Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. email	Zoe E. Lanier to Karen Lewis re: meeting request (partial) (1 page)	04/28/2000	P6/b(6)
002. invitation	re: personal (2 pages)	05/13	Personal Misfile
003a. letter	Trish Parnell to Christopher Jennings (partial) (1 page)	03/01/2000	P6/b(6)
003b. letter	From: Hedy Weinberg re: address and phone number (partial) (1 page)	03/21/2000	P6/b(6)
004. list	re: DOB and SSN (partial) (1 page)	05/09/2000	P6/b(6)
005a. memo	Dick Knapp to Jerry Klepner re: DOB and SSN (partial) (1 page)	05/08/2000	P6/b(6)
005b. fax	Jerry Klepner to Zoe re: SSN and DOB (partial) (1 page)	05/09	P6/b(6)
006. fax	Jeanne Holmberg to Zoe Lanier re: SSN and DOB (partial) (1 page)	04/20/2000	P6/b(6)
007. memo	Toni Snow to Christopher Jennings re: Final Details for May 11th Forum (partial) (1 page)	05/09/2000	P6/b(6)
008. letter	Royce Hanson to Christopher Jennings re: phone and fax number (partial) (1 page)	11/03/1999	P6/b(6)
009. profile	Alliance for Medical Management Education profile re: fax number (partial) (1 page)	11/03/1999	P6/b(6)
010. list	Alliance for Medical Management Education re: SSN, DOB, and fax number (partial) (1 page)	11/03/1999	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Meetings, Trips, Events)
OA/Box Number: 17045

FOLDER TITLE:
Meetings/Event Invitations [October 1999 to May 2000] [1]

2011-0747-S
rc425

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

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P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
011. list	Healthcare Policy and Regulation re: fax number (partial) (2 pages)	11/03/1999	P6/b(6)

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Karen Lewis <lewis@podesta.com>
04/28/2000 11:10:22 AM

Record Type: Record

To: Zoe E. Lanier/OPD/EOP

cc:
Subject: Meeting Request

Dear Zoe:

As discussed, please accept this as a written request for a meeting with Chris Jennings for Ernesto Bertarelli, Serono's CEO, and Tony Podesta on Wednesday, May 3 at 2:30 pm. They would like to do a follow up meeting regarding Serono's Rebif project. There might be one or two other people attending with Tony and Mr. Bertarelli but I don't know at this time. I'll get back to you tomorrow or Monday with clearance information on everyone.

Thank you.

Karen Lewis
Assistant to the Chairman
podesta.com
P6/(b)(6) (direct)

P6/(b)(6)

Anthony
[001]

* pl Rescheduled - canceled by Podesta's office

ps: Sonamy 393-7310

OK, if they wants or reschedule for another time

Yes on calendar

FILE COPY

National Organization for Rare Disorders, Inc.®

NORD • 100 Rt. 37, P.O. Box 8923 • New Fairfield, CT 06812-8923
Tel: (203) 746-6518 • FAX : (203) 746-6481
TDD (for hearing impaired) (203) 746-6927
http://www.rarediseases.org • e-mail: orphan@rarediseases.org

out of the darkness into the light ®

February 1, 2000

Chris Jennings
Deputy Assistant to the President
for Health Policy Development
The White House
1600 Pennsylvania Ave. N.W.
Washington, DC 20500

Via FAX: (202) 456-7431

Dear Chris:

The National Organization for Rare Disorders (NORD) would like to honor you at the NORD Annual Tribute Banquet to be held on the evening of Monday May 8, 2000, at the Capital Hilton Hotel in Washington, DC.

As you know, NORD's Annual Tribute Banquet is a major event that recognizes the accomplishments of individuals and corporations that have contributed to the health and well being of people with rare diseases. During your years in the White House, you have been instrumental in keeping health care at the top of the nation's agenda, and you have led the way in formulating government health policies that will touch the lives of virtually every single American. For this reason, you have been selected as an honoree at our year 2000 Tribute Banquet.

For people with rare "orphan diseases" this means that severely disabled children, who were once uninsurable, can now obtain health insurance through CHIP; the elderly now have hope that Medicare reform will include prescription drug coverage; and through the Kennedy/Kassebaum implementation (HIPA), people who change jobs are no longer forced to go without insurance. You can proudly say that the health care scenario in the United States is vastly different than it was seven years ago when you started at the White House.

We all anticipate that this last year of the Clinton Administration will bring even more reforms to the health care system, and that you may be a bit bruised by the battles that lay ahead. We want you to know that everything you have accomplished in the White House has made a major difference in the lives of our constituents, and we want to recognize this at the May 8 gala which is attended by approximately 300 people.

Dedicated to Helping People with Orphan Diseases

1/99

Please let me know as soon as possible if you agree to accept NORD's Public Service Award on May 8 for your critically important accomplishments.

I look forward to your reply.

Warmest regards,

Abbey S. Meyers
President

ASM:aa

P.S. I am attaching my op-ed from the January 30 Washington Post regarding gene therapy and the informed consent process, in case you haven't seen it.

for Debra Sugasa - 203-746-6518 x 240
203-746-6896

Black • Kelly • Scruggs & Healey

A Burson • Marsteller Company

April 24, 2000

OK
to schedule
5/10 at 1:45

Mr. Christopher C. Jennings
Deputy Assistant to the President
for Health Policy Development
216 EEOB
Washington, DC 20500

Dear Chris:

I am writing this letter on behalf of the Association of American Medical Colleges requesting a meeting with you on May 10, 2000 between noon and 2:30 P.M. to discuss the continuing financial difficulties faced by teaching hospitals. Three or four chief executive officers (CEOs) from various teaching hospitals would be attending the meeting as well as Ralph Muller, Chairman of the Association and President of the University of Chicago Hospitals & Health System, Richard Knapp, and myself. The CEOs will be in town on May 10th for "Teaching Hospital Day".

Thanking you in advance for your consideration.

202-530-4568 (Anna)

Sincerely,

Jerry D. Klepner

cc: Richard Knapp

BJC HEALTH SYSTEM℠

VIA FACSIMILE

OUR MISSION is to improve the health of the people and communities we serve.

April 28, 2000

Will attend mtg w/ AAMC scheduled 5/10 at 1:45

Mr. Christopher Jennings
Special Assistant to the President
For Health Policy Development
Old Executive Office Building, Room 212
Washington, D.C. 20502

Dear Chris;

A few years ago, you met with the leadership of BJC Health System from St. Louis to discuss pending legislative and administrative actions on health policy.

We are scheduling a similar Washington trip for May 10 and 11, 2000 in conjunction with the AAMC's COTH Spring meeting and AAMC/AHA Teaching Hospital Advocacy activities. Our delegation will include our new President and CEO, Steven H. Lipstein; Dr. Ronald Evens, President of Barnes-Jewish Hospital; Immediate Past President of the AAMC, Dr. Bill Peck; Executive Vice Chancellor for Medical Affairs of Washington University, and Dean of the Washington University School of Medicine; Ed Stiften, Chief Financial Officer; myself and other Government Relations and association staff. I understand you have received a related request from the AAMC, and would like to coordinate with them, if possible.

Although we will be spending time meeting with members of the Missouri and Illinois Congressional Delegations, we believe it is critical that we also take our message to the Clinton/Gore Administration. As you know, the Balanced Budget Act (BBA) of 1997 disproportionately impacted major teaching hospitals across the country. Because of the fundamental role teaching hospitals play in medical education, research, and indigent care, it is necessary and appropriate that relief efforts this year include targeted provisions in this area.

I look forward to hearing from you and setting a mutually convenient appointment. Please call me at (314) 286-2037.

Sincerely,

Russ Carnahan
Director, Government Relations

cc: Susan Harris,
State of Missouri Washington Office
Katie Steele

Transmittal Information:

Date: April 20, 2000

Sending Secretary: Spriggs **Ph.:** (202) 342-8418

Client Billing No.: 49390-00801

COLLIER SHANNON SCOTT, PLLC
3050 K Street, N.W., Suite 400
Washington, D.C. 20007
Main Telephone: (202) 342-8400
Telecopier: (202) 342-8451

TO: Chris Jennings **Fax No.:** 456-5557

Conf. No.:

FROM: Doris Matsui **Direct Dial No.:** (202) 342-8834

MESSAGE:

APR 13 PM10:35

NUMBER OF PAGES (INCLUDING THIS COVER PAGE):

PLEASE DELIVER IMMEDIATELY

[redacted]

Fax Operator Initials: SJB

Operator's Second Attempt:

Collier, Shannon, Rill & Scott, PLLC

Attorneys-at-Law
3050 K Street, N.W.
Suite 400
Washington, D.C. 20007

Tel.: (202) 342-8400
Fax: (202) 342-8451

10 Barrack Street
Level 12
Sydney, NSW 2000, Australia
Tel.: 61-2-262-6700
Fax: 61-2-262-3262

Doris O. Matsui
Senior Advisor and Director of
Government Relations and Public Policy
(202) 342-8834
Internet: dmatsui@colshan.com

April 17, 2000

Chris Jennings
Deputy Assistant to the President for Health Policy
Old Executive Office Building
Washington, DC 20502

Re: Meeting Request

Dear Chris:

On behalf of the Sutter Health Public Policy Council, I would like to request a meeting with you on Tuesday, May 9, 2000.

As the seventh largest non-profit health care network in the U.S., Sutter Health touches more than 100 communities in Northern California, Southern Oregon and Hawaii. In each of those places, Sutter Health seeks to enhance the health and well being of the people it serves.

To do so, Sutter Health relies on a synergistic collaboration with many public and private interests. Reflecting the community it serves, Sutter Health's Public Policy Council is comprised not only of medical professionals such as Sutter Health President and CEO, Van R. Johnson but also Modesto city councilwoman Kenni Friedman and California developer Steven H. Oliver.

Along with discussing the value of not-for-profit health systems, the group would like to discuss proposed changes to federal health programs.

If you have any questions about this appointment request or need additional information, please do not hesitate to contact me at (202) 342-8834 or Dustin Painter at (202) 342-8875. I will contact you later this week to arrange a convenient time for this meeting.

Sincerely,

Doris

Doris O. Matsui

TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT

Tufts University

Kenneth I Kaitin, Ph.D.
Director

March 6, 2000

Christopher Jennings
Deputy Assistant for Health Care Policy
The White House
1600 Pennsylvania Avenue
Washington, DC 20502

Dear Mr. Jennings:

On behalf of the Tufts Center for the Study of Drug Development, I would like to invite you to be a featured speaker at our Annual Public Policy Forum on *"Medicare Prescription Drug Benefits and the Research Based Pharmaceutical Industry – Meeting the Health Care Needs of Seniors while Maintaining Incentives to Innovate."* The Forum will be held May 11, 2000, at the Georgetown Conference Center at Georgetown University. Alan Holmer, President of PhRMA, has agreed to provide the pharmaceutical industry's view on this issue. The Forum is not intended to be a debate, but rather an exchange of ideas.

The Tufts Center for the Study of Drug Development is the only independent research organization—in the U.S. or elsewhere—that assesses the pace and nature of new drug development. We testify frequently before Congress on regulatory reform, and our work has helped policy makers, regulators, and pharmaceutical executives better understand, evaluate, and improve the efficiency of the drug development process.

Each year in May we convene a public policy forum to provide senior pharmaceutical industry executives, regulators, academics, and the press an opportunity to learn firsthand from qualified experts about an important drug development issue. This year we are examining the implications for the research-based drug industry of including prescription drug benefits as part of Medicare reform.

By way of background, last year Dr. Kenneth W. Kizer, Under Secretary for Health, U.S. Department of Veteran Affairs, and Dr. Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research, spoke on the issue of drug safety. Earlier forums focused on the impact of the *FDA Modernization Act of 1997* on biopharmaceutical development, and the news media's role in communicating complex medical information.

192 South Street, Suite 550 • Boston, Massachusetts 02111 • U.S.A.
Tel: 617-636-2170 • Fax: 617-636-2425 • www.tufts.edu/med/research/csdd

The Forum on May 11 will start at 1:30 p.m. and conclude by 4:30. I would ask you to speak for approximately 45 minutes.

I have enclosed some materials from the Tufts Center for your information, and will contact you shortly to answer any questions you may have.

Thank you.

Sincerely,

Kenneth I. Kaitin, Ph.D.
Director

KK/tls
Enc.

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The Board of Supervisors of the County of Los Angeles

Cordially Invites You
To A Reception

Wednesday, May 3, 2000
5:30 p.m. - 7:00 p.m.
121 Cannon House Office Building

RSVPs: 202-393-2404

conf call

May 10th?

FAX

PKIDs
PO Box 5666
Vancouver, WA 98668
360-695-0293 voice
360-695-6941 fax
877-55-PKIDS toll-free
www.pkids.org
pkids@pkids.org

TO: Zoey / Chris Jennings

FROM: TRISH PARNELL

SUBJECT: VIRAL HEPATITIS

PAGES: Cover + 8

Zoey - our original letter and some supporting letters.

Thank you so much!

TRISH

-Whatever you & I can do. Did Deborah and one check these people out.

Zoe

I'll meet w/ coalition of these guys. But I want to make sure that everyone who needs to be there is there. In other words I don't want to later hear that some group was "excluded" & I have to meet with them

there Deborah check these guys out

Th

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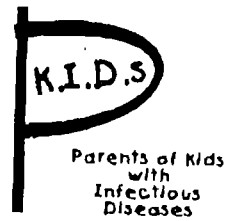

1 March 2000

Christopher Jennings
Health Policy Adviser
The White House
216 Old Executive Office Building
Washington, D.C. 20502

Dear Mr. Jennings,

Our group, PKIDs, would like to meet with you regarding the creation of a council on viral hepatitis – something similar to the Presidential Advisory Council on HIV/AIDS – which would address both adult and pediatric issues surrounding viral hepatitis.

Judith Billings, one of our Advisory Board members, also sits on the Presidential Advisory Council on HIV/AIDS. She suggested I contact your office on this matter because of the President's deep concern for those affected by infectious diseases.

PKIDs (Parents of Kids with Infectious Diseases) is a national nonprofit serving families all over this country and, thanks to the Internet, a few in other countries. PKIDs' mission is to educate the public about infectious diseases, the methods of prevention and transmission, the latest advances in medicine, and the elimination of social stigma borne by the infected; and to assist the families of the children living with hepatitis, HIV/AIDS, or other chronic, viral infectious diseases with emotional, financial, and informational support.

The overwhelming majority of children we help are chronically ill with hepatitis C or B – sometimes both. P6/(b)(6) I founded PKIDs in late '96 when I could not find support or resources for pediatric patients living with chronic hepatitis. Every day our office receives calls from moms who've just found out at least one of their children has hepatitis C or B. We're working with the Hepatitis Branch of the CDC in their efforts to alert certain members of the population to get tested for hepatitis C, and with other nonprofits and agencies around the country in a continuing effort to educate the public and get help for those chronically ill. [0003a]

We believe the existence of such a council would go a long way toward raising awareness of and preventing the spread of viral hepatitis. Of course, it is also our hope that more and more researchers will turn their talents toward helping those already infected. America tends to set the bar for the world in its approach to the care of its citizens' health. A council addressing the issues surrounding the various forms of viral

PO Box 5666 • Vancouver, WA 98668 • 360-695-0293 voice • 360-695-6941 fax

hepatitis would send a positive message to the more than 520 million on this earth chronically infected with hepatitis B or C, as well as all those affected by and infected with the other forms of viral hepatitis.

We represent moms and dads in every state in this country who hope the President will consider our proposal. If we could have a few moments of your time to discuss this in person, we would be grateful.

Thank you for your consideration with this matter.

Best wishes,

Trish Parnell
Director

enclosures

American Liver Foundation

They want a meeting!

April 5, 2000

Christopher Jennings
Health Policy Advisor
The White House
216 Old Executive Office Building
Washington, DC 20502

Dear Mr. Jennings:

On behalf of the American Liver Foundation (ALF), its Board of Directors, and our nationwide network of ALF Chapters that serve millions of people with viral hepatitis throughout the country, I am writing to encourage the Administration to give consideration to the formation of a Presidential Advisory Council on Viral Hepatitis.

The American Liver Foundation is a leading voluntary health agency (VHA) dedicated to the improved treatment and care of viral hepatitis and other forms of liver disease through research and education. We work closely with other VHA's – as well as the Centers for Disease Control and Prevention, the National Institutes of Health, and state and federal legislators – to respond to the public health challenges posed by hepatitis A, B, and C.

We know that PKIDS (Parents of Kids with Infectious Diseases) has already submitted a letter to you requesting a meeting to discuss the possible formation of a Presidential Advisory Council on Viral Hepatitis. We support PKIDS in these efforts, and will be working with them as these efforts unfold. Therefore, I would be happy to attend such a meeting with you.

Millions of Americans are affected by viral hepatitis, a growing public health threat in this country. Central to the formation of a Presidential Advisory Council on Viral Hepatitis would be the great impact realized by the men, women and children in this country whose lives are affected by hepatitis A, hepatitis B, and hepatitis C:

- There are vaccines to prevent hepatitis A and hepatitis B, but they continue to go underutilized. Each year in the U.S., more than 200,000 people are infected with the hepatitis A virus and 1 in 20 people are infected with the hepatitis B virus.

- Hepatitis C has emerged as a major public health crisis in this country. More than 4 million Americans have been exposed to the virus that causes hepatitis C, and the Centers for Disease Control and Prevention estimates that the number of deaths due to hepatitis C could increase from up to 10,000 today to 30,000 within the next 10 to 20 years.

75 Maiden Lane, Suite 603, New York, NY 10038-4810 • (212) 668-1000 • (800) GO-LIVER (465-4837) • (888) 4HEP-ABC (443-7222) • Fax (212) 483-8179

Viral hepatitis is a democratic disease – it affects men, women and children of all ages, race and sexual orientation. The growing public health impact of viral hepatitis, particularly hepatitis C, dictates a comprehensive response, and we encourage you to give consideration to the formation of a Presidential Advisory Council that would address the many challenges posed by viral hepatitis, and set in motion the public health policies that would begin to help improve the public's understanding and awareness of these health matters.

At the American Liver Foundation, our prestigious Hepatitis Council, consisting of the country's top experts in hepatitis and liver disease, is focused squarely on the scientific, medical and economic needs associated with viral hepatitis.

We welcome the opportunity to address any questions that you might have and you can reach me at (212) 668-1000, ext. 123.

In the meantime, thank you very much for your time and attention to this important public health issue. We hope to have the opportunity to speak or meet with you soon.

Sincerely,

Alan P. Brownstein, MPH
ALF President and CEO

cc: Trish Parnell, PKIDS

HEPATITIS FOUNDATION
INTERNATIONAL

Hepatitis Foundation International Backs Creation of Presidential Advisory Council on Viral Hepatitis

March 16, 2000

On behalf of the board of directors of the Hepatitis Foundation International, I want to express support for the initiative to create a Presidential Advisory Council on Viral Hepatitis. We believe it is critical to raise public awareness and understanding of viral hepatitis so that we can advance efforts to guard against them. Clearly, a presidential focus on this illness will give it the attention for which it is so deserving.

The Hepatitis Foundation International is the only nonprofit organization exclusively devoted to the control and eventual eradication of all types of hepatitis. With a national network of more than 425 support groups, HFI is a leader in patient education and support, and in the support of research to better understand hepatitis, its cause and its cure.

The creation of the Presidential Advisory Council would be a giant step forward in our battle against hepatitis. It is a step that we urge be taken today. Every day we fail to act will only add to the unnecessary human toll exacted by this insidious illness. Your support of this initiative is appreciated, and it is necessary.

Sincerely,

Thelma King Thiel
Chairman and CEO

30 Sunrise Terrace, Cedar Grove, NJ 07009-1423 973-239-1035 Fax 973-857-5044
800-891-0707 Web Site: www.HepFI.org e-mail: Mail@HepFI.org

Connection

A hepatitis C network and support system

March 1, 2000

I would like to lend my voice, and that of the Hep C Connection board and staff, to the voices of other concerned advocates who have recently proposed the creation of a council on viral hepatitis – similar, as I understand it, to the Presidential Advisory Council on HIV/AIDS. It is our hope that such a council would address both adult and pediatric issues surrounding viral hepatitis.

