THE CANCER LETTER

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A Conversation With The Cancer Letter

NCCN's First Physician CEO: Carlson Pledges Broader Research, Policy Agendas

By Paul Goldberg

An argument can be made that writing guidelines is one of the most daring exploits in medicine.

Stanford oncologist Robert Carlson found this when he volunteered to chair a committee that put together a synopsis of breast cancer treatment for the National Comprehensive Cancer Network.

The year was 1996, and some of his colleagues in breast cancer passionately believed that high-dose chemotherapy with bone marrow transplantation was the right way to treat breast cancer. The approach seemed to stand to reason, and if its superiority wasn't shown yet, it would be soon enough, they argued.

For the transplanters, the stakes were high.

Had NCCN included transplantation in the guidelines, it would have made it easier to get insurance coverage for the expensive, toxic procedure.

Carlson dug in his heels.

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News Analysis

Industry's Accelerated Recovery Initiative May Push Manufacturers Toward Collusion

By Rena M. Conti

The Federal Trade Commission recently issued an advisory opinion to the Generic Pharmaceutical Association, approving the trade group's effort to help alleviate drug shortages.

The generic manufacturers are launching an Accelerated Recovery Initiative, which seeks to engage generic drug manufacturers and FDA in a coordinated program.

If all goes well, the initiative will increase the transparency of the production process and expand the existing capacity to manufacture small-molecule and biologic-based cancer drugs.

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In Brief

DuBois Named Head of Biodesign Institute

RAYMOND DUBOIS was named executive director of the **Biodesign Institute** at **Arizona State University**. He will also hold the Dalton Chair in the university's School of Health Solutions with joint appointments in chemistry and biochemistry, in addition to a joint appointment with the Mayo Clinic, co-leading the cancer prevention program.

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NCCN To Move Into Health Policy, Coverage Issues

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"It was a great example of how the NCCN process, despite what some of our critics say, is an evidence-based process," recalled Carlson, now 60, who is leaving Stanford to become the NCCN chief executive. "We stuck to the evidence that we had at that time—which was none. We basically said that, until we have more convincing evidence, it's a really intriguing area for clinical investigation, but it doesn't rise to the level of standard care."

The appointment to the top job at NCCN propels Carlson to one of the most influential jobs in oncology. This is in part because the non-profit publishes a compendium that in effect declares which off-label uses of drugs get coverage. Its guidelines are written by experts from cancer centers, updated regularly and promulgated worldwide.

Carlson, the first physician to run the organization, replaces William McGivney, a former insurance company executive with a PhD in pharmacology, who was ousted last December after leading the organization over 15 years (The Cancer Letter, Jan. 13).

The CEO search process made an M.D. degree a job requirement, said NCCN board chairman Thomas D'Amico, chief of the Section of General Thoracic Surgery at Duke University, in an interview earlier this year.

"We call ourselves a clinical and scientific organization, and when you think about the guidelines driving the standard of care medical practice, and increasing coverage, who better than an MD to lead that type of an organization?" said D'Amico (The Cancer Letter, June 15).

Carlson will officially start work at NCCN on Jan. 2, 2013.

He will be leaving his jobs as medical director of inpatient oncology and hematology at Stanford Cancer Institute and professor of medicine in the Division of Oncology and Stanford Medical Informatics at Stanford University Medical Center. He joined the Stanford faculty in 1983.

NCCN was formed two decades ago as a response to the Clinton administration plan to foster "capitation," a business structure where care providers would bid for "oncology carve-outs," basically acting as insurers.

NCCN's three goals were contracting, clinical guidelines and outcomes measurement. The contracting element, which entailed forming a for-profit entity, was quickly abandoned.

Now, NCCN is completing a strategic plan, its first. According to tax filings, the 21-member organization raised $25.4 million in 2010, almost exactly the same amount as it did during the previous year.

Carlson said he anticipates that the organization would pursue a growth strategy.

"We need to grow the number of people who use our guidelines and our products," Carlson said. "We need to grow our relationships with advocacy groups, with payers, with industry, with other professional associations, with governmental agencies like FDA and CMS. We need to grow our partnership and strengthen our partnership with our own member institutions—and I think that it's quite likely that we will also choose to grow our number of institutions. "

The interview with Carlson was conducted by Paul Goldberg.

PG: *Why did you decide to take this job?*

RC: The opportunity to participate in the leadership of NCCN is very exciting and challenging. Over the years, NCCN has evolved to have a major impact on cancer care in the U.S., and increasingly so in other parts of the world. The member institutions individually, especially collectively, represent a wealth of experience and energy that should allow NCCN to move forward and, in the process, improve the quality of cancer care in the U.S.

