Seffrin, who has a Ph.D. in health education, first attempted to streamline the ACS structure—which gave divisions a high level of autonomy—soon after he took the job. However, his initial efforts at centralization ran into internal resistance. As a result, Seffrin chipped away at the task, finally completing the reorganization in 2013 (The Cancer Letter, Nov. 18, 2011).

When Seffrin took office, the society spent 25 cents of every dollar on research. Now, this proportion is lower—about 16 cents.

Research funding by non-governmental organizations like ACS has become more important as the government's programs continue to erode. In the interview, Seffrin said that the mission of ACS is broader than research.

"We are not just going to do research," Seffrin said. "We are also going to do education, we are also going to do advocacy, and we are also going to do service… So the bottom line is, comparing the 25 to the 16 is fine, and those are accurate numbers, but it's an incomplete story because the society has said we are going to be faithful to our mission, and not just going to do cancer research, we're going to do these other things, which by the way cost money to do."

In another change, ACS made a transition to constructing evidence-based guidelines for cancer screening. This change is evident in the guidelines for screening for prostate cancer. In 1991—two decades before clinical trials of PSA were completed—ACS issued a guideline for population-based screening. The guideline was based on a consensus of experts.

However, three years ago, ACS adopted a set of principles for writing guidelines, essentially following a schema laid out by the Institute of Medicine. This produced a genuine evidence-based guideline for prostate cancer screening, which has been adopted by five professional societies over the past three years. The guidelines are largely consistent with those of the U.S. Preventive Services Task Force.

"That is certainly the direction that we have

endorsed and are continuing to follow as a board and as staff, that we want to be evidence-based and not strictly opinions," said Meyerhoffer, executive director at Wickenburg Community Hospital Foundation, located in the Phoenix area. "We have a whole process now for developing guidelines for screening, and treatment, and they are based on research that is either conducted by ACS or through other organizations that we cooperate with to determine exactly what the science does say."

The most recent tax documents, filed in 2012, list the organization's revenues at $925 million, of which total public support was $888.6 million. In 2007, the best-ever year for the society, total revenues were $1,172 billion, of which public support accounted for $1.039 billion.

"We are looking to have somebody who has the vision to help us continue with our programs, but also innovation to help us find even better ways as we go forward," Meyerhoffer said. "Somebody who communicates extremely well is going to be key for us, as well as high-level management experience. ACS is now a $900 million-plus organization. That, obviously, takes great executive management team, which the CEO heads.

"We are anticipating that this is going to be a person with healthcare knowledge. Not necessarily experience in the provision of healthcare directly, having the nationwide perspective and some global insight, and someone who is very open to and skilled at collaborating with other organizations, because we realize that this will require a lot of us working together in order to be able to accomplish doing away with cancer, hopefully in our lifetimes."

The 12-member search committee has not yet been formed.

According to the most recent filing, Seffrin's total pay package was $832.400.

The society's new governance structure eliminates the position of physician president, who is selected annually. Vincent DeVita, of Yale Cancer Center, was the last physician to have served in that role.

In the new governance structure, the volunteer officers include a chair of the board of directors, a vice chair of the board of directors, a board scientific officer, a secretary/treasurer of the board, and an immediate past chair. The vice chair is a ladder position. The board scientific officer must be a member of the medical profession.

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PG: *You've been doing this job for 21 years.*

JS: You're right. Actually, it will be 22. I was selected in May, and then appointed by the board June 8, 1992.

PG: *As you retire, how would you describe the health of the American Cancer Society?*

JS: Well, I think the society is in great shape and in good health, and, most importantly, is postured for success, in my opinion, as never before.

You'll remember last January that we published the first-ever Cancer Facts and Figures in survivorship, noting that there are 28 million cancer survivors in the world, and half of them live in the U.S., which has only 5 percent of the world's population.

So we are making progress. The society, to its credit, decided about four years ago to go through a major transformation that we are completing—we are not totally finished, but we've certainly done a lot of the heavy lifting.

I told the board not this week, but a couple of weeks ago, that I was excited when I became the volunteer chair of the board in I think '89, and I was very excited when I was selected to be the CEO in '92, but I've never been more excited than I am today about the future of the society and our ability to reduce human suffering and save lives from cancer.

PG: *You've actually been doing this for 40 years. You've been a part of ACS for four decades.*

JS: You are right.

PG: *When you got started, ACS had 57 divisions, more than the states, and now you are down to one corporate entity. Was there any moment when you decided that transformation was needed? Was there a trigger?*

JS: You're right, we had 57 geographic divisions, in all the states and then a number of metropolitan areas like Queens and so forth, the area in which our organization got started in the first place. But. Importantly, we had 60 governing boards. and we made definite incremental improvements in that over a number of years.

But I have to say, the triggering event was about this time four years ago. I had done some reading over the holidays about transformations, because my background is in public health and not in business, and also being at this point in my career.

I went to the board in May, four years ago this May, and basically said, "Look, we have a world-class intramural research program. We are virtually the only voluntary health organization in the country with that kind of expertise staff and ongoing research activity."

The bottom line is, I said, here's the evidence: cancer death rates have gone down every year since 1991, and that means essentially we are saving some 350 more lives from cancer per day than we were in 1991.

But look here: based on expertise and evidence and our knowledge of the disease, that number could be 1,000 a day. But I said to them that I cannot see any way that we can get there with our current platform.

We would have to take a hard look at the organization. I gave this speech. I had some notes. but I didn't want to script myself, and when I finished—it was probably only a few seconds, but it seemed like an hour, the board just kind of looked at me.

