THE CANCER LETTER

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Special Issue

Cancer Centers: Permanent Reinvention

NCI's Plan to Limit Growth of Core Grants Prompts Smaller Cancer Centers to Cry Foul

By Paul Goldberg

The NCI leadership has aired a plan to cap the growth of awards to cancer centers while also tightening the requirements for review of its elite club of 66 centers.

Recently, the institute circulated a preliminary draft of guidelines for evaluation of centers, which are posted at http://www.cancerletter.com/categories/documents and available to subscribers of The Cancer Letter.

However, the most controversial aspect of the plan—limiting the growth of cancer centers that have earned the NCI designation—was left blank in the documents, but was mentioned in discussion at a retreat for cancer center directors April 19.

The meeting wasn't open to the public, but according to those present, NCI officials proposed that centers with core grants of $6 million and above be capped at their current level, while centers with smaller grants would be precluded from requesting more than 10 percent increases.

(Continued to page 2)

Capitol Hill

Senate Investigates Opioid Manufacturers, Requests Study of Impact of DEA Policies

By Conor Hale

Two investigations launched recently by the Senate highlight the problems surrounding the use and abuse of pain medication in the U.S.:

• The Senate Finance Committee started an investigation into links between opioid manufacturers, their marketing practices, and the medical groups and physicians that have advocated the use of narcotic painkillers.

• Also, members of the Senate Judiciary Committee requested that the Government Accountability Office analyze how limits managed by the Drug Enforcement Agency are affecting the shortages of prescription drugs.

Pain medications are being used inappropriately, while also being in short supply.

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In Brief

Komen Pinks Tashkent; Suffers D.C. Setback

KOMEN FOR THE CURE lent support to a foundation connected with **GULNARA KARIMOVA**, daughter of **Islam Karimov**, the ruler of Uzbekistan.

The human rights record of the Karimov regime is described as "appalling" by Human Rights Watch.

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Center Directors: NCI Proposal Will Institutionalize Inequity

(Continued from page 1)

The NCI center core grants are, in effect, add-on payments determined in part by the volume of grant funding received by the center and intended to support shared services and communication within that institution.

Overall, the "benchmark ratios," or the ratio of the core grant to total funding, hover around 0.15, NCI officials say.

However, these ratios vary substantially from institution to institution, depending on factors that include the size of the center, its geographical location, its affiliation with a university, the merit of competing applications, the NCI budget, and even the role the center plays in the overall national cancer research strategy.

Political deals struck on Capitol Hill have been known to influence the size of a core grant, too, insiders say. According to critics, an institution's grant can be something of an entitlement. The best predictor of the size of an institution's future core grant is the size of its current core grant, they say.

Benchmark ratios for the centers aren't publically known.

"It's simply intended as a guide for budget requests," said an NCI official who spoke on the condition of not being identified by name. "The actual ratio is calculated each fiscal year by dividing the each center's P30 Cancer Center Support Grant award by its NCI grant base. We don't maintain a publicly available list of these. At this time, it's used only in the review context."

The proposed limits on growth of the center grants recently aired by NCI have triggered objections from directors of smaller cancer centers.

"I believe that the current proposal effectively legislates an inequitable system, which is largely based on history, and effectively excludes consideration of a change in populations and demographics or changing national needs in future times," wrote Kevin Cullen, director of the University of Maryland Greenebaum Cancer Center, in a letter to Linda Weiss, chief of the NCI's cancer centers branch.

Subsequently, a group of 11 center directors expressed similar objections in a separate letter to Weiss.

The letters were obtained by The Cancer Letter. It's not publically known whether additional comments—particularly from institutions that receive larger grants—were submitted to the institute.

In his letter to Weiss, Cullen writes that "one could question that the largest NCI center grant with a benchmark ratio of 23 percent goes to a center with an endowment in excess of $2 billion." The largest grant goes to Memorial Sloan-Kettering Cancer Center.

Similarly, Cullen questions whether the fact that "highest benchmark ratio for a comprehensive center of 33.6 percent is assigned to an institution which raises more than $500 million in philanthropic funds each year." St. Jude Children's Research Hospital raised $570 million in contributions in 2010, tax filings show.

Historically, NCI leadership tries to avoid disputes with cancer centers.