The Hep C Connection is a national hepatitis C network and support system, headquartered in Denver. Our fast-growing organization was founded in 1995 by hepatitis C-challenged patients to educate and support fellow patients nationwide. In addition to our involvement with patient education and support, we are actively involved in disease prevention and in increasing public awareness concerning risk factors.

Viral hepatitis C is a potentially fatal liver disease that is fast assuming epidemic proportions in the United States. My sixth sense tells me that a Presidential Advisory Council on Viral Hepatitis would go a long way toward raising and preventing the spread of viral hepatitis in our country. Time is of the essence as hepatitis issues become more and more daunting. Together we can make a greater difference!

Cordially

Ann L. Jesse
Executive Director

1177 Grant Street, Suite 200
Denver, CO 80203
303-860-0800
1-800-522-HEPC
Fax: 303-860-7481
E-mail: hepc-connection@worldnet.att.net
Web site: www.hepc-connection.org

HEPATITIS B FOUNDATION
700 East Butler Avenue
Doylestown, PA 18901-2697
Phone: (215) 489-4900 Fax: (215) 489-4920
email: info@hepb.org

CAUSE FOR A CURE
www.hepb.org

Hepatitis B Foundation Supports the Establishment of a *President's Advisory Council on Viral Hepatitis*
February 18, 2000

The Hepatitis B Foundation is a national volunteer-powered, nonprofit organization dedicated to the cause and cure of chronic hepatitis B. We seek to eradicate and find a cure for this serious liver disease through programs which fund research, promote public awareness and education, and provide information and support to all those affected.

Hepatitis B is caused by a blood-borne virus that attacks the liver and can result in chronic infections, which can lead to premature death from cirrhosis and/or liver cancer. This is a disease that affects everyone - it does not discriminate. Babies, children, adolescents, young adults, older adults are all vulnerable to this liver infection. Yet, there is a tremendous lack of public awareness about how serious hepatitis B is, and unfortunately, a lot of misunderstanding about how it is transmitted and prevented.

The number of people affected by hepatitis B is staggering. Worldwide, 2 billion people have been infected, almost 400 million have become chronic carriers of the virus, and more than 1 million die each from the complications of hepatitis B. In the United States alone, 1 out of 20 Americans have been infected with hepatitis B, more than 1 million people are chronically infected, and at least 5,000 people die each year from this virus. Despite the availability of a safe and effective vaccine, there are still almost 300,000 new hepatitis B infections each year in this country.

In addition, hepatitis C is a new emerging infectious disease which affects 3 million Americans, and like hepatitis B, it can lead to fatal cirrhosis and/or liver cancer. Although there is no cure for either hepatitis B or C, there is unfortunately not even a vaccine to protect people against hepatitis C.

Americans must be made aware of and educated about the very real threat of viral hepatitis, of which hepatitis B and C are the two most common infections. They must be informed about who is at risk, how these infections are transmitted, how they can be prevented, and what treatment options are available for those who become chronic carriers. This country has a proven track record in responding aggressively and productively to a health threat. But first, we must recognize there is a problem in order to find a solution.

The Hepatitis B Foundation fully endorses and supports the initiative to create a President's Advisory Council on Viral Hepatitis. With more than 4 million Americans suffering from hepatitis B and C, it is time this devastating health problem be given top priority attention. The establishment of a President's Advisory Council would immediately raise the public profile of these infectious diseases. But more importantly, the President's Advisory Council would provide a national forum for addressing how we can work together to solve the problem of viral hepatitis.

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003b. letter	From: Hedy Weinberg re: address and phone number (partial) (1 page)	03/21/2000	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Meetings, Trips, Events)
OA/Box Number: 17045

FOLDER TITLE:
Meetings/Event Invitations [October 1999 to May 2000] [1]

2011-0747-S
rc425

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

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Hedy Weinberg

P6/(b)(6)

[0036]

March 21, 2000

I support the efforts of Trish Parnell, Director of Parents of Kids with Infectious Diseases (PKIDs), concerning the creation of a President's Advisory Council on Viral Hepatitis. I urge you to meet with her regarding this matter.

Most people do not realize that more than 5 million Americans are infected with hepatitis B and/or hepatitis C – far more than the 1.5 million affected by HIV/AIDS. Viral hepatitis plays havoc with peoples' lives, and treatment is extremely costly. Unchecked, chronic hepatitis can lead to cirrhosis. In fact, hepatitis C is now the leading cause of liver transplants.

I personally know the effect of chronic hepatitis on family and friends. I was diagnosed with hepatitis C in 1992. Fortunately, after 22 difficult months of interferon and combination therapy, I am now in remission.

I am the co-author of *Living with Hepatitis C: A Survivor's Guide* and *My Mom Has Hepatitis C*. I've interviewed hundreds of people who deal with liver disease on a daily basis. I am always moved by their stories and their courage.

We need your help. Trish Parnell, who is spearheading this effort, is a terrific and tireless worker. I urge you to meet with her to discuss this project.

Sincerely,

Hedy Weinberg

Hedy Weinberg

Transmittal Information:

Date: May 9, 2000

Sending Secretary: Spriggs **Ph.:** (202) 342-8418

Client Billing No.: 49390-00801

COLLIER SHANNON SCOTT, PLLC
3050 K Street, N.W., Suite 400
Washington, D.C. 20007
Main Telephone: (202) 342-8400
Telecopier: (202) 342-8451

TO: Zoe Lanair **Fax No.:** 456-5557

Conf. No.: 456-5594

FROM: Dustin Painter **Direct Dial No.:** (202) 342-8875

MESSAGE:

Zoe,

Attached is the clearance information for this afternoon's meeting between the Sutter Health Public Policy Group and Chris Jennings. If you have any questions please give me or my assistant, Marcia Spriggs, a call at 342-8418.

Dustin

NUMBER OF PAGES (INCLUDING THIS COVER PAGE):

PLEASE DELIVER IMMEDIATELY

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6-2007

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004. list	re: DOB and SSN (partial) (1 page)	05/09/2000	P6/b(6)

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INFORMATION REGARDING PUBLIC POLICY COUNCIL FOR WHITE HOUSE CLEARANCE

	Name	SSN#	DOB
1.	Van Johnson	P6/(b)(6)	P6/(b)(6)
2.	Steve Oliver		
3.	John Whitelaw		
4.	Cyndi Kettmann		
5.	Kenni Friedman		
6.	Toni Brayer		
7.	Doris Matsui		
8.	Dustin Painter		

[0043]

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Washington, DC 20006 USA
202-2530-0500
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FAX TRANSMISSION

DATE: 5/9

TO: ZEO

COMPANY: WHITE HOUSE

TELEPHONE: 456-5560

FAX: 456-5557

FROM: JERRY KLEPNER

TELEPHONE: 530-4842

FAX: 530-4800

NO. OF PAGES: 2 Including cover page

COMMENTS:

PARTICIPANTS IN MEETING WITH CHRIS ON MAY 10 AT 1:45.

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
005a. memo	Dick Knapp to Jerry Klepner re: DOB and SSN (partial) (1 page)	05/08/2000	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Meetings, Trips, Events)
OA/Box Number: 17045

FOLDER TITLE:
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ASSOCIATION OF AMERICAN MEDICAL COLLEGES
2450 N STREET, NW WASHINGTON, DC 20037-1127
PHONE 202-828-0400 FAX 202-828-1125
HTTP://WWW.AAMC.ORG

May 8, 2000

MEMORANDUM

TO: Jerry Klepner

FROM: Dick Knapp

Rm 248 at 1:45

The following individuals are scheduled to attend the meeting with Chris Jennings at 1:45 p.m. on May 10. I'm telling them all we will meet at 1:30 p.m. at the Pennsylvania Avenue entrance to the Old Executive Office Building.

Ralph W. Muller
President
University of Chicago
Hospitals and Health System
DOB
SSN P6/(b)(6)

Theresa A. Bischoff
Executive Vice President,
Clinical Operations
Mount Sinai/NYU Health
DOB
SSN P6/(b)(6)

Francis Deitz
President and CEO
Memorial Hospital
Pawtucket, RI
DOB
SSN P6/(b)(6)

J. Richard Gaintner, M.D.
Chief Executive Officer
Shands Health Care
Gainesville, Florida
DOB
SSN P6/(b)(6)

Timothy M. Goldfarb
Director, University Hospital
Oregon Health Sciences University
DOB
SSN P6/(b)(6) [005a]

Donald J. Marsh, M.D.
Dean
Brown University School of Medicine
DOB
SSN P6/(b)(6)

Charles M. Smith, M.D.
President/CEO
Christiana Care Corporation
Wilmington, Delaware
DOB
SSN P6/(b)(6)

George Vecchione
President and CEO
Lifespan Corporation
Providence, Rhode Island
DOB
SSN P6/(b)(6)

Richard M. Knapp, Ph.D.
Executive Vice President
Association of American Medical Colleges
DOB
SSN P6/(b)(6)

Jerry Klepner
DOB
SSN P6/(b)(6)

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
005b. fax	Jerry Klepner to Zoe re: SSN and DOB (partial) (1 page)	05/09	P6/b(6)

COLLECTION:
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Domestic Policy Council
Chris Jennings (Meetings, Trips, Events)
OA/Box Number: 17045

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TO: JOE
COMPANY: WHITE HOUSE
TELEPHONE: 456-5560
FAX: 456-5557
FROM: JERRY KLEDNER
TELEPHONE: 530-4842
FAX: 530-4800
NO. OF PAGES: 1 Including cover page

095212

COMMENTS:

1 ADDITIONAL PARTICIPANT FOR AAMC MEETING WITH CHRIS

HERB PARDES, M.D.
PRESIDENT/CEO
NEW YORK PRESBYTERIAN HOSPITAL HEALTHCARE NETWORK

DOB
SSN

P6/(b)(6)

00663

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
006. fax	Jeanne Holmberg to Zoe Lanier re: SSN and DOB (partial) (1 page)	04/20/2000	P6/b(6)

COLLECTION:
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Domestic Policy Council
Chris Jennings (Meetings, Trips, Events)
OA/Box Number: 17045

FOLDER TITLE:
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FAX

TIMMONS AND COMPANY
SUITE 850
1850 K STREET, NW
WASHINGTON, DC 20006

PHONE: 202/331-1760
FAX: 202/822-9376

Number of pages (including cover page): 1

DATE: April 20, 2000

TO: ZOE LANIER

FROM: JEANNE HOLMBERG

Zoe,

The participants in the meeting with Chris Jennings on Tuesday, April 25, 2000 at 3:00pm are as follows:

William H. Cable
DOB P6/(b)(6) 10067
P6/(b)(6)

Michael Scott
DOB P6/(b)(6)
P6/(b)(6)

Dr. Ellison C. Pierce, Jr.
DOB P6/(b)(6)
P6/(b)(6)

Tim Keating will be out of town next week and Bill Cable from Timmons & Co. will be attending the meeting in place of Tim.

Thank you for your assistance.

OLSSON, FRANK AND WEEDA, P.C.

ATTORNEYS AT LAW
SUITE 400
1400 SIXTEENTH STREET N.W.
WASHINGTON, D.C. 20036-2220
(202) 789-1212
FACSIMILE (202) 234-3550

PHILIP C. OLSSON
RICHARD L. FRANK
DAVID P. WEEDA
DENNIS R. JOHNSON
ARTHUR Y. TSIEN
JOHN W. BODE+
STEPHEN D. TERMAN
MARSHALL L. MATZ
MICHAEL J. O'FLAHERTY
JOHN R. FLEDER
DAVID L. DURKIN
NEIL F. O'FLAHERTY

+ ADMITTED IN OKLAHOMA ONLY
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TISH E. PAHL
BRETT T. SCHWEMER
KAREN R. HARNED
PAMELA J. FURMAN
ROBERT A. HAHN*
NAOMI J. L. HALPERN
RICHARD D. SIEGEL
STEPHEN L. LACEY◊
JAN M. BRUNNER◊

OF COUNSEL
MICHELE F. CROWN
JUR. STROBOS, M.D.

March 27, 2000

OK. but I want Jenna to be there w/ our rationale

BY TELECOPY

Mr. Christopher Jennings
Deputy Assistant to the President
The White House
Washington, D.C. 20500

Re: Request For Meeting

Dear Chris:

I am writing on behalf of the National Association of Pharmaceutical Manufacturers (NAPM) with regard to the Health and Human Services budget proposal for Fiscal Year 2001 that proposed an additional generic drug rebate under the Medicaid Program. This proposal would require a dollar-for-dollar payment to the states if generic drug prices exceed the Consumer Price Index-Urban (CPI-U) in any one year. NAPM is concerned about this proposal and would appreciate a meeting with you to further discuss this issue.

Chris, as you know, generic drugs offer significant savings to the health care system. Generic drugs typically enter the market priced 20-30% below the cost of the brand name drug. The savings do not stop there. As competition continues, the price of the generic drug falls further in comparison with the brand name price -- up to 60-70% savings. These savings benefit all Americans, including those covered by the Medicaid Program, by allowing access to needed therapies and keeping overall health expenses lower. Generic drugs are already covered under the general Medicaid rebate program, as are brand name drugs. While the CPI-U rebate applies currently to the brand drug industry, as you can see there are very different considerations which must be weighed before the proposed rebate is applied to the generic drug industry; an industry which saves American consumers $8-10 billion per year in drug costs.

NAPM and I look forward to meeting with you to discuss our concerns. Thank you for your consideration. I will call your office to follow-up.

Sincerely,

Marshall L. Matz
Counsel, NAPM

MLM:lac

Chris,
Thanks
you

Heller Graduate School - MS035
Waltham, MA 02454-9110
Phone: (781) 736-3804
Fax: (781) 736-3905
Email: cummings@brandeis.edu

Brandeis University

Fax

To:	Chris Jennings	**From:**	Ann Cummings
Fax:	202/456-5557	**Date:**	May 8, 2000
Phone:		**Pages:**	7
Re:	Seventh Princeton Conference		

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

•Comments:

Zoe -

Is CJ really going to this? Please remind him that it's in NJ.

Council on the Economic Impact of Health System Change

The Seventh Princeton Conference
Access to Pharmaceuticals

The Nassau Inn
10 Palmer Square
Princeton, NJ 08542
Tel: (609) 921-7500
Fax (609) 921-9385

THURSDAY MAY 11TH – THE NASSAU INN

I. OVERVIEW:

5:00 p.m.	**Stuart Altman**	Chair Council on the Economic Impact Of Health System Change	Introduction
5:10 p.m.	**Stanley Wallack**	Executive Director Schneider Institute for Health Policy Brandeis University	
	Joseph DiMasi	Brandeis University	
	Dominic Hodgkin	Brandeis University	
	Cindy Parks Thomas	Brandeis University	
	Lori Bymark	PCS Health Systems	

Recent trends in national spending on prescription drugs: What are the trends in total spending and out-of-pocket spending by age, income, insurance status, etc.? Who pays for prescription drugs? How is increased spending divided between utilization and price? How might we begin to assess the real value of increased pharmaceutical use in terms of cost, outcomes, and substitution for more expensive care?

5:50 p.m.	Discussion		
6:30 p.m.	Cocktails and Hors D'Oeuvres		
7:15 p.m.	**Uwe Reinhardt**	James Madison Professor of Political Economy Princeton University	Welcome
7:30 p.m.	**Ian Morrison**	Senior Fellow Institute for the Future	

The Brave New World of Prescription Drugs

8:30 p.m. Dinner

FRIDAY MAY 12th – THE WOODROW WILSON SCHOOL

7:30 – 9:00 a.m. Breakfast

9:00 a.m.	**Steven Schroeder**	President Robert Wood Johnson Foundation	Welcome
9:10 a.m.	**Stuart Altman**	Chair, Council on the Economic Impact of Health System Change	

Some believe that we live in a world of limited resources in which increased public spending for pharmaceuticals will reduce spending elsewhere. We should consider that context in our discussions.

II. ACCESS TO PHARMACEUTICALS IN THE PRIVATE MARKETPLACE:

9:30 a.m.	**Elizabeth Dichter**	Executive Vice President, Strategic Marketing PCS Health Systems, Inc.

Trends in the Private Market: Trends in managed care, formularies, cost-sharing, PBMs, mail order prescriptions, etc.

9:50 a.m. Discussion

10:15 a.m.	**Alan Holmer**	President PhRMA
	Ronald Pollack	Executive Director Families USA

Are prescription drugs in the U.S. too expensive, or are current price levels necessary to support expenditures for research and development? Can we get what we have today for less? How does access to and price of pharmaceuticals in the U.S. compare with other industrial nations?

10:45 a.m. Discussion

11:30 a.m.	**Charles Sanders**	Retired Chairman and CEO Glaxo, Inc.
	Leonard Schaeffer	Chairman and CEO Wellpoint Health Networks, Inc.
	Woodrow Myers	Director, Health Care Management Ford Motor Company

FRIDAY EVENING – THE FACULTY CLUB

5:00 p.m. Cocktails and Hors D'Oeuvres

6:30 p.m. Dinner

IV. THE POLITICS OF MEDICARE REFORM

7:30 p.m. **Humphrey Taylor** Chairman, The Harris Poll
Harris Interactive, Inc.

Norman Ornstein Resident Scholar
American Enterprise Institute

The Politics of Medicare Reform: What is the political sentiment in the country and in the Congress for new policies in this area?

8:10 p.m. Discussion

9:00 p.m. Session Adjourns

Perspectives from the private sector: What is working and not working in the private sector to maintain access to pharmaceuticals while controlling utilization and cost? What is the private sector doing to improve access to pharmaceuticals for the poor? What can the private market tell us about structuring government programs?

12:00 p.m. Discussion

12:45 p.m. Lunch

III. STATE POLICIES AFFECTING ACCESS TO PHARMACEUTICALS

2:15 p.m. **Richard Cauchi** Policy Analyst
National Conference of State Legislatures

Survey of pharmaceutical access programs in the individual states across the country. Up-to-date summary of programs that have been instituted at the state level. What are state Medicaid programs doing to improve access to prescription drugs?

2:30 p.m. Discussion

3:00 p.m. **Chellie Pingree** State Senator
State of Maine

Julie Naglieri Acting Director
Elderly Pharmaceutical Insurance Coverage
Program, State of New York

Kathleen Mason Director, Office of Support Services for the Aged
New Jersey Dept. of Health & Senior Services

Lessons from the field: What kinds of innovations have been occurring in state programs? What can we learn from the people who are implementing programs at the state level?

3:30 p.m. Discussion

4:30 p.m. Afternoon Session Adjourns

SAT. MAY 13TH – THE WOODROW WILSON SCHOOL

7:30 – 9:00 a.m. Breakfast

V. FEDERAL POLICIES AFFECTING ACCESS TO PHARMACEUTICALS FOR THE ELDERLY AND THE POOR

9:00 a.m. **Barbara Cooper** Deputy Director, Institute for Medicare Practice
Mount Sinai School of Medicine

Overview of access to pharmaceuticals for Medicare beneficiaries. From what sources are the elderly receiving coverage for prescription drugs? How much are they spending out-of-pocket, and how does coverage vary across age, income, health status, etc.? What issues should we consider in deciding upon the federal role?

9:15 a.m. Discussion

9:30 a.m. **Anna Cook** Senior Research Associate
Mathematica Policy Research

Thomas Garthwaite Deputy Under Secretary for Health
Veterans Health Administration

Uwe Reinhardt James Madison Professor of Political Economy
Princeton University

The potential role of pharmacy benefit managers in a Medicare prescription drug benefit. What is likely to work or not work if Medicare employs pharmacy benefit management?

10:00 a.m. Discussion

10:40 a.m. **Mary Nell Lehnhard** Senior Vice President
Blue Cross/Blue Shield Association

Michael Gluck Director of Health Policy Studies
National Academy of Social Insurance

Judith Wagner Senior Analyst
Congressional Budget Office

Presentations and panel discussion: Given the developments in the private market, the programs instituted at the state level, and the existing political realities, how could the federal government structure and finance a program to increase access for pharmaceuticals?

11:10 a.m. Discussion

VI. CONFERENCE SUMMARY

12:00 p.m. **Stuart Altman**

12:30 p.m. Meeting Adjourns – Box lunches available

MEDICARE PRESCRIPTION DRUG BENEFITS AND THE RESEARCH BASED PHARMACEUTICAL INDUSTRY - MEETING THE HEALTH CARE NEEDS OF SENIORS WHILE MAINTAINING INCENTIVES TO INNOVATE

Annual Spring Forum, hosted by
The Tufts Center for the Study of Drug Development

Thursday, May 11, 2000
1:30 pm to 4:00 pm
Georgetown University, Washington, DC

Concepts for expanding Medicare coverage of prescription drug benefits will be looked at from the veiwpoints of two leading U.S. Senators, a senior White House Administration official, and the head of a leading industry trade group. They will discuss the current outlook for Medicare reform, implementation, and cost factors involved in expanded prescription drug coverage. The forum will conclude with a brief Q&A period.