Finally Tim Byers [associate dean of the University of Colorado School of Public Health], who was a board member then and who is an epidemiologist, raised his hand and said, "John, you've given us a lot to think about," and then he paused and said, "You're saying this is a moral issue."

I purposely didn't use that word in my speech. I later wrote the change story to disseminate among all our volunteers and staff, and I had a section there that I called the moral imperative.

The bottom line is, as you know, that the growing numbers are different from when the organization got started; the growing numbers of people suffering and dying needlessly from cancer for various reasons. But the point being is, we know what kinds of things need to be done to increase the number of people who survive from 350 per day to 1,000.

So I think that was the triggering event. That was in May four years ago, and in the following August the board passed a resolution in support of transformation. And what a three and a half years it's been.

We've made a lot of changes, and the society's changed over many years and decades obviously, but never a change on quite this scale.

PG: *Let's roll back the clock a little more than four years. I'm old enough to remember your campaign for 'One ACS' in the 1990s, where you were basically trying to do something very similar to what you've just finished doing. Why do you think it took so long to accomplish this?*

JS: That's a wonderful question, when we did that and I'm going to say it was roughly 93 or 94, but in any event, I have to say my best analysis is the following: One, we did not have the evidence that we have now that it has needed.

Second, we had not painted a vision, like let's get to 1,000 lives saved per day. And thirdly, I think there was a lack of organizational readiness, if that makes any sense.

This transformation is much broader than the "one organization" thing was. The one organization was to go to one governing board and have nothing else on the plate, so to speak. And this has a lot more than that.

But I think even a few years ago, I would doubt that the organization would—I would doubt that if we had started this a few years earlier, that we would have come close to having the success that we would have had this time.

Some consultant or somebody made some comment that, of all the transformations they've seen, that we've come the furthest, the fastest, and with the best attitude that they thought they've ever seen.

"Of all the transformations they've seen...we've come the furthest, the fastest, and with the best attitude."

In any event, I'm awfully pleased that we are where we are. And I think that the whole issue of organizational readiness was an important part of that.

PG: *It probably didn't hurt to have the economic downturn, because the downturn helps people focus a little better.*

JS: I think so. I know it's palpable. The idea of trying to get to a 1,000 lives a day galvanized the organization.

But you're correct, we had data on market share and other things, and I said to them, "We've got to be honest with one another; there's a new normal and none of us knew exactly what that means or what it is." But clearly, it was in our face, and we needed to look hard at it.

We were the first voluntary health organization in the world to get to the half-billion dollar mark, and then we were the only one to make it to the billion dollar mark.

No one else has gotten there yet. We've been there for two successive years, and of course fell back during the great recession. So you're right, the economic circumstances came into play right about the time when we were talking about transformation.

PG: *I'm plagiarizing [NCI Director] Harold Varmus, actually. He says—and I'm paraphrasing, of*

course—that when times are good, there is no reason to change. Which makes sense.

JS: I think he is right about that.

But one thing I'm kind of proud of is that when we first started this I said, "What other organization has come out and shown data relative to the decline in mortality, given explanations as to what is causing that decline, and then said that isn't good enough?"

We know that it can be a lot better than that. And so, in my opinion and based on feedback I've gotten, people saw the light.

There was a time when like the "one organization" [plan] that you mentioned for governing trustees to vote themselves out of existence was just not—might as well not bring it up, because that's not going to happen. And, by golly, it happened this time.

PG: *What have you accomplished with this transformation so far?*

JS: Well, I think the most important things, and much more will come forward I believe.

First, I think now we are essentially one organization. We 're one 501(c)(3) with one fiduciary board. So I would say that's very high up there.

We now have a single enterprise program of work and supporting resource allocation plans, which allows us to make decisions about applying the society's resources to things we know will make the greatest impact.

In the past, some outside consultant said something like, I've never seen an organization where so many people could say no and so few could say yes. And that's all changing, and it has changed.

We have streamlined the board.

The board just voted in November and implemented in January to go from 43 members to 21. So now we have one board with 21 trustees who, I'm telling you, are taking their jobs very seriously.

And one thing that's interesting is, because we are 100 years old this year, for the first time we have a standardized what we call DOM, a division operating model. So, basically, the alignment of our organizations throughout those divisions is now the same. I would say those are the biggest things.

I should say this about revenue: one of the reasons we were hit hard during the great recession was because the tens of millions of people who donate to us are the groups that were perhaps the most adversely affected by it.

So, as part of the transformation, we are diversifying our fundraising portfolio, and we are going to be focusing a lot more on corporate and leadership giving, with our program of CEOs Against Cancer.

We now have over 400 CEOs as members of 14 CEOs Against Cancer chapters. So there are some things that are different today than just a few years ago when we started the transformation.

PG: *What do you give up as a result of this kind of transformation? Let's go back maybe 50 years, actually not even that long. I always thought of ACS as something similar to a political machine, where there were block captains. Everything was local. Now, critics might say that you are now just another national fundraising group, and there are many of them. Are critics wrong?*

JS: I think they are.

We take a lot of pride—it's like a mantra—about being evidence-based. So what we've given up is, by the way, the status quo.

"One of the reasons we were hit hard during the great recession was because the tens of millions of people who donate to us are the groups that were perhaps the most adversely affected by it.

So, as part of the transformation, we are diversifying our fundraising portfolio, and we are going to be focusing a lot more on corporate and leadership giving."

And when I say that I think I can accurately speak for our volunteers and staff. Most of us, if not all of us, are very proud of the organization and its history, and giving up the status quo is disquieting.

But at the very beginning, the only thing we said we are taking off the table is our mission statement, and our mission statement is that the American Cancer Society is the nationwide community-based public health organization dedicated to eliminating cancer as a major public health problem by preventing it, by saving lives from it, and by reducing suffering through research, education, advocacy, and service.