The reason for this is simple: every cancer center is a source of civic pride in its state, as well as jobs. That is why every center can be presumed to have the patronage of two U.S. senators and at least one House member, who often lobby for designation of centers and weigh in on funding decisions.

The political clout of the cancer centers may be one reason why NCI Director Harold Varmus obtained the blessings from the centers before trimming the centers' budget by 5 percent in 2010.

Recently, NCI officials said the budget for centers and the Specialized Programs of Research Excellence grants will remain flat in fiscal 2012.

The proposal to cap the centers' growth may place NCI in a difficult political situation.

Smaller centers would like to grow, but under the institute's proposed plan, their growth may be stunted

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because NCI is devoting resources to larger centers.

Also, cancer programs that are preparing applications for NCI designation are worried about the changing entry criteria and limitations on rewards that come with admission to the club.

These centers, too, can be presumed to have the support of members of their states' congressional delegations. Any efforts to trim the funding of larger centers can have similarly unpleasant consequences on Capitol Hill.

According to a memo from NCI's Weiss to the center directors, the institute is pursuing five objectives in revamping the criteria for evaluation of centers:

1) incorporate a greater focus on the quality of science;

2) foster collaboration and integration across NCI mechanisms and between centers and other institutions;

3) facilitate clinical and translational research by offering a broader array of support options;

4) develop new guidance on eligibility for application and budget requests; and 5) reduce the burden of the application process.

The guidelines are scheduled to be presented to the National Cancer Advisory Board, scheduled for June 25-26.

If the board approves, NCI would issue an accompanying Funding Opportunity Announcement in the fall of 2012, and the new guidelines would be implemented in 2013.

NCI officials declined to discuss the new guidelines with The Cancer Letter prior to the NCAB meeting.

The move to limit the centers' growth comes at a time of financial crunch for the institute. Recently, NCI officials said that they intend to keep a constant level of funding for the cancer center core grants and the SPOREs.

After a 5-percent cut during fiscal 2010, the aggregate budgetary line item for centers and SPOREs dropped to $598 million in 2011, and has stayed at the same level during the current year, institute officials said.

In 2013, funding for centers and SPOREs may increase slightly, to $598.3 million, according to Congressional justifications of the administration's budget proposal.

SPOREs received $121.9 million in 2011, but the level of funding for these programs hasn't been determined for the current year, institute sources said. Funding for these programs isn't mentioned in the Congressional justifications for 2013.

With the NCI budget likely to remain flat in the foreseeable future, it's unclear how the institute will manage to fund the crop of emerging cancer centers while also helping existing centers play a growing role in genomic, translational and clinical research.

For centers, the problem is urgent, because state money has become increasingly scarce, and the pursuit of charitable funds has become more intense (The Cancer Letter, April 20, special issue http://www.cancerletter.com/articles/20120420)

A table listing the cancer centers and the size of their grants, which first appeared in the April 20 issue of The Cancer Letter, appears on p. 5. The table is arranged by the size of core grant.

The benchmark ratios for the centers couldn't be obtained by deadline

Cullen: Plan Institutionalizes Inequity

In a letter dated May 1, Cullen used his institution's grant as an example of what he described as the inequity of the existing system.

The text of Cullen's letter to Weiss follows:

Dear Linda:

This letter is in response to your request for comments on the proposed modifications of the CCSG guidelines.

While I am in favor of the general changes to the guidelines which have been outlined, I have significant concerns about the proposal for funding of the Centers Program which you outlined at the directors' retreat in April.

At that meeting you proposed that centers with grants above $6 million would be capped at their present amount and that centers with smaller grants could request no more than a 10% increase, or an increase to $1.5 million for the smallest centers.

I believe that the current proposal effectively legislates an inequitable system, which is largely based on history, and effectively excludes consideration of a change in populations and demographics or changing national needs in future times.

As I said at the retreat, I understand that the overall centers budget is constrained and the strategic decision has been made to decrease funding to centers in order to support the total number of new research grants awarded by the NCI.

I also understand that there is no perfectly equitable funding formula that can be designed, given the number and diversity of cancer centers supported by this program. However, your funding proposal significantly disadvantages smaller and new centers and institutionalizes the significant disparity that already

exists across the range of centers supported by this mechanism.

The top 25% (17 of 66) centers funded account for fully half of the budget. In contrast, the bottom quarter all have grants of less than $2 million, and these account for less than 10% of the overall budget. Many of these smaller centers, mine included, serve significant populations of under-represented minorities, the urban poor and those in rural areas.