MODERATOR:

Kenneth I Kaitin, Ph.D.
Director, Tufts Center for the Study of Drug Development

FEATURED SPEAKERS:

Senator Rod Grams (R-Minnesota)
Sponsor of Medicare Ensuring Prescription Drugs for Seniors (MEDS) Act.

Christopher Jennings
Deputy Assistant to the President for Health Policy Development

Senator Ron Wyden (D-Oregon)
Co-author of Seniors Prescription Insurance Coverage Equity (SPICE) Act.

Alan F. Holmer
President and CEO, Pharmaceutical Research and Manufacturers of America (P*h*RMA)

There will be a reception immediately following the forum.

GEORGETOWN UNIVERSITY
CONFERENCE CENTER

Marriott Conference Centers

3800 Reservoir Road, NW
Washington, DC 20057
(202) 687-3200

Directions To The Georgetown University Conference Center

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Note: Route 66 is designated for car pools with three or more people between 6:30 a.m. until 9:00 a.m. traveling East into Washington and 3:30 p.m. until 6:00 p.m. traveling West into Virginia.

★★★

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FROM ROUTE 270:
Follow 270 South towards Washington/Virginia. Take I-495 South to Virginia. Follow to Cabin John Parkway Exit 40 (Glen Echo). Continue on the Parkway past Chain Bridge and take a left at the light. This is Arizona Avenue. Take a right onto MacArthur Blvd. The road will eventually divide: bear left onto Reservoir Road. At Reservoir Road take a right and enter the Georgetown University Hospital at Entrance #1. (There will be four possible entrances, Entrance #1 will be the last one.) Follow the road straight back, it will dead end into our underground parking lot. The Conference Center is located directly above the garage on the right hand side. Please note that the Conference Center is located within a building called the Leavey Center.

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We are pleased that you will be visiting the Georgetown University Conference Center. We hope these directions will be helpful to you in planning your trip.

SAVE THE DATE!

Thursday, May 11, 2000

Tufts Center for the Study of Drug Development
1:30 - 4:00 p.m. — *Reception following*
Georgetown University, Washington, DC

Annual Spring Public Policy Forum

Medicare Prescription Drug Benefits and the Research Based Pharmaceutical Industry — Meeting the Health Care Needs of Seniors While Maintaining Incentives to Innovate

Featured Speakers:

Senator Rod Grams (R-Minnesota), *sponsor of Medicare Ensuring Prescription Drugs for Seniors (MEDS) Act*

Senator Ron Wyden (D-Oregon), *co-author of the Seniors Prescription Insurance Coverage Equity (SPICE) Act*

Christopher Jennings, *Deputy Assistant to the President for Health Policy Development*

Alan F. Holmer, *President and CEO, Pharmaceutical Research and Manufacturers of America (PhRMA)*

Speakers will address the following questions:

- What is the view of the U.S. Congress and the research based industry on providing prescription drug coverage to Medicare beneficiaries?
- How can government and industry work together to identify ways to pay for a Medicare prescription drug benefit?
- Should a prescription drug benefit be implemented within the framework of comprehensive Medicare reform, or can it simply be added as a stand-alone benefit?

TO CONFIRM YOUR ATTENDANCE, COMPLETE REGISTRATION ON REVERSE SIDE

Call for details: 617-636-2187

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Fax to: 617-636-2425

MAY 11: *Medicare Prescription Drug Benefits and the Research Based Pharmaceutical Industry — Meeting the Health Care Needs of Seniors While Maintaining Incentives to Innovate*

Name _____
Last *First* *MI* *Degree*

Title _____

Organization _____

Address _____

City_____ State_____ Zip _____

Country _____

Tel (_____) _____ Fax (_____) _____

E-mail _____

Registration: Complete this registration form and **fax it to the above number**. Registrations received after May 3 will be accepted only if space permits.

Payment: Tufts CSDD sponsors, and government and academic employees will be admitted free of charge. All others will be charged a $150 registration fee. **Payment is due by May 3, 2000.** Make checks payable to **Trustees of Tufts College** and mail with this completed form to the attention of **Toni Snow, Administrative Manager, Tufts CSDD, 192 South St., Suite 550, Boston, MA 02111.** To pay by credit card, complete the following information.

To pay by credit card, (MasterCard or Visa only), complete the following information:

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Cancellation Policy: Cancellation and refund requests must be received by May 3, 2000. Requests received prior to May 3 will be assessed a $50 processing fee. No refunds can be given to requests received after May 3. Substitutions may be made at any time.

About the Tufts Center: *The Tufts Center for the Study of Drug Development is an independent, nonprofit, multidisciplinary research group affiliated with Tufts University. For over twenty years, through the maintenance and development of its unique historical databases, the Center has contributed to the exploration of scientific, economic, legal, and public policy issues related to pharmaceutical and biopharmaceutical research, development, and regulation throughout the world. By addressing the interaction between science, government, industry, and public health, the Center strives to raise the level of national and international debate on issues related to new drug and biotechnology product development and regulation.*

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
007. memo	Toni Snow to Christopher Jennings re: Final Details for May 11th Forum (partial) (1 page)	05/09/2000	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Meetings, Trips, Events)
OA/Box Number: 17045

FOLDER TITLE:
Meetings/Event Invitations [October 1999 to May 2000] [1]

2011-0747-S
rc425

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT
Tufts University

MEMORANDUM

THREE PAGE FAX: 202-456-5557

To: Zooey for Christopher Jennings

From: Toni Snow, Administrative Manager TLS
Tufts Center for the Study of Drug Development

Subject: Final Details for May 11th Forum on the Provision of a Medicare Prescription Drug Benefit -- 1:30-4:00 p.m., Georgetown University Conference Center

Date: May 9, 2000

I am attaching driving directions to the Georgetown University Conference Center. The Conference Center is located at 3800 Reservoir Road, NW, in the Leavey Building. Mr. Jennings is scheduled to speak at 2:15 p.m. for approximately 30 minutes. We expect to have some members of the press covering the forum and are delighted that Mr. Jennings will be participating.

[007]

In the event of any questions, I can be reached by cell phone at P6/(b)(6) on Wednesday and Thursday. Many thanks to you for your excellent help in scheduling this event!

P6/(b)(6)

cc

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TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT

Tufts University

April 11, 2000

Christopher Jennings
Deputy Assistant for Health Care Policy
The White House
1600 Pennsylvania Avenue
Washington, DC 20502

Dear Mr. Jennings:

I'm delighted you'll be joining us as a featured speaker on Thursday, May 11th at our Annual Public Policy Forum. The forum will begin promptly at 1:30 p.m. You will be the second speaker of the afternoon, at 2:15 p.m. The total time allotted for your talk will be 30 minutes.

I believe we have an excellent program planned. The other speakers include Senators Rod Grams (R-Minnesota) and Ron Wyden (D-Oregon), and Alan Holmer, President, Pharmaceutical Research and Manufacturers of America. Enclosed you will find a program flyer and agenda, as well as directions to the Georgetown Conference Center.

The audience will be comprised primarily of members of the drug development community, government, and the media. The forum will end with questions and comments from the audience and will be followed immediately by a reception, which I hope you can also attend.

Please feel free to contact me or our Administrative Manager, Ms. Toni Snow, if you have any questions regarding the forum.

Sincerely,

Kenneth I Kaitin, Ph.D.
Director

KK/ts
Encs.

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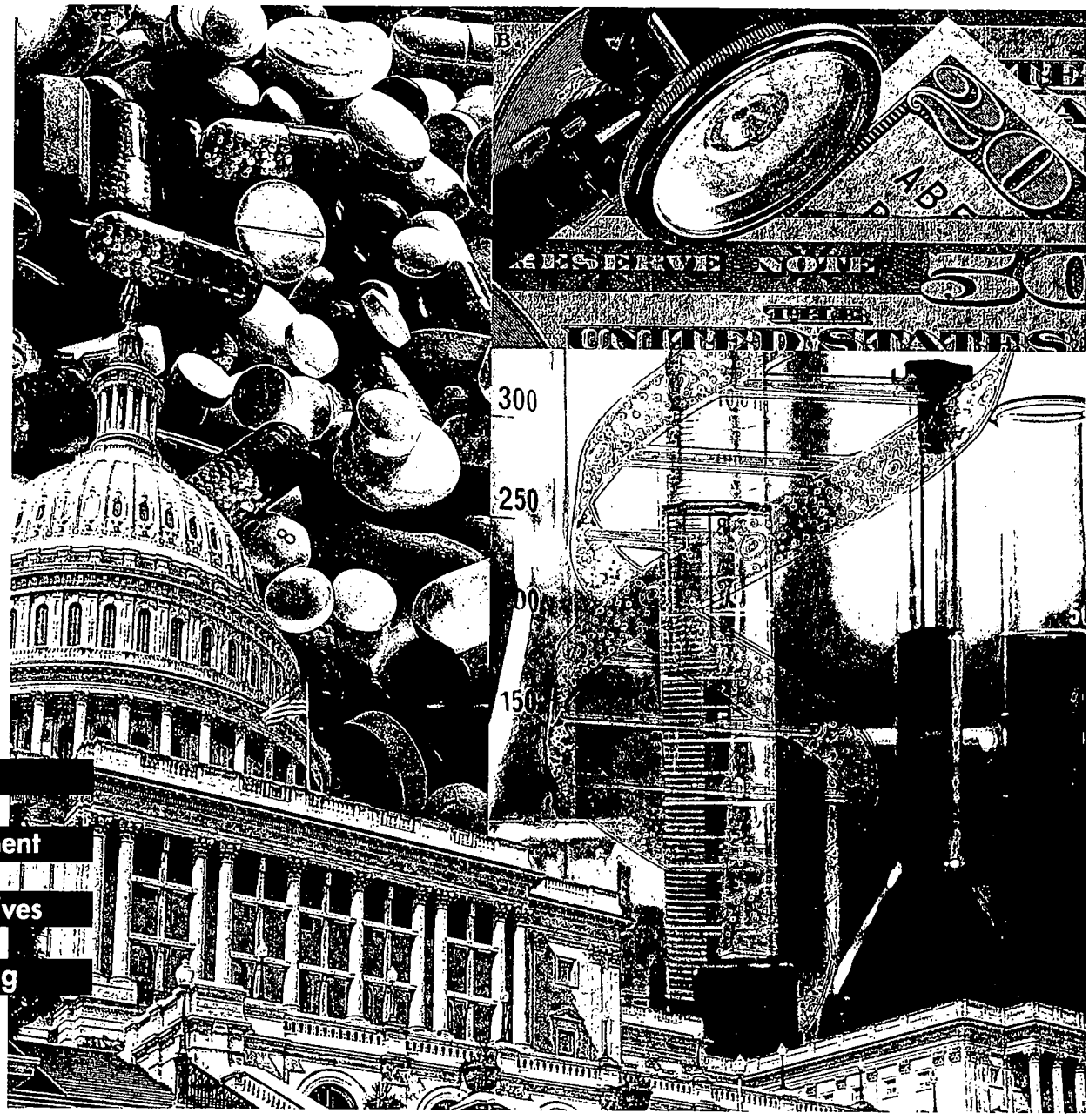

Industry Efficiency

Regulatory Environment

Biotechnology Initiatives

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Tufts Center for the Study of Drug Development

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Volume 2 • January 2000

Tufts Center for the Study of Drug Development

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Effective data use drives portfolio management and global strategies

Doing the right R&D—and doing it right—starts with corporate strategy

- Closely linking project priorities to corporate strategy forms the foundation for sound project management.
- Senior management buy-in and the right information are critical factors that help to ensure that the right projects get continued support.
- A specific metric will not by itself indicate which compounds to pursue, but will help to inform a process that accounts for marketing, pharmacoeconomic, and regulatory needs.
- Although simultaneous global launch is not currently achievable, simultaneous regulatory submissions help companies prepare for subsequent launches.
- Accelerated development strategies are appropriate in some instances, but require enormous effort and expense, and increase the risk of making mistakes.

There probably is no more consequential issue within the pharmaceutical industry than effective portfolio management, for it is new compounds that will shape company growth. Even more to the point, effective portfolio management—which gives promising compounds the best chance to succeed—more than anything else, will determine company pipelines and market value over the next five years.

Last November, the Tufts Center for the Study of Drug Development organized the third annual R&D management workshop, providing attendees an opportunity to learn firsthand how leading, as well as emerging, drug companies manage R&D projects. While each presenter focused on a specific aspect of portfolio management or global submissions, all referenced the enormous influence that effective use of information has on project success. That and other highlights are presented in this Impact Report.

Join us at our next R&D management workshop—Nov. 9, 2000, in Philadelphia.

The Role of Project Management in Product Development

Doing the right R&D—and doing it right—starts by aligning project priorities with corporate strategy

Are we doing the right R&D?

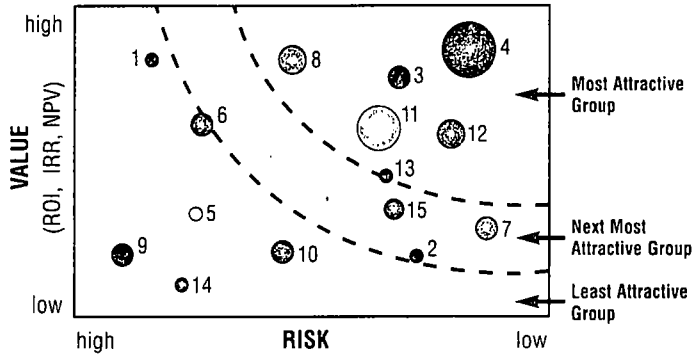
- What is the value of the portfolio? Is it enough?
- Are we getting a good return on our R&D?
- Will sales steadily increase over time?
- Do we have the right project balance?
- Which projects should get high/low priority?
- Do we have enough resources to do the job?
- Does the portfolio have value to different customer types?
- Does the portfolio fit with corporate strategy?

Are we doing R&D right?

- How valuable is this project? What is driving value?
- What resources will it require?
- How can we increase value, and what are the costs?
- What are the risks? How do we manage them?
- Should the project go to the next phase?
- What priority should we give this project?
- What is the impact of delaying the project?

Senior management buy-in and the right information help projects get continued support

Succinct Delivery of Complex Data is Key



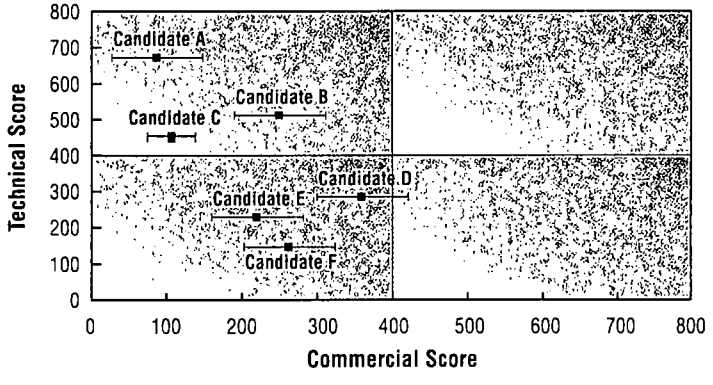
Note: Each bubble represents a drug in development. Area of bubble = anticipated total remaining development cost.

Critical success factors for projects include:

- Senior management involvement—from the beginning and throughout the project.
- The right models and processes that link project value, from research through market support.
- The right balance of simplicity, precision, and depth of understanding.
- Appropriate access to information.
- Fully resourcing the portfolio review process.

Excellent decision-making is the goal of a portfolio planning process

Consistent Analysis Fosters Good Decisions



Evaluating all drugs in development along the same dimensions won't tell you which single drug to focus on, but will facilitate the discussion that will lead to a conclusion.

- Scenario planning helps project managers understand what they will do if their primary scenario does not work out—and lets them respond quickly to changes.
- All the unknowns can't be eliminated. Therefore, don't overestimate your ability to determine the unknowns.
- Development teams add value by creating detailed assessments of the scientific rationale, clinical feasibility, and potential risks of projects.

Developing an Integrated Global Strategy

Simultaneous global launch, while laudable, is not currently achievable

- **Logistical difficulties preclude simultaneous launches, but simultaneous regulatory submissions help companies prepare for subsequent launches.**
- **A strategic global plan that includes sequential submissions in major markets lets companies:**
  - Roll out a proactive approach, which enables them to retain control.
  - Coordinate critical launches.
  - Enhance the potential for consistent labeling and messaging.
- **Companies may not want to embark on a global submission plan for good reason:**
  - Protection of intellectual property may not be possible. If companies must disclose information early in one market, it may leak out elsewhere.
  - Dealing with different regulatory authorities at the same time may overwhelm the company's capacity to manage the process.
  - Objections from one authority may delay the entire launch.

Begin with the end goal in mind when developing integrated global product lifecycle plans

- **Companies should aim to get the best label they can worldwide—even if it means walking away from a market if a local authority demands a change the company can't live with. The label should also help the company:**
  - Develop efficacious and safe medicinal products with commercial advantages.
  - Focus effort on activities necessary to realize the label quickly.
- **There should be one regulatory response team that can answer queries from around the world.**
  - The team should develop detailed answers to likely questions to shorten response times when questions arise.
  - It should carefully manage the knowledge it amasses.
  - The team should be kept in place after approval is received.
- **In five years, the leading drug companies will be those that best harness technology to collect, analyze, and communicate data to regulators and customers faster and better than their competitors.**

Speed can be achieved, but it is often risky and expensive

- **Accelerated development strategies require enormous effort and expense—and some luck. They also increase the chance of making mistakes that could imperil the success of the compound.**
- **A continuously updated Product Development Plan, signed off by all parties, is essential and should have full buy-in and sign-off from the marketing, pharmacoeconomic, and regulatory functions.**

■ **Acceleration strategies have their place, but they bring attendant risks:**

- ***Skipping Phase I studies***—Possible in selected cases, such as cancer, but must know the maximum tolerated dose and also have adequate pharmacokinetic (PK) data to ensure the best chance of demonstrating efficacy in Phase II.
- ***Skipping Phase II studies***—Might apply to drugs coming into the U.S. from abroad, where the dose and effectiveness are known, but is inherently much riskier than skipping Phase I studies.
- ***Blending Phase I and Phase II studies***—Could be an appropriate approach to obtaining approval in certain cases, such as herbal medicines, some of which have been in use for thousands of years.
- ***Conducting lean studies***—They are quick and cheap, but if they fail, companies run the risk of having to rerun the studies and incur still more costs.

Workshop Presenters

Kenneth I. Kaitin, PhD – Chairman
Director
Tufts Center for the Study of Drug Development

David Ebersman
Vice President, Product Development
Genentech

Susan T. Hall, PhD
U.S. Site Director, Worldwide Project Planning, Strategy, and Redesign
Glaxo Wellcome, Inc.

Jeffery S. Kasher, PhD
Director, Pharmaceutical Products
Eli Lilly and Company

Thomas P. Lawler III, MBA
Process Integration & Measurement Group Leader
AstraZeneca

Sampat M. Singhvi, PhD
Director, World Wide Regulatory Affairs
Bristol-Myers Squibb Company

William M. Wardell, MD, PhD
Senior Science Officer
Covance

About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development, affiliated with Tufts University, provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. The Tufts Center conducts a wide range of in-depth analyses on pharmaceutical issues and, in addition, hosts symposia, workshops, and public forums on related topics throughout the year.