Every marketing person and every strategic planner said it's too many words, it's too long, but I guarantee you, our staff and volunteers love it and feel passionate about it.

So we said we would sustain, maintain, and, hopefully, expand our community presence. And so, as I speak to you today, we have 3 million volunteers and we have 6,000 professional staff in 5,300 communities.

So our community presence is very much being preserved, and having grass roots is part of our heritage. I've had conversations with other organizations that are newer. They have a different model, and I think that's probably smart, because to build that community presence today would be very difficult to do. But once you have it, the last thing you want to do is lose it.

I think that would not be an informed criticism, that we don't have grass roots, because indeed we do. We now have trained volunteer cancer survivors in all 435 congressional districts.

PG: *So the grass-roots structure is functioning?*

JS: It is. When I got involved 40 years ago, I was at Purdue University, and I would take the drive downtown into Lafayette, and I would go into this little place for the unit board meeting, where they agreed to the minutes… that's not the way we look today at all.

Instead, a better image is, I think, the 100,000 cancer survivors around the country that lead the first lap of the Relay for Life event. So we look different, but we are still very much in the community.

And we want to protect that, because, frankly, that's where the lion share of our income comes from. The average donation last year was something like $48. We obviously have some major donors, but not as many as we would like to have in the future.

"So our community presence is very much being preserved, and having grass roots is part of our heritage.

To build that community presence today would be very difficult to do. But once you have it, the last thing you want to do is lose it."

PG: *I guess corporate donations would certainly help.*

JS: Yes, they would. We are in such a different place. The organization's transformed, and we are postured as never before—but, in addition, we are at an unprecedented place in that journey now, following the United Nations' high-level meeting on non-communicable diseases, including cancer.

I was a non-voting official delegate to that UN high-level meeting in September 2011 that produced a 13-page political declaration.

Think about this: you know when the millennium development goals were made by the UN and the WHO coming into this new millennium—obviously done in the 1990s, coming up to the year 2000—there was not one word about cancer, or one mention about non-communicable diseases.

HIV, AIDS, tuberculosis, malaria was everywhere, as it should be. But cancer wasn't even mentioned.

Now, we have a political declaration passed by the UN, with metrics targets and goals for cancer and non-communicable diseases and it says four things. It says cancer and non-communicable diseases will be the number one health disease and disability issue of the 21st century. So we might have bird flu, but nothing will trump it.

Secondly, it says we have a number of best buys—and they actually use the term "best buy," interestingly—meaning we've got interventions that can be funded for $1 to $3 per person, per year that work.

And third, the World Economic Forum and Harvard University say that if we fail to intervene, there will be a $47 trillion loss in economic output. So, it couples for the first time that I know of, dealing with cancer and non-communicable diseases as an economic issue, and not just a public health and humanitarian issue.

And the fourth thing it says is that we can't solve the cancer problem without engaging the private sector.

And so for us, we say we have to work more with the private sector. And clearly not just to raise more money, but that's part of it, also to know that… creating smoke-free workplaces.

Over a billion people go to work every day that are healthy, but are exposed to cigarette smoke all day, and so forth and so on.

I think the society is postured for success, but there are also things out there in the bigger environment. I was the president for four years of the Union for International Cancer Control, and I had very little success in getting cancer on the agendas of health ministers in low- and medium-income countries; the developing countries.

But now, there's reaching out to us, because they need help with it. They have to move in this direction.

PG: *Getting back to the U.S., Dr. [Vincent] DeVita is the last physician president that ACS will have. Is it fair to say that you might be de-emphasizing the role of the medical profession in the society?*

JS: No, absolutely not.

And this new board, I think our chairman, and if you talk to Pamela [Meyerhoffer, ACS board chair], you can ask her the same question, but I think I heard her say we are going to do it this way, and if it doesn't serve us well we can always go back and look at it again.

The bottom line is the reason that Dr. DeVita will

likely be our last president is because the assembly that the president presided over voted itself out of existence.

So technically we don't need a president, per se. However, one third of our board, by statute, comes from the medical scientific community, and one of our five officers is a board scientific officer. So that guarantees that there's no way to de-emphasize that. No other class gets that kind of distinction.

PG: *When you came in and took this job as CEO, 25 percent of the money that ACS raised went to fund cancer research. How much are you spending now?*

JS: Well the audited figures for 2012 is that we're spending $160.1 million on research and occupational training, and that represents an increase of $12 million over 2011.

We got serious about research in 1946; I was two years old at the time. The society has invested $3.8 billion in cancer research, and we're the only NGO in the world that has funded 47 beginning cancer investigators that have gone on to win the Nobel Prize.

So our commitment to research is huge, but one of the 11 initiatives that the transformation dealt with was Research 3.0. [A strategic plan for the ACS research program proposed by a working group.]

And we heard back loudly and clearly from them, so we want to increase what we are doing in research.

That's tough, but we've already got plans and things coming that I anticipate will become visible even in the next few weeks, certainly in the next few months, of major increases in our efforts to raise money for and to fund research.

PG: *What's the percentage you are spending now?*

JS: Sixteen percent.

PG: *So it went up from 15 to 16 percent?*

JS: Yes. Back when it was 25 percent, it's important to recognize that we didn't have anything like the National Cancer Information Center, where we answer a million calls a year.

We didn't have the Health Insurance Assistance Service, where we try to help one out of five people who call us—we help get them access to the healthcare they need, because of their lack of insurance.

And so the bottom line is that people are proud of that comprehensive mission. There are a number of good cancer fighting organizations out there, but none, not one, have the two things that we have.