And why wouldn't someone want the opportunity to participate in that? I'm sure you've seen me over

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the years at NCCN meetings and activities—I've seen you—so it's also just the natural evolution of my involvement within NCCN, over the 17 years that the organization has been in existence.

PG: *I think we met at the first NCCN meeting.*

RC: That very well may be.

PG: *And that was quite a meeting, because there was a nice fight between the evidence-based people and the transplanters, who wanted to make [high-dose chemotherapy with autologous bone marrow transplantation] the standard of care for breast cancer. I'm sure I recall this correctly, you basically said, "No way, only clinical trials." That's my memory. What did that episode teach you?*

RC: Well, I think that, in retrospect, I wouldn't characterize it as a fight—I would characterize it as a difference in perspective and approach to a very significant and substantial clinical problem.

One of the things that experience taught me was that, no matter how convincing lower-level evidence is, you always need to be skeptical of evidence until it becomes high-level evidence and, hopefully, is replicated multiple times.

It was a great example of how the NCCN process, despite what some of our critics say, is an evidence-based process. And we stuck to the evidence that we had at that time—which was none. We basically said that, until we have more convincing evidence, it's a really intriguing area for clinical investigation, but it doesn't rise to the level of standard care.

PG: *Had they won there would be no NCCN as we know it.*

RC: Well, that's an interesting perspective. But I think that NCCN is a stronger organization than any single decision, but it certainly helped us establish credibility, especially down the road a few years.

PG: *Well, you can get it wrong later in your history, but not early on like that. That was the beginning. That was the first meeting.*

RC: It was early, and we did get it right, fortunately.

PG: *And you were the one who did it.*

RC: I think it was the panel that did it.

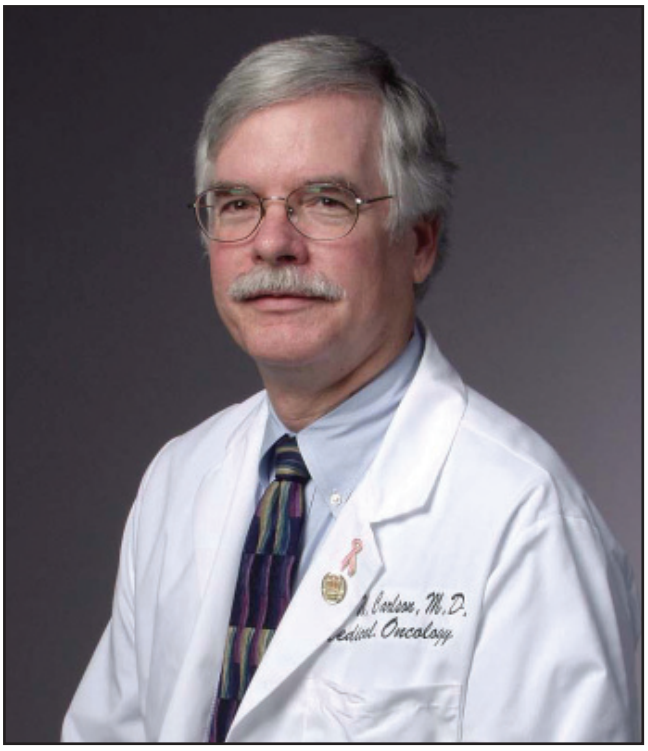
PG: *Do you think that now NCCN would be going closer to evidence-based guidelines? And I am using a strict definition of evidence-based guidelines.*

RC: The process that NCCN typically uses in its panels has been historically misunderstood by outsiders. The panels do use evidence. And whenever there is evidence in a clinical situation, the panel reviews it, reviews it very well, thoroughly, and then makes a judgment as to whether the evidence rises to the level of inclusion or modification of the guideline.

We do use an evidence-based approach. We don't give 50 papers to a statistician and have a statistician cull the data points out of those 50 papers and then do a complete review of the literature. And part of that is because, typically, when you look at a large area of oncology that has a lot of evidence, when all is said and done, clinicians typically go to two or three of those papers only. And they say, these are the highest quality papers, and these are the papers we should pay attention to, as we approach this.

The expertise of the panels is such that they don't need a statistician to do that for them. They already know what the data is; they know the context of the data in the clinic.

I actually do think it is in many ways an evidence-based approach. It's not a systematic review,



After 30 years at Stanford, breast cancer expert Robert Carlson becomes the first physician to run NCCN.