Tufts Center for the Study of Drug Development
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TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT

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Kenneth I Kaitin, Ph.D.
Director

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TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT
Tufts University

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Boston, Massachusetts 02111

Kenneth I Kaitin, Ph.D.
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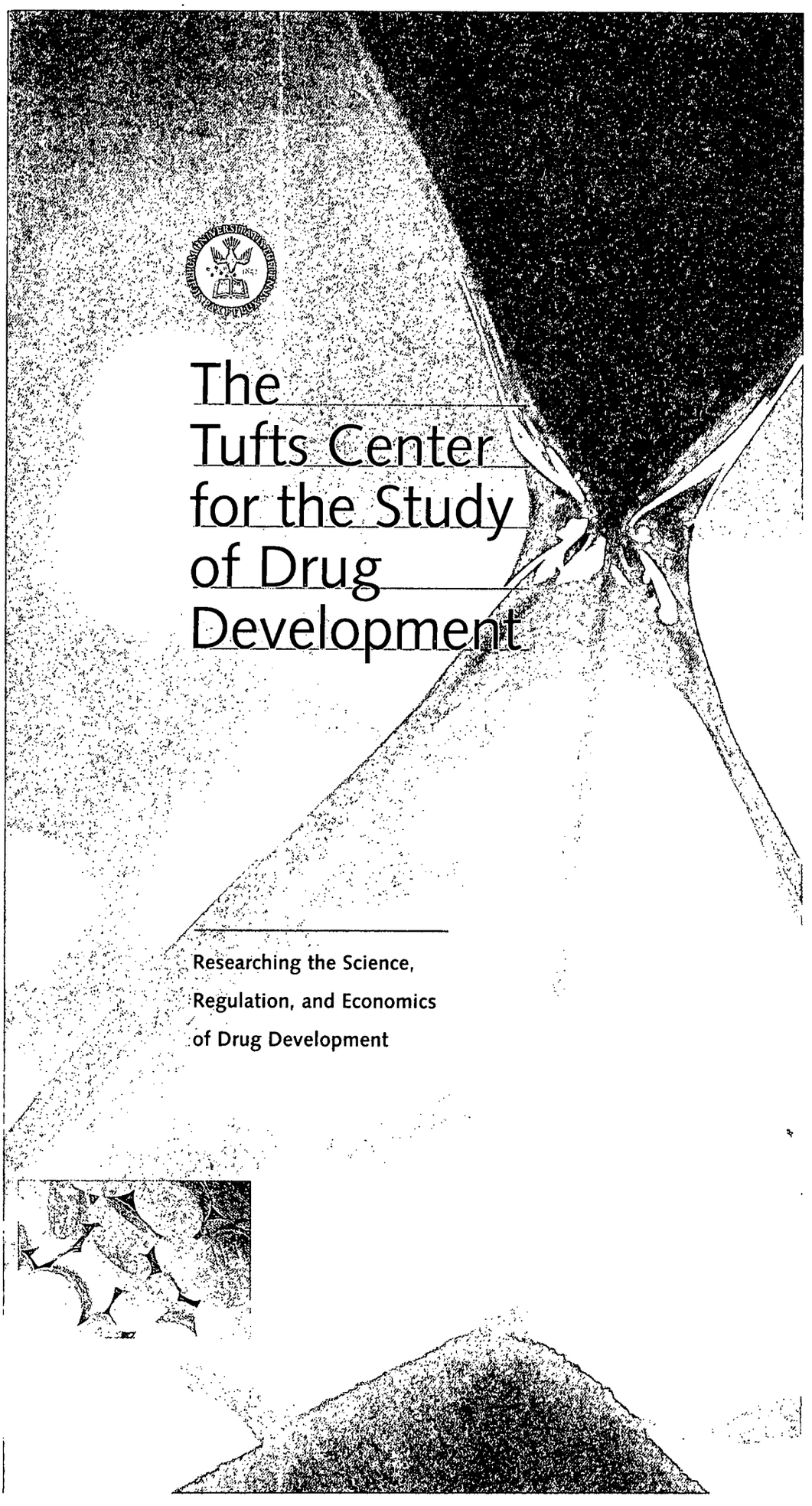


The Tufts Center for the Study of Drug Development

Researching the Science, Regulation, and Economics of Drug Development

Aims of the Tufts Center

The Tufts Center for the Study of Drug Development is an independent, academic, nonprofit research group affiliated with Tufts University in Boston, Massachusetts. Founded in 1976 by Dr. Louis Lasagna, an internationally renowned pioneer in clinical and basic pharmacology, Tufts CSDD is the foremost authority on drug development policy.

Dr. Kenneth I Kaitin
Director

For over twenty years, Tufts CSDD has played an active role in formulating public policy and contributing to improvements in the drug development process. Its unique cumulative databases on investigational and approved new drugs and biopharmaceuticals allow Tufts CSDD to monitor the rate of pharmaceutical innovation and to track trends in the time, cost, and risks associated with new product development.

Objectives

- To monitor and report on the development, regulation, and utilization of new drugs and biopharmaceuticals
- To explore the economic, legal, scientific, and public policy issues affecting pharmaceutical and biopharmaceutical innovation worldwide
- To serve as a resource for information on the development and review of new therapeutic agents
- To sponsor public forums and conferences that bring together the perspectives of government, industry, academia, and public health advocates
- To raise the level of national and international debate on issues related to new drug and biotechnology product development and regulation

Research Activities

Tufts CSDD research over the past twenty years has helped shape and inform policy debates on drug development, approval, and regulation. In addition, results from center studies have provided valuable benchmarking information for industry in its efforts to improve the efficiency and speed of the development process. Tufts CSDD has pioneered work on innovation in the pharmaceutical industry, the drug lag, the cost of new drug development, the decline of effective patent life, and innovation in the biotechnology industry. Recently, Tufts CSDD was an important contributor to the public debates on the *FDA Modernization Act of 1997,* reauthorization of the *Prescription Drug User Fee Act of 1992,* and pharmaceutical patent extension.

Tufts CSDD's current research agenda includes the following high priority projects: calculating a new estimate of the cost of new drug R&D; evaluating the impact of recent regulatory initiatives on new drug development; examining the integration of pharmacoeconomic studies in drug development programs; estimating success rates in biopharmaceutical development; and exploring the impact of FDA's recent pediatric initiative on development strategies.

Data Resources

Tufts CSDD maintains several unique databases that constitute the most detailed source of historical information available on pharmaceutical and biopharmaceutical innovation in the U.S. Through annual surveys of companies marketing new therapeutic agents and triennial surveys to U.S. companies doing investigational work, Tufts CSDD obtains data on drugs and biologics that have entered human testing for the first time worldwide as well as those that have received approval for marketing in the U.S. Tufts CSDD databases contain data on products approved from 1963 to the present.

Dr. Louis Lasagna
Chairman of the Board and
Adjunct Scholar

Corporate Support

Tufts CSDD is a nonprofit organization funded primarily by contributions from pharmaceutical and biopharmaceutical companies, trade associations, contract research organizations, and consulting firms. This funding is unrestricted, allowing Tufts CSDD researchers to maintain academic freedom and ensuring objective and unbiased studies.

Tufts CSDD relies on the financial contributions of its nearly fifty corporate sponsors. Benefits of corporate sponsorship include access to more than thirty years of aggregate data on new and investigational drugs and biologics, confidential benchmarking reports, and reduced registration fees to Tufts CSDD sponsored events. In addition, corporate sponsors are invited to attend Tufts CSDD's annual corporate sponsors meeting, to review progress on ongoing studies and to suggest areas for future research. In funding Tufts CSDD, corporate sponsors are directly supporting independent and objective research vital to the industry. For more information on becoming a Tufts CSDD sponsor, please contact Dr. Kenneth Kaitin, director.

Other Activities

Newsletter

The *Tufts CSDD Newsletter* is sent to more than 2,500 individuals three times a year. Included with the newsletter are reprints of articles published by Tufts CSDD staff members and other articles of interest.

Conferences

Tufts CSDD sponsors symposia on a range of issues. Recent meetings include the 1998 annual spring forum, entitled, "Improving the Process of Biopharmaceutical Development: Impact of Recent Initiatives"; the annual workshop on R&D management, focusing on project management initiatives in the pharmaceutical and biotechnology industries; and the biennial symposium at the Tufts University European Center in Talloires, France, entitled, "Dynamics of the International Pharmaceutical Marketplace: Major Forces in the Late 1990s."

Library Services

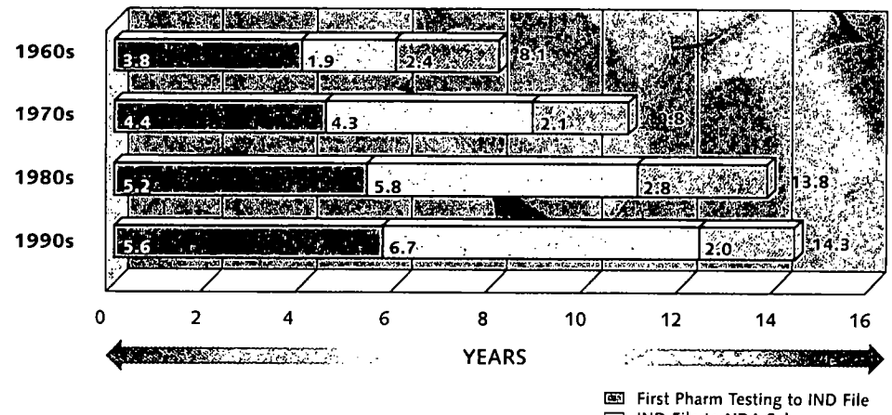
Tufts CSDD regularly responds to requests for information from industry, government, national organizations, the media, and other interested individuals. Our research librarian provides knowledgeable, authoritative, and informed responses to reference questions. Tufts CSDD's library on drug development and regulation contains more than 18,000 items. Books, journal articles, government publications, and trade and popular articles are included.

Courses

Tufts CSDD's Annual Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation is a unique four-day program designed as an introduction to and overview of such topics as pharmacokinetics, clinical pharmacology, the design and analysis of clinical drug studies, crisis management, and drug development and regulation.

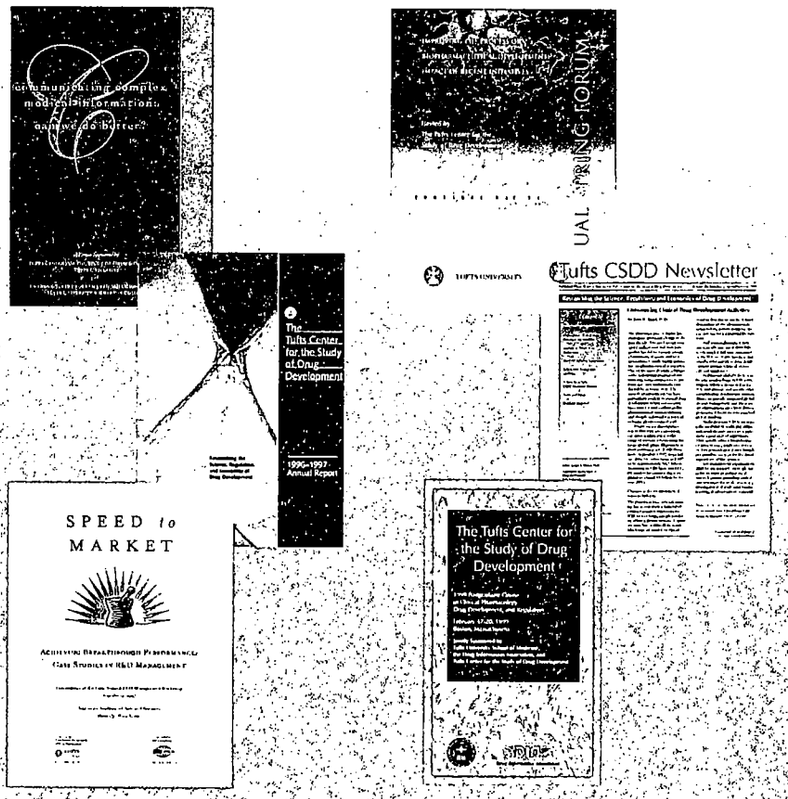
For more information, contact Tufts CSDD's administrative manager or access our site on the World Wide Web: http://www.tufts.edu/med/research/csdd

Time from First Pharmacological Testing to New Drug Approval, 1963–1997



Source: Tufts CSDD, 1998

Tufts CSDD Publications



Recent publications available from Tufts CSDD

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Tufts Center for the Study of Drug Development

Research MILESTONES

1976	**Center for the Study of Drug Development is established and conducts first comprehensive analysis of innovation** in the U.S. pharmaceutical industry.
1976	**Identifies the "drug lag"** by documenting the delayed availability of drugs in the U.S. relative to the U.K.
1979	**Conducts first comprehensive study on the cost to develop a new drug**, pegging it at $54 million.
1981	**Demonstrates the dramatic decline in effective patent life** for new therapeutic compounds and identifies a significant disincentive to drug innovation. Helps set the stage for Title II of the *Drug Price Competition/Patent Term Restoration Act of 1984.*
1982	**Provides first comprehensive evaluation of R&D effort** of the U.S. pharmaceutical industry by assessing its competitive position along several dimensions.
1982	**Completes first analysis of availability of drugs for limited populations**, paving the way for the *Orphan Drug Act of 1983*, which gave drug firms incentives to develop drugs for rare diseases.
1984	**Develops first comparison of the rate of drug safety withdrawals** in the U.S. compared to other industrial countries, highlighting the therapeutic impact of U.S. regulatory conservatism.
1987	**Publishes first comprehensive analysis of FDA's practice** of requiring post-approval research as a condition of approval.
1991	**Updates its seminal study on drug development costs**, and determines that it now costs $231 million to bring a new drug to market in the U.S. This figure becomes widely used throughout the pharmaceutical industry and in Congressional debate on pharmaceutical pricing.
1993	**Develops first international comparison of biotechnology** product discovery, development, and marketing rates in the U.S., Europe, and Japan.
1995	**Publishes first comprehensive analysis of biotechnology success rates**, comparing development of biotech products with that of new chemical compounds.
1996-98	**Provides critical data and public testimony at Congressional hearings**, leading to development of the *FDA Modernization Act of 1997* (FDAMA).
1997	**Completes comprehensive analysis of FDA/sponsor meetings**, showing that meetings reduce the time of new drug development by speeding reviews and improving communication between the FDA and sponsors.
1999	**Publishes analysis of impact of *Prescription Drug User Fee Act of 1992*** (PDUFA), finding that drug development times have decreased following implementation of the new law.

About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development, affiliated with Tufts University, provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. The Tufts Center conducts a wide range of in-depth analyses on pharmaceutical issues and, in addition, hosts symposia, workshops, and public forums on related topics throughout the year.

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Priority access to information developed from Tufts CSDD's proprietary databases.	More than 30 years of aggregate data on new and investigational drugs and biologics.	Improve your internal assessments of drug development issues.
On-site presentations.	In-depth, authoritative briefings on emerging industry issues.	Better evaluate how your company may be affected by rapid industry changes.
Access to the full array of Tufts CSDD information services.	Entrée to our extensive drug development library, containing more than 18,000 documents, letters, and reports.	Make use of the most comprehensive source of drug development information in the United States.
The opportunity to serve on Tufts CSDD's Advisory Board.	Regular meetings to review Center activities and help shape strategic objectives.	Influence key Center activities and exchange views with other senior level industry executives and FDA leaders.
The opportunity to attend Tufts CSDD courses, conferences, and workshops at reduced rates.	Professional development and continuing education for staff throughout your company.	Hear directly from industry, regulatory, and academic leaders on key drug development issues, and meet with industry peers.
An invitation to attend our annual corporate sponsors meeting and spring forum.	A firsthand look at the upcoming Tufts research agenda.	Refine your organization's approach to drug development.

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Tufts Center for the Study of Drug Development

Sponsors SPEAK

"The Tufts Center plays a significant role in illuminating the evolving drug R&D process. The industry, regulators, academic scientists, the government, and the general public all benefit from the Center's research and analysis."

John F. Niblack, PhD
Executive Vice President, Research & Development
Pfizer Inc

"The Tufts Center makes an absolutely invaluable contribution by delineating the drug development process in the US so that it is understood by the government and consumers."

Lawrence E. Posner, MD
Senior Vice President, Pharmaceutical Development
Bayer Corporation

"Tufts' work in assessing the cost of drug development helps us determine how effective we are in developing a new chemical compound. Without Tufts, we would have to piece together the picture, which would not be as reliable."

David Blois, PhD
Vice President, Worldwide Regulatory Affairs
Merck Research Laboratories

"The Tufts Center's research is used and respected by nearly everyone—the Congress, the FDA, the public, and the pharmaceutical industry. It's essential that we maintain this source of critical industry analysis as the healthcare environment continues to undergo rapid change."

Irwin G. Martin, PhD
Vice President, Worldwide Regulatory Affairs
Parke-Davis Pharmaceutical Research

"Without the Tufts Center, it would be impossible to develop the same level of authoritative information, both for internal use and to make our case to the FDA and the Congress."

Gary T. Shearman, PhD
Senior Vice President, Worldwide Pharmaceutical Development
Rhône-Poulenc Rorer

"The industry and the public need a voice to say 'this is what the data says.' Tufts CSDD fulfills that role by informing the drug development debate with quality data and scholarly research."

Bruce Burlington
Senior Vice President
Wyeth-Ayerst Research

"The Tufts Center uses primary research data to demonstrate that continuous improvement lies at the core of progress. The 'age of FDAMA' came about also due to the Center's decades of effort that led to a better understanding of the drug development process and its constraints."

Alberto Grignolo, PhD
Senior Vice President and General Manager, Worldwide Regulatory Affairs
PAREXEL International Corporation

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Sponsor INFORMATION

The Tufts Center for the Study of Drug Development invites you to become a sponsor. Completion of this form will provide the information we need to maintain contact with you and your organization. If you have questions, please call Toni Snow, Administrative Manager, at (617) 636-2187, or e-mail to tsnow@infonet.tufts.edu.

Please mail this form in the enclosed envelope to: Tufts Center for the Study of Drug Development, 192 South Street, Suite 550, Boston, MA 02111 USA, or fax to (617) 636-2425.

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Total Employees in U.S._____ Total Employees Worldwide _____

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Type of Organization

- ☐ Pharmaceutical company
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- ☐ Contract research organization
- ☐ Medical device developer
- ☐ Consulting firm
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Name _____
Last *First* *MI*

Title _____

Department _____

Mailing Address _____

City_____ State_____ Zip _____

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Last *First* *MI*

Title _____

Department _____

Mailing Address _____

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Country _____

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Telephone: (703) 836-8808
FAX: (703) 549-0976

November 5, 1999

William J. Clinton
President of the United States
1600 Pennsylvania Avenue
Washington, DC 20500

Dear President Clinton,

On behalf of the Federated Ambulatory Surgery Association (FASA), an organization representing the ambulatory surgery industry nationwide, I am writing to express concerns regarding your letter to Chairman Roth about several Medicare issues. That letter indicates that HCFA intends to implement a new payment system for ASC services in 2000. This would be a serious mistake. Our concerns with the proposed rule are detailed in the comments that we submitted on the proposed rule in September. (A copy is enclosed.) Without reliable data that will soon be available through the 1999 Medicare Cost Survey, the proposed system is fundamentally flawed. The cost data used to support these new payment classifications and rates is either nonexistent or so antiquated that it is not a useful predicator of current costs. For example, HCFA itself noted in the preamble to the proposed rule that they did not have the data for 60 percent of the procedure groups.

A few points are worth highlighting. Unlike hospital outpatient departments ASCs are already paid on a prospective basis and have been since the inception of the Medicare ASC benefit in 1982. Since then, millions of Medicare beneficiaries have received services in an ASC, at a great cost savings to both Medicare beneficiaries and the Medicare program. ASCs are proud of the role they have played in providing quality and cost-efficient services to Medicare beneficiaries. We are also pleased with the relationship that we have had with HCFA.

Given the positive and cooperative relationship that has existed, we are surprised by HCFA's insistence, on moving forward with the proposal when the ASC community is urging delay while better and more current data is collected. In the attachment to the Roth letter, the only argument advanced for moving forward at this time is that waiting for more current data will result is three additional years before the new system is implemented. We believe the significance of this proposal and its impact on Medicare beneficiaries and the ASC industry warrants doing it right. It is extremely inefficient for HCFA and the ASC industry to implement a totally new system now only to have to redo it completely. Although we believe it can be done more quickly than three years, even if it takes time we believe it is worth doing right.

Moreover, we are unaware of any argument for moving forward with this proposal immediately. Unlike many Medicare modifications directive to make this change. Rather this is a proposal of the Administration and therefore the Administration can choose an implementation schedule. In fact, to our knowledge, the only

Members of Congress that have expressed views on this proposal urge that the Administration delay to so that the new data can be used. Moreover, the statute requires ASC payments to be based on actual cost data. This proposal, which extrapolates data for 60 percent of the payment groups, is not based on actual data.