One is a comprehensive mission, where we say we are not just going to do research, we Are also going to do education, we're also going to do advocacy, and we are also going to do service. We have 30 Hope Lodges around the country, where people can stay free of charge to go to a comprehensive cancer center to get treated, etc.,

So the bottom line is, comparing the 25 to the is fine, and those are accurate numbers, but it's an incomplete story because the society has said we are going to be faithful to our mission, and not just going to do cancer research, we are going to do these other things, which by the way cost money to do.

PG: *So it's sort of a competition for resources within the society, and research hasn't done as well as other opportunities to do good; is that what you are saying?*

JS: Not exactly. Because I don't think came down that way.

For example, research is the only area that has had board policy assuring a certain percent in the past, as opposed to say a policy that sets a certain percentage for prevention, our services like Hope Lodge, and so on.

"Obviously, 16 percent of $900 million is a much bigger figure than 25 percent of the $362 million when I took this job...

No program or its department has received as much money as research has on an ongoing basis."

Obviously, 16 percent of $900 million is a much bigger figure than 25 percent of the $362 million when I took this job. Obviously, there can be competition, or to put it differently, there can be volunteers who say we need more for this and we need more for that—and they are all correct, but, historically, as far back as I can remember, no program or its department has received as much money as research has on an ongoing basis.

PG: *When you came in, ACS had a less than rigorous review of screening guidelines, and I'm really talking about the 1991 prostate cancer screening guideline. Basically ACS recommended aggressive screening two decades before the first randomized trial was completed. What have you learned about cancer screening over the past two decades?*

JS: First, the society continues to believe that screening is one prong, one way we need to reduce human suffering and save lives from cancer.

We've also learned that we have to be very rigorous with respect to the formulation of our guidelines.

And we've done guidelines before, and we're doing them now, and I think we will continue to do them.

We are proud that we've adopted the Institute of Medicine recommendations on screening guidelines. I anticipate that we will not deviate from those guidelines moving forward, because we know screening is not without risks. We want to be sure we have that risk-benefit ratio correct, and that's why I'm very proud and pleased that we have people like [Chief Medical and Scientific Officer] Otis [Brawley] and [Chief Cancer Control Officer] Rich Wender working on these issues.

PG: *Looking back on the past three years, let's just stay with the prostate screening guideline, your guideline has been adopted by five professional societies over the past three years. Was there a big cultural change within ACS to make you move away from a consensus of experts to evidence-based medicine in guideline making?*

JS: I think so, and it probably has been incremental as opposed to one fell swoop, but I think Harmon Eyre, who was my former chief medical and scientific officer, started that process, and Dr. Brawley has taken it to yet another level. Otis mentioned to me the other day that he appointed Wender, when Rich was still a volunteer, but a past-president of the society, he appointed him as a volunteer representative to help us move toward the IOM guideline.

We are proud that we've adopted the Institute of Medicine recommendations on screening guidelines.

I anticipate that we will not deviate from those guidelines moving forward, because we know screening is not without risks.

So I think we are there to stay and we've gotten some feedback from independent sources congratulating us on being able to do it in a way that is hopefully beyond reproach.

PG: *The current prostate guideline is certainly getting a lot of support. Let's move to the Affordable Care Act for a few minutes. You came out in support of it, which is really a political stance—or do you see it as a political stance? Do you see it as a policy stance? How would you describe it?*

JS: I would describe it as a policy stance.

And I'm very proud of the American Cancer Society; some 15 years ago the board voted to approve the creation of the American Cancer Society Cancer Action Network, which is a 501(c)(4) organization.

In 2006—and if I were ever to write a memoir or something, this would be something that I would be very proud to share—I went to our board and showed them, with the help of people like Otis and our intramural research program, that here's the progress we are making but we won't make our 2015 goal of 50 percent reduction in cancer mortality.

And they said, "John, you come back and tell us what we need to do to make the goal." So I came back to them in 2006 and said, we've got to redouble research, we've got to increase research.

And of course we advocated like hell, along with a lot of other people, to double the NIH budget over a five-year period.

"We've got to promote prevention into public policy everywhere and we've got to provide access to quality healthcare to everyone facing cancer where and when they need it."

And I said to them that we discovered something in this process: that lack of access to health care is the only thing that could keep us from ever getting to our 2015 goals.

And I said to them, "Look, I'm not going there without you. We can't fix the healthcare system, but we are the largest volunteer health organization in the world, and we have lots of experience and expertise, and the bottom line is to see to the broken healthcare system, and we might be able to play a leadership role in getting something done," and by golly we did.

"And at that meeting or the next meeting they approved a resolution allowing us to step out on this issue. I called some of my colleagues in other large voluntary health organizations and they said we'll cheer you on, but we're not going to go there.

But we did. And we did it on the basis of the fact that, obviously as you know, it was despicable: you get a diagnosis of cancer, and you could kiss your insurance goodbye.

If you previously had cancer, like my wife did, you are not going to get any insurance. There were lifetime caps. All of that is gone. Now the Affordable Care Act didn't roll out very well, and it's far from being perfect, and we're going to have to work to make it better, but the bottom line is we have a chance that we never had before—and that is to build out a decent healthcare

system. I'm very excited about it.

And it got extraordinarily controversial, so it wasn't easy. But I think the society did itself proud. I had one call from a donor, asking me why aren't you talking up prevention? Because both sides of the aisle have agreed on that, that's not controversial. The bottom line is, again, that we are in an unprecedented place.

We have a chance now to start seeing those death rates from cancer go down, and instead of a slope, but much more rapid drop.