CCSG funding decisions have historically been based not simply on priority scores, but have taken into consideration location, whether the center is freestanding or part of a larger research university, as well as the center's unique characteristics and how those contribute to the national cancer program *as a whole.*

In that light, funding a center that develops widely used murine models of cancer and other diseases at significantly more than its NCI direct base makes sense.

By contrast, one could question that the largest NCI center grant with a benchmark ratio of 23% goes to a center with an endowment in excess of $2 billion or that the highest benchmark ratio for a comprehensive center of 33.6% is assigned to an institution which raises more than $500 million in philanthropic funds each year. This is not in any way to detract from the importance of these centers.

New and small centers must demonstrate proficiency in all the essential characteristics and are subject to the same scientific scrutiny that larger centers face in their reviews. The new funding proposal will permanently leave these centers in an under-funded state no matter the size of their grant portfolio and no matter whether they bring unique and important capabilities to the national cancer effort.

Our own center came off its initial three-year $1 million cap in the same year that global reduction in the centers budget was implemented. At the time of our site visit in 2011, we held $16.3 million in direct NCI funding.

As a result, there are currently 12 centers with equal or lesser total NCI funding whose center grants are as much as two to three times the total award we received. My concern here is not simply the status of my own center, but the fact that these proposed guidelines will effectively freeze the distribution of funding where it is for the foreseeable future.

The Centers Program has been one of the great achievements of the National Cancer Act of 1971. Interestingly, that legislation mandated a cap of no more than $5 million per center per year. It may be time to consider that once again. The current distribution of funding is inequitable and does not represent the best investment of the NCI's funds to promote cancer research and cancer care in all parts and all populations of the country.

I strongly encourage consideration of an alternative funding scheme for CCSG awards. One model would place a reasonable cap on awards and allow a more equitable benchmark ratio that would allow some leeway based on priority score and an institution's unique contributions.

This mechanism would permit center budgets to expand or decrease over time, thereby incentivizing emerging centers to compete effectively, especially when they can make significant contributions not adequately represented in the current cancer centers portfolio.

Center Directors Call for Cap on Large Core Grants

In a letter dated May 4, the directors of 11 smaller centers similarly asked NCI to bring about a more equitable distribution of cuts.

The directors called on NCI to consider a budgetary cap for a CCSG of $8-10 million annually.

"Such a cap would lead to a relatively modest or minimal reduction in the overall budgets of larger NCI Centers, while freeing up significant funds for reallocation to other Centers in the program on competitive review," the letter states.

The letter was written on the stationery of the University of New Mexico Cancer Center and signed by Cheryl Willman, director and CEO of that institution and the Maurice and Marguerite Liberman Distinguished Chair in Cancer Research Professor of Pathology and Medicine.

The letter was co-signed by:

• Mary Beckerle, Huntsman Cancer Institute, University of Utah.

• Kenneth Cowan, Eppley Cancer Center, University of Nebraska.

• Brian Drucker, Knight Cancer Institute, Oregon Health & Sciences University.

• Gordon Ginder, VCU Massey Cancer Center.

• Andrew Kraft, Hollings Cancer Center, Medical University of South Carolina.

• Patrick Loehrer Sr., Indiana University Simon Cancer Center Director.

• Frank Meyskens, UC-Irvine Chao Family Comprehensive Cancer Center.

• Timothy Ratliff, Purdue University Center for Cancer Research.

• Ian Thompson, Cancer Therapy and Research

Center, UT-San Antonio.

• Louis Weiner, Georgetown Lombardi Comprehensive Cancer Center.

• Cheryl Willman, University of New Mexico Cancer Center.

• James Willson, Simmons Comprehensive Cancer Center, UT-Southwestern.

• Walter Curran, Emory Winship Cancer Institute.

The text of the letter follows:

Dear Dr. Weiss,

Thank you for the opportunity to provide our comments regarding the proposed revisions to the NCI P30 CCSG guidelines and funding thresholds.

We, the undersigned group of NCI Cancer Center Directors, would like to express our strong support for the statements submitted for your consideration by Dr. Kevin Cullen, director of the University of Maryland Greenebaum Cancer Center (dated May 1, 2012; enclosed herein).