In the description accompanying your response to Senator Roth, you refer only to that data's age. Age, is a part of our concern, but the main problem is the data. It has extremely limited volume, for many procedures there is no data, and some data just plain doesn't make sense. We believe the new Medicare Cost Survey will rectify these problems. We have worked extensively with HCFA on the cost survey and, with minor exceptions, believe it represents a significant improvement over the last survey. Moreover, we plan to conduct educational seminars for facilities required to complete the survey to ensure the surveys are completed appropriately. We are committed to assisting HCFA in moving forward as quickly as possible on this survey.

In conclusion, we ask you to reconsider your decision to move forward on implementation for the following reasons:

1. The system, as proposed, could cause significant problems for the industry. Correcting the mistakes three years from now may be too late for some centers. Assuming the best, it is a waste of time for HCFA and the ASC industry to implement a new system just to undergo drastic changes again when the new data is available.

2. No additional expense will be incurred by the government to collect the new data, as the cost survey is required by law.

3. The Administration is not being pushed to move forward with this proposal. In fact, the ASC industry is united behind a delay.

4. According to HCFA's own analysis this proposal is essentially budget neutral. There is no group that benefits from moving forward. The only benefit to this proposal is to have a more fair reimbursement system. If the system is based upon bad data or for most procedures no data, it cannot be a more fair reimbursement system.

Thank you for your consideration of your views. We look forward to the opportunity to discuss this further.

Sincerely,

Kathy Bryant

Kathy Bryant
Executive Director

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July 30, 1999

The Honorable Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
Room 309-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Update of the Ratesetting Methodology, Payment Rates, Payment Policies, and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective October 1, 1998; Proposed Rule; HCFA-1885-P

Dear Administrator Min DeParle:

The Federated Ambulatory Surgery Association (FASA), the largest national association of single- and multi-specialty ambulatory surgery centers (ASCs) and the health care professionals who deliver services in such ASCs, submits these comments regarding the proposed rule issued by the Health Care Financing Administration (HCFA) on June 12, 1998. HCFA proposes to 1) implement a new payment system for ASCs utilizing an Ambulatory Payment Classification (APC) grouping system, 2) modify the list of procedures that Medicare covers when provided in an ASC, and 3) make changes in the regulations governing Medicare-certified ASCs. The proposed APC system will, if implemented, dramatically alter the method of calculation as well as the rate of facility payment for virtually every surgical procedure performed in an ASC setting. These changes represent some of the most sweeping reforms to face the ASC community since the inception of the Medicare ASC benefit in 1982.

FASA believes an APC system could be a reasonable way of reimbursing ASCs for the care provided to Medicare patients. However, we are deeply concerned that this particular proposal will have a negative impact on the ability of ASCs to function as viable suppliers of Medicare services, particularly for certain procedures. As ASCs are forced to alter the services offered, Medicare beneficiaries will be forced to have certain procedures in the hospital setting that were previously available in an ASC. Many of the problems result from the flawed and outdated data upon which the proposed system is based. We believe that it is possible for HCFA to obtain better data and, therefore, implement a better system. Accordingly, we strongly urge HCFA to delay implementation

of this proposed APC system until the 1999 ASC cost survey is completed, and HCFA is able to use these results in determining groupings and payment rates. FASA believes that it is not prudent to conduct a massive overhaul of ASC reimbursement based on outdated and flawed data, especially when accurate data will be available in the near future. Other portions of the proposed rule can, and should, move forward promptly.

Before commenting on the specifics of the proposed rule, we would like to thank HCFA for extending the comment period on this rule to allow FASA and others more time to analyze the proposal and develop responses. Moreover, we appreciate HCFA's decision to implement the APC system for ASCs concurrently with the hospital outpatient department (HOPD) prospective payment system. By making these decisions, HCFA had the opportunity to work closely with the ASC community. FASA hopes that in the weeks and months ahead we can maintain a dialogue with HCFA on this proposal. As the nation's leading ASC association, we are in a unique position to assist HCFA with quality of care, clinical, cost, and implementation issues.

COMMENTS ON REGULATORY CHANGES

FASA is pleased that HCFA has incorporated many of FASA's recommendations for changes in the regulations governing ASCs.

Elimination of the 90-minute/4 hour rule and Site of Service Restrictions: Section 416.22
FASA has long advocated the elimination of unnecessary regulatory restrictions and therefore, strongly endorses HCFA's decision to eliminate the 90-minute operating time/four-hour recovery time regulation, which limits the procedures that Medicare covers when performed in an ASC. These restrictions are outdated and do not reflect the realities of medical practice today. Moreover, these rules hamper ASCs' ability to provide patients with a wide range of procedures. As you are aware, the statute provides Medicare ASC coverage for procedures that are "appropriately performed on an inpatient basis" and that "can be performed safely on an ambulatory basis" in an ASC. Thus, the statutory language gives HCFA broad latitude to adjust the criteria for coverage to reflect the capabilities of the modern ASC. We commend HCFA for utilizing this authority. Over the past two decades ASCs have demonstrated the ability to perform safely virtually any outpatient surgical procedure, with outcomes matching those produced by hospital outpatient departments. With the development of short-acting general anesthetics and other technological improvements, the length of operating time is no longer material in determining whether a procedure is appropriately performed in an ASC. The key question is the patient's medical condition, not how long the operation takes. Thus, the elimination of the 90-minute operating time/four-hour recovery time regulation is appropriate.

We are also pleased that HCFA indicates that it will abandon its numerical criteria for determining which procedures were performed on an inpatient basis or performed in a physician's office a majority of the time. This so-called 20/50 site-of-service criterion was based on a simplistic interpretation of the statute. With outpatient cases now constituting a majority of all surgery performed in the United States, a requirement that a procedure must be performed 20 percent of the time on an inpatient basis for it to be eligible for the ASC list is simply obsolete. Cataract

extraction is the perfect example of a procedure that is not performed on an inpatient basis 20 percent of the time and yet no one would argue that Medicare should not cover it when provided in an ASC. Likewise, FASA has long believed that it is overly simplistic to exclude automatically procedures performed more than 50 percent of the time in the office setting from reimbursement if performed in an ASC. The fact that it is safe and appropriate to perform a particular procedure in a physician's office some or even most of the time does not necessarily mean that it is safe or appropriate to do so all of the time. Patients' specific needs vary on a case by case basis. For example, it is sound medical practice to monitor patients with cardiac or pulmonary problems throughout the procedures, even during procedures that would not normally require monitoring. This generally cannot be done effectively in the office setting. Yet, the 50 percent criterion has been an all or nothing rule — no ASC facility fee was available for a procedure that is performed more than 50 percent of the time in a physician's office, even if for a particular patient an ASC was a more appropriate setting.

Therefore, we strongly support HCFA's discontinuing the use of site of service as the principal determinant of which procedures should be on the ASC list. FASA believes that the inclusion of a procedure on the ASC list is a determination better made based on a variety of factors as opposed to arbitrary numeric thresholds.

The proposed criteria are a significant improvement over the current criteria. We do recommend some modifications to the proposed regulations. First, it must be emphasized the prime criterion for where a particular surgery should be done must be the medical assessment of the patient and the capability of the facility to handle the procedure and likely risks or complications for this patient. HCFA recognizes this reality in the preamble to the proposed rule. On page 32298 HCFA states, "we recognized that an ASC might be appropriate for some procedures shifting from an inpatient to an outpatient setting for the patient who is generally healthy and is capable, but that an ASC would be a questionable setting for those procedures among the greater Medicare population whose health is more likely to be compromised by age or disability." HCFA also noted, on page 32299, that for some patients all procedures need to be performed on inpatient basis, saying "We recognize that for individuals with certain medical conditions, no procedure on the ASC list may be safely performed except on an inpatient basis." After discussing this, HCFA goes on to say, "Therefore, we emphasize that the choice of operating site remains ultimately a matter for the professional judgement of the patient's physician..."

Although we appreciate HCFA's recognition of the importance of the medical assessment of the patient, as long as a list exists, strong incentives, and in some cases absolute prohibitions, will interfere with the physician making the best judgment for his or her patient. We recognize that this problem is inherent in a list and that the statute does not give HCFA the discretion to abandon the list altogether. However, the statute does give HCFA wide latitude in determining what is on the list. By interpreting broadly what procedures are included on the ASC list, HCFA puts the decision of where to perform surgery in the hands of the physician. Accordingly, we strongly urge you to include procedures on the list if they meet the criteria for any patients. Doing so allows individual patients to receive care in the operating site that is best for them.

Having stated our argument for a broad list, we will now comment on the specifics of the criteria

HCFA proposes. Criterion (a)(1) which is "Require surgical facilities and services of the kind that are typically provided in a hospital inpatient setting," seems to overstate the situation. To require what is needed for a hospital inpatient, for outpatient surgery is counterintuitive. If the patient needs the same services as a hospital inpatient, he or she would be a hospital inpatient. The appropriate criteria, in our view is that contained in (a)(3), which is "Require a dedicated operating room (or suite) or procedure room and a room for post-operative recovery." This criterion combined with the requirements of (a)(2), which is "Would not be expected to necessitate admission as an inpatient to a hospital either to perform the procedure or to recover from the procedure post-operatively" are sufficient criteria to determine what procedures belong on the ASC list. Accordingly, FASA recommends that criterion (a)(1) not be included in the final rule. FASA does not object to the exclusionary criteria contained in Section 416.22(b).

Definition of an ASC: Section 416.2

The proposed definition of ambulatory surgical center states that an ASC must be "a separate entity with respect to its licensure, accreditation, governance, professional supervision, administrative functions, clinical services, record keeping, and financial and accounting systems." In the preamble, HCFA notes that this revised definition means that an ASC must be "totally separate" and distinguishable from "any other entity or type of facility." While recognizing the need to distinguish ASCs from hospital outpatient departments, physician offices, and clinics, FASA nevertheless believes that this provision is overly broad and will result in inefficient use of health care resources. Indeed, HCFA acknowledges in the preamble that this requirement may be onerous to ASCs that are owned by large health care systems seeking to share services or to consolidate with other member entities. However, this impact could be minimized — while still achieving the purposes of the proposed definition — by requiring that an ASC or group of ASCs be a separate and distinct entity from any other non-ASC entity providing outpatient surgical services. In this way, health systems would still be able to share services or consolidate their ASCs in those situations where there would be no concern that Medicare payments for ASC facility services could be made improperly to an entity that actually was a hospital outpatient department, a physician's office, or a clinic.

We are concerned, in addition, about the possible interpretation of the requirement that a facility must have its own "separate" clinical services, administrative functions, and record keeping. This requirement might be interpreted to preclude an ASC from entering into an agreement with an outside management company to perform much of the ASC's administrative and record keeping duties. Such an interpretation would cut ASCs off from many avenues of cost efficiency and savings.

In the preamble, HCFA states that another purpose of the proposed rule's definition is to "distinguish the costs and services which emanate strictly from the ASC" so that HCFA may verify that "the data we are using to determine payment rates are truly reflective of ASC costs alone." It appears to us, however, that this goal could be readily achieved through cost reporting protocols that would be far less burdensome than a broadly sweeping rule that prohibits administrative efficiencies that could benefit the health care system.

Requirement for State Licensure: Sections 416.3 (b) & 416.2

FASA requests that HCFA modify section 416.3 in which HCFA proposes mandating licensure for ASCs in those states in which licensure is required. In general, this requirement is appropriate. We are concerned that this language could be interpreted so as to prohibit facilities located in states that require licensure of ASCs, but not all ASCs, from serving Medicare patients. In New Jersey, for example, an ASC license is required only of facilities with two or more operating rooms. If a facility only has one operating room, it is considered a physician's office for state regulatory purposes. Currently, such a facility is eligible for Medicare certification and therefore, to provide services to Medicare patients. We know of no reason to deny these facilities Medicare participation simply because New Jersey has decided that these facilities do not need a license. In New Jersey, less than one-third of the Medicare-certified ASCs would be eligible to participate in the Medicare program if this provision were implemented. Therefore, FASA recommends that this section be modified to read "Have State licensure if the State requires a license for the particular ASC." This language would make clear that an ASC had to abide by relevant state licensing laws to participate in Medicare.

In a similar vein, FASA suggests that additional clarifying language be included in section 416.2, regarding the definition of an ASC. The requirement that an ASC be separate with regard to its "licensure" could be taken as a requirement that licensure is required in all cases, not just when required by state law, and therefore some states' ASCs would be inappropriately excluded.

Mandatory Assignment Section 416.3(g)

Current regulations require ASCs to accept assignment for all facility services furnished in connection with procedures on the ASC list. ASCs that provide other non-facility services, such as prosthetics and orthotics, radiology, and durable medical equipment, under other provisions of the Medicare program have the same choices regarding balance billing, as do other providers of these services. Under the proposed regulations, however, an ASC must "accept assignment for all items and services that it furnishes to Medicare beneficiaries," regardless of whether those items or services are facility services. In the preamble to the proposed rule, HCFA refers to this change as a "technical change." We must strongly disagree with this characterization. Currently, ASCs are prohibited from billing Medicare beneficiaries more than the Medicare payment and allowable copayments and deductibles for facility services. For other items and services, if other providers or suppliers are allowed to choose whether or not to balance bill, ASCs have the same choice. We are unaware of any problems that would motivate HCFA to make this change. Absent some compelling reason to treat ASCs differently, we urge HCFA to leave Section 416.30(e) as it currently exists.

Of major concern, section 416.3(g) appears to include physicians' services under its balance billing prohibition, at least if they are billed for by the ASC. While usually the physicians providing services in an ASC would bill Medicare directly for their own services there may be some ASCs that choose, and are permitted under applicable law, to bill for physician services. Similar to the situation above, if the physician can choose to accept assignment or not, then the ASC, which is billing the physician, should be able to choose whether or not to accept assignment.

If HCFA did not intend to apply this requirement to physician services, it must be clarified. The

proposed section 416.3(g) offers no such indication. It says only that the ASC must "Accept assignment for all items and services that it furnishes Medicare beneficiaries for which payment may be made under Medicare Part B in connection with procedures on the ASC list." This rather broad statement would appear to cover services provided by physicians if billed by the ASC. More troubling is language in the preamble that says the new items and services for which assignment is required are those items and services "such as those listed in Section 416.21(b)." Section 416.21(b) lists those items not considered ASC services for which payment may be made under other parts of Medicare and lists some examples, beginning with "physician services."

We urge HCFA not to include this proposed change in the final rule. Should HCFA go forward with the change, we urge you to make very clear exactly what is covered and what is not. In this vein, FASA urges HCFA to clarify that physicians and other practitioners, who are authorized to bill Medicare directly for their professional services, are not required to accept assignment of their fees for services simply because an ASC billed for the service.

PROPOSED APC SYSTEM

For the past few years, FASA eagerly anticipated a new system for reimbursing ASCs based upon an APC system. After participating in the HCFA Town Meetings during the summer of 1996, we believed that the APC system would be beneficial to HCFA, the ASC industry, and Medicare beneficiaries. Unfortunately, this goal has not been realized in the proposed rule. Reimbursement rates proposed for most of the highest volume surgical procedures have dropped precipitously and, in many cases, are significantly below the costs incurred by ASCs to perform the procedures. According to HCFA information, the APC system would reduce program expenditures by only two percent. FASA has serious doubts about the accuracy of this estimate. The vast majority of high volume ASC procedures are subject to double-digit reductions in reimbursement rates. Even if one assumes an increase in the utilization of other procedures (which we believe is not warranted since the ASCs have no control over the physician and patient's site of service selection) the numbers do not appear to add up. It would take an unrealistically high increase in utilization for hundreds of CPT codes to begin to make up for the reimbursement reductions proposed by HCFA for the two highest volume procedures – CPT 66984 Extra Capsular Cataract Removal and CPT 66821 YAG Laser. These two procedures alone comprised 46 percent of the ASC Medicare volume in 1996.

FASA's analysis of this proposed rule has been severely compromised by the unavailability of the underlying data and accompanying notes used to compile this proposal. FASA has requested access to the underlying data, and is disappointed by HCFA's failure to provide us with access to all relevant information.

Using data and information from our membership, FASA has analyzed the proposed system. From this review, we have concluded that the proposed system has serious flaws that need to be addressed before it is implemented. The proposed APC system does not meet HCFA's stated objective of classifying procedures in a homogenous manner from both a clinical and a cost-based perspective. Moreover, HCFA's flawed methodology and admittedly inadequate survey data have resulted in payment rates that are in many cases far below a facility's actual procedure costs. Of the 105 APCs, we have identified a significant number contained glaring problems that must be remedied if the system is to make sense.

Specific Examples of Procedures Inappropriately Grouped in APCs

In the Appendix A, we have provided you with numerous examples of procedures that we believe are categorized in inappropriate APCs. For the APC system to work properly and fairly, the procedures within each APC must share similar clinical characteristics and comparable resource costs. Under the proposed APC groupings, however, an ASC that treats a disproportionate share of either expensive or inexpensive cases within a grouping will not receive appropriate reimbursement. Moreover, incorrect groupings create incentives for ASCs to provide only the least costly procedures within a particular grouping. If ASCs respond according to the incentives HCFA is proposing, Medicare beneficiaries could be forced to have the more costly procedures in each APC in a hospital. Not only does this increase beneficiaries' cost, but it decreases their ability to choose the setting most appropriate and comfortable for them. We urge HCFA to address the problems discussed in Appendix A.

Specific Examples of Procedures with Inappropriate Payment Rates

For a large number of CPT codes, our data shows significant disparities between the proposed payment rates and the average cost expended by the facility to perform a procedure. Under this new system, many specialty facilities will be inappropriately asked to provide high-volume Medicare procedures at or below cost. Given that HCFA developed 64 of the APCs with severely limited cost data, we are concerned that HCFA has calculated incorrect payment rates for many of the highest volume procedures. The consequences of this miscalculation, of course, would be devastating to facilities specializing in those procedures.

In Appendix B, we have identified a number of specific procedures with particularly egregious differences between cost and the proposed payment rates. FASA urges HCFA to increase the payment rates for these procedures to recognize the actual procedure costs based upon reliable data. We also request that you reexamine the payment disparities of these procedures when provided in an ASC as compared to an HOPD. In many instances, HOPDs are paid a significantly higher reimbursement rate to perform procedures, despite the fact that their costs are only marginally higher.

Data Problems

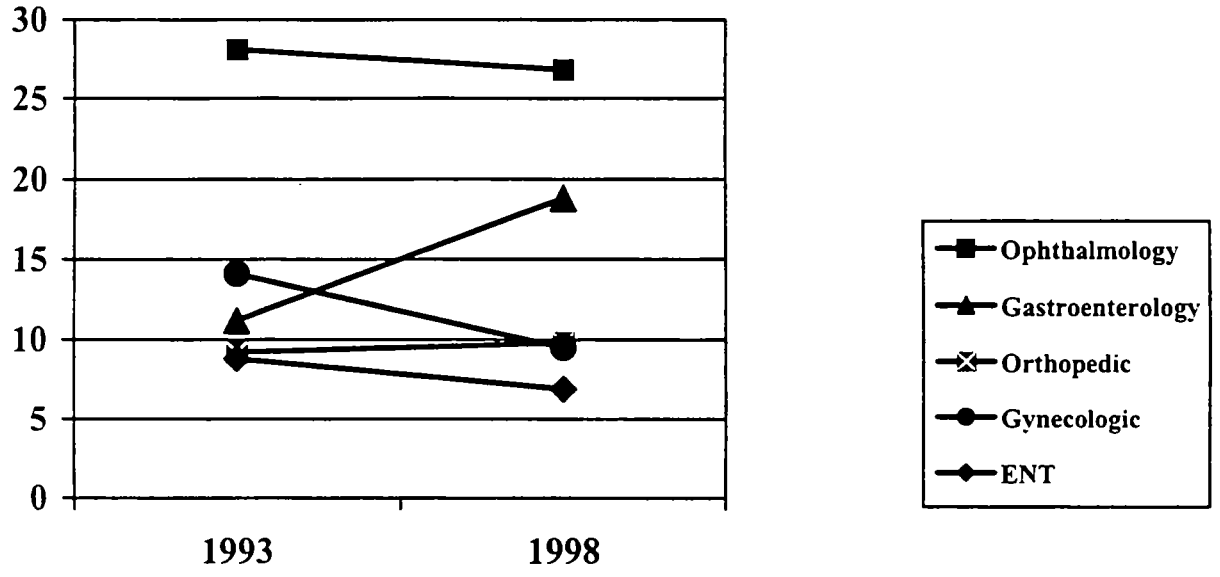
FASA believes that many of the problems identified with the APC system are a direct result of the unreliable and outdated data that HCFA used in creating the system. HCFA itself admits the data is not reliable. HCFA's commentary accompanying the proposed rule acknowledges that HCFA is "disappointed by...[its] lack of success...in gathering usable cost data." HCFA's acknowledgment

that it could not "establish weights and base ASC payment rates on the resource cost data" from the 1994 ASC survey militates against using it as a basis for determining new APC rates.