"NCCN needs to move more into healthcare policy and healthcare coverage issues within cancer care. We need to do that to ensure that our patients continue to have access to optimal, state-of-the-art care, in a way that is affordable for them and readily available to them."

that's absolutely correct. But, on the other hand, most decisions in oncology and hematology are places where there is not high-level evidence, and so you can't do systematic reviews or approaches to the data, even if you wanted to.

But there are enough of those places, that if you did a systematic review at each and every one of those places where there is high-level evidence available, you would drown yourself in an inability to move forward, because of the mass of data you'd have to look at and the mass of decisions that you'd have to make.

You would just paralyze yourself in the process.

PG: *Do you see any reason to change the process?*

RC: We always need to change the process, and we always need to improve it.

I do think that the Institute of Medicine report that came out about a year ago now—NCCN did review, did pay attention to, and has modified some of its processes as a result of that report. I'm confident that we'll continue to evolve the process over time. We have to continue to evolve and improve; otherwise, we will go out of business.

PG: *I didn't know you changed anything.*

RC: I think that that's one of the issues. The transparency of our process does need to improve, and there are efforts to do that.

We need a compiled document that outlines what our process actually is. And it's probably been 10-12 years since a publication was issued. By my recollection, it was Rodger Winn and Joan McClure who authored the article that actually described our process, and we need a new such article or a part of our website to outline exactly what the process is that we go through. [The paper is posted at http://www.jnccn.org/content/1/1/5.abstract.] It's a pretty strict process.

PG: *What's your vision on where NCCN will be five years from now?*

RC: Well, we are in the middle of a strategic planning process, and we have been asking ourselves those very questions as well. I think that—while the strategic planning process is still in progress, and so the strategic plan is a document in evolution as well—I do think that there are some things that we can be confident that will be included in that document.

And that, hopefully, will help define where the organization is going to be in five years.

The very first and primary goal is to have the guidelines, and the various products and services that are derived from the guidelines, remain the gold standard of cancer care in the U.S.

And, hopefully, we will not only remain the gold standard of care, but we will expand that recognition and those areas of influence beyond where our guidelines are currently.

Second, I think that NCCN needs to move more into healthcare policy and healthcare coverage issues within cancer care. We need to do that to ensure that our patients continue to have access to optimal, state-of-the-art care, in a way that is affordable for them and readily available to them.

PG: *What role can you play in that? In the financing of healthcare, or cost of drugs, for example.*

RC: I think we can work with payers to help identify situations in which less-costly treatments may be equivalent to more-costly treatments. And in the process, help define the places where costly treatments are necessary.

I think we can help define and work with payers and governmental organizations to better understand what kind of coverage should be available; what is the minimal data set that is available. We also have an initiative with the National Business Group on Health to help define what types of coverage large businesses should insist be included in their healthcare plans.

I think those are some of the ways we can help define that. I'm not a public policy expert—we have a number of such individuals within our institutions, and we have a number of these individuals at headquarters—so I look forward to learning from, and with, those people about how best to do this, and in helping to move the NCCN agenda forward in that regard.

PG: *Is funding going to change for you?*

RC: One of the issues that we do have to deal with is that we have to improve and enhance the financial foundation of NCCN.

I think that that's going to happen in many ways, both through the diversification of revenue sources, and we are working hard to establish new partnerships.

A lot of the association with McKesson, that was announced recently, and with other such collaborations we will see overall growth in NCCN and its programs. And in all of those different arenas we'll be able to solidify our financial foundation.

The NCCN is in good financial status. We are not on the ropes by any means—we are a vital, well-funded organization. But as you know, this is an economic situation where all not-for-profits, but especially not-

for-profits within the healthcare and medical field, have new and evolving challenges.

And we are going to meet them.

PG: *What about the guidelines? Will the nature of guidelines change?*

RC: I think the nature of guidelines will change. I think they are going to change in a variety of ways. One is that we need a better and more enhanced computer platform. We are in a time where a flat PDF file is not an adequate representation of the guideline.

It needs to be a more dynamic document than that. I think we will see platform changes. My expectation is that, through those platform changes, the documents will become more dynamic. It will be much easier to change and link to other information resources, like the NCCN compendium and the chemotherapy templates, and other derivative products.

I think that it's likely that we will, through the partnership with McKesson, and through other partnerships—I would expect that the guideline documents be more seamless with the pathway approaches to the delivery of care.