So I would anticipate, and I would be hopeful that, after I retire, the society will continue to put a lot of emphasis on it. I've said in a lot of speeches to the board and I think in writing too, that the ultimate conquest of cancer, which I think is possible in this century for the first time in all of history, that it's as much a public policy issue as it is a medical and scientific challenge.

PG: *I'm probably splitting hairs, but just so that I would understand it, how would you distinguish a policy stance from a political stance from a partisan stance? Is there a difference?*

JS: I think so. I certainly understand there are nuances. In the bylaws, when we formed a 501(c)(4), it prohibits electioneering, as you might expect, but it also prohibits backing any candidate and so forth. The organization is very tough on being non-partisan.

It's tough to get into the policy arena and not appear to be partisan. I would simply say that we have in writing that we are not to be partisan, but we are to take stands on policy issues that affect people facing cancer.

So we had no problem in coming out and saying healthcare needs to be reformed, because people facing cancer are discriminated against by health insurance companies. Treatment of cancer sometimes gets extraordinarily expensive, and people go over their caps. It's a major cause of bankruptcy.

These things are not easy. But to me, for the society to be faithful to its mission, it had to speak out.

One interesting little tidbit, and you probably know this because Otis has talked about it a lot, but when I was a volunteer, we voted to co-found with the American College of Surgeons the National Cancer Database, which of course is different than SEER.

It's the only database on cancer in this country where you have reliable information on stated diagnosis, outcomes, and whether they had insurance or not. So we could triangulate that, and we were able to show that a person with stage II colon cancer with insurance was more likely to survive five years than a person with stage I colon cancer without insurance.

So that kind of information and evidence was very powerful in showing policymakers, who may not be experts in public health or health issues, why it was so important that we have healthcare reform.

PG: *Well, your fundraising hasn't recovered in recent years, what would be your greatest concerns as you leave?*

JS: I'm very optimistic, and I believe that before I actually leave that we will have at least preliminary evidence that we've turned a corner. I say that because I've looked at the figures.

I anticipate total revenue will start going up in 2014.

Market share and certain markets have already started to go up, and obviously the economy, while it's slow, has recovered some.

And our plans include outreach to the corporate world and partnerships that are different than before.

I anticipate total revenue will start going up in 2014. Market share and certain markets have already started to go up, and obviously the economy, while it's slow, has recovered some. And our plans include outreach to the corporate world and partnerships that are different than before.

It's not going to be easy, but I'm optimistic that we will start and continue to grow, in part because I think we're going to get even better at telling our story about why this is an important place to invest.

There are so many pressing issues out there, but I like to use the example that cancer research in my career has gone from a good bet to a sure bet. Not that every experiment works, but we've gotten very good at it.

We have so many interventions now, from a public health perspective, that if implemented get results. So it seems to me if someone wanted to say, "I want to put an investment where I'm pretty darn sure I'm going to get a return on that investment," doing something about the cancer problem is one of those things. Certainly more promising than us knowing what to do about terrorism. or something like that.

PG: *How much have the costs dropped—[costs] of maintaining and running the organization as a result of the transformation?*

JS: I can't give you a specific metric, but we are no question more efficient than we were before.

Before transformation there was no direct linage between the staff executive on the ground, what we used to call the regional vice president, and me, because they reported up to a separate board. But now there are about five steps between me and the board and the staff executive on the ground that makes it happen on a daily basis.

So it's too early to have some specific numbers, but I can assure you that we are already more efficient and more effective than we were, and that's only going to increase.

PG: *And you are going to start seeing that soon right? Are you seeing the costs drop now? Or is that going to happen in a few years?*

JS: It's happening. I can show you some now, but it's modest. It's going to grow, I'm very certain of that.

The new division operating model is arranged in such a way that we're going to get economies of scale and some efficiency. The big bucks have yet to come in but they will. The early returns promise even bigger returns down the road.

PG: *In one sentence, what would be your advice to your successor?*

JS: Keep your eye on the prize; understand that you've got to save more lives faster and get to those 1,000 lives a day as soon as possible—and to do that, know that you've got to hire the best and the brightest, maintain community presence, and that you've got to do both research and intervention.

Capitol Hill

ASCO, COA Present Two Plans For Changing Payment Structure

(Continued from page 1)

The Jan. 22 statement by the two organizations, as well as AmerisourceBergen/ION and McKesson/US Oncology, said they had agreed on principles for changing the health care payment systems to emphasize high-quality, high-value cancer care.

"Traditional reimbursement models currently do not provide adequate support for the care coordination and complex disease management necessary for delivery of high quality, high value care in oncology," the two organizations said in the statement.

"Improving the quality and value of the care provided to individuals with cancer may require changes that ensure adequate financial, administrative and data support for oncology providers to engage in new approaches that reduce the frequency and severity of clinical complications."

The groups propose two approaches as alternatives to the existing system:

• **Oncology Medical Home** (developed by COA). Investing in changes to clinical practices and operations under an oncology medical home model can improve the quality of care and significantly reduce the aggregate costs of cancer care by reducing the frequency of avoidable complications, emergency department visits and unscheduled hospitalizations.

Adopting the oncology medical home requires investment in information technology infrastructure and other practice support to provide the full range of services needed by patients with cancer—throughout

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the course of their treatment and transition to survivorship.

This four-phase, five-year payment reform model would apply to both Medicare and private insurance.

• **Monthly Payments** (developed by ASCO). Monthly, non-visit based payment provides flexible and predictable payment to support comprehensive disease management, including telephone and email contact between physicians and patients, visits with non-physician staff, proactive outreach for medication and symptom management, extended practice hours and other services in addition to traditional office visits with physicians.