Dr. Cullen articulately outlines how the proposal to limit the CCSG budgets of smaller NCI Centers to a 10% increase, or an annual budget of $1.5 million for the smallest Centers, only serves to perpetuate the historic and significant funding inequities in the NCI Cancer Centers Program.

This proposal disproportionately harms the smaller NCI Centers, many of which conduct research that includes underserved populations and which contribute to the nation's cancer research mission with unique scientific and clinical programs.

When the NIH and NCI budgets were expanding and federal funds were more readily available, several of the larger and well-established NCI Cancer Centers were able to be fully funded at 15% of their total NCI funding base.

However, as federal budgets have steadily declined, there have been insufficient funds to fully fund other NCI Cancer Centers at similar proportionate levels, even though many grew considerably and achieved outstanding scores on peer review.

In these times of severe fiscal constraints, it is only fair that the entire NCI Cancer Centers program should have to "shoulder the burden." More fair allocation models should be derived that do not disproportionately harm or limit the growth and stability of the smaller NCI Centers.

It is time to re-consider a budgetary cap for a CCSG of $8-10 million annually per Center. Such a cap would lead to a relatively modest or minimal reduction in the overall budgets of larger NCI Centers, while freeing up significant funds for reallocation to other Centers in the program on competitive review.

We would like to request a meeting or an opportunity to discuss these issues further. Again, thank you for the opportunity to submit our comments.

The Core Grants at a Glance

Insiders say that the best predictor of the size of a future core grant is the size of its current core grant. A list of 2011 core grants, ranked by grant size, follows:

Source: NCI

Rank	INSTITUTION	Principal Investigator	Grant #	FY2011 Awarded TC (in $)
1	Sloan-Kettering Institute For Cancer Res	Craig Thompson	008748	13,185,550
2	Dana-Farber Cancer Institute	Edward Benz	006516	11,164,583
3	Fred Hutchinson Cancer Research Center	Lee Hartwell	015704	10,429,029
4	University of Texas MD Anderson Can Ctr	John Mendelsohn	016672	10,015,161
5	University of Pennsylvania	Caryn Lerman	016520	7,696,742
6	University of California San Francisco	Frank McCormick	082103	7,206,672
7	Johns Hopkins University	William Nelson	006973	6,995,274
8	University of North Carolina Chapel Hill	H. Shelton Earp	016086	6,839,993
9	University of Southern California	Peter Jones	014089	6,160,984
10	Vanderbilt University	Jennifer Pientenpol	068485	5,898,751
11	Duke University	H. Kim Lyerly	014236	5,723,821
12	University of Michigan	Max Wicha	046592	5,694,947