And finally, in an area that is very near and dear to my heart, is the expectation that we will have resources stratified in the guidelines. So that they're applicable not only in the U.S. but also in geographical locations with much more limited resources than we typically have available here.

PG: *NCCN has had an outcomes program for years; how is that going?*

RC: We do have an outcomes program that has been quite active over the years. The outcomes program is one of our programs that is being reevaluated currently. Almost certainly there will be major changes.

Exactly what those changes are going to look like is not clear.

We have found that one of the strengths of the current outcomes database is the richness of data. It's extraordinarily detailed. And has a very extensive data dictionary that goes along with it. That richness of data is also a weakness of the database—in that, the richer a database is, the more difficult it is to maintain completeness in a cost-effective manner.

So we are exploring ways to do a better job of that, either through linkages with other computer systems by simplifying the database, or potentially by restricting disease sites that have outcomes databases associated with them.

This also may be something that we may learn a great deal from the McKesson group. And it may also be something that we can figure out a better way to link the outcomes database with the actual guidelines documents themselves, so that the outcomes database becomes almost automatically populated, if you will, with fields based upon what the guidelines actually look like.

I think there's a lot of opportunity there. The outcomes program is one of our programs that we can be confident is going to change over the next few years.

PG: *What's the future of the international programs?*

RC: The international programs are a challenge, in part because the international arena is so large, and the cultural issues, political issues, financial issues, and so on, vary from geographic region to geographic region.

I do think that it's really important for NCCN to remain in that space. It's totally incredible for me to go to Beijing and give a lecture and have someone from a small provincial hospital in western China come up to me and say, "You've never met me before, we're in this hospital in this, what for China is a relatively small city, and we use your guidelines all the time." It's just totally impressive.

So we are making an impact in those areas. I think we need to be more systematic on how we actually do it. But it really is a challenge, because a guideline for China is different than a guideline for South America is different than a guideline for the Middle East is different for a small community hospital in the Central U.S., and so we need to find out a better system for being very systematic in how we approach those different geographical regions, being sensitive to the different social and cultural issues, and also being confident that whatever we do fits within the political structure of those regions as well. It's a challenge.

PG: *But you are going to keep some international presence?*

RC: Yes. I think you can be very confident that NCCN will remain in the international space. Exactly what that's going to look like in terms of whether we will choose to focus on specific reasons or be more expansive, and what those partnerships are going to look like with nongovernmental or governmental agencies and regions is not yet fully defined.

PG: *What about the U.S.? Do you think more members might be invited in—or allowed—in?*

RC: I think that growth within an organization like NCCN, especially a relatively young organization like NCCN, is really essential to its vitality.

I view growth in this context in many ways. We need to grow the number of people who use our

guidelines and our products. We need to grow our relationships with advocacy groups, with payers, with industry, with other professional associations, with governmental agencies like FDA and CMS. We need to grow our partnership and strengthen our partnership with our own member institutions—and I think that it's quite likely that we will also choose to grow our number of institutions.

Again, that falls within the area of strategic plan. That strategic plan has not been finalized. But I would expect growth to happen within the NCCN in all of those different dimensions.

PG: *That will be fascinating to watch. You bring something to the table that no one else had brought to the table at NCCN: your clinical expertise. How do you feel that's going to affect the way the organization is run?*

RC: My term will be the first time that the CEO has been a physician. And I think that as the organization has evolved and become more sophisticated, medical leadership at headquarters has become more essential.

I understand the issues of access, and drugs, and therapies, or lack thereof that patients experience. I know what it's like to tell a long-term patient that they are approaching their death. I understand how a lack of healthcare coverage impacts the lives of cancer patients, because I see it all the time in the clinic. And I've experienced, every week, both the successes of cancer care and the failures of cancer care. So I know what it's like to practice cancer care.

Importantly, many of the needs—many of which are unmet—are of healthcare systems to provide cancer care. So I think I bring a measure of reality. And a sense of what the real impact is, that the wonderful group of people that work at headquarters provides to our broader community.

I also think that medical systems and academic systems are very different than business systems. NCCN has typically been run as a business, and for the most part that does need to continue. But we are what we are. And we are consortium of academic centers, and so many of the principles and cultures of the academic centers should be reflected in our headquarters.

I will bring that to the headquarters as well. It's a dimension, both medically and academically, that has just not necessarily been present previously. And it's not a deficiency of NCCN; it's part of the evolution of NCCN as a relatively young not-for-profit organization.