These monthly payments would be higher for patients with conditions requiring more labor-intensive services or patients who are at more acute stages of illness. In return for this more flexible payment methodology, the oncology practice may be required to take responsibility for whether patients avoid oncology-related emergency department visits, hospitalizations and complications. The approach is described on the ASCO website.

The two approaches are intended to advance a unified model of payment reform that can be adopted by both the Medicare program and private insurers. The plans are proposed at a time when Congress is working to replace a sustainable growth rate formula for Medicare. The House and Senate have approved legislation to replace the formula, and the bills are being reconciled.

Oncology Medical Home

The "oncology medical home" is a refinement of a "medical home" model that has been used by family practitioners for decades, said Ted Okon, executive director of COA.

Okon credits John Sprandio, an oncologist in Drexel Hill, Penn., with the idea of applying the approach to cancer treatment.

"When a person becomes a cancer patient, their oncologist becomes the focal point of their care," Okon said to The Cancer Letter. An oncologist becomes a gatekeeper.

"What we have done from the COA perspective is look at refining overall the methods for measuring quality and value," Okon said. An18-member task force at COA also created an approach for transition from the fee for service system.

Though the payment reform model initially focused on Medicare, it's also applicable to private insurance, is compatible with the ASCO plan, and can be used as a basis of accreditation of oncology practices, Okon said.

The four phases of the medical home transition model are described on page 12.

The ASCO Plan

ASCO's plan was formulated by the Clinical Practice Committee, which formed a Payment Reform Working Group, which focused on the task of identifying, researching, and analyzing alternative payment models.

The working group, which as been in existence since July 2012, was instructed to set aside preconceived notions and existing constraints and address the following: "If we could build a logical Medicare model for oncology reimbursement from scratch, what would it look like?"

The entire proposal has not been published. However, it was summarized on ASCO's website.

The working group identified five components to reform payment, maintain viability of community oncology practices, and control costs. Although the model retains some fee-for-service features, it collapses payment-for-patient management into monthly payments that recognize discrete stages of patient care:

1. New Patient Payment. When a new patient is referred to an oncology practice, the practice would receive a single payment to cover all of the time involved in initial patient evaluation, treatment planning and patient education. The costs of any diagnostic testing ordered by the practice would be paid in addition to this amount (on a fee-for-service basis), but no Current Procedural Terminology (CPT)-based Evaluation and Management (E&M) payments would be made.

2. Treatment Month Payment: If the patient begins treatment with the oncology practice, the practice would receive a single payment each month in which the patient is receiving treatment (oral or parenteral) ordered by the practice. This payment would replace all current CPT-based payments for chemotherapy administration, therapeutic injections/infusions, hydration services, and established patient E&M visits. The practice could receive both a Treatment Month Payment and a New Patient Payment in the same month.

• There would be four different levels of Treatment Month Payment to reflect the differences in time and effort involved in treating different patients;

Medicare Payment Reform for Oncology

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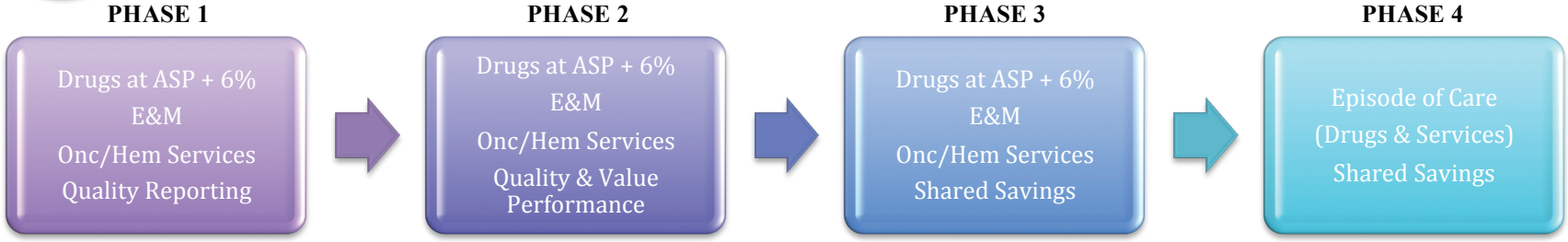

Implement within 1 year

Current fee-for-service (FFS) payment structure for drugs and services (E&M and Oncology/Hematology [Onc/Hem] specific codes).

Additional payment tied to Measures *reporting* & Oncology Patient Satisfaction (OPS) *reporting* — 0% to 2% Quality/Value Adjustment (QVA) based on formula.

Compliance with Measures/OPS* reporting qualifies practice to receive Medicare Economic Index (MEI) increase.

*Measures are Stage I (see following pages) and full OPS reporting.

Implement within 2 years

Current FFS payment structure for drugs and services (E&M and Onc/Hem specific codes).

Additional payment or decrease tied to *relative* Measures *performance* & OPS *performance* — -2% to 5% QVA based on a specific formula. Any increases from Phase 1 built into formula such that Phases 1 & 2 are revenue neutral.

Compliance with Measures/OPS* reporting qualifies practice to receive MEI increase.

*Measures are Stage I & II and full OPS reporting.

Implement within 3 years

Current FFS payment structure for drugs and services (E&M and Onc/Hem specific codes).

Additional 50/50 shared savings benchmarked against regional or national comparison group. Savings quantified on ER utilization and hospitalizations, and drug/infusion costs (if available by diagnosis). Imaging and radiation costs also included if provided by provider. Practices must hit established quality Measures/OPS* targets to qualify for any savings.

Compliance with Measures/OPS* reporting qualifies practice to receive MEI increase.

*Measures are Stage I & II and full OPS reporting.