Rank	INSTITUTION	Principal Investigator	Grant #	FY2011 Awarded TC (in $)
13	St. Jude Children's Research Hospital	Michael Kastan	021765	5,674,815
14	University of Alabama at Birmingham	Edward Partridge	013148	5,476,332
15	Mayo Clinic Coll of Medicine, Rochester	Robert Diasio	015083	5,470,597
16	University of Pittsburgh	Nancy Davidson	047904	5,139,549
17	Case Western Reserve University	Stanton Gerson	043703	4,849,180
18	Northwestern University	Steven Rosen	060553	4,829,858
19	Ohio State University	Michael Caligiuri	016058	4,582,303
20	University of California Los Angeles	Judith Gasson	016042	4,575,716
21	University of Wisconsin Madison	George Wilding	014520	4,555,705
22	Washington University	Timothy Eberlein	091842	4,380,520
23	Cold Spring Harbor Laboratory	Bruce Stillman	045508	4,306,037
24	University of Chicago	Michelle Le Beau	014599	4,150,987
25	Fox Chase Cancer Center	Michael Seiden	006927	4,038,908
26	University of Colorado Denver	Dan Theodorescu	046934	3,995,527
27	Roswell Park Cancer Institute	Donald Trump	016056	3,960,459
28	University of Arizona	David Alberts	023074	3,953,813
29	Burnham Institute	Kristiina Vuori	030199	3,886,604
30	Massachusetts Institute of Technology	Tyler Jacks	014051	3,854,331
31	Columbia University Health Sciences	Riccardo Dalla-Favera	013696	3,816,425
32	University of California San Diego	Dennis Carson	023100	3,805,377
33	Yeshiva University - Albert Einstein	I. David Goldman	013330	3,725,702
34	University of Minnesota Twin Cities	Douglas Yee	077598	3,430,367
35	University of California Davis	Ralph deVere White	093373	3,138,579
36	Dartmouth College	Mark Israel	023108	3,125,750
37	Stanford University	Beverly Mitchell	124435	3,091,618
38	Univ of Med/Dent Nj-R W Johnson Med Sch	Robert DiPaola	072720	3,001,679
39	Thomas Jefferson University	Richard Pestell	056036	2,947,311
40	Salk Institute for Biological Studies	Tony Hunter	014195	2,935,545
41	Baylor College of Medicine	C. Kent Osborne	125123	2,934,758
42	H. Lee Moffitt Cancer Ctr & Res Inst	William Dalton	076292	2,657,144
43	Wayne State University	Gerold Bepler	022453	2,553,798
44	New York University School of Medicine	William Carroll	016087	2,512,026
45	Wistar Institute	Dario Altieri	010815	2,401,347
46	University of Iowa	George Weiner	086862	2,363,638
47	University of Virginia Charlottesville	Michael Weber	044579	2,290,048
48	City of Hope/Beckman Research Institute	Michael Friedman	033572	2,225,352
49	Jackson Laboratory	Richard Woychik	034196	2,143,525
50	University of New Mexico	Cheryl Willman	118100	1,934,104
51	Yale University	Thomas Lynch	016359	1,795,225
52	University of Maryland Baltimore	Kevin Cullen	134274	1,565,163
53	Georgetown University	Louis Weiner	051008	1,550,495
54	University of Nebraska Medical Center	Kenneth Cowan	036727	1,504,111
55	University of Texas-Southwestern	James Willson	142543	1,425,001
56	University of Utah	Mary Beckerle	042014	1,409,422
57	Medical University of South Carolina	Andrew Kraft	138313	1,401,250
58	Emory University	Walter Curran	138292	1,356,978
59	Wake Forest University Health Sciences	Frank Torti	012197	1,318,600
60	University of Texas Hlth Sci Ctr San Ant	Ian Thompson	054174	1,300,530
61	University of California Irvine	Frank Meyskens	062203	1,249,323
62	Purdue University	Timothy Ratliffe	023168	1,195,345
63	Indiana Univ-Purdue Univ at Indianapolis	Patrick Loehrer	082709	1,145,097
64	Oregon Health And Science University	Brian Druker	069533	1,135,337
65	Virginia Commonwealth University	Gordon Ginder	016059	878,310
66	University of Hawaii at Manoa	Michele Carbone	071789	720,185

Capitol Hill

Senate Requests Information From Drug Makers, Patient Groups

(Continued from page 1)

In oncology, physicians are often reluctant to prescribe pain medications out of fear of being targeted for an investigation by DEA and other authorities.

"There has been a longstanding issue in the cancer care community about cancer patients having their pain treated adequately. It has shown to be a very difficult problem for patients, for their families, and physicians," said Leonard Lichtenfeld, deputy chief medical officer of the American Cancer Society.

Lichtenfeld said he is in no position to comment on the investigations, but was able to address the problems with pain medications in general.

"The doctors are worried that they will be targeted by virtue of the fact that they treat cancer patients. They don't get the reassurance they need for their state licensure boards, DEA and state agencies.

"The abuses of these pain medications by some health professionals, some pharmacists and some individuals has hampered the ability of cancer patients to get ready access to needed medicines. We at ACS have been working very hard to collaborate with states to address these issues without being so punitive."

The investigations could make an important contribution to the systematic assessments of the causes of current drug shortages, said Rena Conti, an economist at the University of Chicago Department of Pediatrics, Section of Hematology/Oncology. "It is clear from initial empirical work that there are likely multiple rationales underlying the emergence and persistence of drug shortages among the many therapeutic classes affected.

"A focus on the unique features of the organization, regulation and financing of prescription drugs in short supply by therapeutic class are critical directions for empirical investigation and future policy making. These efforts to elucidate the timeliness of regulatory approval of the supply of pain drugs for medically necessary uses and the supply and promotion of these drugs for non-FDA approved uses are important steps forward."

The Senate Finance Committee sent letters requesting information from Purdue Pharma, Endo Pharmaceuticals, and Johnson and Johnson May 8.

The committee requested detailed reports of any payments from the pharmaceutical manufacturers to patient groups and individual physicians involved with pain management or palliative care, dating back as far as 1997.