PG: *How will you be keeping grounded as a physician? It's a policy job. Do you plan to continue to practice?*

RC: One of the most difficult things about leaving Stanford to take this wonderful position at NCCN will be leaving my patients.

There are many relationships with my patients that have been over a decade old; many over two decades old. And they're really intense, as you can imagine, loving relationships. I recognize that and also recognize the importance of the NCCN leadership remaining sensitive to the issues within the clinic.

Part of my negotiation for the CEO job was my insistence that I be able to maintain a part-time clinical practice. My expectation is that I will be spending about half a day a week at Fox Chase Cancer Center in Philadelphia in direct patient care. And I do that to maintain my skill set, but also and more importantly, to maintain awareness and credibility within what it does take to deliver patient care.

PG: *A job like this can become a policy grind…*

RC: I'm a true believer that you select a profession and a job that you really, really, enjoy, so that you never have to go to work. And if this job turns out not to be fun, then it's not the right job for me.

PG: *I was thinking more in terms of keeping grounded clinically. I'm sure that this will be very interesting to do both policy and clinical work.*

RC: Well, I think it's essential to do both. And I think it's possible to do both. The opportunity at Fox Chase has afforded me is a really wonderful opportunity within their breast cancer program at their women's cancer center. And I'm really looking forward to participating in that.

PG: *What will you be doing there specifically?*

RC: That is in the process of being defined as well. I will be a volunteer clinical faculty member within their breast cancer program. I will be working with fellows, seeing patients and so forth, and exactly how that is going to look when all is said and done is still in evolution.

PG: *What are you looking forward to the most?*

RC: I think that there are many very incredible resources within NCCN. Within the individual member institutions, within the totality of the member institutions, and, I think, there is an absolutely incredible headquarters staff that are all in place.

What I hope to do, and really look forward to doing, is figuring out ways to facilitate all of those different relationships and areas of expertise to really make the organization so much more than it is now.

I think we have the capability of doing that. But it takes work, and a lot of listening. It's going to take a lot of understanding and it's going to take developing a

shared vision of what that vision should be.

That's why I think that the strategic planning process that's going on now is so key to all of this.

I think we have the capacity and capability of being a truly dynamite organization that can continue to grow as much as it has in the past 17 years. I mean, if you were at the first guidelines conference and remember—I think in the first iteration of the guidelines there were four or five disease types represented. Maybe not even that many. And it was a very small staff, I'm not sure there was anybody who was full-time for the organization.

PG: *There was [former executive director] Cathy [Harvey], but she wasn't full time.*

RC: And she worked from home. And look where we are now.

The organization has really thrived over the past 17 years, and if we can expand the influence and quality of the product that the organization has over the next 10 to 15 years. Wow, what an accomplishment that would make. I want to be a part of that.

PG: *What were your thoughts about this organization 17 years ago, when I ran into you?*

RC: I thought it was a really neat idea. I enjoyed the process of putting the guidelines together and getting to know colleagues at other institutions. I had no clue—I don't think any of us had any clue—what the organization would really become and how much influence the guidelines would actually have. So I'm pleased with where the organization is now, and I'm surprised.

PG: *This is not an organization you would design from the ground up. This is an historical evolution. Even by the time we met, 17 years ago at that meeting, there was a lot of evolution and a lot of abandoned roads. A lot of paths not taken.*

RC: Right, and you have to do that. At an organization like this, especially really early on, you really do have to focus in the places where you can make a difference and where you have appropriate expertise and resources to do a good job.

News Analysis

ARI Raises Concerns About Anti-Competitive Practices

(Continued from page 1)

On the down side, the future implementation of the program may differ from the current proposal in ways that will facilitate collusion among the limited number of competing manufacturers of generic drugs. Therefore, federal regulators, the industry and academics should keep an eye on the program's implementation.

The intent of ARI is to provide timely information regarding the manufacture and supply of drugs in the U.S. to drug manufacturers and the FDA. This is done with the hope that the type of information gathered and disseminated through the ARI will increase early visibility and communication between FDA and the generics industry about current and potential drug shortages.

The information provided by the ARI will likely enable FDA staff to "more efficiently and effectively to accelerate the recovery of critical drugs in short supply" and thereby to help ensure patients have access to the drugs they need.

The majority of cancer drugs in short supply in the U.S. are generic, multi-source specialty drugs. This is also true of other therapeutic classes. Therefore, a critical element of the ARI is an agreement among generic and branded manufacturers, including those who directly compete in the multisource drug market, to share and compile information on product manufacturing and supply over time.