Implement within 5 years

Practice is paid based on a predetermined episode of care (by cancer type; adjuvant and metastatic) that combines services and drugs. A demonstration project will be fielded by CMS at least 3 years prior to national implementation in order to develop/refine episode payments.

Shared savings benchmarked against comparison group as in PHASE 3 but increases to 60/40 (practice/Medicare) for greater risk assumption by providers.

MEI increase applied to episode of care payments.

Measures are Stage I, II & III (III if feasible), to-be-developed outcomes measures, and full OPS reporting.

NOTES

- Assumes suspension of the SGR for oncology/hematology.
- "*Onc/Hem Services*" includes infusion, imaging, radiation, and others provided.

the payment level for an individual patient would be based on the patient's diagnosis, comorbidities, risk factors, and performance status, on the number of drugs or treatments the patient is receiving, and the typical complication rate associated with the treatment regimen.

3. Non-Treatment Month Payment. If the patient is still under the care of the oncology practice but does not receive any anti-cancer treatment (oral or parenteral) during a particular month, either because of a temporary pause in treatment or because of the completion of treatment, the oncology practice would receive a Non-Treatment Month payment.

• There would be two levels of the Non-Treatment Month Payment; a higher amount would be paid during the months immediately following the end of treatment, and a lower amount for patients for long-term monitoring.

4. Transition of Treatment Payment. When a patient begins a new line of therapy or ends treatment without an intention to continue, the practice would receive an additional payment to reflect the additional time involved in treatment planning and patient education.

• There would be two levels of the Transition of Treatment Payment; a higher payment would be made for a patient who has been off treatment and has a recurrence.

5. Continued FFS Payment for Some CPT Codes. An oncology practice would continue to be paid for services using current CPT code-based payments, such as laboratory tests, bone marrow biopsies, and use of portable pumps.

The payment levels for each component would be standardized by Medicare to ensure that they reflect the relative amount of time and cost incurred by oncology practices during each phase of patient care described in the five components.

In the initial phases of the program, practices that choose to participate would be protected from significant downside risk.

"This episode-based approach to payment puts patient care first, while ensuring oncologists are fairly reimbursed for their time and services," Clinical Practice Committee Chair Anupama Kurup-Acheson said in a statement. "The appeal of this proposed model is that by incentivizing high-quality, high-value patient care—patients win, oncologists win, and ultimately the American people will win with a stable, sensible, sustainable health care system."

ASCO is proposing a period of transition to any new payment model in order to ensure stability, understand impact on patient care, and provide ample time for practices to adapt to the new environment. The ASCO proposal assumes a minimum three-year transition phase, during which oncology practices can make adjustments needed to participate in the new system.

"This payment reform proposal represents a real shift in the way oncologists would be reimbursed," ASCO President Clifford Hudis said in a statement. "ASCO is offering a new and different perspective on how oncologists should be compensated that recognizes their expertise as well as the care and services they are providing to patients. It's a revolutionary concept, and one that may not be popular

The ASCO proposal recognizes previously under- or uncompensated activities, including quality measurement, disease management, care coordination, and participation in clinical trials.

Practices would receive additional compensation based on their participation in the following indicators of high-quality care:

• Performance on Quality Measures: Oncology practices would be rewarded for measuring the quality of care they deliver and for achieving high levels of performance on quality measures.

• Use of and Adherence to Pathways: Practices would receive an increase for using high-value approaches to care through the use of value-based care pathways.

• Utilization of Other Resources: Oncology practices would be compensated for managing patient care in a way that minimizes emergency room visits and avoidable hospitalizations due to complications of treatment.

• Participation in Clinical Trials: In order to offset the additional time and costs associated with having patients enrolled in clinical trials, oncology practices would receive higher treatment month and non-treatment month payments.

"We are eager to hear from our members and others in the oncology community on this proposal and other promising options for oncology payment reform," said Kurup-Acheson. "If we do not work together to develop a solution for oncology reimbursement, then it will be forced upon us. We've seen the consequences that can bring—let's get this done."

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Cancer Advocacy

Komen Revenues Drop 18 Percent After Planned Parenthood Debacle

(Continued from page 1)

The world's leading breast cancer advocacy group collected $325 million in the most recent fiscal year, compared to $339 million in fiscal 2012. Komen operates on a budget that ends in March; its 2013 fiscal year began April 1, 2012.

Observers attribute the drop in contributions to the controversy over Komen's funding of Planned Parenthood (The Cancer Letter, Feb. 3, 2012).

Participation in Komen's 2012 fundraisers declined in cities nationwide. In Washington, D.C., participation in the 2012 Race for the Cure dropped by as much as 30 percent compared to the year before (The Cancer Letter, June 8, 2012).

"We had additional issues from our reputational issues in 2012," Komen spokesperson Andrea Rader said to The Cancer Letter. "I don't think we can quantify it. We've asked the question ourselves many times."

The controversy was one among many factors that affected Komen's revenues, she said.

"We've got issues that everybody else had," Rader said. "It's a tough environment and the economic uncertainty in the past couple years certainly had an impact on our profits, of course.

"Since about 2008, since the market crashed and the recession began, we've seen a softening, especially since 2010," Rader said. "So we can't say X percent is because of Planned Parenthood or why, because of the economic impact."

In June 2013, the charity canceled its 3-Day Walk in seven cities, saying at the time that declining participation made it difficult to sustain the event in 14 cities.

"We have not made any decisions on reinstating [the 3-Day Walk in those cities] at this point," Rader said. "It's a 12- to 18-month lead-time on reinstating any of them, so we're focused on our 2014 events at this moment."

Pay Cuts and Severance Payments

Komen founder Nancy Brinker took a $159,000 pay cut, the charity announced in a Dec. 30, 2013 disclosure statement in response to post-controversy scrutiny of Brinker's compensation.