The investigation follows a rising trend of accidental deaths and addiction resulting from increased sale and use of narcotic painkillers, including Oxycontin (oxycodone), Vicodin (hydrocodone), and Opana (oxymorphone).

"According to CDC data, 'more than 40 percent (14,800)' of the '36,500 drug poisoning deaths in 2008' were related to opioid-based prescription painkillers," said the committee's letters. "Deaths from these drugs rose more rapidly, 'from about 4,000 to 14,800' between 1999 and 2008, than any other class of drugs."

The letters were signed by Sens. Max Baucus (D-Mont.) and Chuck Grassley (R-Iowa).

The committee also sent letters to the American Pain Foundation, the American Academy of Pain Medicine, the American Pain Society, the Center for Practical Bioethics, the Wisconsin Pain and Policy Study Group, the Joint Commission on Accreditation of Healthcare Organizations, and the Federation of State Medical Boards.

The letters requested information regarding any payments taken from manufacturers of opioid painkillers, as well as a detailed history of seed and grant funding and revenue from publications. The committee said that these inquiries will "help to establish whether they have promoted misleading information about the risks and benefits of opioids while receiving financial support from opioid manufacturers."

The committee cited previous investigative reporting by the Milwaukee Journal Sentinel, MedPage Today, and ProPublica, which revealed ties between opioid manufacturers and the named non-profit advocacy groups. Those stories can be found at: http://www.propublica.org/article/the-champion-of-painkillers, and. http://www.medpagetoday.com/Neurology/PainManagement/31256.

The American Pain Foundation announced on its website that the organization would "cease to exist, effective immediately," on the evening of May 8, following the Senate's letters earlier that day. The foundation said its board had voted May 3 to dissolve the organization, due to "irreparable economic circumstances."

The foundation was the subject of an investigation conducted by ProPublica and The Washington Post, which found that the group received 90 percent of its funding from the pharmaceutical and medical device industry in 2010.

"Its guides for patients, journalists and policymakers had played down the risks associated with opioid painkillers while exaggerating the benefits," wrote

Charles Ornstein and Tracy Weber, of ProPublica, in a story published May 8 by The Washington Post: http://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups.

An excerpt from the Senate committee's letter to the chairman of Purdue Pharma, John Stewart, follows.

Each letter sent by the committee can be found on their website, at: http://www.finance.senate.gov/newsroom/chairman/release/index.cfm?id=021c94cd-b93e-4e4e-bcf4-7f4b9fae0047.

Dear Mr. Stewart:

It is clear that the United States is suffering from an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers. According to CDC data, "more than 40 percent (14,800)" of the "36,500 drug poisoning deaths in 2008" were related to opioid-based prescription painkillers. Deaths from these drugs rose more rapidly, "from about 4,000 to 14,800" between 1999 and 2008, than any other class of drugs, killing more people than heroin and cocaine combined. More people in the United States now die from drugs than car accidents as a result of this new epidemic. Additionally, the CDC reports that improper "use of prescription painkillers costs health insurers up to $72.5 billion annually in direct health care costs."

Concurrent with the growing epidemic, the New York Times reports that, based on federal data, "over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks" while "[d]ata suggest that hundreds of thousands of patients nationwide may be on potentially dangerous doses."

There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs' safety and effectiveness. In 2007, top executives from Purdue Pharma, the original manufacturer of OxyContin, one of the most notorious and heavily abused painkillers, "pleaded guilty…in federal court to criminal charges that they misled regulators, doctors and patients about the drug's risk of addiction and its potential to be abused."

In addition to illegal off-label marketing, which has been prevalent in the pharmaceutical and medical device industries, drug and device companies have been found to engage in marketing, regulatory, and public relations activities through supposedly independent medical organizations financed by industry. Recent investigative reporting from the Milwaukee Journal Sentinel/MedPage Today and ProPublica revealed extensive ties between companies that manufacture and market opioids and non-profit organizations such as the American Pain Foundation, the American Pain Society, the American Academy of Pain Medicine, the Federation of State Medical Boards, and the University of Wisconsin Pain and Policy Study Group.

Although it is critical that patients continue to have access to opioids to treat serious pain, pharmaceutical companies and health care organizations must distribute accurate information about these drugs in order to prevent improper use and diversion to drug abusers.