The compilation and sharing of this information across manufacturers of a given drug and the multi-source specialty drug market raises important concerns regarding anti-competitive practices between manufacturers. The FTC is one of a number of oversight institutions in the U.S. charged with evaluating anti-competitive practices between businesses. Anti-competitive business practices may ultimately harm consumers, including patients, their physicians and the health care system.

The advisory opinion to the GPhA examined the likelihood of potential anti-competitive practices entailed by the ARI and proposed program features to mitigate these concerns.

The critical anti-competitive concern raised by the ARI stems from the fact that it involves an agreement among competitors to pool information about their present and planned future output.

Generally, the U.S. antitrust laws don't prohibit

trade associations from collecting data from competing manufacturers of a given drug and collectively providing information and analysis to government officials. Such activity, undertaken for legitimate purposes, may serve to promote rather than harm competition and consumer welfare.

However, under some circumstances, data-gathering programs by trade associations can serve to facilitate collusion among competing manufacturers and thereby present a substantial risk of anti-competitive harm. Collusion between rival manufacturers may be harmful to consumers by increasing prices above competitive levels and mitigating additional firm entry.

Such programs are not unlawful per se, unless they are part of a larger scheme to fix prices or exclude potential competitors from the market. Instead, they are judged under the "rule of reason," based on their likely effects on competition, in light of the particular circumstances.

In the case of ARI, the FTC said the proposal appears "not likely to harm competition." Although the manufacturer data that GPhA proposes to collect is competitively sensitive and the ARI would raise substantial antitrust concerns if this information were shared with competitors, "the proposed program includes many safeguards designed to insure that such sharing does not occur."

The approved program proposes to mitigate anti-competitive behavior between participants in at least four ways.

First, an independent third party—IMS Health—will collect and transmit the data to the FDA. IMS will use this data, along with market data it currently collects, to analyze whether, and to what extent, the anticipated supply of a given drug is likely to fall short of the projected demand over the next several months and then provide this information to FDA staff.

IMS will not use the information generated under the ARI for any other purpose other than to gather information from manufacturers of selected drugs, perform an analysis for each drug included in the ARI program, and submit reports to the FDA.

IMS communications with individual manufacturers is limited to that which is necessary to gather the data needed to perform the analysis for an ARI drug. All communications with manufacturers concerning their ability to increase their production or supply of a drug will continue to be undertaken by the FDA. IMS will not make recommendations to the FDA regarding how the agency should seek to address a given drug shortage.

Second, the scope of the program is limited. The FDA, with input from GPhA, will decide on the initial group of drugs to be addressed through the ARI program. GPhA anticipates that the initial focus of the program will be on a subset of drugs currently on the FDA's published list of drugs in shortage.

Other criteria for inclusion in the ARI are expected to include the following: the drug is expected to be in shortage for more than 90 days; there is no therapeutic alternative (defined by the American Society of Health-System Pharmacists' list); and that it is multi-source. The FDA will reserve the discretion to include drugs that do not meet all of these criteria, depending upon emergent circumstances.

Third, manufacturer participation in the program is voluntary and participants must make a commitment not to use the ARI program activities to "exchange, discuss or agree on the price, output, cost, or other terms of competition, regarding any Shortage Drug or any other product or service."

IMS Health, with assistance from GPhA, will recruit drug manufacturers to participate in the program. All manufacturers of drugs covered by the ARI will be invited to participate, regardless of whether they are members of GPhA and regardless of whether they are manufacturers of branded or generic drugs. When a drug is added to the ARI program, manufacturers of that drug that are not already ARI participants will be invited to join the program.

Manufacturers who choose to join must execute a participation agreement that requires them to pay annual ARI dues and to comply with specified confidentiality rules, antitrust guidelines, and prohibitions on misuse of the ARI process. Participants who breach those obligations will be terminated from ARI.

Fourth, the role of the trade organization, GPhA, is strictly limited to shield it from access to competitively sensitive information. GPhA will receive monthly reports from IMS, which it may disseminate to its members and others, but these will provide no information relating to the production data that IMS has collected, nor will they identify potential shortage drugs that IMS has analyzed.

The implemented program may differ from the FTC-approved version in ways that facilitate collusion among competing manufacturers over time. Trade association programs that involve sharing of competitively significant information among competitors under the rubric of increasing consumer welfare, and in this case public health, have a history of being a subject of anti-trust scrutiny once they are

implemented.

In addition, the existing empirical work on this market, although limited in time and scope, suggests markets for the sale of generic specialty injectables have fewer manufacturers compared to small molecules used in the primary care setting.