Brinker stepped down as CEO in August 2012 to assume the position of chair of global strategy after Judith Salerno was hired as president and CEO.

Brinker's salary is set at $390,000 to reflect her new role, down from the $548,000 she earned as CEO in 2012, Rader said.

Her total compensation in 2012 was pushed to nearly $700,000 by a bonus of about $125,000.

Komen also spent nearly $400,000 in severance payments to four executives in fiscal 2013, including nearly $270,000 to its former president, Elizabeth Thompson, who left in August 2012.

"Those are severances for people who left throughout 2012, and we had some turnover that year," Rader said. "Of course, the bulk of that was for our former president. That was her unpaid vacation. She was a resident of California, so there were unused time and all that, that we were legally required to pay her, plus her salary and severance payments."

Thompson was paid $392,198 in her final full year as president, including a base salary of $321,725 and bonus of $51,000.

According to Komen's Internal Revenue Service Form 990, other executives who received severance payments in the last fiscal year were:

• Nancy MacGregor, former vice president, global networks ($82,793), who left in June 2012;

• Larry Lundy, former director, business development ($21,486), who left in November 2012; and,

• Samuel Cheng, former controller ($18,739), who left in September 2012.

Saleno's annual salary as president and CEO has been set at $475,000, according to the disclosure, which asserts that her compensation is "conservative versus those of CEOs at other major charities and well below those on the 2013 Charity Watch Top 25 compensation packages."

Independent consultants were engaged in determining Salerno and Brinker's compensation plans, the disclosure stated.

Komen: People Have Moved On

The impact of the Planned Parenthood controversy began to stabilize in late 2012 and early 2013, Rader said to The Cancer Letter.

"We were starting to turn a corner," Rader said. "We are seeing signs that people have moved past the Planned Parenthood situation.

"We reversed that decision right away, continued to fund 16 Planned Parenthood clinics across our system, and never wanted to, and never did abandon women's health.

"In 30 years, we had one reputational issue, we

think that people have really moved past it, and we have the same issues other charities have, which is to raise the maximum amount of money in a really challenging economic environment where there is a lot of competition for donor dollars," Rader said.

Besides a merging of Komen's Aspen affiliate into the larger Colorado affiliate, there were no closures in the last fiscal year, Rader said.

"We think we are attracting new partners," Rader said. "The registration is just now opening for our 2014 races. We've seen, anecdotally, a lot of evidence that shows a lot of people are supportive of our mission, they know that we are the only organization that's not only funding research but that is working in a lot of communities to take care of people who need our help.

"They're coming back."

FDA News

FDA Approves Reagent System For Graft-Versus-Host Disease

FDA approved Miltenyi Biotec's CliniMACS CD34 Reagent System as a Humanitarian Use Device for the prevention of graft-versus-host disease in patients with acute myeloid leukemia in first complete remission undergoing allogeneic stem cell transplantation from a matched related donor.

The system removes donor T cells from the graft prior to transplantation by enriching CD34+ blood stem cells, which go on to repopulate the patient's immune and blood building systems.

Approval was based on data from a phase II, single-arm, multi-center study (BMT CTN 0303) conducted by the Blood and Marrow Transplant Clinical Trials Network.

The trial showed that following intensive myeloablative conditioning, stem cell transplantation from an identical sibling donor processed using the system as the sole means of GVHD prophylaxis lead to a low incidence of chronic GVHD (19 percent at two years after transplantation) without negatively affecting relapse, engraftment, overall survival or disease-free survival.

FDA launched the advisory committee membership nomination portal that allows individuals to submit nominations for membership to any of the agency's 33 advisory committees.

The portal allows applicants to complete their entire application online. Currently, applications must either be emailed or mailed to the agency.

Nominations for scientific members and consumer and industry representatives may be submitted by professional societies, industry and consumer groups, and other interested persons and organizations.

Potential candidates are asked to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts in order to permit evaluation of possible sources of conflict of interest.

In conjunction with the launch of the nomination portal, the FDA is also posting a set of presentation slides on conflicts of interest for potential members, which can help in answering preliminary questions.

FDA granted an Orphan Drug Designation to BL-8040, developed by BioLineRx, as a treatment for stem cell mobilization, in addition to the orphan designation previously granted to BL-8040 as a treatment for Acute Myeloid Leukemia.

The designation was granted for use of BL-8040 in combination with granulocyte colony-stimulating factor to mobilize human stem cells from the bone marrow to the peripheral blood for collection for autologous or allogeneic transplantation.

BL-8040 is a short peptide that functions as a high-affinity antagonist for CXCR4, a chemokine receptor that is directly involved in tumor progression, angiogenesis, metastasis and cell survival. CXCR4 is over-expressed in more than 70 percent of human cancers and its expression often correlates with disease severity. BL-8040 mobilizes cancer cells from the bone marrow and may therefore sensitize these cells to chemo- and bio-based anti-cancer therapy. Importantly, BL-8040 has also demonstrated a direct anti-cancer effect by inducing apoptosis.

The EU Committee for Medicinal Products for Human Use has recommended approval of Roche's subcutaneous formulation of MabThera (rituximab) using Halozyme's recombinant human hyaluronidase (rHuPH20) for the treatment of patients with common forms of non-Hodgkin lymphoma.

Currently, MabThera is delivered by an intravenous infusion which takes approximately 2.5 hours. The new MabThera SC formulation comes as a ready-to-use, fixed dose, 1,400 mg solution.

The CHMP opinion is based primarily on data from Roche's phase III SABRINA study. Roche expects a final decision from the European Commission in the coming months.