As part of our effort to understand the relationship between opioid manufacturers and non-profit health care organizations, please provide the following information:

1) Provide a detailed account of all payments from 1997 to the present between Purdue and the following organizations in table format:

a. Organizations
   i. The American Pain Foundation
   ii. The American Academy of Pain Medicine
   iii. The American Pain Society
   iv. The American Geriatric Society
   v. The Wisconsin Pain and Policy Study Group
   vi. The Alliance of State Pain Initiatives
   vii. The Center for Practical Bioethics
   viii. Beth Israel Medical Center, Department of Pain Medicine and Palliative Care
   ix. The Joint Commission (and all related entities)
   x. The Federation of State Medical Boards

b. Individuals
   i. Russell K. Portenoy, M.D. – Chairman, Department of Pain Medicine And Palliative Care at Beth Israel Medical Center
   ii. Scott M. Fishman, M.D. – Chief, Department of Pain Medicine, University of California, Davis
   iii. Perry G. Fine, M.D. - Professor of Anesthesiology, Pain Research Center, University of Utah School of Medicine
   iv. Lynn R. Webster, M.D., F.A.C.P.M., F.A.S.A.M. – Medical Director and Founder, Lifetree Clinical Research & Pain Clinic
   v. Rollin M. Gallagher, M.D., M.P.H. – Director of Pain Management, Philadelphia Veteran Affairs Medical Center
   vi. Bill McCarber, M.D. – Founder of the Chronic

Pain Management Program for Kaiser Permanente in San Diego, CA

vii. Martin Grabois, M.D. – President, American Academy of Pain Medicine

viii. Myra Christopher – Kathleen M. Foley Chair for Pain and Palliative Care, Center for Practical Bioethics

c. For each organization or individual identified in 1(a) and 1(b), provide:

i. Date of payment.

ii. Payment description (CME, royalty, honorarium, research support, etc.).

iii. Amount of payment.

iv. Year-end or year-to-date payment total and cumulative total payments for each organization or individual.

2) All documents and communications from 2004 to the present pertaining to the book, "Responsible Opioid Prescribing: A Physician's Guide," distributed by the Federation of State Medical Boards.

a. Provide the names, titles, and job descriptions of all employees who collaborated with the Federation of State Medical Boards, Dr. Scott Fishman, or third-party contractors on the development of this book.

b. For each employee identified in 2(a), provide a summary of the work performed pertaining to the book.

3) All documents and communications from 2007 to the present pertaining to the development or changes to JCAHO's19 pain management standards, including but not limited to communications with the American Pain Society and other organizations involved in developing JCAHO pain management standards.

4) All documents and communications from 2007 to the present pertaining to the development or changes to The American Pain Society's pain guidelines.

5) All documents and communications from 2004 to the present pertaining to the American Pain Foundation's Military/Veterans Pain Initiative.

6) All documents and communications from 2007 to the present pertaining to any policies, guidelines, press releases and/or position papers distributed by the American Pain Foundation.

7) All presentations, reports, and communications to Purdue's management team or board of directors from 2007 to the present pertaining to the funding of and/or collaborations with of any of the organizations or individuals specified in [this] request.

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GAO Investigation of DEA Policies

DEA laws set limits on the volumes of controlled substances that pharmaceutical companies can produce.

The Senate Judiciary Committee asked GAO to focus on whether the current production quotas for certain controlled medical substances, such as opioid pain relievers, accurately reflect market demand.

The request also asked "whether DEA regulations and policies and the application and enforcement thereof adversely impact or exacerbate the shortage of drugs used to treat patients with emergency and critical conditions and traumatic injuries, or otherwise impede the ability of emergency physicians, and EMS and CCT physician medical directors and agencies to maximize access to a limited supply of controlled substances for their patients."

The request was signed by Sens. Grassley and Sheldon Whitehouse (D-R.I.), who requested that the study be completed within one year.

An excerpt from the committee's request follows.

In researching and writing this report, we request that the GAO examine the following issues:

1. With respect to annual quota requests: the timeliness of responses from the DEA to drug manufacturer initial annual quota requests; the proximity to the subsequent calendar year that the DEA responds to such requests; the data that manufacturers provide and the data the DEA uses in granting quota requests; the processes, methodology, and data used by the DEA to determine whether and to what extent to grant a manufacturer's initial annual quota request; whether drug manufacturer annual quota requests accurately predict lawful market demand for the product in a subsequent year; and whether allowing manufacturers to provide annual quota requests later in the calendar year would improve the accuracy of such requests.