This is in part because they require specialized knowledge and production facilities and are subject to rigorous and specific safety standards. Given the costs entailed in producing these drugs, firm concentration in such a market may make it more susceptible to collusive business practices based on available manufacturing schedules, inventory and future planned production data.

Consequently, future empirical work is needed to evaluate the ARI's effect on manufacturing firm entry, exit and price competition in the market for multisource specialty drugs.

Finally, it is important to note that none of the participants in the ARI program (the FDA, the GpHA, and a trusted third party data vendor) can compel manufacturers to supply these drugs in perpetuity, nor maintain additional capacity to manufacture these drugs in the event of unforeseen supply interruptions.

The advisory opinion is posted at http://www.ftc.gov/os/2012/08/120808gphaopinion.pdf.

The author is an assistant professor of health economics and policy at the University of Chicago.

In Brief

DuBois Named Exec. Director Of ASU's Biodesign Institute

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DuBois will take the position Dec. 1. He joins the university from MD Anderson Cancer Center, where he served as provost, executive vice president, and professor of cancer biology and cancer medicine.

Before MD Anderson, DuBois was director of the Vanderbilt-Ingram Cancer Center and was the B.F. Byrd Jr. Professor of Medical Oncology as well as a professor of medicine, cell biology and cancer biology at Vanderbilt University. He also directed the university's Division of Gastroenterology, Hepatology and Nutrition.

He is a Fellow of the American Association for the Advancement of Science, is a past president of the American Association for Cancer Research and serves on the executive committee of the Aspen Cancer Conference. In addition, he is a founding scientific advisor for both the National Colon Cancer Research Alliance and Stand Up To Cancer.

In the 1990s, DuBois and colleagues reported that colorectal tumors contained high levels of the enzyme cyclo-oxygenase-2 (COX-2). This enzyme is a key step in the production of pro-inflammatory mediators such as prostaglandin E2 (PGE2). The DuBois team was the first to show that colorectal cancers over-expressed COX-2 and their research defined a series of critical molecular pathways involved in COX-2 expression—namely, that blocking or inhibiting the COX-2 enzyme would cause colorectal tumors to shrink. This work led to clinical trials and the treatment of precancerous polyps with Celebrex, an arthritis drug that selectively inhibits COX-2.

At MD Anderson, Thomas Buchholz, head of the radiation oncology division and chair of the radiation oncology department, has begun serving as provost and executive vice president ad interim during the institution's recruitment process.

LISA CAREY was appointed chief of the Division of Hematology and Oncology at the **University of North Carolina School of Medicine** and physician-in-chief of the **N.C. Cancer Hospital**.

Carey, a member of the UNC faculty for more than ten years, is the Richardson and Marilyn Jacobs Preyer Distinguished Professor in Breast Cancer Research, professor of medicine, medical director of the UNC Breast Center, and associate director for clinical research at UNC Lineberger Comprehensive Cancer Center.

STAND UP TO CANCER and the **ST. BALDRICK'S FOUNDATION**, along with the **American Association for Cancer Research**, have begun receiving applications for a new pediatric cancer dream team.

The SU2C-St. Baldrick's **Pediatric Dream Team Translational Cancer Research Grant** will provide funding of up to $14.5 million over a four-year period for translational pediatric cancer research projects poised to deliver near-term patient benefit through

investigation by a multidisciplinary, multi-institutional, synergistic dream team of expert investigators.

This is the first Stand Up To Cancer Dream Team focused solely on pediatric cancer research since the charity was launched in 2008.

AACR has been the scientific partner of Stand Up To Cancer and provided scientific leadership, expert peer review and grants administration. The AACR is responsible for administering these grants and provides ongoing scientific oversight to ensure that progress is being made. A SU2C-St. Baldricks Joint Scientific Advisory Committee will conduct an evaluation of the applications through a multi-step review process.

The committee is chaired by Nobel laureate Phillip Sharp, an institute professor at the David H. Koch Institute for Integrative Cancer Research at the Massachusetts Institute of Technology, and will be co-chaired by researchers representing SU2C and the St. Baldrick's Foundation.

Letters of intent for the pediatric dream team grant must be submitted by Noon ET, Nov. 1., using proposalCENTRAL at: https://proposalcentral.altum.com. The dream team is expected to be announced in April 2013.

For general information on eligibility criteria, the application process and other details about the grant, visit: http://www.aacr.org/su2cfunding. Inquiries may also be directed to the SU2C Grants Office at: (267) 765-1049 or su2c@aacr.org.