FASA also is critical of the eventual sample size upon which HCFA relied. We understand that because of insufficient data, HCFA audited only 96 of the 300 surveyed facilities and then according to a calculation, "standardized" the results to the remaining 194 facilities in order to compensate for faulty data. Understandably, the ASC community is reluctant to embrace payment rates for more than 2,700 ASCs that are based on data from only 96 facilities, data which HCFA itself acknowledges as disappointing and unreliable.

Even if the data were a reliable reflection of 1993 costs, using it to update the current reimbursement system for the year 2000 and beyond is questionable. To propose an entirely new reimbursement system on the 1993 data is totally without merit.

In almost any industry the use of 7-year old data would be inappropriate. In a dramatically changing field, such as the ASC industry, it is even more troubling. In addition to the usual increases in resource costs, such as labor, rent, and utilities, the ASC industry has evolved and changed rapidly since 1993. The mix of cases is one example of the significant change that has occurred. For example, between 1993 and 1998 the percentage of cases that were gynecologic decreased by 32.6 percent while the percentage that were gastroenterology increased 67.9 percent. The following chart shows the changes for specialties accounting for more than 6 percent of cases in 1998. Such significant change in the mix of services delivered without a doubt affects the costs of providing services.



Some of this change in case mix is due to the numerous new technologies, devices and drugs that are now used in ASCs. These changes do not necessarily reduce costs. In fact, in many cases the reverse is true. New technologies do, however, significantly improve the quality of care by

increasing the options for addressing health problems and by allowing correction of problems that only a few years ago one simply had to endure. New technologies may also reduce the risk associated with a treatment. Many do so at an increased cost. Moreover, the costs incurred may shift from one type of cost to another. As HCFA is aware, MedPAC shares FASA's concern that the 1993 data may not reflect the current costs of ASCs. In its August 11, 1998 letter to HCFA, MedPAC stated that "the 1994 cost data collected . . . may not accurately reflect changes in medical technology and clinical practice that have occurred in the intervening years."

Not only has the ASC mix of cases changed, but the number of ASCs has expanded from 1,986 in 1993 to 2,712 in 1998, and volume has increased from just over 3 million cases to more than 5.5 million. Reimbursement in the year 2000 and beyond that is based upon 1993 data cannot possibly be characterized as reimbursement based upon actual costs, as the statute requires, and is not likely to be perceived as fair reimbursement.

Not only is the data unreliable overall, but for 42 percent of the codes proposed for the ASC list, HCFA "determined payment rates for 1058 CPT codes (42 percent of the 2499 codes proposed for the ASC list) for which we had little or no cost data." This is obviously what caused HCFA to "extrapolate" 64 of the 105 APC codes, either for which HCFA had aberrant data or were limited Medicare volume procedures. Unfortunately, that extrapolation was not developed through a formula known in any way, shape or form to the industry. Despite acknowledging flaws in the 1994 survey for the past few years, HCFA never provided information to affected parties regarding its need to rely so heavily on non-cost related data to compile payment rates. Instead, HCFA asks the ASC community to accept reimbursement based on "extrapolated" facility payment rates for fully 60 percent of the APCs. We believe the statutory requirements require more accurate information. The language of Section 1395l(i)(2)(A) of the Social Security Act requires a relationship between the payment rates and actual costs. HCFA is not in compliance with its statutory obligations when it substitutes its own "extrapolated" non-cost data formula for tangible survey cost data. As such, we believe HCFA should not proceed with any APC derived from this "extrapolated" formula. MedPAC also expressed concern about this extrapolation.

Moreover, FASA is concerned about HCFA's decision to set the maximum hourly wage index by only using wage data below the 75th percentile for each staffing category. HCFA asserts that it found rates over the 75th percentile "to be too erratic" and therefore inappropriate to use. We fail to understand why wage levels above the 75th percentile are any more "erratic" than wage levels below the 25th percentile. Clearly chopping off of data above the 75th percentile would necessarily result in a downward adjustment of wage levels. We request that you make public the statistical rationale for arbitrarily selecting the 75th percentile as a cutoff without a corresponding elimination of the wage data from the bottom 25th percentile. We urge HCFA to revisit this decision and utilize a statistical process that does not guarantee a downward adjustment of payment rates.

We also are concerned about HCFA's exclusion of hourly pay rates for administrative and medical staff in those cases where a facility owner holds the position. HCFA states that it believes "the reported hourly rates of owner's compensation were excessively high relative to the hourly pay for non-owners in the same positions." We believe this is an inappropriate way to deal with HCFA's apparent concern with the over-compensation of facility owners. Excluding such wages entirely

means that these costs are unaccounted for in their entirety. We believe it would be more appropriate in those cases where a position is held by an owner to include the average hourly wage for the position. This should address HCFA's concern regarding over-compensation, while more fairly reflecting an ASC's reasonable costs.

Equalizing Payments for ASC/HOPD

The proposed ASC rates are even more disconcerting when compared to the proposed payment rates for many procedures when performed in a HOPD. There does not appear to be a cost-based rationale for such disparate reimbursement rates between the two settings. Maintaining this inequitable reimbursement scheme does a disservice to Medicare beneficiaries, who as a result of higher reimbursement to hospitals must also pay more for the service, and to ASCs, which seek fair reimbursement. In light of the passage of the HOPD reforms in the Balanced Budget Act of 1997, FASA believed that the payment rate differential between the ASC and HOPD settings would be narrowed considerably. Needless to say, FASA is sorely disappointed that such significant payment disparities exist between the proposed rates for ASCs and HOPDs. While we recognize there may be legitimate reasons why hospitals are paid more for certain procedures, it is difficult to fathom why the payment rates for ASCs and HOPDs can vary so significantly by procedure and specialty area. Using MedPAC's five percent beneficiary claim sample for 1996 data, FASA calculated the percentage difference in payments for the most frequently performed ASC procedures on Medicare patients by specialty area. These procedures comprised more than 90 percent of the total ASC Medicare volume. The chart below shows how much more HOPDs would be paid for these high-volume procedures than ASCs under the proposed rates for each venue.

Specialty Area	Higher Payment in HOPD
Derm/Reconstructive	25%
Gastroenterology	1%
General Surgery	44%
OB-GYN	42%
Ophthalmology	28%
Orthopedic	48%
Otolaryngology	38%
Urology	27%
Vascular	33%

Such widely disparate reimbursement rates between ASCs and HOPDs will have negative consequences for Medicare beneficiaries. Many ASCs may cease offering certain procedures, thereby reducing patient choice and channeling more patients to HOPDs. For the foreseeable future, beneficiaries will continue to pay substantially higher copayments for services when they are furnished in a hospital outpatient department. This anomaly results from hospitals being allowed to assess the beneficiary's 20 percent copayment on the basis of their charges for outpatient services, rather than the Medicare reimbursement amount. As a result, Medicare beneficiaries pay, on average,

37 percent of the costs of hospital outpatient procedures, compared to 20 percent for ASC procedures.[1]

FASA requests HCFA to address this payment disparity issue in its final rule. Although we understand statutory constraints require HCFA to reimburse ASCs, on average, less than hospitals, we believe the proposed rule's difference is excessive and erratic. HCFA derived the new HOPD rates from 1996 hospital cost data and through an analysis of more than 98 million outpatient claims compared to the older, much smaller set of data for ASCs. The more recent hospital data and its much larger volume should produce a higher level of confidence. Therefore, HCFA should question whether some of the much lower costs for ASCs are in reality data errors.

Delay Implementation of APC System

Having discussed the numerous problems with the 1993 data, FASA strongly recommends that HCFA delay implementation of this new system until the data from the 1999 ASC cost survey can be used. If the objective of the proposal is to produce a fair reimbursement system, this cannot be achieved using flawed and outdated data. FASA believes that it would be far better to use current and accurate data as soon as possible after it is available even though this would mean a delay. Once the 1999 data is available, procedures could then be appropriately grouped using current and complete information. New payment rates could be proposed. Not only do we believe the 1999 ASC cost survey data will be more current, but we also believe it will also be more accurate.

FASA has worked with American Association of Ambulatory Surgery Centers (AAASC) to assist HCFA in obtaining a realistic test of the 1999 ASC cost survey. Thirty ASCs identified by FASA and AAASC have tested the 1999 ASC cost survey by attempting to complete the survey, including using the computer software. Although some problems were identified in instructions, information requested, and the computer software program, based upon this test we believe that the 1999 ASC cost survey will produce far more reliable data than the previous one. To help assure that the 1999 ASC cost survey results in more reliable data than the previous one, FASA has not only helped with designing and testing the survey but we have committed to conducting seminars to help our members respond to the survey. Moreover, because of increase in industry volume we believe that the 1999 ASC cost survey will produce cost data on virtually all procedures eliminating the need to extrapolate payment rates. Delaying the implementation of this new system until the 1999 data is available is beneficial to everyone involved, HCFA, ASCs, and Medicare beneficiaries. For HCFA, the delay allows it to implement a system that has validity and can be defended. ASCs would avoid having to make massive changes to adjust to a flawed payment system, only to need to adjust again when the system is revised based upon the 1999 data. Medicare beneficiaries would benefit from continued availability of services in ASCs.

This does not mean that the entire proposed rule should be delayed. To the contrary, much of the proposed rule is important improvements in the ASC benefit and should be implemented as soon as possible. Changes such as modifying the criteria for determining which procedures will be reimbursed in an ASC are desperately needed. These changes have nothing to do with the APC

[1] Although the Balanced Budget Act of 1997 corrects this problem due to its lengthy phase-in, beneficiaries will pay higher copayments for years into the future. According to some estimates, the phase-in could take 36 years even if Medicare payments increase at a rate of 5 percent per year.

system and are linked to it only because one all-encompassing rule on ASCs was published rather than separate rules. In fact, had HCFA proposed a separate rule on changes to the criteria for including procedures on the ASC list, we believe these changes would be in effect already. These changes are widely supported within the ASC community and it is likely that only minor modifications have been recommended as part of this comment period. FASA urges you to move forward immediately with implementation of these changes.

In addition, HCFA should immediately add new procedures to the ASC based upon this new criteria. In the proposed rule, HCFA indicated procedures that it viewed as meeting this new criteria and HCFA should review the comments on procedures and publish a new approved list by the beginning of the new year or as close to the new year as possible. The additional procedures would simply be added to one of the existing eight reimbursement groups. We believe this can be done fairly and easily in consultation with the ASC community. FASA would be eager to assist you with this process.

Although we think HCFA should finalize these changes to the criteria for including procedures on the ASC list immediately, if HCFA chooses to delay issuing a final rule, HCFA should move forward with updating the list based upon the existing criteria in Section 416.65. There is not a reason for HCFA to delay updating the ASC list. In fact, the statute actually requires the updating of the list every two years and it has now been four years since the list was last updated.

Implementation

Should HCFA ignore the concerns of FASA and the ASC community and move forward with implementation of this controversial new system, we urge you to allow ASCs time to familiarize themselves with the new system and to make appropriate adjustments in their operations. Recognizing the complexity of the proposed system and its significance, HCFA has repeatedly extended the time period for commenting to allow us the opportunity to prepare meaningful comments. We appreciate this.

Once this rule is finalized, it will require sweeping changes in the operation of ASCs. These facilities need a reasonable time from publication of the final rule to its effective date to modify their operations to comply with new system. Even though the proposed rule has been available for more than a year, their preparations cannot begin until the final rule is published for a couple of reasons. First, many of our facilities are small businesses and simply cannot keep on top of government proposals, rather they struggle to keep informed of changes in government regulations and new laws with which they must comply. Moreover, the only information available even now is a proposed rule. We anticipate, and have advised our members, that based upon the comments you receive, changes will be made. Given the volume of comments received, the largest ever on an ASC proposal, it is reasonable to expect lots of changes. Thus, it would be imprudent for our members to begin plans for implementing this new system until a final rule is published.

In our view, a reasonable period of time from publication to implementation is 120 days. Given the work that will have to be done, this is a short period of time. Facilities need to obtain copies of the final rule. Then, the rule will have to be analyzed and interpreted. Once this is complete, ASCs will have to modify internal forms and systems. Purchasing equipment, recruiting surgeons, and hiring,

dismissing, or retraining staff all take time. ASCs would be extremely unwise to do any of these things until a final rule is published. For most facilities to complete all of this in 120 days would require shifting resources and much hard work. To do so in less time would be almost impossible. Highly efficient facilities might be able to complete this change in 90 days, but any less than that is doomed to create problems.

Implementation will be most difficult if it comes near to the new year. As HCFA has grappled to be Y2K compliant, so have ASCs. Although we believe, in general, our facilities will be fully operational on January 2, 2000, like other business we expect there may be some problems to address. Having to implement a totally new regulatory scheme from HCFA at this time would be extremely difficult. Accordingly, we urge you to consider this in timing the release of the new rule if you chose to go forward with the APC system prior to the 1999 ASC cost survey.

Phase-In Implementation Schedule

In the proposed rule, HCFA notes that the APCs could "affect the revenues of individual ASCs, depending on factors such as patient volume and case mix and the type of procedures performed." HCFA further adds that facilities specializing in "cataract-related procedures are going to be affected more dramatically by the proposed rebased rates" than other facilities. Indeed, it is difficult to see how many ophthalmic facilities specializing in cataracts will remain viable providers of Medicare services under this proposal. We are equally concerned about the impact on gastroenterology, urology, and pain management facilities. These ASCs are ill prepared to adjust to such dramatic changes in their reimbursement rates. For example, an ASC specializing in pain management will have great difficulty staying in the Medicare business after absorbing the cuts to its reimbursement and the deletion of many of its CPT codes from the ASC list. With that in mind, we believe it is in the best interests of HCFA to phase in the new reimbursement rates over a four-year period. Such an approach would be the most equitable way to ensure that patient care is minimally disrupted. Moreover, even for those facilities that can adjust, time for such adjustment will be necessary.

PROCEDURES PROPOSED FOR DELETION FROM ASC LIST

FASA is extremely concerned about the proposed deletion of a number of codes from the ASC list. We are particularly concerned because HCFA provided little or no insight in its proposal as to why these codes were inappropriate to perform in an ASC setting. We believe HCFA should elaborate, on a code-by-code basis, its rationale for deleting procedures from the ASC list. HCFA broadly states that it is deleting 203 codes from the ASC list because they are not safe or otherwise reasonable and necessary in an ASC setting. HCFA does not, however, comment on any particular procedures – that is, HCFA does not state <u>why</u> it has determined that each procedure is not safe or necessary to be performed in an ASC. HCFA should say why it feels a particular code is no longer safely able to be, or necessary to be, performed in an ASC. This is necessary to accord the public meaningful opportunity for comment. We would note that since these procedures are currently being performed in ASCs, one would expect evidence of poor outcomes, if the procedures could not safely be performed in an ASC. We are unaware of any such data.

We are also interested in further explanation of the rationale for codes that HCFA proposes to delete from the list because HCFA believes they are more appropriately performed in an office setting. Again, it would be helpful for HCFA to provide code-by-code explanations, rather than a general statement.

Meaningful comment on the proposed deletions is difficult without further explanation by HCFA. We strongly urge HCFA to defer all of the proposed deletions until such time as HCFA releases to the public, code-by-code explanations of the rationale for deletion and the public has opportunity for comment. Although we are limited in our ability to respond without specific information, we do have some comments on several of the proposed deletions.

Facet joint nerve blocks and neurolysis (CPT 64442, 64443, 64622, 64623); Sympathetic nerve blocks, neurolysis and removal (CPT 64510, 64520, 64530, 64680, 64802); Intercostal nerve blocks and neurolysis (CPT 64420, 64421, 64620); Trigeminal nerve blocks and neurolysis (CPT 64600, 64610); Pudendal nerve blocks (CPT 64439); Implant spinal catheter (CPT 62355): HCFA proposes to delete these codes from the ASC list because of its view that these procedures can be safely performed in a physician's office. FASA disagrees. We do not believe that these procedures can, on a consistent basis, be performed safely or appropriately in a physician office setting. These procedures involve insertion of needles into the spine and include administration of drugs. Precision in needle placement is critical to avoid adverse effects. To achieve accuracy in needle placement a flouroscope is used. Moreover, the administration of sedative medications to avoid excessive movement during needle placement is often quite critical to the success of the operation. This type of sedation requires extensive monitoring, as the drugs are known to be associated with cardiovascular adverse events. This extensive monitoring can rarely be accomplished within the confines of a physician office setting. These procedures require conscious sedation, full monitoring, and fluoroscopy for proper medical care, and can usually only be safely performed in an ASC or a HOPD. In addition, these procedures require significant precautions to prevent infections and to reduce the possibility of complications. Moreover, the volume of these procedures in ASCs demonstrates that in the treating physician's judgment the ASC is the appropriate environment to perform these procedures. According to the MedPAC five percent beneficiary claim sample, two of these procedures (CPT 64442 & CPT 64443) were performed in an ASC more than 9,000 times each in 1996, another two (CPT 64510 & CPT 64520) were performed almost 2,000 times each and another four were performed more than 300 times each. In the preamble to the proposed rule HCFA discusses the importance of the physician making the judgment as to the appropriate site of service delivery based upon the needs of his or her patient. For HCFA to remove procedures that physicians have chosen to perform a significant number of times in an ASC, denies the Medicare beneficiary the site his or her physician believes is the most appropriate. Moreover, for many patients the physician's office will not be an option so the patient will be forced to have these procedures in the hospital setting, raising the costs for the Medicare program and the beneficiary.

Insertion of Supra Pubic Catheter (CPT 51010): FASA believes that this procedure should also remain on the ASC list. CPT 51010 can be a lengthy procedure. For Medicare patients with concomitant medical conditions, the choice to perform this procedure in an ASC where the patient

can be sedated if necessary and closely monitored should be available to patients and their physicians. Although for some patients this procedure can be performed in physician's office, it cannot be appropriately performed in a physician's office for all patients.

Urodynamic Procedure Codes (CPT 51726, 51772 & 51785): We believe that these procedures are appropriately performed in an ASC setting. These procedures are invasive and can put the patient at significant risk. They involve multiple catheterizations, multiple exposures of the catheterized urinary tract to pathogens involving the infusion of fluids and withdrawal of catheters. Many urologists have contacted FASA to discuss the need for urodynamic testing on Medicare patients with certain incontinence procedures. These urodynamic procedures require costly machinery that makes it financially impossible for most urologists to perform these procedures in their office. According to MedPAC data, 4500 of these procedures were performed in ASCs in 1996, suggesting that many physicians believe an ASC to be the appropriate delivery site for these codes.

HCFA's PROPOSED ADDITIONS TO ASC APPROVED LIST

FASA is pleased HCFA proposes to add a number of the procedures recommended by us and others for inclusion on the list. We support the proposed additions to the list. Although FASA opposes current implementation of the proposed APC system until after completion of the 1999 ASC cost survey, we urge HCFA to add these procedures to ASC list immediately so that Medicare beneficiaries can benefit from increased choice and decreased costs. Should HCFA accept our recommendation to delay implementation of APC system, FASA would be happy to suggest proposed groupings under the current system for these procedures.

FASA would like to comment on a few of the added procedures in particular.

Upper Eyelid Blepharoplasty (CPT 15822, 15823): These procedures are performed to repair defects in the upper eyelid, which may obscure vision. When performed on Medicare patients for medically necessary reasons, ASCs provide a safe and appropriate environment for the surgery. In addition, elderly patients with concomitant medical conditions may be closely monitored during the surgery. FASA urges HCFA to include these codes on the ASC list. Of course, because Medicare does not provide coverage of cosmetic procedures, when performed for cosmetic reasons Medicare would not reimburse ASCs.