2. With respect to supplemental quota requests: the timeliness of responses from the DEA to drug manufacturer supplemental quota requests; the data that manufacturers provide to the DEA and the data the DEA uses in granting quota requests; and the processes, methodology and data used by the DEA to determine whether to grant the manufacturer's supplemental quota request and how much to grant.

3. With respect to related issues: whether an appeals process for manufacturers that disagree with the quota granted by DEA would help alleviate drug shortages; whether the DEA includes inventory allowance requirements when providing an annual

quota, and provides manufacturers increased inventory allowances if necessary to mitigate the risk of drug shortages; whether processes exist for manufacturers to obtain increases in quotas to respond to emergencies or unforeseen circumstances; and any other issues deemed necessary by the GAO related to quotas.

The full letter can be found here: http://www.grassley.senate.gov/about/upload/2012_05_03-CEG-and-SW-to-GAO-DEA-drug-shortage.pdf.

In Brief

Joe Biden Will Not Host Komen's D.C.'s Global Race for the Cure

(Continued from page 1)

Altogether, over 60,000 people took part in the May 1 event that pinked the capital city of Tashkent, where the International Race Ambassador of Susan G. Komen for the Cure, **Donna Sanderson** presented awards.

Official accounts of the Tashkent event are posted on Karimova's foundation website http://fundforum.uz/en/news/susan-g-komen-uzb-tan-race-for-the-cure-draws-20000-people/ and, separately, on her personal Russian-language website http://gulnarakarimova.com/.

Pictures of happy runners notwithstanding, Uzbekistan isn't a happy place. "Torture remains endemic in the criminal justice system," Human Rights Watch wrote in a recent report. "Authorities continue to target civil society activists, opposition members, and journalists, and to persecute religious believers who worship outside strict state controls."

Recently, a coalition of human rights groups petitioned U.S. Secretary of State Hillary Clinton to urge the Uzbek government to take immediate steps to end forced labor, including the state-sponsored mobilization of children in the harvesting of cotton.

According to an account of the Race for the Cure Tashkent event on Karimova's website, at the start and finish lines, doctors answered questions from the public and handed out brochures on breast self-examination.

A story about the Tashkent race was first reported by the blogger Nathan Hamm, who tracks the former Soviet Central Asia and Afghanistan: http://registan.net/index.php/2012/04/19/due-diligence-googoosha-and-komen-for-the-cure/.

VICE PRESIDENT JOE BIDEN will not take part in the **Global Race for the Cure** in Washington June 2.

Scheduling conflicts will prevent the vice president from hosting a pre-race barbeque, the White House said initially, later clarifying that the conflict was the wedding of the Bidens' daughter.

No conflicts have come up over the past 22 years since since vice president Dan Quayle hosted such an event during the administration of George H. W. Bush. However, Komen for the Cure, the organization supporting the race, has been embroiled in controversy over refusing to fund the screening programs of Planned Parenthood (The Cancer Letter, Feb. 3, Feb. 10).

The reception will be held at the Canadian embassy instead.

The story of Biden's scheduling conflict first appeared in The Daily Beast: http://www.thedailybeast.com/articles/2012/05/04/more-bad-news-for-komen-vice-president-biden-will-skip-d-c-event.html.

BRUCE KORF is the new president of the **ACMG Foundation for Genetic and Genomic Medicine**.

Korf takes over for geneticist and pediatrician R. Rodney Howell, who had been president for nine years. The foundation was formerly known as the American College of Medical Genetics Foundation.

"The rapid pace of discovery and the development of new technologies are enabling new approaches to improving health and diagnosing and treating both rare and common disorders," said Korf. "The ACMG and the ACMG Foundation are at the forefront in the integration of genetics and genomics into medical practice."

Currently he is the Wayne H. and Sara Crews Finley Chair in Medical Genetics, professor and chair of the department of genetics, and director of the Heflin Center for Genomic Sciences at the University of Alabama at Birmingham.

Korf is immediate past president of the American College of Medical Genetics and Genomics. He has completed terms as president of the Association of Professors of Human and Medical Genetics, and is a member of the boards of directors of the American College of Medical Genetics and Genomics.