The **FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY** published a series of factsheets describing the value of NIH funding across the country.

Each factsheet contains information on the level of funding, and provides examples of how locally funded research has improved health, increased innovation, strengthened the economy and helped to train the next generation of scientists.

The factsheets complement an earlier series focusing on the benefit of NIH funding in each state.

"In the current fiscal climate, it is imperative that scientists and concerned citizens educate their elected officials about the value of NIH funding in their communities," said FASEB President Judith Bond.

The factsheets can be found on FASEB's website, at: http://bit.ly/QB6e2o.

The **SCRIPPS RADIATION THERAPY CENTER** opened with a ribbon-cutting ceremony Oct. 3 in San Diego.

The $43.9 million center will have the capacity to treat approximately 1,200 patients annually. It is expected to draw patients primarily from Scripps' 23 outpatient centers and five hospital campuses.

The center consolidates Scripps' two existing radiation oncology centers at Scripps Memorial Hospital La Jolla and Scripps Green Hospital. The radiation oncology program at Scripps La Jolla was fully relocated to the new center in late September, while the program at Scripps Green is expected to be fully relocated to the new center by late November. Most patients will receive their care on an outpatient basis.

The facility includes three new linear accelerators, each manufactured by Varian Medical Systems of Palo Alto, Calif.

One of the accelerators, the TrueBeam STx, has the ability to choreograph 3D tumor imaging, beam delivery and motion management. This allows for the external beam radiation therapy to be delivered to the patient with extraordinary speed and accuracy. This holds true even if the tumor is on the lung and moving as the patient breathes.

Other technology and patient amenities at the new center include a 16-slice CT simulator with 4D imaging capability, which will enable radiation oncologists to more accurately treat tumors that move, while minimizing the impact on surrounding critical organs. Additionally, the center offers a rooftop garden, patient education resource library, clinical research space, patient locker and gowning areas and physician offices. The center is designed with sufficient space to add two more linear accelerators.

Ken Shimizu and Donald Fuller are the center's associate medical directors. The new facility has a staff of 30 professionals, including radiation therapists, physicists, nurses, dosimetrists and patient services representatives.

Letter to the Editor

CPRIT Executive Denies Undue Influence in Award Of MD Anderson Grant

In response to The Cancer Letter article that appeared Sept. 28, "Nobel Laureate Gilman Prepares to Leave," I would like to take this opportunity to provide some additional insights. Dr. Al Gilman, as CPRIT's Chief Scientific Officer, brought instant credibility to our fight against cancer. This occurred at a time when we were building the Institute from scratch—on the run so to speak, in 2009. In a matter of a few months, we were able to begin the process of funding promising research projects throughout the State, and Dr. Gilman played a critical role in making this happen.

We at CPRIT value and respect the processes that have been established; in particular, our peer review system that is designed to select only the very best projects. CPRIT's Oversight Board recognizes the integrity of the system, and to that end each and every grant that research reviewers have recommended in three years to our Board—324, totaling $675 million—has been ratified and funded.

Your article asserts that the CPRIT Board members inappropriately influence the review or funding process. Nothing can be further from the truth. Our Legislators designed CPRIT to give the overwhelming control of grant funding to our peer reviewers. More specifically, the CPRIT Board, by statute, can only disapprove a slate of grants by a super majority (2/3rd) vote.

The 100% ratification rate by our Board is quite a testament to what has been built over the first three years. What has been built will remain the cornerstone of how CPRIT reviews and awards grants.

I fully anticipated that Dr. Gilman would leave CPRIT before the end of its 10-year life. As a matter of fact, he stated in his resignation letter that it is "my intention to resign from CPRIT, effective on October 12, 2012. At that time I will have worked for CPRIT for over three years—I believe longer than originally anticipated."

We pride ourselves on being a learning organization and CPRIT is moving forward—we have embarked on a Future Directions initiative asking our Texas researchers, prevention experts and commercial partners what we should do to achieve success by 2020. To date, these engagements have involved over 800 individuals from all over the State. The way forward that these stakeholders are helping us map will be announced early next year after approval by the CPRIT Board.

While I can't predict the final recommendations that will come from the Future Directions initiative, I can say with certainty that CPRIT will continue to fund the very best prevention and research projects (both academic-based and commercial), maintain the gold standard peer review process that has been put in place, and make a difference in the lives of Texans and their families.

Sincerely,
William "Bill" Gimson
CPRIT Executive Director