Percutaneous Skeletal Fixation of Metacarpal Fracture (CPT 26608): Percutaneous fixation of metacarpal fractures is quite similar clinically to CPT 26650, 26676, and 26727, which involve fractures and dislocations of the bones of the hand, and are on the ASC list. HCFA's addition of CPT 26608 to the ASC list is appropriate.

Flexible Sigmoidoscopy (CPT 45330): FASA welcomes the addition of this procedure to the ASC list. This will allow physicians to perform this procedure in an ASC when a Medicare patient's condition warrants, such as when sedation or close monitoring is required.

Extracorporeal Shock Wave Lithotripsy (CPT 50590): FASA supports HCFA's proposal to add extracorporeal shock wave lithotripsy (ESWL) to the ASC list as a covered procedure. We concur with HCFA's view that it is safe and appropriate to perform ESWL in the ASC setting.

However, we believe the proposed payment level of $2,107 is inadequate. Given the extremely high costs of the equipment needed, ASCs will have to perform an unrealistically high number of procedures in order to break even on their costs. HCFA notes in the proposed rule that it is compelled "to provide and reinforce the efficient use of shrinking resources." FASA agrees and believes our industry does much to help HCFA achieve this goal. However, as a government program, HCFA also has an obligation to assure its beneficiaries access and to help them control their costs. Rural ASCs, which necessarily have a limited patient population, cannot possible reach the volume to make $2,107 cover the costs of performing ESWL. The low reimbursement rate will restrict Medicare patient access to ESWL in rural areas. Medicare beneficiaries in rural areas will have to obtain ESWLs in HOPD settings, thereby paying considerable additional money in copayments and costing Medicare more.

In addition to assuming too high of a volume, FASA sees other flaws in the way HCFA collected and dealt with the ESWL data. First, HCFA attempted to collect ESWL data only from "Medicare-approved" ASCs. Collection of ESWL data from Medicare ASCs resulted in data from only 15 ASCs. We believe this is an exceedingly small sample on which to base reimbursement. Since ESWL had not been approved for Medicare coverage when performed in an ASC the collected data was not Medicare data anyway. It makes no sense to collect data only from Medicare-certified ASCs. Furthermore, we understand the reported procedure charges in the 1994 survey varied significantly, from as low as $400 to as high as $10,000. Such extreme variance certainly calls into question the reliability of the data. Moreover, HCFA states that it rejected use of the Moore survey at least in part because the Moore survey collected data from non-Medicare-approved ASCs. Yet HCFA itself now is using non-Medicare data (from Medicare-approved ASCs). If HCFA is willing to accept non-Medicare data, it certainly could have accumulated good and more abundant ESWL information from additional non-Medicare facilities, as opposed to HCFA's limited pool of 15 Medicare surveyed facilities.

Payment for Injection into Spinal Canal (CPT 62298): FASA applauds the addition of this code to the ASC list. It is clinically similar to CPT 62289 (injection into lumbar or caudal epidural space), which has been on the ASC list for more than a decade. This would support inclusion of CPT 62289. The proposed payment rate should be increased. CPT 62289 requires use of fluoroscopy, monitoring, sedation and skilled ancillary staff time. FASA's 1997 survey showed an average cost of $433 for performing this procedure, and thus the proposed rate of $241 will be woefully inadequate and fail to cover the cost of performing the procedure. Few ASCs will be willing to perform the procedure at this rate.

FASA's Suggested Additions to ASC List

In addition to the codes HCFA proposes adding to the list, FASA believes that other procedures merit inclusion as well. Allowing these procedures to be reimbursed in an ASC will provide physicians with added flexibility to choose the proper setting to conduct a patient's surgery and provide the patient with a more desirable place to have certain procedures. We strongly recommend

including the following procedures in the new ASC list. FASA would be happy to suggest proposed groupings under the current system for these procedures.

Laparoscopy, surgical and vaginal hysterectomy (CPT 56308): In properly selected patients, laparoscopically aided vaginal hysterectomies are an alternative to abdominal hysterectomies. Many ASCs have been performing this procedure in non-Medicare patients with excellent results. In select Medicare patients, the safety of this procedure should parallel those in non-Medicare patients. The procedure can be performed in a properly staffed ASC. FASA urges HCFA to add CPT 56308 to the ASC list.

Laparoscopy surgical cholecystectomies (CPT 56340, 56341, 56342): Although generally thought of as an inpatient procedure, the advancement of medical technology and anesthetic agents in recent years have allowed these procedures to be performed safely in an ASC setting. Numerous ASCs have performed these procedures safely on non-Medicare patients. In the past, HCFA indicated that these procedures were not included on the list because a post-surgical observation period longer than the four hours was required. With the proposed change in the criteria for the ASC list this objection is removed. Certainly for many patients this procedure is best performed on an inpatient basis. Emphasizing what we have said throughout our comments, the primary factor in whether it is appropriate to perform in an outpatient setting is the medical condition of the particular patient. For otherwise healthy Medicare patients, an outpatient setting may be appropriate. For many Medicare patients, it will not. HCFA should include it on the ASC list and let physicians and patients decide what is best for each individual beneficiary.

Changes in IOL Reimbursement

FASA is particularly concerned about the proposed facility rate for the IOL insertion procedures in APC 668 (CPT codes 66983, 66984, 66985 and 66986). First, Congress has consistently set the IOL reimbursement rate by law and we find it problematic that HCFA has suddenly decided to lower the rate by regulation. We urge HCFA not to do so. HCFA states that the weighted mean cost for IOLs is $100 we believe many facilities will have to pay considerably more. HCFA should consider several factors in determining IOL reimbursement. The available cost data is based on 1993 cost and, as we have stated, this does not produce a reasonable value for 2000. In addition, newer and better IOLs exist presently than were available in 1993. Current IOLs cost more than their 1993 predecessors, and cost significantly more than the proposed reimbursement rate, but provide better, higher quality care to beneficiaries. We urge HCFA to reconsider its decision to change the IOL reimbursement by regulation.

Elimination of Separate Payment for Acquiring Corneal Tissue

We oppose the proposed elimination of separate payment for acquiring corneal tissue in connection with corneal transplant procedures. HCFA should not combine the facility and corneal tissue payments. It is inappropriate to view corneal tissue acquisitions and storage as a fixed cost. Corneal tissue is not a manufactured product, and its availability is thus immune to traditional market forces. However, combining payment would not be as problematic if the corneal transplant procedure's proposed reimbursement factored in an adequate amount for corneal tissue acquisition. The indefensibly low proposed facility fee of $1,648 for this procedure, however, will not even cover the expense of such acquisition, let alone the cost of the entire procedure. Acquisition of the corneal

tissue alone, while varied across the nation, can easily cost up to $1,800. A significant argument can be made that even at this cost corneal tissue already is provided well below the actual cost to the eye banks, due to the significant charitable underwriting of eye banks. Its availability varies significantly, and therefore the costs of acquiring it vary significantly. In addition to the cost of the corneal tissue itself, procurement costs can include significant transportation costs, sometimes including even the price of an airline ticket. Thus, the entire Medicare facility fee for the transplant procedure of $1,648 will be taken up by the cost of acquisition alone.

Once the actual facility costs of the procedure are added to the tissue acquisition costs, it is clear that many ASCs would lose a substantial amount of money by providing this service at the proposed Medicare rate. If ASCs respond to this financial incentive, Medicare beneficiaries will suffer, as the procedure will no longer offered in the ASC setting. Beneficiaries will be forced to obtain this procedure in the HOPD setting, and incur a more costly copayment, as well as adding additional cost to the Medicare program. FASA, therefore, strongly recommends that HCFA set the reimbursement for this procedure at the current $941 payment rate, adjusted for inflation and provide separate reimbursement for the acquisition of the tissue that reflects a fair estimate of the actual costs of acquisition should be provided.

FORMATION OF ADVISORY GROUP

FASA has always strongly supported the formation of an advisory group to assist HCFA in the development of ASC regulations, payment groupings, and payment rates. We are disappointed that HCFA indicates that it is deferring a decision on this until the provisions of this proposed rule are implemented. It is precisely on the kinds of issues raised in the proposed rule that an advisory group could be useful to HCFA. HCFA also notes that it is considering use of an existing group such as AMA's CPT/Relative Value Committee (RUC) or the Medical Carriers Medical Directors Workgroup. Although each of these groups does its job well, to use them for ASC issues misses the point. The purpose of an ASC group would be to give HCFA the advantage of those experienced in the ASC industry. To what extent those on either group have experience in the ASC setting is unknown, but it is clear that if one was selecting individuals based upon knowledge, and experience in the ASC industry, the composition of the group would be very different. Moreover, because these groups are selected for another purpose they are made up of almost entirely physicians. To have adequate representation of the ASC community, nurses, administrators, and owners must be included. Without the involvement of these individuals HCFA will not get the best advice. FASA would be happy to advise HCFA on the appropriate composition of such a group. We believe the contribution that the ASC industry makes to the Medicare program deserves special attention by HCFA. Moreover, given the complexity and the dynamic nature of the ASC industry, HCFA would be well served by a panel of administrators, physicians, nurses, and industry representatives who have an intimate knowledge of the specific regulatory, quality of care, and financial concerns facing ASCs. An advisory group has worked well in the physician reimbursement context; it would work equally well for ASCs.

Joint Meetings to Discuss Reimbursement Rates and Procedures on ASC List

At the same time, as a means of reaching a consensus on the proposed payment rates and the scope of the ASC list, we suggest convening a series of meetings between FASA, HCFA and other interested parties. After the conclusion of the comment period, HCFA will have a significant amount of time prior to implementation to work with industry groups to modify the proposed system. During this time, FASA, HCFA, and other organizations can work collaboratively to revise the proposal in a mutually agreeable manner. In light of the lack of data available to HCFA to formulate this rule, this approach will be necessary to develop sound and equitable reimbursement rates and policies.

CONCLUSION

On behalf of its members, FASA expresses its appreciation to HCFA for considering our comments. The APC system will have a dramatic impact on the future of the ASC industry and the delivery of outpatient care well into the 21st Century. We look forward to speaking with you about the issues we have raised. Please do not hesitate to contact FASA if we can be of any assistance.

Sincerely,

Kathy J. Bryant
Executive Director

Attachments

APPENDIX A
PROPOSED CHANGES TO SPECIFIC APC GROUPS

APC 122: Although all the codes within this group are needle biopsies, they range dramatically in complexity and are quite dissimilar in terms of resources used. The group includes needle biopsies of the thyroid (CPT 60100) and testis (CPT 54500); needle biopsy of the breast (CPT 19100), which may require stereotactic mammographic localization; and needle biopsy of the pancreas (CPT 48102), which is performed under computerized tomographic guidance in a facility where that modality is available. These procedures are not clinically similar and therefore are inappropriately grouped in the same APC. Moreover, this grouping results in inappropriate reimbursement for the more complex procedures. This group should be modified to address these problems.

APC 162: This group has a mixture of benign, malignant, burn, and Mohs-technique lesion excisions – some as simple as superficial muscle biopsy and others as complex as open-technique shoulder operations. The operating times on these procedures vary considerably. The procedures that require more operating room and recovery time should be removed to an APC group with a higher and more appropriate reimbursement. One example of a procedure inappropriately placed in this APC CPT 11404 (Removal of Skin Lesion). This procedure is very similar to CPT 11406 (excision of benign lesion diameter over 4.0 cm), which is in APC 163. According to the 1994 HCFA ASC Reported Survey Data, the operating room time for CPT 11404 is 45 minutes, while the operating room time for CPT 11406 is 41 minutes. From both a clinical and cost perspective, this procedure belongs in APC Group 163 with CPT 11406. FASA recommends moving it there.

APC 163: APC 163 contains 77 widely disparate CPT codes, including: biopsy of the soft tissues of the thigh (CPT 27327), radical resection of malignant neoplasm of soft tissue pelvis and hip (CPT 27049), and excision of sacral pressure ulcer with ostectomy (CPT 15933), a procedure requiring special equipment. These three procedures require significantly different operating room times, recovery room times, and supplies and, thus, should not be grouped together. These are but three examples of the problems in this group.

APC 181: FASA believes it would be more appropriate to split the 42 procedures in this grouping. This APC, for example, includes simple suture repairs of 2.5 cm or less (CPT 12001), injection of a sinus tract (CPT 20500), and layer closures of wounds up to 30 cm (CPT 12056). More complex procedures that require more time, such as large layer closures, should be reimbursed at a higher rate.

APC 183: This grouping has 61 CPT codes ranging from simple pinch grafts up to 2 cm in diameter (CPT 15050) to split grafts to the face up to 100 square cm (CPT 15120). According to the 1994 HCFA ASC Reported Survey Data, operating room times vary from 48 minutes for CPT 15630 (delay or sectioning of flap) to 90 minutes for CPT 15120. The more technically complex procedures requiring more operating room and recovery time should be moved to an APC with a higher reimbursement rate.

APC 197: This group inappropriately contains breast procedures involving surgery and radiological processes. For example, CPT 19101 (biopsy of breast) may require stereotactic equipment, which makes the procedure significantly more costly than others within this group. Further, the equipment and time required to perform CPT 19140 (mastectomy for gynecomastia) is clearly different from CPT 19290 (preoperative placement of needle localization wire). Therefore, this group should be re-formulated so that it contains procedures that are clinically similar.

APC 198: Procedures in this category are related both to the definitive treatment of breast cancer and plastic and reconstructive operations of the breast. CPT 19162 (partial mastectomy with axillary lymphadenectomy) and CPT 19182 (subcutaneous mastectomy) are more complex and involve more operating time (97 minutes and 80 minutes, respectively, according to the 1994 HCFA ASC Reported Survey Data) and resources than CPT 19160 (partial mastectomy), which requires 65 minutes in the 1994 Survey. As such, CPT 19162 and 19182 should be moved into an APC with a higher reimbursement rate.

APC 216: Procedures in this grouping vary significantly in operating room times. There are 103 CPT codes in APC 216, including the open treatment of almost all bone fractures, which range from relatively simple finger and toe fractures to major long bone fractures. Also, several procedures on this list require extensive resources to perform. CPT 25620 (open treatment of distal radial fracture or epiphyseal separation), CPT 24546 (open treatment of humeral supracondylar or transcondylar fracture with intercondylar extension) and CPT 25526 (open treatment of radial shaft fracture) may utilize expensive hardware, that alone equals the $580 proposed reimbursement rate. FASA notes that the comparable reimbursement rate for this grouping in the HOPD setting is $1,033 – almost 78 percent more.

APC 251: APC 251 contains 77 widely disparate CPT codes, including CPT 23100 and CPT 24100 (arthrotomies with biopsies), CPT 25248 (exploration with removal of foreign body) and CPT 27704 (removal of ankle implant). The procedures that require specialized equipment and more operating room time should be moved to an APC group with higher reimbursement.

APC 252: APC 252 contains 139 widely diverse CPT codes, including CPT 20900 (bone graft, small donor site), CPT 20692 (application of multiplane external fixation system), CPT 25251 (removal of wrist prosthesis, complicated) and CPT 27396, 27580, 27665, and 27695 (various tendon procedures). Procedures that require specialized equipment, implantables, and more operating room time should receive a higher reimbursement.

APC 281: APC 281 is comprised of arthroscopy with surgical procedures. While an arthroscope is needed for all procedures, the repair performed may mandate different additional equipment and differing times to complete. Hence, this grouping is not homogeneous with respect to the time required to perform the procedure nor costs. We believe that it would be more appropriate to transfer complex elbow and wrist procedures (CPT 29826, 29838, 29839, 29846, 29847, 29848, 29861, 29862 and 29863) into an APC with a higher reimbursement rate.

APC 313: This group contains 103 otorhinolaryngology CPT codes, which are widely disparate operating and recovery room times for procedures in this group. For example, according to the 1994 HCFA ASC Reported Survey Data, CPT 42410 (excision of parotid tumor or parotid gland, lateral lobe, without nerve dissection) and CPT 30620 (septal or other intranasal dermatoplasty) require 90 and 108 minutes of operating room time, respectively. On the other hand, the survey shows that CPT 41010 (incision of lingual frenum) requires 20 minutes. The more complex procedures should be moved into an APC with a higher reimbursement rate.

APC 367: Procedures in this group include ligation of major arteries and veins, which are usually performed as emergencies in the inpatient hospital setting, and elective ligation and stripping of lower extremity varicose veins of variable complexity. Costs vary dramatically for these procedures, with a simple ligation and division of the saphenous vein on the low end of the cost scale, and the stripping of long and saphenous veins on the high end. For example, according to the 1994 HCFA ASC Reported Survey Data, CPT 47780 (ligation and division of short saphenous vein) requires 60 minutes operating room time, while CPT 37735 (ligation and division and stripping of long or short saphenous veins with additional procedures) requires 137 minutes – more than twice as much operating room time. Procedures that require additional resources and operating room time should be moved to an APC grouping with a higher reimbursement rate.

APC 523: FASA believes it would be more appropriate to place some of the procedures in APC 523 into a different grouping. CPT 52335-52338 (cystourethroscopy with additional procedures) are more technically demanding and sophisticated than the other procedures in this APC. As such, these codes should be assigned to an APC with a higher reimbursement rate.

APC 551: This group is comprised of 8 laparoscopic procedures. Milliman and Robertson's cost profiles indicate that the cost for ASCs to perform these procedures ranges from $916 to $1,346. The high costs of disposables and equipment for these procedures contribute to the high overall costs. The proposed reimbursement rate is $831. Moreover, the wide range in cost among procedures in the group suggests that the procedures are not similar enough to be grouped together.

APC 684: This group has 61 ophthalmic procedures ranging in complexity from the relatively straightforward suture repair of an ectropion (CPT 67914) to the complex eyelid reconstructions with full thickness tarsoconjunctival flap transfer (CPT 67971). Milliman and Robertson data indicate that the cost of CPT 67914 is at least $535 and the cost data for more complex procedures is correspondingly higher. The proposed reimbursement rate is $491. This grouping needs to be significantly revised, with the relocation of the more complex procedures that require increased operating room time to an APC grouping with a higher reimbursement rate. In addition to overall regrouping, several procedures (CPT 67900, 67902, 67903, 67904, 67909 and 67911) are grossly undercompensated. We are disturbed with the proposed payment rates for these CPT codes, both from the perspective that they are being reimbursed significantly below cost and because HOPDs are paid 39 percent more for performing the same procedures. These procedures are highly complex and require a significant amount of operating time. For that reason, we believe it would be appropriate to create a new APC with these codes that provides a reimbursement rate that reflects

the actual costs. These procedures are more costly to perform than other procedures, such as CPT codes 67908, 67914, and 67921, yet HCFA proposes to provide the same reimbursement.

APPENDIX B
RECOMMENDED CHANGES TO REIMBURSEMENT RATES

Removal of Breast Lesion (CPT 19120): The proposed payment rate for this CPT code, $411, pales in comparison to the costs associated with performing this procedure. FASA's 1997 survey shows an average cost of $913 for performing this procedure, more than $500 more than the proposed payment.

Excision of Breast Lesion (CPT 19125): The proposed reimbursement for this procedure has been reduced 15 percent to $411. HOPDs proposed reimbursement is $614 for this procedure, 49 percent more than ASCs. This procedure removes a breast lesion after preoperative placement of a radiological marker. We question the wide payment disparity between the ASC and HOPD settings in this circumstance. The ASC rate should be increased.

Gynecomastia (CPT 19140): The payment rate for this procedure should be increased since it is substantially similar to a partial mastectomy, CPT 19160. CPT 19140 is the removal of the breast tissue of a male, while CPT 19160 is unspecified sex. HCFA has increased the payment rate of CPT 19160; it should do the same for CPT 19140.

Repair of Shoulder Tendons (CPT 23410): While FASA appreciates that the proposed is increased significantly over the current rate, we believe it does not reflect the costs to perform this procedure. Our members have noted that the costs for implantables involved in this procedure can range from $660 to $1,400 depending upon the condition of the shoulder. In addition, the 1994 HCFA ASC Reported Survey Data indicates that the procedure requires 102 minutes of operating room time. We urge HCFA to review the cost data for this procedure in order to reflect adequately the high cost of implantables.

Wrist Cartilage Repair (CPT 25107): The proposed reimbursement is $574. According to the 1994 HCFA ASC Reported Survey Data indicates that the procedure requires 59 minutes of operating room time. Given the length of the procedure, $574 is an inadequate reimbursement. We urge HCFA to increase the reimbursement for this procedure.

Upper GI Endoscopy, Biopsy (CPT 43239): FASA's 1997 survey data shows an average cost of $521 to perform this procedure. Therefore, a $327 reimbursement rate would force the procedure to be performed at a loss in most instances. We would suggest an increase in payment rates to reflect the actual costs of performing this procedure. HCFA's proposed payment reduction for this procedure will have a particularly devastating impact on GI single-specialty facilities, where this is a high-volume item.

Upper GI Endoscopy with dilation, guidewire (CPT 43248): This procedure requires an endoscope plus specialized equipment to dilate the esophagus. The proposed reimbursement rate of $348 is only $21 more that that for CPT 43235 diagnostic upper GI endoscopy. With the cost of the specialized equipment and additional procedure time needed for CPT 43248, this payment rate would not cover the additional costs in performing the procedure.

Upper Gastrointestinal Endoscopy with Dilation (CPT 43249): The addition of this procedure to the ASC list increases the availability of the procedure to properly selected Medicare patients. However, the proposed reimbursement rate of $348 will not cover some of our members' costs, who state that the actual cost of the procedure is $427. Adding it to the list without appropriate reimbursement will not make the procedure available to Medicare patients.

Diagnostic Colonoscopy (CPT 45378): ASCs responding to FASA's 1997 survey report the average cost for this procedure is $587; significantly above the proposed reimbursement rate of $354. A colorectal cancer screening benefit was instituted in 1998 to improve Medicare beneficiaries' use of this important preventive benefit. Without appropriate reimbursement, Congress's goal of improving access to this service will not be achieved.

Colonoscopy and Biopsy (CPT 45380): FASA's 1997 survey shows an average cost of $542, the resulting payment amount of $354 is inadequate. At this rate facilities will lose an average of $188 per procedure performed. Clearly, reimbursement of this level fails to meet the statutory requirement that reimbursement be based on actual costs.

Colonoscopy with Lesion Removal (CPT 45384, 45385): CPT 45384 and 45385 combine diagnostic colonoscopy (CPT 45378) with removal of a lesion. Removing the lesion requires additional equipment, disposables, and time as compared to a diagnostic colonoscopy alone. HCFA proposes to pay $405 for CPT 45384 and 45385 or only $51 more for all these extra services. FASA's 1997 survey showed an average facility cost of $799 for CPT 45385 or 36% more than the $587 for CPT 45378. HCFA's proposed reimbursement rate is not reasonable when compared to the average costs of facilities nor when compared to the reimbursement for CPT 45378. Under no circumstances can it be reasonable for a facility to lose $445 per procedure performed. The reimbursement rate should be increased.

Cystoscopy (CPT 52000): Under the proposed rule, reimbursement for this procedure would drop to $212. FASA estimates that the mean costs incurred by an ASC to perform this procedure are approximately $324, far in excess of the $212 proposed reimbursement rate. The HOPD proposed rate would reimburse $251 – 18 percent higher than that proposed for in ASCs. The proposed decrease from current rates is also extremely large – 32 percent. It appears to us that there was an error in calculating this rate or a major flaw in the underlying data.

Cystoscopy with treatment (CPT 52265): While FASA appreciates HCFA's willingness to add this procedure, the proposed reimbursement rate of $212 is insufficient to cover the cost of the procedure. Milliman & Robertson's cost profiles indicate that the cost of the procedure is $306 to $362, depending on the method of anesthesia delivered. The proposed reimbursement rate for HOPDs is 18 percent higher. FASA urges HCFA to reevaluate its decision to place CPT 52265 in APC Group 521 and to increase the reimbursement rate for this procedure.

Laser Surgery of the Prostate (CPT 52647): The $1,131 payment level for laser surgery of the prostate barely covers the cost of the laser fibers used for the procedure. Cost of these laser fibers

ranges from $600 to $1,000 and are used only once. To compensate for these costs, a new APC with a higher reimbursement rate should be created for this procedure.

Injection of Spinal Anesthetic (CPT 62278): This procedure also deserves a higher reimbursement rate due to the use of fluoroscopy, extensive monitoring, and sedation. Reported costs from member facilities are $314 to $428. The proposed reimbursement of $241 will not cover the costs.

Injection into Lumbar or Caudal Epidural Space (CPT 62289): The proposed payment rate for this code and the entire APC should be increased. This procedure requires fluoroscopy, monitoring, sedation, and skilled ancillary staff time. A 1997 FASA survey indicated an average cost of $433 for performing this procedure. Thus, at the proposed reimbursement rate of $241, facilities will lose, on average, $192 per procedure performed, and will be unlikely to perform the procedure.

Glaucoma Surgery (CPT 66170): The costs for this procedure are clearly much higher than the proposed reimbursement of $415. One ASC reported a cost of $683 to perform this procedure. This procedure takes more operating time than cataract surgery. In many instances, Mitomycin, which is not separately reimbursed, is used at a cost of $136 per bottle. The ASC payment rate for this CPT code, moreover, pales in comparison to the HOPD reimbursement and calls into serious question the validity of HCFA's cost numbers. HOPDs would be paid 103 percent more for this procedure.

YAG Laser (CPT 66821): FASA believes that HCFA has miscalculated the costs for performing this procedure. The proposed 35 percent reduction would be devastating to many ASCs. The impact is especially troubling considering that this procedure is the second most frequently performed procedure, representing more than 11 percent of all ASC volume in 1996. A 1997 survey of FASA members found an average cost of $395 for performing this procedure. With a $274 reimbursement rate, an ASC will lose $121 on each procedure performed. The same 1997 survey showed an average Medicare volume for this procedure of 206, meaning facilities performing this procedure would lose on average if $24,926. Much of the cost is the expensive machine required to perform, a cost that ASCs cannot control.

Extra Capsular Cataract Removal (CPT 66984): We believe that the proposed $863 facility fee does not reflect the expenses of performing this procedure. This procedure requires expensive, specialized equipment, instruments, and pharmaceuticals, such as Phaco-emulsification machine and disposable supplies. A 1997 FASA survey indicated that the average ASC facility cost for this code was $1,276. Consequently, we suggest at the very least reinstating the existing payment rate of $928 since that would more accurately reflect the cost of maintaining the technology associated with performing this procedure safely. Moreover, FASA is opposed to including the cost of the IOL in the reimbursement of the procedure. The reduction in reimbursement for the procedure does not take into account the actual costs of acquiring IOLs, and thus may condemn ASCs to not using current state of the art IOLs.

Repair of Eyelid Defect (CPT 67917): The proposed reimbursement for this procedure has been reduced 17 percent to $491. Milliman & Robertson's cost profiles indicate that the ASC cost for this procedure is $535 to $647, depending on the type of anaesthesia used. Few ASCs will perform

procedures that lose money for each patient served. We also question the payment disparity between the ASC and HOPD settings. HOPDs will be reimbursed $682 for this procedure, 39 percent more than ASCs. The ASC rate should be increased.

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008. letter	Royce Hanson to Christopher Jennings re: phone and fax number (partial) (1 page)	11/03/1999	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Meetings, Trips, Events)
OA/Box Number: 17045

FOLDER TITLE:
Meetings/Event Invitations [October 1999 to May 2000] [1]

2011-0747-S
rc425

RESTRICTION CODES

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P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

November 3, 1999
ATTN: Sarah Brown—Replacement letter--In my haste I erred on dates: please note corrections
Mr. Christopher C. Jennings
Deputy Assistant to the President
For Health Policy
The White House
Fax: 202-456-5557

Dear Mr. Jennings:

ALLIANCE FOR MEDICAL MANAGEMENT EDUCATION

2601 North Floyd Road
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The University of Texas at Dallas
School of Management

SOUTHWESTERN
THE UNIVERSITY OF TEXAS
SOUTHWESTERN MEDICAL CENTER
AT DALLAS

The Alliance for Medical Management Education, a joint program of the UTD School of Management and Southwester Medical Center, is bringing 37 physician-managers to Washington November 4-12 for a seminar series on Health Policy and Regulation. The Washington seminars are designed to acquaint these physicians with the policymaking process and to help them develop skills for dealing with the regulatory and legislative issues confronting health care organizations. A brief description of the AMME program, class list and a list of names, SSNs, and birth dates are enclosed.

We would like to arrange a one-hour seminar with you or another person from the White House health policy staff, at any of the following times:

Thursday, November 4 during the morning between 8:00 a.m. and noon;
Monday, November 8, at 8:00 or 8:30 a.m.;
Tuesday, November 9 following the White House tour Congressman Martin Frost's office has arranged; or
Wednesday November 10 at 8:00/8:30.

We could bring the group to the White House, or meet at the St. James Hotel, 24th and K streets, N.W., where the group is staying.

While the group is interested in the full range of health care legislation currently before the Congress, it is using the Patient's Bill of Rights and Medicare reform proposals as case studies. We would especially like you to talk with them about how the Administration formulates health policy and develops and manages the health policy agenda.

During the nine days the group will be in Washington they will meet congressional leaders, executive and regulatory agencies, interest groups, media, and public policy organizations that have had major roles in the health care debates.

I can be reached most easily by phone locally at P6/(b)(6) or at P6/(b)(6) With thanks for your consideration, I am

[008]

Sincerely yours,

Royce Hanson
Professor Emeritus
University of Texas at Dallas

Fax 5-5631
Notified Dan. left message asking him to speak 11/3

Dan cannot do this - called Mr. Hanson to say Gary Clayton who speaks to them next week can cover it

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009. profile	Alliance for Medical Management Education profile re: fax number (partial) (1 page)	11/03/1999	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Meetings, Trips, Events)
OA/Box Number: 17045

FOLDER TITLE:
Meetings/Event Invitations [October 1999 to May 2000] [1]

2011-0747-S
rc425

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
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About the Alliance

The Alliance for Medical Management Education is a strategic partnership between The University of Texas at Dallas School of Management and The University of Texas Southwestern Medical Center at Dallas. The mission of the Alliance is to: Prepare physicians to assume a more effective role in the leadership and management of medicine.

Program Objectives

The Alliance offers a fully accredited, nationally recognized graduate program in medical management open to physicians only. The curriculum is taught by senior professors from a top-ranked school of management and school of medicine.

The program develops the managerial and interpersonal skills physicians need to:

- *understand the social and economic forces driving the healthcare revolution*
- *become effective physician leaders and communicators*
- *improve service quality and patient satisfaction*
- *identify and evaluate alternative organizational strategies*
- *efficiently manage human, financial and information resources*

Credentialing

The 36-credit hour graduate program is open to both degree and non-degree seeking physicians. Successful completion of the 18-credit hour core curriculum is recognized by a Certificate in Medical Management. Those choosing to continue their studies and complete the 18-credit hour advanced curriculum are awarded a Master of Science in Medical Management by The University of Texas at Dallas.

Coursework is eligible for both graduate academic credit and Category 1 CME credit toward the AMA Physician's Recognition Award.

Instructional Format

The modular residential format is designed to make the most effective use of physicians' time. The core is composed of six, 5-day residential courses covering the critical business and communications skills required to lead a medical organization. Physicians may take some or all of the core depending upon their interests and personal objectives.

The advanced curriculum is composed of two 9-day residential courses plus a faculty supervised research study of the physician's own medical organization. It is open to physicians who have completed the core and are committed to medical management as a major element of their professional career. The advanced curriculum develops an understanding of the economic and regulatory forces shaping health-care reform and the strategic thinking and change management processes required to deal successfully with them.

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
010. list	Alliance for Medical Management Education re: SSN, DOB, and fax number (partial) (1 page)	11/03/1999	P6/b(6)

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ALLIANCE FOR MEDICAL MANAGEMENT EDUCATION

PHYSICIANS SSNs AND BIRTH DATES FOR WASHINGTON SEMINARS

Name	Social Security Number	Birth Date
Robert Adams, DO	P6/(b)(6)	P6/(b)(6)
Catherine Brandon, MD		
Michael Burgess, MD		
Dolores Carruth, MD		
L. Chinsoo Cho, MD		
E. A. (Andy) Clark, MD		
William Estabrook, MD		
Leslie Garb, MD		
Edward Gilbert, MD		
David Herman, MD		
Mario Jimenez, MD		
Robert Johnstone, MD		
Roy Kingry, MD		
Mark Laney, MD		
Mary Mancini, MD		
Jeffrey Martinez, MD		
Waenard Miller, MD		
Abraham Miranda, MD		
Janet Morehouse, MD		
Truman Plainer, MD		
Delwin Quenzer, MD		
James Rellas, MD		
Glenn Roberson, MD		
Frank Rodriguez, MD		
Samuel Ross, MD		
Richard Rouse, MD		
Jill Sumfest, MD		
Erica Swegler, MD		
David Teegarden, MD		
David Weidensaul, MD		
David Winter, MD		
James Woessner, MD		
Faculty		
John F. McCracken, PhD		
Robert Kennedy, MD		
Royce Hanson, PhD,JD		

[0103]

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
011. list	Healthcare Policy and Regulation re: fax number (partial) (2 pages)	11/03/1999	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Meetings, Trips, Events)
OA/Box Number: 17045

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Healthcare Policy and Regulation
Washington, DC
November 3-12, 1999

Robert Adams, DO
Chairman, Department of Obstetrics & Gyn
UNT Health Science Center, Ft. Worth

Michael Burgess, MD
President, Ob Gyn Associates of Lewisville
Chief of Staff, Lewisville Hospital

L. Chinsoo Cho
Assistant Professor of Oncology
UT Southwestern Medical Center, Dallas

William Estabrook, MD
Medical Director
Glen Oaks Hospital, Dallas

Edward Gilbert, MD
Medical Director
Baylor Richardson Cancer Center, Dallas

Mario Jimenez, MD
Managing General Partner
Rio Grande Family Health Center

Roy Kingrey, MD
Chairman, Department of Surgery
UT Health Center at Tyler

Mary Mancini, MD
Associate Professor of Surgery
LSU Medical Center, Shreveport

Waenard Miller, MD
Managing Partner
Texas Regional Heart Center, Dallas

Janet Morehouse, MD
President
Morehouse Medical Clinic, Bossier City, LA

Delwin Quenzer, MD
President
Des Moines Orthopaedic Surgeons

Catherine Brandon, MD
Medical Director
The Ross Breast Center, Tyler

Dolores Carruth, MD
Chairman, Health Affairs
Texas Higher Education Coordinating Board

E. A. Clark, MD
President
Diagnostic Clinic of Longview

Leslie Garb, MD
Associate Medical Director
OneCare Health Industries, Inc., Houston

David Herman, MD
Associate Professor of Ophthalmology
Mayo Clinic and Foundation, Rochester

Robert Johnstone, MD
Chief of Staff
Wilson N. Jones Hospital, Sherman TX

Mark Laney, MD
Medical Director, Neurophysiology Lab
Cook Children's Medical Center, Ft. Worth

Jeffrey Martinez, MD
Staff Vascular Surgeon
Portsmouth Naval Medical Center

Abraham Miranda, MD
President, Institute for Infectious Diseases
Chairman, South Texas Physicians Alliance

Truman Plainer, MD
Medical Director
Southwestern Eye Center, Chandler, AZ

James Rellas, MD
Managing Partner
Cardiovascular Consultants, Dallas

Glenn Roberson, MD
Chairman, Department of Radiology
Texas Tech Health Science Center

Samuel Ross, MD
Senior Vice President and Medical Director
Parkland Health and Hospital System, Dallas

Jill Sumfest, MD
Medical Director
Preferred Health System, Inc., Wichita

David Teegarden, MD
Executive Vice President
Trinity Mother Frances Health System, Tyler

David Winter, MD
President
MedProvider, Dallas

Frank Rodriguez, MD
Department of Urology
UT Health Center at Tyler

Richard Rouse, MD
Chairman, Dept. of Cardiovascular Surgery
Santa Rosa Children's Hospital, San Antonio

Erica Swegler, MD
Group Practice Partner
North Hills Family Practice, Roanoke, TX

David Weidensaul, MD
Medical Director
Hutchinson Clinic, KS

James Woessner, MD
President
US Phys Med, Dallas

National Committee for Quality Health Care

Advancing Quality Health Care

for the schedule
Kim Short
331-7536
Canceled 2/29

February 18, 2000

Christopher C. Jennings
Deputy Assistant to the President for Health Policy Development
Old Executive Office Building
17th and G Street Entrance
Washington, DC 20502

Dear Mr. Jennings:

On behalf of the Board of the National Committee for Quality Health Care, I am pleased to invite you to be the closing speaker at our annual conference entitled "Patient Safety: Emerging Opportunities in the Health Care System". The Conference is scheduled from 2:00 PM Wednesday, March 1st through 12:30 PM Thursday, March 2nd. Your remarks would be scheduled from roughly 11:30 AM through 12:15 PM on Thursday, March 2nd. The meeting is being held at The Washington Monarch Hotel on 24th and M Streets, NW.

I am aware of your commitment to the National Health Council, an organization whose board I once served on, for Thursday, March 2nd from 10:00AM –11:30 AM and would be flexible with our schedule in order to accommodate you. Richard Fromm from Kaiser Permanente encouraged me to write to you after he spoke with you on Thursday.

The National Committee for Quality Health Care is into its third decade of serving the health care industry. Its membership is comprised of CEOs and other senior decision-makers representing all sectors of the health care industry. Health care leaders expected to be in attendance at our conference include the CEO's from Duke University Medical Center, Baptist Memorial Health Care System, the Picker Institute, Munson Medical Center, Hospital for Sick Children Foundation, University of Alabama at Birmingham Health System, Thomas Jefferson University Hospital, MedStar Health and Cedars Sinai Medical Center to name a few.

We convene forums with this diverse group, publish reports, conduct some research on the field and each year present an award to an outstanding provider who has accomplished innovative strategies and practices in quality health care. This award is cosponsored with Modern HealthCare magazine. Former winners include the Henry Ford Health System, Evanston Northwestern Health Care, Intermountain Health Care, St. Luke's Hospital in Kansas City, MO, University of Pennsylvania Health System and BJC Health System, St. Louis. We will present the 2000 award at dinner on March lst.

1100 Connecticut Ave, NW, Suite 545 ▪ Washington, DC 20036 ▪ 202·331·7535 ▪ 202·331·7532 *fax* ▪ ncqhc@erols.com

Enclosed is material describing NCQHC in more detail. Please know how grateful we would be if you would be able to provide us with an understanding and some insight on the goals the administration has for patient safety and quality health care in the future.

I await your early reply and thank you in advance for our consideration.

Sincerely,

Catherine E. McDermott
President & CEO

Enclosures:
Information packet
Conference brochure

Catherine E. McDermott
President and CEO

Catherine McDermott has been president, CEO and a member of the board of trustees of The National Committee for Quality Health Care (NCQHC) since June 1997. In the course of her tenure, Ms. McDermott has worked closely with the Board to map new directions for this 22-year-old organization, including sharpening its mission, re-incorporating as a 501 (c)(3) educational membership organization, and building new relationships with the public and private sectors. Under her leadership, NCQHC has convened major conferences and symposia and has broadly disseminated the proceedings. Issues examined at recent NCQHC meetings have included the "continuum" of standards in quality health care, how quality goals can serve to "lock" segments of the health care system together, models from corporate America for improving quality services, and emerging opportunities to improve quality through medical technologies.

Prior to joining NCQHC, Ms. McDermott was the founding president of Grantmakers In Health (GIH). She led this national nonprofit organization for over 15 years in its mission to facilitate communication, organize information sharing, and promote collaboration among corporations and foundations in health philanthropy as well as with public sector agencies such as the CDC and HRSA. Previously, Ms. McDermott was on the staff of The Robert Wood Johnson Foundation, served as an officer at The Carnegie Corporation of New York, and was a founding member of Women and Foundations/Corporate Philanthropy.

On international issues, Ms. McDermott has served as a member of the State Department Task Force on International Interdependence under President Ford, was founding president and trustee of Ireland's Children, a member of the Czech Council of Advisers of the Ministry of Health, and a delegate to the 1996 Canada-U.S.A. Women's Health Forum in Ottawa.

Currently, she is a member of the board of directors of Research!America. She is also a member of the New York and Washington, DC chapters of the International Women's Forum, and has served as a volunteer advocate with a number of major organizations, including the board of directors of the National Health Council and the Independent Sector.

February 2000